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Decision aids for people facing health treatment or screening decisions (Review)

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Decision aids for people facing health treatment or screening decisions .
Cochrane Database of Systematic Reviews 2024 , Issue 1 . Art. No.: CD001431.
DOI: 10.1002/14651858.CD001431.pub6.

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[Intervention Review]

Decision aids for people facing health treatment or screening decisions

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Editorial group: Cochrane Consumers and Communication Group.
Publication status and date: New search for studies and content updated (conclusions changed), published in Issue 1, 2024.

Citation: Stacey D , Lewis KB , Smith M , Carley M , Volk R , Douglas EE , Pacheco-Brousseau L , Finderup J , Gunderson J , Barry MJ , Bennett CL , Bravo P , Steffensen K , Gogovor A , Graham ID , Kelly SE , Légaré F , Sondergaard H , Thomson R , Trenaman L , Trevena L . Decision aids for people facing health treatment or screening decisions . *Cochrane Database of Systematic Reviews* 2024 , Issue 1 . Art. No.: CD001431 . DOI: 10.1002/14651858.CD001431.pub6.

ABSTRACT

Background

Patient decision aids are interventions designed to support people making health decisions. At a minimum, patient decision aids make the decision explicit, provide evidence-based information about the options and associated benefits/harms, and help clarify personal values for features of options. This is an update of a Cochrane review that was first published in 2003 and last updated in 2017.

Objectives

To assess the effects of patient decision aids in adults considering treatment or screening decisions using an integrated knowledge translation approach.

Search methods

We conducted the updated search for the period of 2015 (last search date) to March 2022 in CENTRAL, MEDLINE, Embase, PsycINFO, EBSCO, and grey literature. The cumulative search covers database origins to March 2022.

Selection criteria

We included published randomized controlled trials comparing patient decision aids to usual care. Usual care was defined as general information, risk assessment, clinical practice guideline summaries for health consumers, placebo intervention (e.g. information on another topic), or no intervention.

Data collection and analysis

Two authors independently screened citations for inclusion, extracted intervention and outcome data, and assessed risk of bias using the Cochrane risk of bias tool. Primary outcomes, based on the International Patient Decision Aid Standards (IPDAS), were attributes related to the choice made (informed values-based choice congruence) and the decision-making process, such as knowledge, accurate risk perceptions, feeling informed, clear values, participation in decision-making, and adverse events. Secondary outcomes were choice, confidence in decision-making, adherence to the chosen option, preference-linked health outcomes, and impact on the healthcare system (e.g. consultation length).

We pooled results using mean differences (MDs) and risk ratios (RRs) with 95% confidence intervals (CIs), applying a random-effects model. We conducted a subgroup analysis of 105 studies that were included in the previous review version compared to those published since that update (n = 104 studies). We used Grading of Recommendations Assessment, Development, and Evaluation (GRADE) to assess the certainty of the evidence.

Main results

This update added 104 new studies for a total of 209 studies involving 107,698 participants. The patient decision aids focused on 71 different decisions. The most common decisions were about cardiovascular treatments (n = 22 studies), cancer screening (n = 17 studies colorectal, 15 prostate, 12 breast), cancer treatments (e.g. 15 breast, 11 prostate), mental health treatments (n = 10 studies), and joint replacement surgery (n = 9 studies). When assessing risk of bias in the included studies, we rated two items as mostly unclear (selective reporting: 100 studies; blinding of participants/personnel: 161 studies), due to inadequate reporting. Of the 209 included studies, 34 had at least one item rated as high risk of bias.

There was moderate-certainty evidence that patient decision aids probably increase the congruence between informed values and care choices compared to usual care (RR 1.75, 95% CI 1.44 to 2.13; 21 studies, 9377 participants).

Regarding attributes related to the decision-making process and compared to usual care, there was high-certainty evidence that patient decision aids result in improved participants' knowledge (MD 11.90/100, 95% CI 10.60 to 13.19; 107 studies, 25,492 participants), accuracy of risk perceptions (RR 1.94, 95% CI 1.61 to 2.34; 25 studies, 7796 participants), and decreased decisional conflict related to feeling uninformed (MD -10.02, 95% CI -12.31 to -7.74; 58 studies, 12,104 participants), indecision about personal values (MD -7.86, 95% CI -9.69 to -6.02; 55 studies, 11,880 participants), and proportion of people who were passive in decision-making (clinician-controlled) (RR 0.72, 95% CI 0.59 to 0.88; 21 studies, 4348 participants).

For adverse outcomes, there was high-certainty evidence that there was no difference in decision regret between the patient decision aid and usual care groups (MD -1.23, 95% CI -3.05 to 0.59; 22 studies, 3707 participants).

Of note, there was no difference in the length of consultation when patient decision aids were used in preparation for the consultation (MD -2.97 minutes, 95% CI -7.84 to 1.90; 5 studies, 420 participants). When patient decision aids were used during the consultation with the clinician, the length of consultation was 1.5 minutes longer (MD 1.50 minutes, 95% CI 0.79 to 2.20; 8 studies, 2702 participants).

We found the same direction of effect when we compared results for patient decision aid studies reported in the previous update compared to studies conducted since 2015.

Authors' conclusions

Compared to usual care, across a wide variety of decisions, patient decision aids probably helped more adults reach informed values-congruent choices. They led to large increases in knowledge, accurate risk perceptions, and an active role in decision-making. Our updated review also found that patient decision aids increased patients' feeling informed and clear about their personal values. There was no difference in decision regret between people using decision aids versus those receiving usual care. Further studies are needed to assess the impact of patient decision aids on adherence and downstream effects on cost and resource use.

PLAIN LANGUAGE SUMMARY

Patient decision aids to help people who are facing decisions about health treatment or screening

Review question

How effective/beneficial are patient decision aids for adults making decisions regarding health treatment or screening?

Key messages

- Patient decision aids are pamphlets or videos used in person or online. They clearly identify the healthcare decision to be made, provide information on options (benefits and harms), and help people clarify what is most important to them. Decision aids are designed to enhance and supplement consultation with the clinician, not replace it.

- Over 200 studies showed that patient decision aids helped adults be more involved in making health decisions by improving their knowledge and expectations of benefits and harms, and choosing an option that reflected what was most important to them.

- There were no unwanted effects for adults who used a patient decision aid.

What are patient decision aids?

Patient decision aids can help guide people making decisions when there is more than one option, including status quo (no change). They are pamphlets, videos, or web-based resources that state the decision, describe the options, and help people think about which features of the options are most important to them (which features matter most). Usual care was defined as general information, risk assessment, clinical practice guideline summaries for health consumers, placebo intervention (e.g. information on another topic), or no intervention.

What did we want to find out?

We wanted to find out if patient decision aids used by patients who are facing health treatment or screening decisions are better than the usual care for choosing an option that reflects what is most important to them. We also wanted to find out if patient decision aids were associated with any unwanted effects.

What did we do?

We updated a previous Cochrane review that was first published in 2003 and then updated in 2017. Our search included studies that compared a patient decision aid with usual care in adults who were facing health decisions for themselves or a family member. Usual care may have been general patient information or nothing. We compared and summarized the results of the studies and rated our confidence in the certainty of the evidence.

What did we find?

We found 209 studies that involved 107,698 adults. The patient decision aids focused on 71 different decisions. The common decisions were about: surgery, screening (e.g. prostate cancer, colon cancer, prenatal), genetic testing, and long-term medication treatments (e.g. insulin injections for diabetes, or statins for high cholesterol).

We are moderately confident that adults given patient decision aids were more likely to choose an option that reflected what features of the options were most important to them. Our confidence in the evidence is only moderate because the studies that provided results for our review represent only a small set of the studies evaluating patient decision aids. We are confident that when adults used patient decision aids, they had large increases in their knowledge, expectations of benefits and harms, and participation in making the decision. We are also confident that they felt better informed and were more clear about what mattered most to them. We are confident that patient decision aids did not cause any unwanted effects such as regret about the decision.

What are the limitations of the evidence?

Further research could strengthen the confidence in the evidence for choosing options that reflect which features of the options are most important to people.

How up-to-date is this evidence?

This review updates our previous review published in 2017. The evidence is up-to-date to March 2022.

Summary of findings 1. Patient decision aids versus usual care for adults facing treatment or screening decisions

Patient decision aids compared with usual care for adults facing treatment or screening decisions

Patient or population : adults considering treatment or screening decisions

Settings : all settings

Intervention : patient decision aid

Comparison : usual care

Outcomes	Illustrative comparative benefits* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed benefit	Corresponding benefit				
	Usual care	Patient decision aid				
Congruence between informed values and choice - all studies Based on the proportion of participants who made a decision that aligned with what was most important to them. Assessed soon after exposure to the decision aid.	**295 per 1000** [c]	**481 per 1000** The proportion of participants who made an informed values choice was probably higher.	**RR 1.75** (1.44 to 2.13)	9377 (21 studies)	⊕⊕⊕⊝ **Moderate** [a,b,d]	—
Knowledge - all studies Standardized on a scale from 0 (no knowledge) to 100 (perfect knowledge). Assessed soon after exposure to the decision aid.	The mean knowledge score was 58.61% across control groups, ranging from 27.0% to 89.9%.	The mean knowledge score in the intervention groups was 11.90 higher (10.60 to 13.19 higher).	—	25,492 (107 studies)	⊕⊕⊕⊕ **High** [a,b]	Higher scores indicate better knowledge. 82 out of 107 studies showed an improvement in knowledge.
Accurate risk perceptions - all studies Based on the accuracy of perceived outcome probabilities according to the percentage of individuals whose judgments corresponded to the scientific evidence	**281 per 1000** [c]	**532 per 1000** The proportion of participants who accurately perceived their risk was higher.	**RR 1.94** (1.61 to 2.34)	7796 (25 studies)	⊕⊕⊕⊕ **High** [a,b]	—

about the chances of an outcome for similar people. Assessed soon after exposure to the decision aid.						
Decisional conflict: uninformed subscale - all studies Standardized on a scale from 0 (informed) to 100 (uninformed). Assessed soon after exposure to the decision aid.	The mean for the outcome 'feeling uninformed' ranged across control groups from 6.4% to 85.0%. Scores ≤ 25 are associated with following through on decisions. Scores > 38 are associated with delay in decision-making.	The mean feeling uninformed value in the intervention groups was 10.02 lower (12.31 to 7.74 lower).	—	12,104 (58 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling more informed.
Decisional conflict: unclear about personal values subscale - all studies Standardized on a scale from 0 (clear) to 100 (unclear). Assessed soon after exposure to the decision aid.	The mean for the outcome 'feeling unclear about personal values' ranged across control groups from 4.28% to 56.9%. Scores ≤ 25 are associated with follow-through with decisions. Scores > 38 are associated with delay in decision-making.	The mean feeling unclear value in the intervention groups was 7.86 lower (9.69 to 6.02 lower).	—	11,880 (55 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling clearer about values.
Participation in decision-making: clinician-controlled decision-making - all studies Based on the proportion of participants who indicated a passive role in decision-making where the decision was primarily made by the clinician. Assessed soon after consultation with the clinician.	**257 per 1000** [c]	**188 per 1000** The proportion of participants who had a passive role in decision-making (clinician-controlled) was lower.	**RR 0.72** (0.59 to 0.88)	4348 (21 studies)	⊕⊕⊕⊕ **High** [a,b]	Patient decision aids aim to increase patient involvement in making decisions; a lower proportion of clinician-controlled decision-making is better.

Adverse events: decision regret - all studies Standardized on a scale from 0 (no regret) to 100 (high regret). Assessed weeks to months after the decision is made.	The mean regret score was 15.6% across control groups, ranging from 6.4% to 27.0%.	The mean regret score in the intervention groups was not different -1.23 (-3.05 to 0.59).	—	3707 (22 studies)	⊕⊕⊕⊕ **High** [a,b]	—

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI : confidence interval; **RR** : risk ratio

GRADE Working Group grades of evidence
High certainty : further research is very unlikely to change our confidence in the estimate of effect.
Moderate certainty : further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low certainty : further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low certainty : we are very uncertain about the estimate.

[a] The vast majority of studies measuring this outcome were not at high risk of bias.
[b] We did not downgrade for inconsistency (heterogeneity) given the generally consistent direction of effects across studies for the decision aid compared to usual care groups.
[c] The data source for the assumed risk was the mean control event rate.
[d] We downgraded for possible publication bias. See funnel plot in Figure 1 . It is unclear the extent to which there is publication bias for this primary outcome. Therefore, we used a cautious approach and downgraded the certainty of evidence. This outcome is more challenging to measure because it is a composite measure. Hence, it is more likely that it is not measured in most studies rather than not reported.

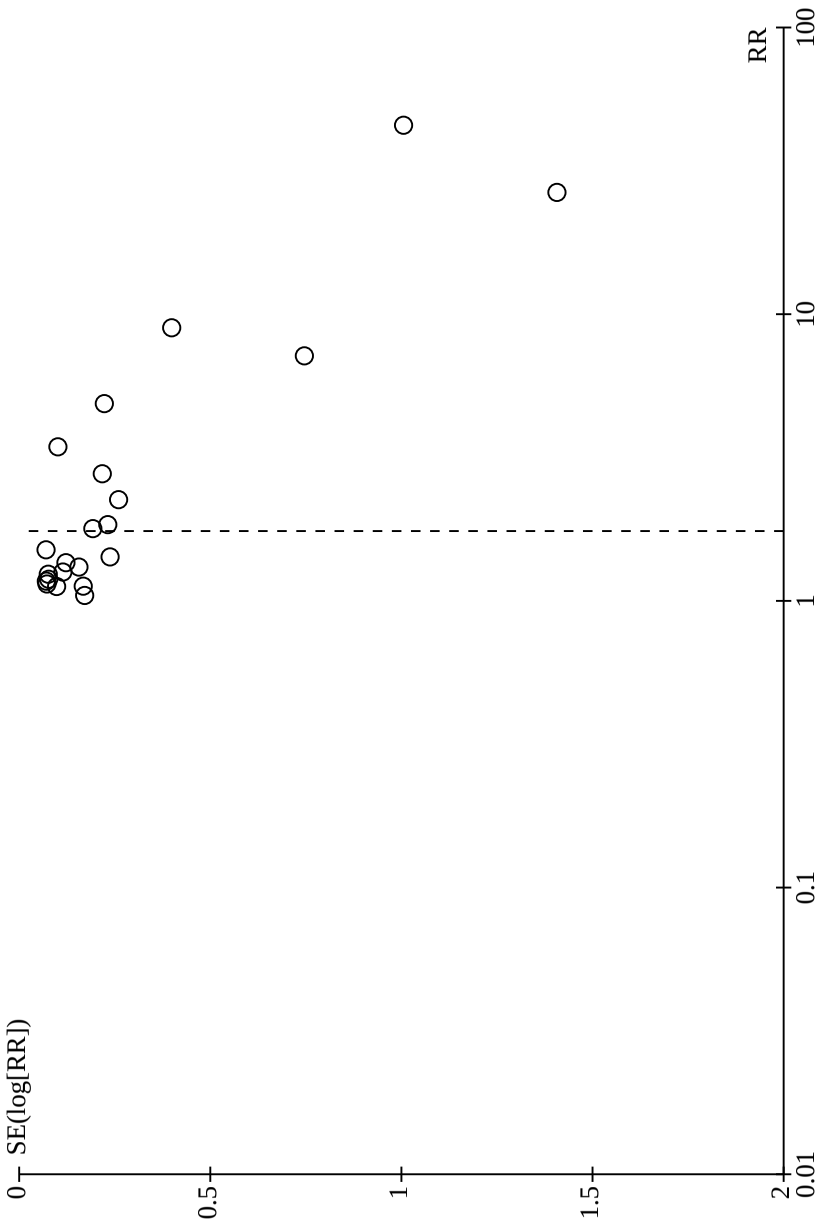


Figure 1. Funnel plot of comparison: 3.1 Informed values-choice congruence - all studies

BACKGROUND

Many health treatment and screening decisions have no single 'best' choice. Many, if not most, healthcare decisions are considered 'preference-sensitive' because there is insufficient evidence about outcomes associated with specific options or there is a need to trade off known benefits and harms across options. Patient decision aids are interventions that can be used to present the evidence about known benefits, harms, and outcomes related to the options and have patients consider what is important to them (or what matters most to them) (Brouwers 2010). Our original Cochrane review of patient decision aids was first published in 2003 (O'Connor 2003); the most recent update, published in 2017, was the top most-accessed active review for Cochrane Consumers and Communication and up to 2022 it has received the highest number of guideline citations overall (Stacey 2017), with authors of clinical practice guidelines from around the world citing the 2017 review 94 times (CDSR 2022). For example, this review provided the foundational evidence used in the shared decision-making guideline from the UK National Institute for Health and Care Excellence (NICE) (NICE 2021), which recommends using high-quality patient decision aids. Since 2015, the US Centers for Medicare & Medicaid Services requires the use of patient decision aids for reimbursement of some health services.

Description of the condition

This review focuses on the use of patient decision aids compared to usual care for all healthcare conditions.

Description of the intervention

Patient decision aids are evidence-based tools designed to help patients make specific and deliberate choices from among healthcare options; they are intended to supplement (rather than replace) clinicians' counseling about options. For this review, we are using the terms *patients* to refer to healthcare consumers, clients, and people in general making decisions for themselves or another close person, given that most patient decision aid studies are used in the healthcare system; we are using the term *patient decision aids,* given that decision aids are also used for decision support interventions for clinicians only. Patient decision aids meet the definition of complex interventions given the characteristics of their content and the way the content is presented (Skivington 2021). According to the International Patient Decision Aid Standards (IPDAS) Collaboration (Elwyn 2006 ; IPDAS 2005a ; Joseph-Williams 2013 ; Stacey 2021), patient decision aids, at a minimum, include the following elements:

1. they explicitly state the decision that needs to be considered for the target population;
2. they provide evidence-based, balanced information about a health condition, the options, associated benefits, harms; and
3. they help patients clarify, either implicitly or explicitly, the value they place on the benefits and harms of each option. To accomplish this, patient decision aids may describe the options in enough detail that patients can imagine what it is like to experience the physical, emotional, and social effects (to implicitly clarify values), or they may guide patients to consider which benefits and harms are most important to them using an explicit values clarification exercise.

Patient decision aids differ from health education materials. Whereas health education materials help patients to understand their diagnosis, treatment, and management in general terms, patient decision aids offer a process: they make the decision being considered explicit, providing a detailed, specific, and sometimes personalized focus on options and outcomes for the purpose of engaging patients in decision-making. Given their broader perspective, health education materials are not focused on specific decision points or the decision-making process; thus, they do not necessarily facilitate patients participating in decision-making. Many patient decision aids are based on a decision-making conceptual model or theoretical framework, where most health education materials are based on other conceptual models or theoretical frameworks, if used at all (Durand 2008 ; Mulley 1995 ; O'Connor 1998b ; Rothert 1987).

In response to concerns about heterogeneity in the quality of patient decision aids, the IPDAS Collaboration developed the original IPDAS criteria for judging their quality based on evidence syntheses (Elwyn 2006). The criteria address three domains of quality: clinical content, development process, and effectiveness. In 2013, an international team of researchers reached consensus on a shorter set of qualifying (n = 6), certifying (n = 6 for treatment, 10 for screening), and quality criteria (n = 28) (Joseph-Williams 2013). The IPDAS group updated the evidence on core IPDAS domains published in a series of papers (Stacey 2021). The Washington State Health Care Authority launched the first patient decision aid certification program in 2016, based on the work of the IPDAS group (Washington State Health Care Authority 2016). The IPDAS criteria are also used by the Norwegian Health Authority, the Center for Shared Decision Making in Denmark, and the Patient Decision Aid Research Group's International A to Z Inventory of publicly available patient decision aids (Dahl Steffensen 2022 ; Helsedirektoratet Norway 2017 ; Ottawa Hospital Research Institute 2023). Developers of patient decision aids are increasingly using the IPDAS framework to guide their development and evaluation processes.

How the intervention might work

Patient decision aids can be used before, during, or after a clinical encounter to facilitate patients becoming active, informed participants in making healthcare decisions. These decision support tools are typically process-oriented; thus, they structure and support the decision-making process with specific steps. Providing the patient decision aid before the consultation allows patients more time to digest the information and be ready to discuss the decision with the clinician, although this may not be feasible in some situations (e.g. antibiotics for upper respiratory infections). Patient decision aids can also facilitate shared decision-making. Shared decision-making is defined as a process through which clinicians and patients make informed healthcare choices together by using the best available evidence and incorporating patient's informed preferences (Légaré 2018 ; Makoul 2006). However, the way in which a clinician provides verbal information may strongly affect a patient's preferences (Hibbard 1997), prompting the need for standardized, balanced information offered by patient decision aids. Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences (Hibbard 2013 ; Hughes 2018 ; Shay 2015). Also, patient decision aids are geared at helping patients grasp the probabilistic nature of evidence and, hence, help them

navigate uncertainty, the hallmark of health evidence. In summary, patient decision aids may help clinicians and patients achieve a high-quality decision-making process, which will ultimately result in quality decisions, grounded in the patient's values and considering the potential trade-offs between benefits and harms across different options.

Why it is important to do this review

As never before, choice amongst multiple options exists for patients who are facing health decisions. To make quality evidence- and values-based decisions that are best suited for their circumstances, patients need access to the best available evidence about the possible options, opportunities to get them thinking about what is most important to them, and guidance to deliberate. Patient decision aids are designed to achieve this. Interest in patient decision aids has grown exponentially since the first Cochrane review on this topic was published in 2007. Given this growing interest, and their acknowledgment in over 90 clinical practice guidelines and in health policies internationally, there was a need to update this review. More specifically, we wanted to identify studies on new decisions or studies conducted in a broader range of countries and to strengthen the synthesized evidence in favor of patient decision aids for outcomes that do not yet have high-certainty evidence, as per GRADE.

Results from previous reviews were used to inform clinical practice guidelines such as those from the National Institute for Health and Care Excellence (NICE) (NICE 2021), Patient Experience in Adult NHS Services (NCGC/NICE 2021), and Collaboration and Shared Decision-Making Between Patients and Clinicians in Preventive Health Care Decisions and US Preventive Services Task Force (Davidson 2022). Some groups have established strategies to collaboratively develop patient decision aids from clinical practice guidelines and evidence summaries to accelerate translation of best evidence to patients and increase the quality of decision-making between clinicians and patients (Alonso Coello 2022 ; NICE 2021 ; van der Weijden 2019).

Previous updates of this review have been used to conduct subgroup analyses focused on outcomes of anxiety (Bekker 2003), adherence (Trenaman 2016), values-choice congruence (Munro 2016), and quality of life (Housten 2019 ; Rutherford 2019). Other subanalyses were about patients' motivation for participation in a patient decision aid trial on patient decision aid efficacy (Brown 2015), factors explaining the heterogeneity of effects on knowledge of outcome probabilities (Gentles 2013), strategies for presenting overdiagnosis in cancer screening patient decision aids (Housten 2019), and cancer-related decisions (McAlpine 2018).

Other systematic reviews were conducted on the use of patient decision aids as one type of intervention to facilitate shared decision-making in clinical practice (Coyne 2013 ; Duncan 2010 ; Elwyn 2013 ; Irish 2023 ; Légaré 2018 ; Mitropoulou 2022).

OBJECTIVES

To assess the effects of patient decision aids in adults considering treatment or screening decisions using an integrated knowledge translation approach.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published individual or cluster-randomized controlled trials (RCT) evaluating patient decision aids. There were no restrictions on language or settings.

Types of participants

We included studies involving adults aged 18 years or older who were making health decisions about screening or treatment options for themselves, a child, or as a proxy for a significant other. We excluded studies in which adults were making hypothetical choices.

Types of interventions

We included studies that evaluated a patient decision aid. Patient decision aids were defined as an intervention designed to help patients make specific and deliberated choices among options (including the status quo), by, at a minimum, making the decision explicit, providing information on the options and outcomes (e.g. benefits/harms) relevant to a person's health status, and implicit or explicit methods to clarify values. The patient decision aid also may have included: information on the disease/condition; costs associated with options; probabilities of outcomes tailored to personal health risk factors; an explicit values clarification exercise; information on others' experiences; personalized tailoring of information based on clinical characteristics; and guidance or coaching in the steps of making and communicating decisions with others.

We excluded studies if interventions focused on: decisions about lifestyle changes, social care, clinical trial entry, or general advance directives (e.g. do not resuscitate); education programs not geared to a specific decision; and interventions designed to promote adherence or elicit informed consent regarding a recommended option. Interventions focused on these decisions were excluded in the original review and subsequent updates continued to exclude them for consistency with the approved protocol (O'Connor 2003). We also excluded studies when the relevant patient decision aid(s) were not adequately described in the article(s) or available from the authors, such that our team was not able to determine the aids' characteristics and whether or not they met the minimum criteria to qualify as a patient decision aid.

Types of comparisons

We included studies that compared adults exposed to a patient decision aid to adults exposed to usual care. For the purpose of this review, usual care is defined as general information, risk assessment, clinical practice guideline summaries for health consumers, placebo intervention (e.g. information on another topic), or no intervention. We excluded studies that compared different formats or delivery methods of patient decision aids or compared two different types of patient decision aids (e.g. simpler versus more complicated) without also including a usual care comparison.

Types of outcome measures

We specified all primary and secondary outcomes in advance of the review (Table 1).

Primary outcomes

The outcome measures were mapped onto the International Patient Decision Aid Standards (IPDAS) criteria for evaluating the effectiveness of patient decision aids (Elwyn 2006 ; IPDAS 2005b ; Sepucha 2013). The IPDAS criteria were attributes related to the choice and to the decision-making process. For this update, there were enough studies reporting on attributes of the choice that knowledge and accurate risk perceptions were moved to process measures.

- Attributes of the choice made:
  - Does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient (as demonstrated by informed values-choice congruence)?
- Attributes of the decision-making process:
  - Does the patient decision aid help patients:
    - know the options and their features (knowledge, accurate risk perceptions, and feeling informed);
    - be clear about the features that matter most to them (clear values);
    - become involved in their preferred ways (participation in decision-making);
    - adverse events;
    - improve communication with their clinician (patient-clinician communication);
    - feel more satisfied with the decision-making process; and
    - be more prepared to make decisions?

Secondary outcomes

Secondary outcomes were choice (the actual choice implemented; if not reported, the patients' preferred option was used as a surrogate measure), confidence in decision-making, adherence to the chosen option, preference-linked health outcomes, and impact on the healthcare system (consultation length, costs, healthcare resource use).

Search methods for identification of studies

This is an update of a Cochrane review first published in 2003 (O'Connor 2003), and last updated in 2017 (Stacey 2017). For this update, the author team revised and streamlined the search strategies, based on their acquired knowledge of updated terms and practices. These revisions were achieved by testing altered terms against the search yield and with the use of 20 key and current references that were used to validate the strategy yields. We did this by checking that the references all appeared in the search results of the various databases searched. We also undertook forward citation checking of all 20 validation references. Our comprehensive search process included a range of electronic medical and social science databases, two clinical trial sites, forward citing of validation references, and grey literature sites known to the authors. New for this update was the use of the Cochrane RCT classifier to focus on identifying studies that were identified as RCTs and cluster-RCTs.

Electronic searches

The cumulative search of electronic databases is as follows.

- Cochrane Central Register of Controlled Trials (CENTRAL 2022, Issue 3) in the Cochrane Library (searched to 11 March 2022).
- MEDLINE Ovid (1966 to 11 March 2022).
- Embase Ovid (1980 to 11 March 2022).
- PsycINFO Ovid (1806 to 11 March 2022).
- CINAHL Ovid (1982 to September 2008), then in EBSCO (to 11 March 2022).

We present the search strategies in Appendix 1 , Appendix 2 , and Appendix 3 .

Searching other resources

We searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for ongoing/unpublished studies. We also searched the reference lists of newly included studies, and of systematic reviews of patient decision aids or interventions to support shared decision-making across various health conditions. We identified newly published studies from the trials in progress reported in the 2017 update (Stacey 2017).

Data collection and analysis

We conducted this Cochrane review following the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022). Using an integrated knowledge translation (KT) approach (CIHR 2015), our team consisted of a study executive including a patient partner (DS, KBL, MS, RJV, ED, MC) that met every two weeks for decision-making and a steering committee of an international group of researchers and knowledge users that were engaged in the entire systematic review process (Bowen 2013). For each step of the review development process, we invited team members to participate to the degree they were able to, considering their interest and expertise (Lewis 2023) (see Contributions of authors).

For this current update, we focused data collection only on newly published studies and any secondary publications of the original studies included in the previous update (Stacey 2017). The new data were analyzed together with the data from the previous update.

Selection of studies

Two independent authors (CB, MB, MC, KDS, ED, JF, AG, KBL, LPB, DS, RT, RJV) screened identified citations in Covidence (Covidence 2022) using a two-step screening process: (i) titles and abstracts; (ii) screening the full text of any citations identified as potentially relevant by at least one review author during the first step (Figure 2). Any disagreements were discussed with the principal investigator (DS) and/or the executive committee (DS, KBL, MS, MC, ED, RJV, SK). Then study interventions (e.g. articles, patient decision aids if available) were screened by two independent review authors to ensure they met the minimal definition for a patient decision aid. We provided citation details and reported details of additional publications relevant to the included studies, so that each study (rather than an individual publication of the trial results) was the unit of interest. We described ongoing studies with available information. No review authors made eligibility decisions about their own studies in this update, nor in any previous versions of this review.

Figure 2. PRISMA flow diagram

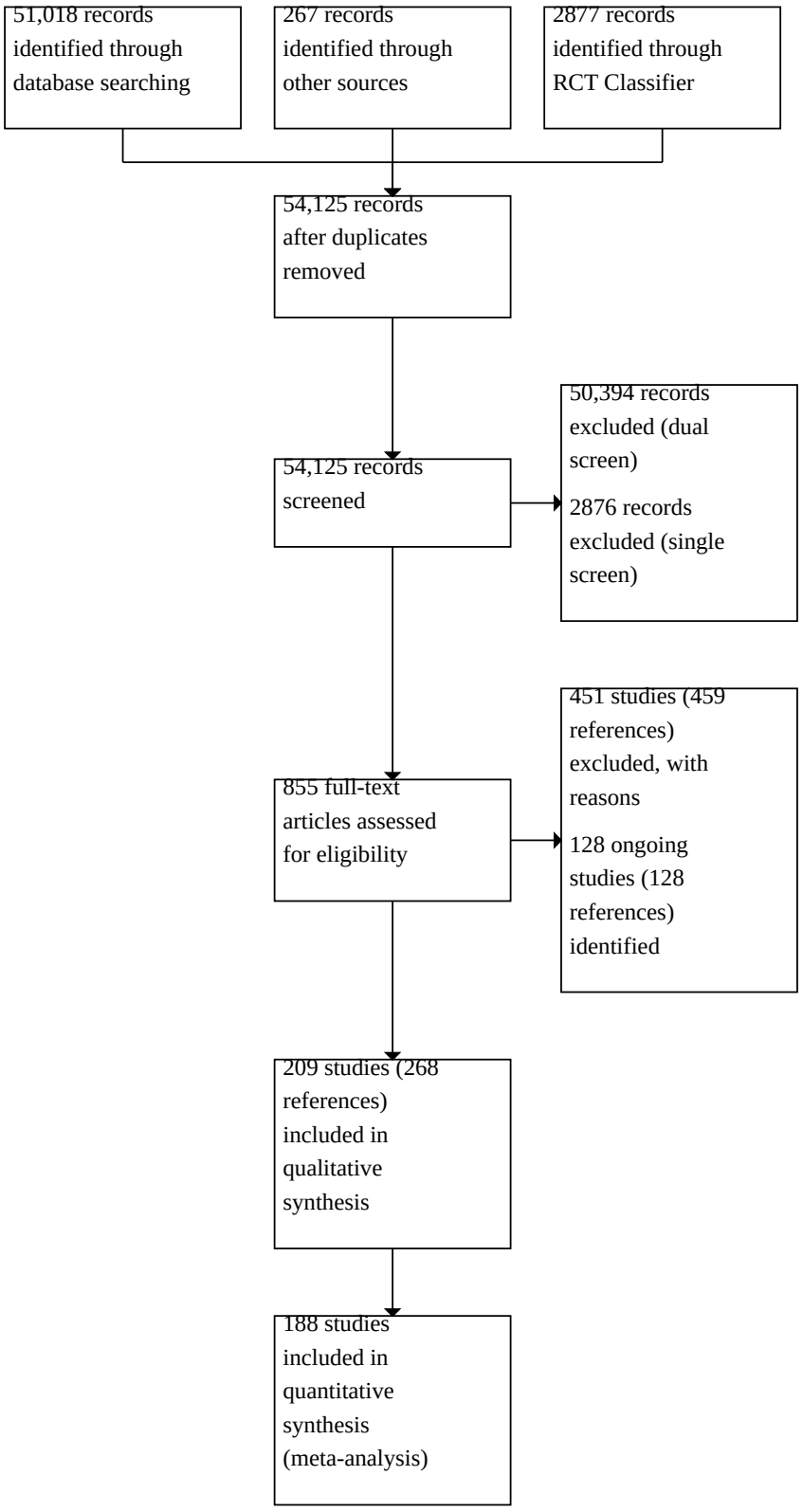
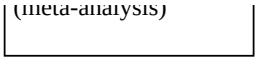


Figure 2. (Continued)



All articles excluded from step two were reported with reasons in Characteristics of excluded studies . One author screened all citations excluded using the RCT classifier to verify that it was not an RCT.

Data extraction and management

Two authors (LPB, JZ, MH) independently extracted data on the intervention, control, and outcomes, one of whom extracted data on all newly included trials (LPB). One author extracted data on the characteristics of the paper and Guidance for Reporting Involvement of Patients and Public (GRIPP2) (Staniszewska 2017). One author (MC) compared findings and flagged inconsistencies to be resolved through discussion with the principal investigator (DS) and/or the executive committee (DS, KBL, MS, MC, ED, RJV). No review authors extracted data for their own studies in this update nor in any previous versions of this review.

One author (MC) entered all extracted data into Review Manager (RevMan Web 2023). Results were audited by two authors (DS, KBL).

Assessment of risk of bias in included studies

Two authors (LPB, JZ, MH) independently appraised studies using the Cochrane tool for assessing risk of bias in randomized trials (Higgins 2011), as we did for the previously published version (Stacey 2017). We judged each item as conferring high, low, or unclear risk of bias as set out in the criteria provided by Higgins 2011 , and we provided a quote from the study report and a justification for our judgment for each item in the risk of bias table (Characteristics of included studies).

For the item on 'other' potential sources of bias, the assessment included: whether the same clinician provided consultation to both the intervention and usual care groups with measures taken post-consultation, and potential sources of bias reported by the authors in the study limitations. For cluster-RCTs, we considered other potential sources of bias when clustering was not accounted for in the analysis and if there was selective recruitment of cluster participants (Higgins 2022). Studies were deemed to be at the highest risk of bias if any item on the risk of bias tool was scored at high risk.

We resolved inconsistencies by discussion with the principal investigator (DS) and, when necessary, with the executive team (DS, KBL, MS, MC, ED, RJV). No review authors appraised risk of bias for their own studies in this update, nor in any previous versions of this review.

Measures of treatment effect

For dichotomous outcomes, we analyzed data based on the number of events out of the total number of patients observed in the intervention and comparison groups. We used these data to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analyzed data based on the reported means (or measure of central tendency), standard deviations (SD) (or dispersion measure), and number of patients assessed for both the intervention and comparison groups to calculate the mean difference (MD) and 95% CI.

The a priori comparison was patient decision aids versus usual care. For the 26 studies in which there were more than one intervention group, we extracted data from the two groups that provided the strongest contrast in intervention attributes (i.e. intensity) between the intervention and control groups. We pooled results across studies in cases where investigators used the same or similar outcome measures, and the effects were expected to be independent of the type of decision studied. For example, we expected patient decision aids to improve knowledge and create accurate perceptions of options, benefits, and harms; to reduce decisional conflict; and to enhance active participation in decision-making. Therefore, we pooled data from included RCTs for these outcomes if trials used comparable measures. To facilitate pooling of data for some outcomes (e.g. knowledge, decisional conflict), we standardized the scores to range from 0 to 100 points. When analyzing the effects of patient decision aids on choices, we pooled outcomes on homogeneous subgroups of decisions (choice of major surgery over conservative options by surgery type; choice of screening versus no screening by test type; choice for starting diabetes medication).

Unit of analysis issues

Given that we included both RCTs and cluster-RCTs, we assessed for unit of analysis errors. Where we found errors and sufficient information was available, we re-analyzed the data using the appropriate unit of analysis by taking account of the reported intracluster correlation (ICC). As required, we obtained missing estimates of the ICC by contacting authors of included studies, or we imputed them using estimates from external sources. For five studies, it was not possible to obtain sufficient information to re-analyze the data, and we reported these studies as being at high risk for 'other' bias based on these unit of analysis errors (Kupke 2013 ; Lewis 2010 ; Perestelo-Perez 2016 ; Saunier 2020 ; Stubenrouch 2022). For outcomes where these studies were included in the meta-analysis, we conducted subanalysis without these studies identified as high risk of bias.

Dealing with missing data

Where possible, we conducted analyses on an intention-to-treat basis; otherwise, we analyzed data as reported. We reported on the levels of loss to follow-up and assessed this as a source of potential bias.

Assessment of heterogeneity

If there was significant statistical heterogeneity according to the I^2 inconsistency index, we further examined the heterogeneity through visual assessment of forest plots.

For this update and in previous versions of the review, we grouped studies with the aim of assessing the effectiveness of patient

decision aids across conditions. Given that patient decision aids are a well-defined and clearly delineated type of intervention, we decided that this approach was defensible. On the basis of grouping studies across conditions, we anticipated that there would be a substantial degree of heterogeneity in our pooled effect estimates due to differences in the population, patient decision aid elements, comparators, and settings. However, we decided that we would consider the variability in the direction of effects rather than variability in the size of effects, as the major basis for our interpretation of heterogeneity.

In the 2009 update, we explored possible reasons for variability by conducting subgroup analysis when heterogeneity was present in pooled effect estimates (O'Connor 2009b). The post hoc analysis included the IPDAS effectiveness criteria to explore heterogeneity according to the following factors: the type of decision (treatment versus screening), the format of the patient decision aid (video/computer versus audio booklet/pamphlet), and the possibility of a ceiling effect based on usual care scores (resulting in the removal of studies with lower scores for knowledge and accurate risk perception and higher scores for decisional conflict using the subscales measuring levels of feeling uninformed and unclear values). We analyzed the effect of removing the biggest outlier(s) according to a visual inspection of forest plots. Given that these post hoc analyses did not alter the findings in the 2009 update, we have not re-conducted these post hoc analyses in any subsequent update.

Assessment of reporting biases

If more than 10 studies were identified and included meta-analysis, we explored publication bias using funnel plots and visual assessment of funnel plot asymmetry.

Data synthesis

We used RevMan Web 2023 to estimate a weighted intervention effect with 95% confidence intervals (CIs). For continuous measures, we used mean differences (MD); for dichotomous outcomes, we calculated pooled risk ratios (RRs). We analyzed all data with a random-effects model because of the diverse nature of the studies being combined and then anticipated variability in the populations and interventions of the included studies.

Subgroup analysis and investigation of heterogeneity

For outcomes where meta-analysis was possible, we conducted several subgroup analyses as follows: a) excluding studies rated as high risk of bias (see Sensitivity analysis); b) studies published since 2015 (n = 104 studies) (i.e. new studies included in this update) versus studies published prior to 2015 (n = 105 studies); and c) for studies measuring informed values-choice congruence using Multi-Dimensional Measure of Informed Choice (MMIC) (Michie 2002) (n = 13) versus studies that used other measures for calculating this outcome (n = 8). We pursued a subgroup analysis for newer versus older studies, given that there was a doubling of new studies added, the International Patient Decision Aid Standards Collaboration published minimal standards for patient decision aids in 2013 (Joseph-Williams 2013), which may have influenced the quality of patient decision aids being evaluated, and usual care may be improving with more clinical practice guidelines recommending use of patient decision aids (CDSR 2022) and health policies recommending shared decision-making in clinical practice (Bravo 2022). For the subgroup analysis of studies using MMIC versus studies using other measures, given the different approaches for calculating informed values choice congruence (Munro 2016), we were keen to know if those that used the most commonly used measure, MMIC, were the same or different from the other measures.

Sensitivity analysis

We performed post hoc sensitivity analyses to examine the effect of excluding studies that were at high risk of bias for any of the categories in the risk of bias assessment (Higgins 2011).

Summary of findings and assessment of the certainty of the evidence

We prepared Summary of findings 1 to present the results for the major comparison based on the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2022). We provided a source and rationale for each assumed risk cited in the table and used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to rank the certainty of the evidence for key primary outcomes (informed values-choice congruence, knowledge, accurate risk perceptions, decisional conflict, participation in decision-making, adverse events) on each of the following domains: risk of bias, inconsistency, imprecision, indirectness, and publication bias. Team members (DS, KBL, MS, MC, ED, RJV, LoT, JF) assessed the certainty of the evidence together using GRADEpro GDT in a meeting. We downgraded the evidence from high certainty by one level for serious study limitations (risk of bias), serious inconsistency, imprecision of effect estimates, indirectness of evidence, or potential publication bias . For our interpretation of heterogeneity, we considered the variability in the direction of effects rather than variability in the size of effects. Unlike drug trials where there is a standardized dose of a medication that is tested across trials in different people, patient decision aids are multi-component complex interventions that have minimal elements to meet the definition but may include other elements (see descriptions in the Characteristics of included studies section). In addition, the comparator is usual care and there can be variability across studies in how the patient interacts with the clinical team (e.g. clinician only, interprofessional team). Hence, we were advised to focus on the variability in the direction of effects for our interpretation of heterogeneity. This decision meant that for those pooled effect estimates where the direction of effect was consistent across studies, we did not downgrade the GRADE rating for inconsistency, despite some variability in the size of effects across individual studies.

RESULTS

Description of studies

This current version of our review updates our 2017 version (Stacey 2017) with 104 newly included studies, bringing the total to 209 included studies that evaluated patient decision aids compared to usual care (Figure 2 ; Characteristics of included studies). Of the 104 new studies, only 10 (9.6%) reported patient involvement on the study research team. Few studies provided details on their involvement according to the GRIPP reporting guideline (Staniszewska 2017). For example, one study reported providing training for patients on the team (Durand 2021), two studies discussed the aim of patient involvement (Hess 2016 ; LeBlanc 2015b), three studies described the methods used to involve

patients on the team (Durand 2021 ; Hess 2016 ; Singh 2019), and one study reported results of involving patients on the team and discussed the extent to which patient involvement influenced the results (Meier 2019).

Results of the search

In total, we identified 53,895 citations from the electronic database searches and 267 citations from other sources. Of these, we assessed 796 full-text citations for eligibility (see Figure 2).

Included studies

The updated search yielded 104 new studies that met our inclusion criteria, leading to a total of 209 studies included in this update. The 209 studies, involving 107,698 patients, presented results from 19 countries (including nine new countries as indicated by *): USA (n = 106), Canada (n = 23), United Kingdom (n = 21), Australia (n = 17), the Netherlands (n = 10), Germany (n = 8), China (n = 7), Spain (n = 6), Denmark* (n = 2), Finland (n = 2), France* (n = 2), Japan* (n = 2), Greece* (n = 1), Italy* (n = 1), Malaysia* (n = 1), New Zealand* (n = 1), Sweden (n = 1), Switzerland* (n = 1), Turkey* (n = 1), and four studies that were conducted in two countries. We present study details below and in Characteristics of included studies .

Unit of randomization

One-hundred and seventy-five studies randomized individual patients and 34 studies randomized clusters. For 26 studies, the cluster effect was taken into account in the published outcome data, and the meta-analysis used published results. Although Hamann 2006 did not account for the cluster effect in the published outcome data, the way this study was reported did not allow us to include it in the meta-analysis, so we did not re-analyze the data and report the study separately. For McAlister 2005 , meta-analysis was done applying the design effect (based on the published ICC). For Fraenkel 2012 , the authors stated that adding a random effect for clinician clusters did not contribute to better-fitting regression models, and we removed it from the analysis. Kupke 2013 , Lewis 2010 , Perestelo-Perez 2016 , Saunier 2020 , and Stubenrouch 2022 did not account for clustering in their analyses.

Patient decision aids

The 209 included studies evaluated patient decision aids that were focused on 71 different decisions. The most common decisions were about cardiovascular treatment (n = 22 studies), cancer screening (n = 17 studies colorectal, 15 prostate, 12 breast), cancer treatment (e.g. 15 breast, 11 prostate), mental health (n = 10 studies), and joint replacement surgery (n = 9 studies). The most common new treatment decision topics are in obstetrics (n = 4 studies), cardiovascular disease (n = 2 studies), kidney disease (n = 4 studies), obstructive sleep apnea (n = 3 studies), lung cancer screening (n = 2 studies), and upper extremity conditions (n = 3 studies). There were no decision aids related to COVID-19.

The patient decision aids used different formats, including 89 (43%) paper-based, 70 (33%) web-based or computer program, 33 (16%) including combinations of audio, video, web/computer-based, and paper-based, 15 (7%) video, and two (1%) scripts read aloud. Usual care consisted of various types of controls (e.g. usual care, general information, risk assessment, clinical practice guideline summaries for health consumers, placebo intervention (e.g. information on another non-relevant topic such as use of seat belts), or no intervention). We noted the details of the usual care approach when reported (see Characteristics of included studies).

According to the definition of a patient decision aid, all of the studies evaluated patient decision aids that included information about the options and outcomes and provided at least implicit clarification of values. Most patient decision aids included information on the clinical problem (92%) as well as outcome probabilities (88%). Fewer patient decision aids provided explicit methods to clarify values (67%), guidance in the steps of decision-making (66%), and/or examples of others' experiences (36%) (see Characteristics of included studies).

Excluded studies

We excluded 451 studies upon close perusal of the full texts (see Characteristics of excluded studies ; Figure 2). The reasons for exclusion were: the study was not a randomized controlled trial (n = 73 studies); the decision was hypothetical, with patients not actually at a point of decision-making (n = 30 studies); the intervention was not focused on making a choice (n = 25 studies); the intervention offered no decision support in the form of a patient decision aid (n = 166 studies) or did not provide enough information about the patient decision aid intervention (n = 15 studies); no comparison outcome data were provided (n = 3 studies); the study did not evaluate the patient decision aid (n = 11 studies); the study was a protocol (n = 1 study); the patient decision aid was about clinical trial entry (n = 2 studies), lifestyle choice (n = 4 studies), or advanced care planning (n = 18 studies); the study involved testing the presentation of the patient decision aid, but with no difference in the content of the patient decision aid between study groups (n = 9 studies); pediatric population (n = 2 studies); no outcomes of interest to this review (n = 12 studies); not a treatment or screening decision (n = 16 studies); or the study compared a detailed versus simple patient decision aid (n = 64 studies).

We also identified 128 ongoing studies through trial registration databases, personal contact, and published protocols in the electronic database searches (see Characteristics of ongoing studies).

Risk of bias in included studies

Details on the ratings and rationale for risk of bias are in the Characteristics of included studies table and displayed in Figure 3 and Figure 4 .

Figure 3. Risk of bias summary as percentages across all included studies.

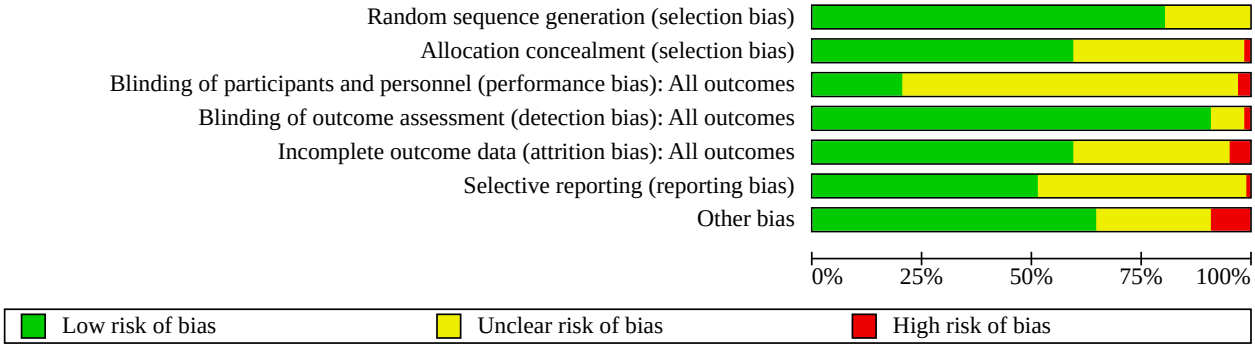
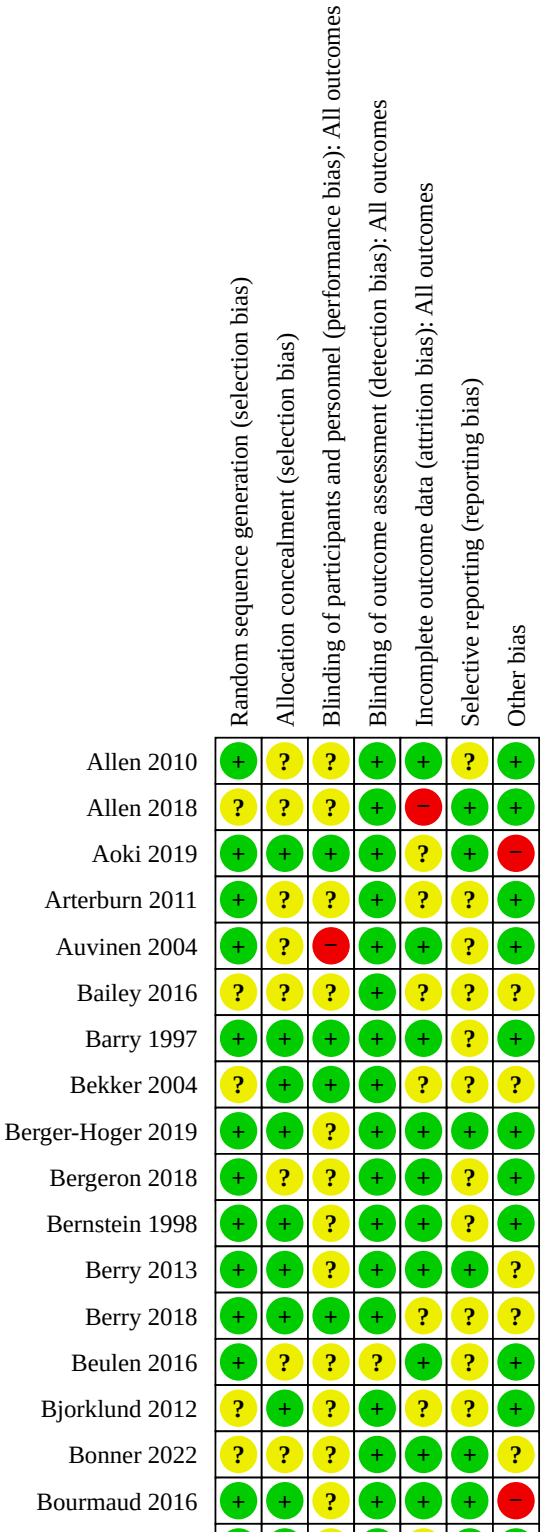


Figure 4. Risk of bias summary for each included study.



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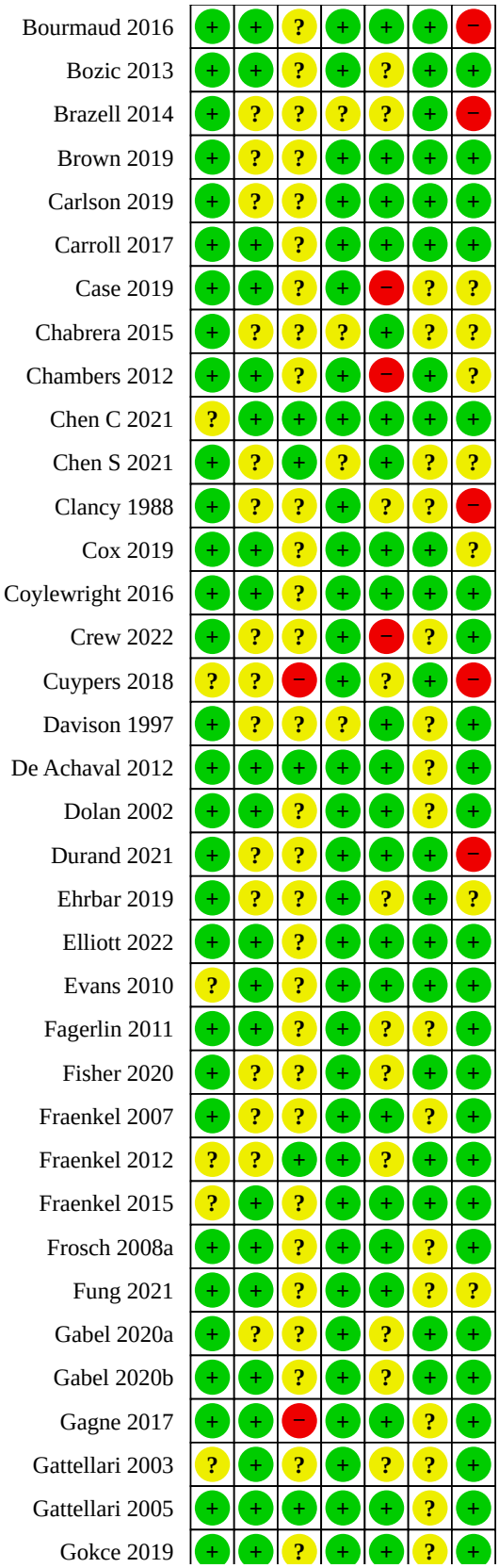

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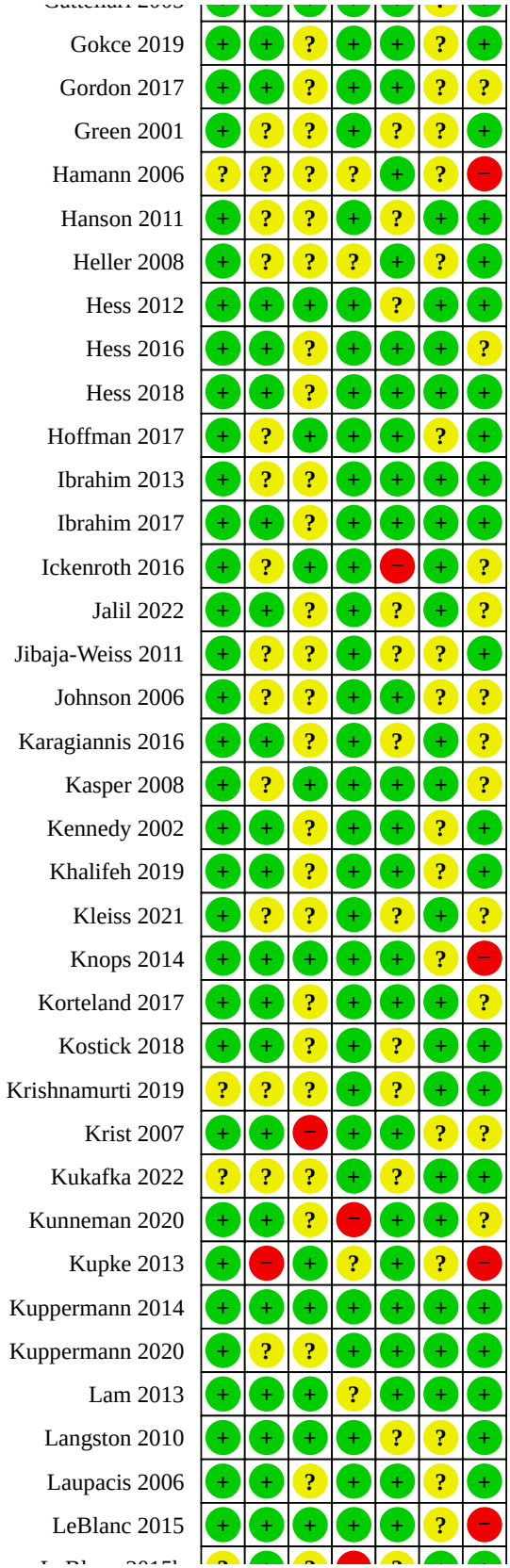

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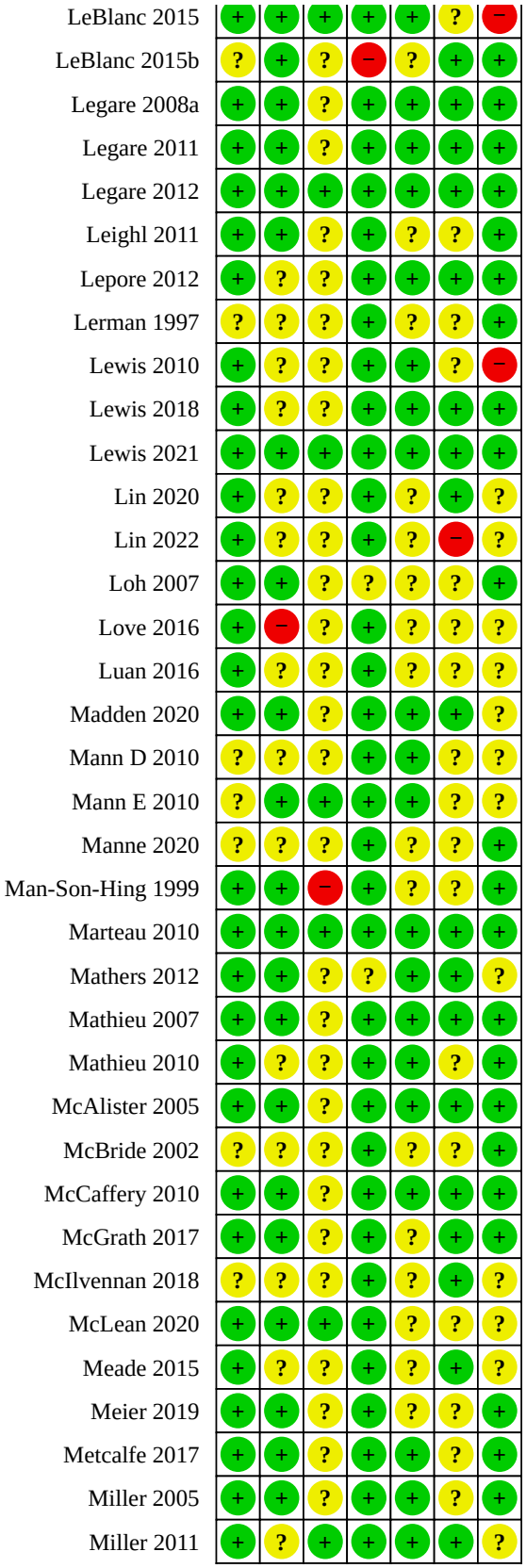

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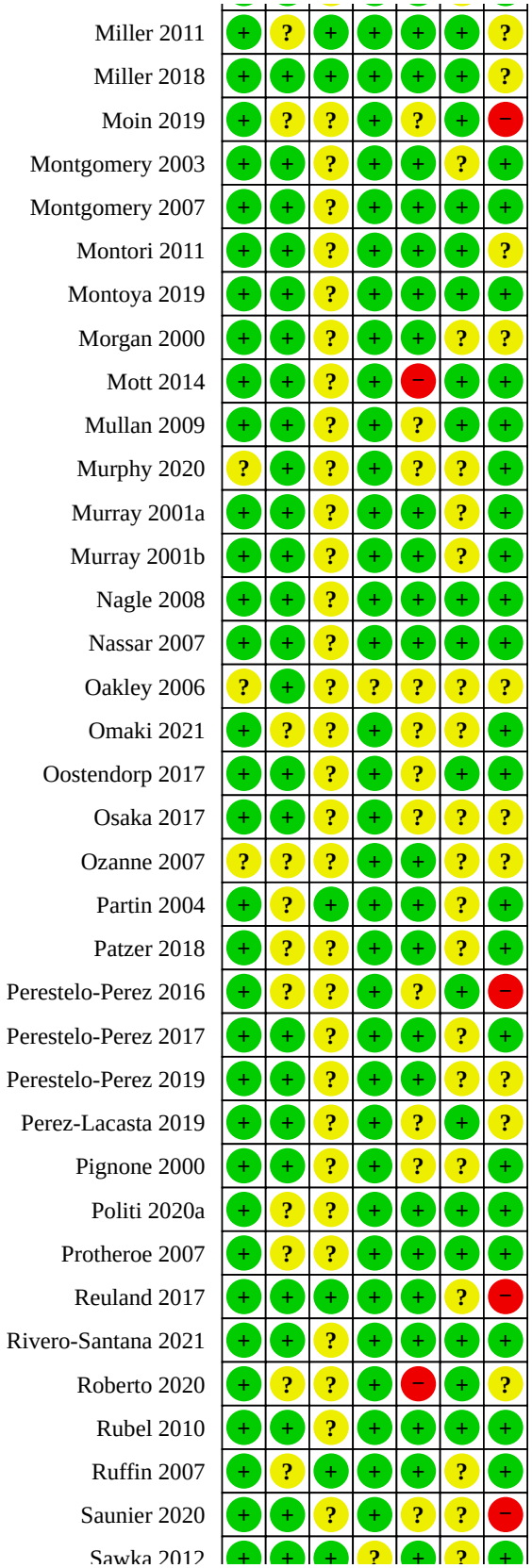

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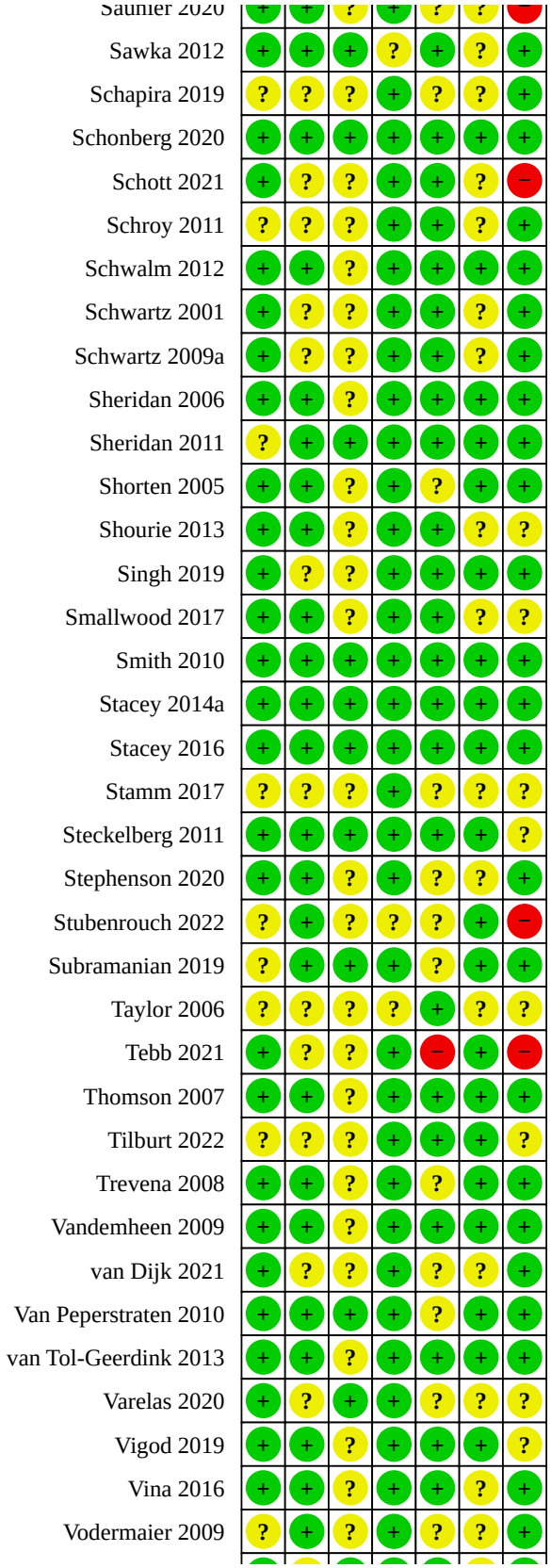

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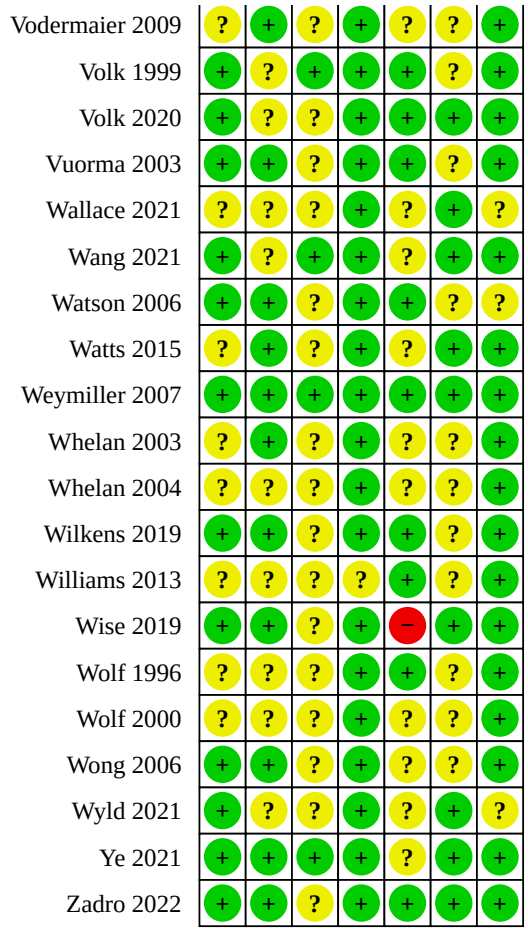


Allocation

When assessing risk bias for sequence generation, we rated all 209 studies as being at low (169 studies) or unclear risk of bias (40 studies). Allocation concealment methods prompted a rating of low in 125 studies, unclear in 82 studies, and high risk of bias in two studies (Kupke 2013 ; Love 2016).

Blinding

We judged 204 studies to be at low (43 studies) or unclear risk (161 studies) of performance and detection bias for the blinding of participants and personnel, while five (2.4%) studies were at high risk of bias. High risk of bias was due to lack of blinding of clinicians to the status of patients randomized to the patient decision aid and alternative interventions (Auvinen 2004 ; Cuypers 2018 ; Gagne 2017 ; Krist 2007 ; Man-Son-Hing 1999).

We rated the blinding of outcome assessment as leading to low risk in 192 studies or unclear risk in 15 studies, while two (0.96%) studies were at high risk of bias. High risk of bias was due to lack of blinding of assessors for observer-reported outcomes (Kunneman 2020 ; LeBlanc 2015b).

Incomplete outcome data

For 200 studies, aspects related to incomplete outcome data conferred low (125 studies) or unclear risk of bias (75 studies). In nine (4.3%) studies (Allen 2018 ; Case 2019 ; Chambers 2012 ; Crew 2022 ; Ickenroth 2016 ; Mott 2014 ; Roberto 2020 ; Tebb 2021 ; Wise 2019), there was high risk of bias due to high attrition rates (e.g. less than 90% of enrolled patients were included in the analysis) and significant differences in missing outcome data across groups (Hartling 2012).

Selective reporting

We rated 208 studies as being at either low risk of bias (108 studies) because the protocol was registered publicly or at unclear risk of bias (100 studies) because we could not assess the extent or the impact of any reporting bias, while one study was at high risk of bias. The high risk of bias was because it was stated that knowledge was a primary outcome in the trial registry, but the study failed to report any results for this outcome (Lin 2022).

Other potential sources of bias

Of the 209 studies, we rated 191 as being at low (n = 136) or unclear (n = 55) risk of other potential sources of bias. The other 18 (8.6%) studies discussed other potential risks of bias (Aoki 2019 ; Bourmaud 2016 ; Brazell 2014 ; Clancy 1988 ; Cuypers 2018 ; Durand 2021 ; Hamann 2006 ; Knops 2014 ; Kupke 2013 ; LeBlanc 2015 ; Lewis 2010 ; Moin 2019 ; Perestelo-Perez 2016 ; Reuland 2017 ; Saunier 2020 ; Schott 2021 ; Stubenrouch 2022 ; Tebb 2021). See Characteristics of included studies for details.

Effects of interventions

See: **Summary of findings 1** Patient decision aids versus usual care for adults facing treatment or screening decisions

1. Primary outcomes

Attributes of the choice made: does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient (informed values-choice congruence)?

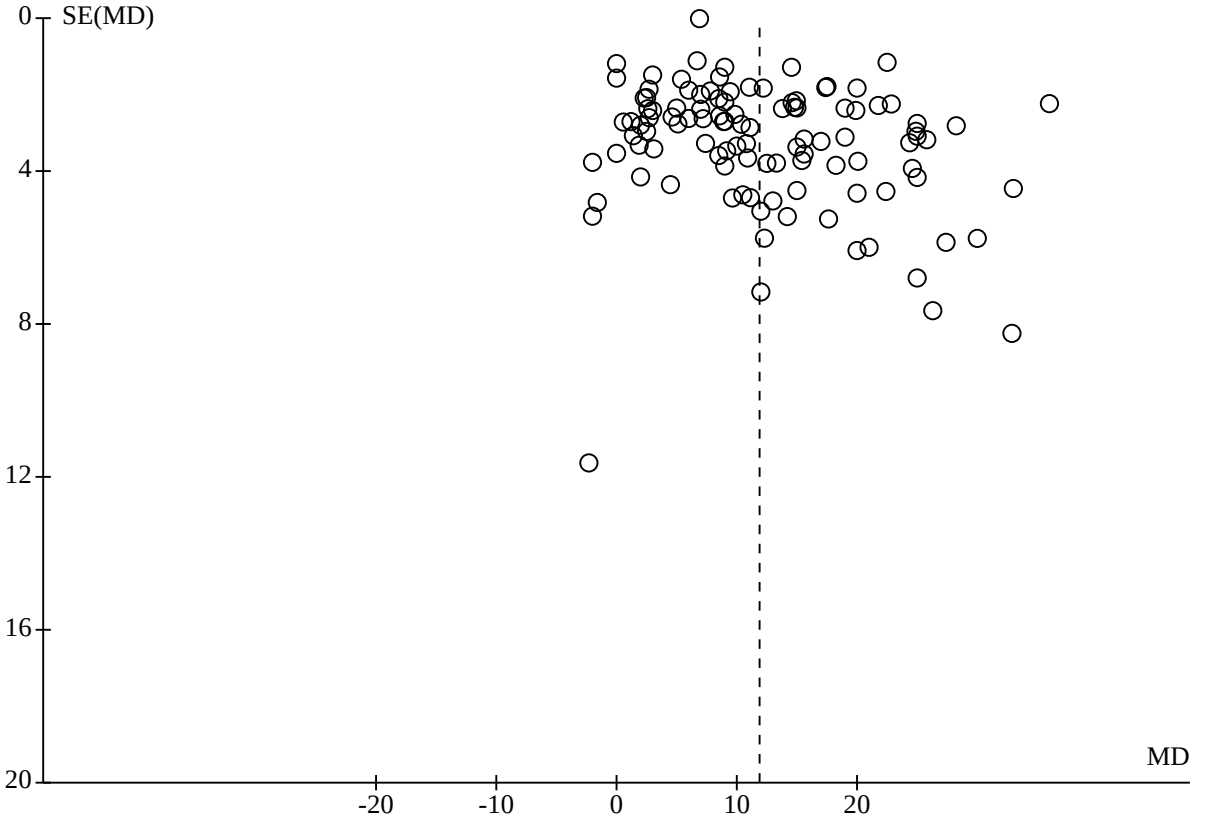
Of 209 studies, 35 (16.7%) measured congruence between the chosen option and the informed patients' values with 21 studies pooled (Analysis 1.1) and 14 not pooled (Table 2). There was moderate certainty in the evidence, downgraded for possible publication bias (Figure 1), that patient decision aids were probably more effective than usual care for selecting an option that was congruent with their informed values (RR 1.75, 95% CI 1.44 to 2.13; 21 studies) (Analysis 1.1). The average proportion of patients selecting an option that was congruent with their informed values, by study arm, was 48.6 out of 100 patients in the patient decision aid group compared to 30.5 out of 100 patients in the usual care group. When the three studies assessed as high risk of bias were removed, the findings were similar (RR 1.96, 95% CI 1.54 to 2.50; 18 studies) (Analysis 1.2). There were no differences between older and newer studies (Analysis 1.3). A subanalysis of the 13 studies that used the Multi-Dimensional Measure of Informed Choice (MMIC) (Michie 2002) showed that patient decision aids were probably more effective than usual care for this outcome (RR 1.75, 95% CI 1.37 to 2.23) (Analysis 1.4). A subanalysis of the eight studies that used different measures showed similar findings (RR 1.82, 95% CI 1.29 to 2.55) (Analysis 1.5).

Attributes of the decision process: does the patient decision aid help patients know the options and their features (knowledge and feeling informed), be clear about the features that matter most to them (clear values), become involved in their preferred ways (participation in decision-making), improve communication with their clinician (patient-clinician communication), feel more satisfied with the decision-making process, and be more prepared to make decisions?

Knowledge

Of 209 studies, 149 (71.3%) assessed the effects of patient decision aids on knowledge with 107 studies pooled (Analysis 2.1) and 42 studies not pooled (Table 3). High-certainty evidence indicated that patient decision aids were more effective than usual care on knowledge scores (mean difference (MD) 11.90 out of 100, 95% CI 10.60 to 13.19; 107 studies) (Analysis 2.1). The funnel plot shows that these studies are at low risk for publication bias (Figure 5). The average knowledge score by study arm was 70.9 out of 100 in the patient decision aid group compared to 58.6 out of 100 in the usual care group. When 12 studies assessed as high risk of bias were removed, the findings were similar (MD 12.13, 95% CI 10.74 to 13.52; 95 studies) (Analysis 2.2). There was no difference between older and newer studies (Analysis 2.3).

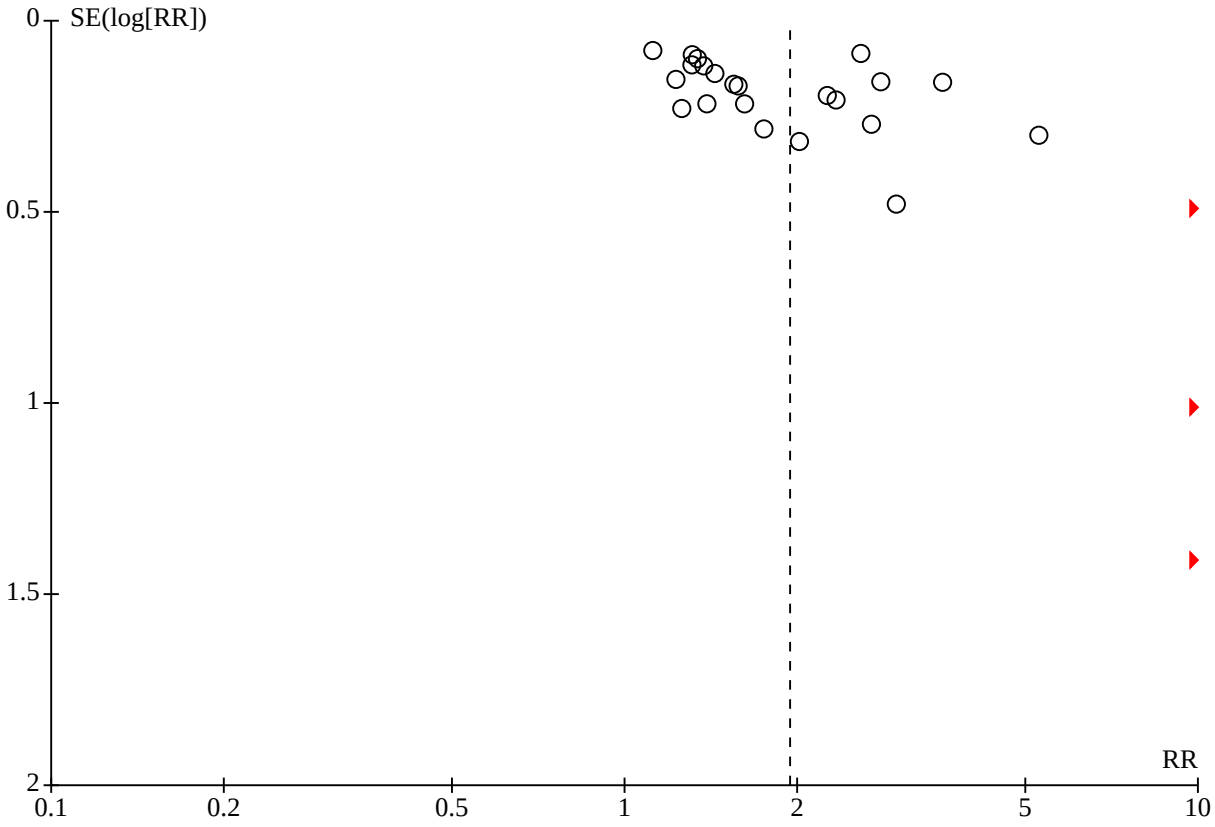
Figure 5. Funnel plot of comparison: 1 Knowledge, outcome: 1.1 Knowledge - all studies.



Accurate risk perceptions (perceived probabilities of outcomes)

Of 209 studies, 37 (17.7%) examined the effects of patient decision aids on the accuracy of patients' perceived probabilities of outcomes with 25 studies pooled (Analysis 3.1) and 12 studies not pooled (Table 4). There was high certainty in the evidence that patient decision aids were more effective than usual care for achieving accurate risk perceptions (risk ratio (RR) 1.94, 95% CI 1.61 to 2.34; 25 studies) (Analysis 3.1). The funnel plot shows that these studies are at low risk for publication bias (Figure 6). The average proportion by study arm was 53.2 out of 100 patients in the patient decision aid group who accurately interpreted risk compared to 28.1 out of 100 patients in the usual care group. When five studies assessed as high risk of bias were removed, the findings were similar (RR 1.99, 95% CI 1.60 to 2.48; 20 studies) (Analysis 3.2). There was no difference between older and newer studies (Analysis 3.3).

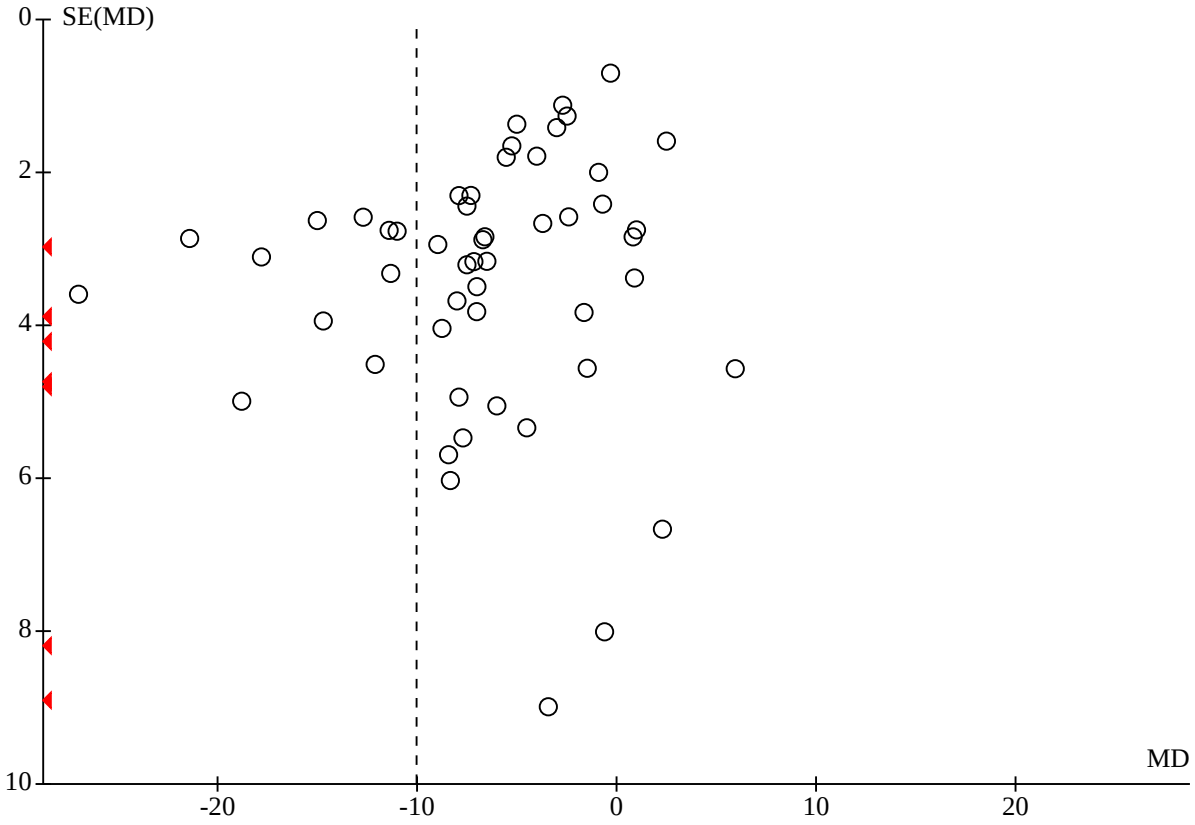
Figure 6. Funnel plot of comparison 2.1 Accurate risk perceptions - all studies



Decisional conflict subscales – feeling uninformed and unclear values

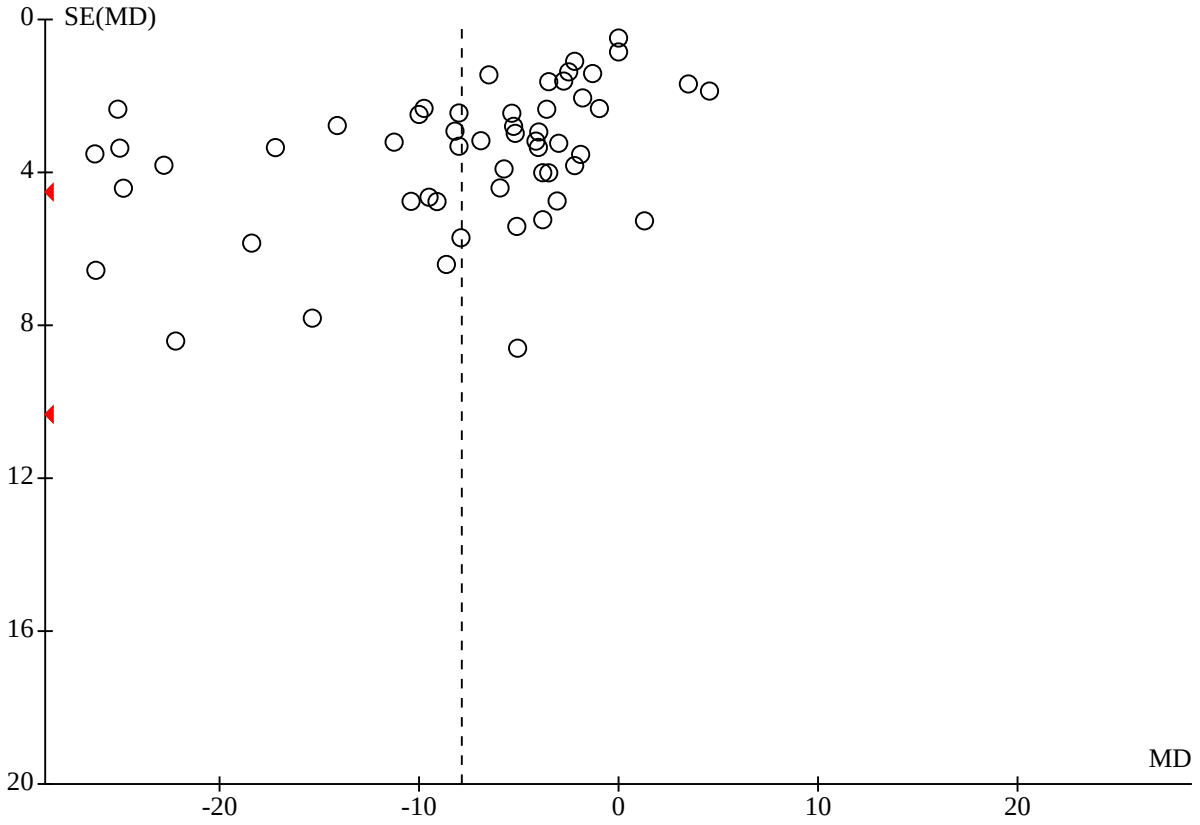
Of 209 studies, 75 (35.9%) measured patients' 'feeling uninformed' using the subscale of the Decisional Conflict Scale with 58 studies pooled (Analysis 4.1) and 17 studies not pooled (Table 5). There was high certainty in the evidence that patient decision aids were more effective than usual care in reducing patients' degree of 'feeling uninformed' about options, benefits, and harms (MD -10.02 out of 100, 95% CI -12.31 to -7.74; 58 studies) (Analysis 4.1). The funnel plot shows that these studies are at low risk for publication bias (Figure 7). The average scores by study arm were 20.9 out of 100 in the patient decision aid group compared to 31.6 for the usual care group, with lower scores indicating feeling less uninformed. When seven studies assessed as high risk of bias were removed, the findings were similar (MD -11.18, 95% CI -13.82 to -8.54; 51 studies; Analysis 4.2). There was no difference between older and newer studies (Analysis 4.3).

Figure 7. Funnel plot of comparison: 4.1 Decisional conflict: Uninformed - all studies



Of 209 studies, 71 (34.0%) measured patients' 'feeling unclear about values' using the subscale of the Decisional Conflict Scale with 55 studies pooled (Analysis 4.4) and 16 studies not pooled (Table 5). There was high certainty in the evidence that patient decision aids were more effective than usual care for reducing patients' degree of 'feeling unclear about values' (MD -7.86 out of 100, 95% CI -9.69 to -6.02; 55 studies) (Analysis 4.4). The funnel plot shows that these studies are at low risk for publication bias (Figure 8). The average scores by study arm were 19.9 out of 100 in the patient decision aid group compared to 28.8 for the usual care group, with lower scores indicating feeling less unclear about values. When seven studies assessed as high risk of bias were removed, the findings were similar (MD -8.60, 95% CI -10.73 to -6.47; 48 studies) (Analysis 4.5). There was no difference between older and newer studies (Analysis 4.6).

Figure 8.



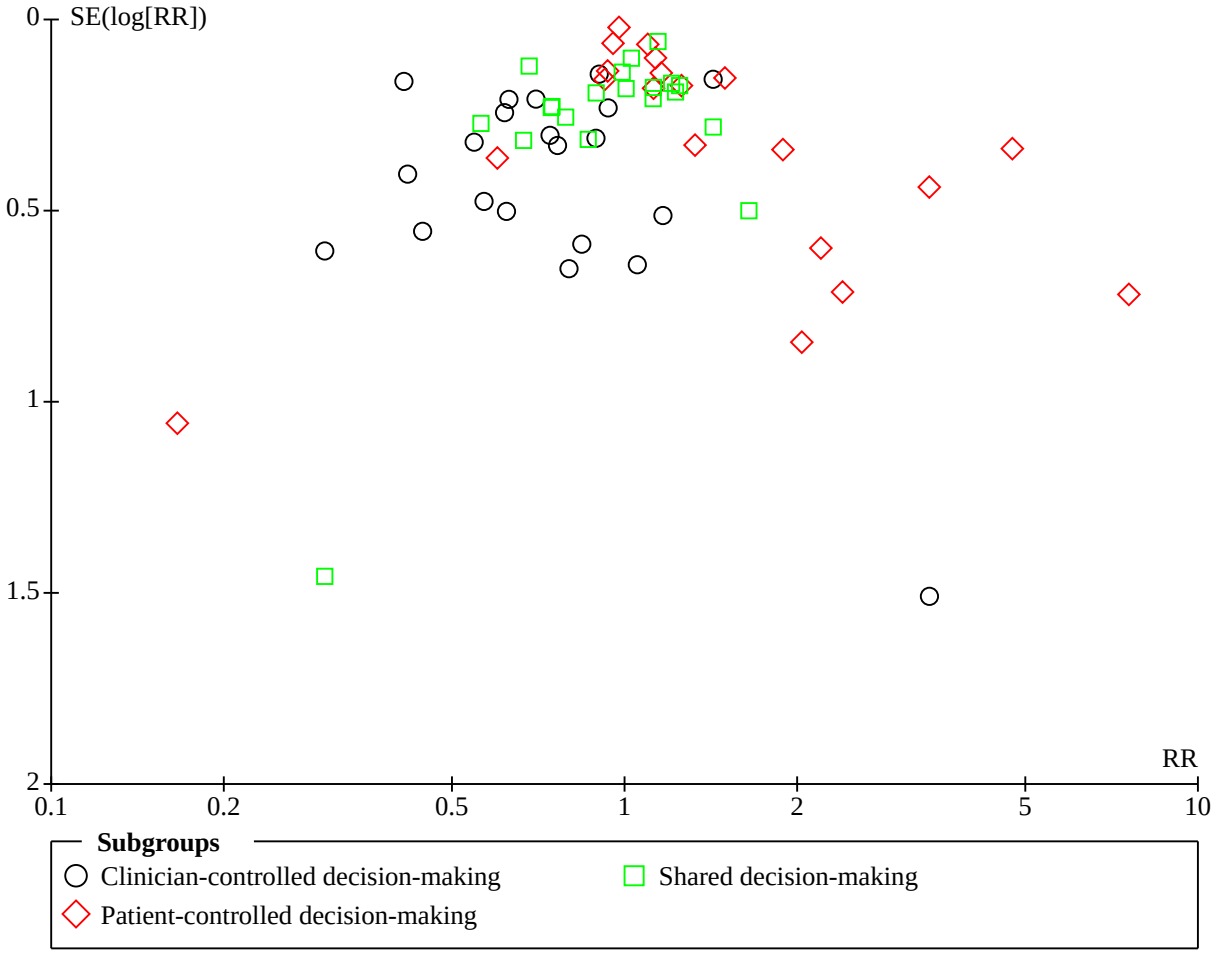
Participation in decision-making

Of 209 studies, 42 (20.1%) measured the effect of patient decision aids on patients' perceived role in decision-making with 25 studies pooled (Analysis 5.1) and 17 studies not pooled (Table 6). We conducted meta-analyses using the groupings of the Control Preferences Scale (Degner 1997).

Clinician-controlled role in decision-making

There was high certainty in the evidence that patient decision aids were more effective than usual care for reducing clinician-controlled decision-making (RR 0.72, 95% CI 0.59 to 0.88; 21 studies) (Analysis 5.1). The funnel plot shows that these studies are at low risk for publication bias (Figure 9). The average proportions for clinician-controlled decision-making by study arm were 18.8 out of 100 patients for the patient decision aid group compared to 25.7 out of 100 patients for the usual care group. When four studies assessed as high risk of bias were removed, the findings were similar (RR 0.81, 95% CI 0.66 to 0.98; 17 studies; Analysis 5.2). There was no difference between older and newer studies (Analysis 5.3).

Figure 9.



Patient-controlled role in decision-making

Patient decision aids were more effective than usual care for increasing patient-controlled decision-making (RR 1.22, 95% CI 1.05 to 1.43; 20 studies) (Analysis 5.1). The average proportions for patient-controlled decision-making by study arm were 48.2 out of 100 patients for the patient decision aid group compared to 36.8 out of 100 patients for the usual care group. When five studies assessed as high risk of bias were removed, there was no difference between groups (RR 1.20, 95% CI 0.99 to 1.45; 15 studies) (Analysis 5.2). There was no difference between older and newer studies (Analysis 5.4).

Shared role in decision-making

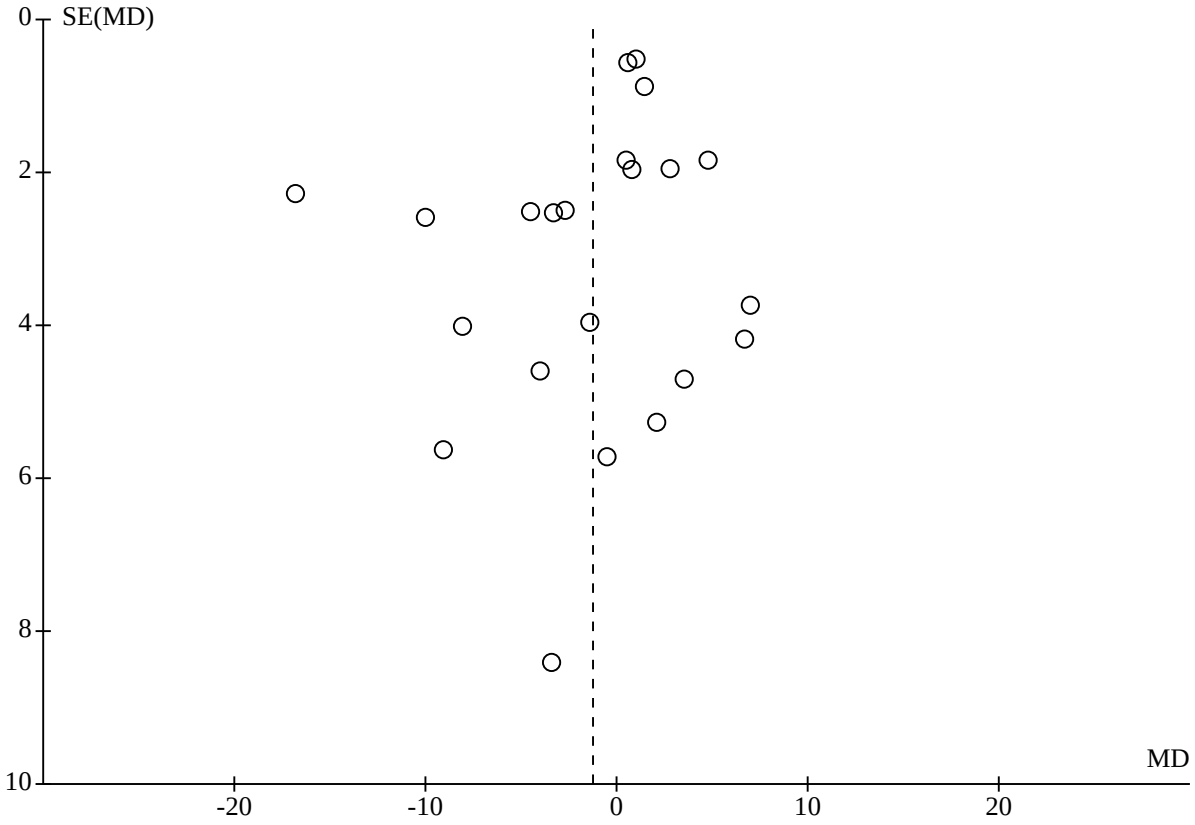
There was no difference between patients in the patient decision aids compared to usual care groups on patients' perception of achieving shared decision-making with their clinician using the Collaborative role on the Control Preferences Scale (RR 0.98, 95% CI 0.88 to 1.09; 20 studies) (Analysis 5.1). The average proportions for shared decision-making by study arm were 38.3 out of 100 patients for the patient decision aid group compared to 41.4 out of 100 patients for the usual care group. When four studies assessed as high risk of bias were removed, the findings were similar (RR 0.96, 95% CI 0.83 to 1.10; 16 studies) (Analysis 5.2). There was no difference between older and newer studies (Analysis 5.5).

Adverse events

Decision regret

Of 209 studies, 30 (14.4%) measured the effect of patient decision aids on decision regret, using the five-item Decisional Regret scale (Brehaut 2003) with 22 studies pooled (Analysis 6.1) and eight not pooled (Table 7). There was high certainty in the evidence that there was no increased decisional regret in patients exposed to patient decision aids as compared to those exposed to usual care (MD -1.23, 95% CI -3.05 to 0.59; 22 studies) (Analysis 6.1). The funnel plot shows that these studies are at low risk for publication bias (Figure 10). When five studies assessed as high risk of bias were removed, the findings were similar (MD -2.58, 95% CI -5.16 to -0.01; 17 studies) (Analysis 6.2). There was no difference between older and newer studies (Analysis 6.3).

Figure 10.



Emotional distress

Of 209 studies, five (2.4%) studies assessed the effect of patient decision aids on emotional distress, using various measures (Table 7). In four studies, there was little to no difference between groups. In one study, women with a positive BRCA result reported significantly less cancer-related distress at six months post-patient decision aid compared to women receiving usual care (mean 9.3 (SD 13.2) versus 25.2 (SD 14.5), P = 0.01) (Metcalfe 2017).

Proportion undecided

Of 209 studies, 46 (22.0%) measured the proportion of patients remaining undecided with 42 studies pooled (Analysis 7.1) and four studies not pooled (Table 8). A lower proportion of patients remained undecided after exposure to a patient decision aid (RR 0.68, 95% CI 0.58 to 0.80; 42 studies) (Analysis 7.1). The average proportion by study arm was 16.7% undecided for the patient decision aid group compared to 24.8% for the usual care group. When five studies assessed as high risk of bias were removed, the findings were similar (RR 0.68, 95% CI 0.57 to 0.81; 37 studies) (Analysis 7.2). There was no difference between older and newer studies (Analysis 7.3).

Patient-clinician communication

Of 209 studies, 36 (17.2%) measured the effect of patient decision aids on patient-clinician communication. Shared decision-making was measured using the observer-reported OPTION scale (n = 13), the patient-reported CollaboRATE (n = 7), and the patient-reported SDM-Q-9 (n = 5). Other measures of patient-clinician communication included reporting that the decision topic was discussed with the clinician (n = 11) and/or other items (n = 8) (Table 9). Analysis was conducted by instrument.

The analysis of eight studies that used the observer OPTION-12 (Elwyn 2005) showed that patient decision aids used during the consultation were more effective than usual care for improving patient-clinician communication (MD 12.14 out of 100, 95% CI 8.12 to 16.16) (Analysis 8.1). There were no differences between groups when patient-clinician communication was measured using OPTION-5 (MD 20.46, 95% CI -1.98 to 42.90; 2 studies) (Analysis 8.1), CollaboRATE (MD 1.76, 95% CI -0.50 to 4.03; 2 studies) (Analysis 8.1), or SDM-Q-9 (MD 1.38, 95% CI -2.50 to 5.25; 3 studies) (Analysis 8.1).

A subanalysis of 11 studies that reported whether the decision topic was discussed with the clinician also showed that patient decision aids were more effective as compared to usual care for improving patient-clinician communication (RR 1.42, 95% CI 1.19 to 1.70) (Analysis 8.2). When studies assessed as high risk of bias were removed, the findings were similar across measures (Analysis 8.3 ; Analysis 8.4).

Satisfaction with the decision-making process

Of 209 total studies, 16 (7.7%) measured satisfaction with the decision-making process with 12 studies pooled (Analysis 9.1) and four studies not pooled (Table 10). Patient decision aids were more effective than usual care for improving patient satisfaction with the decision-making process (MD 3.33 out of 100, 95% CI 1.18 to 5.48;

12 studies) (Analysis 9.1). The average scores by study arm were 79.4 out of 100 in the patient decision aid group compared to 76.4 for the usual care group. When four studies assessed as high risk of bias were removed, the findings were similar (MD 3.90, 95% CI 1.71 to 6.09; 8 studies) (Analysis 9.2). There was no difference between older and newer studies (Analysis 9.3).

Preparation for decision-making

Of 209 studies, 16 (7.7%) measured patients' preparation for decision-making using the Preparation for Decision Making Scale (Bennett 2010) with eight studies pooled (Analysis 10.1) and eight not pooled (Table 11). There was no difference in preparation for decision-making by group (MD 6.63, 95% CI -3.09 to 16.35; 8 studies) (Analysis 10.1). When one study assessed as high risk of bias was removed, patients exposed to patient decision aids felt more prepared for decision-making than those receiving usual care (MD 9.24, 95% CI 4.78 to 13.71; 7 studies) (Analysis 10.2). There was no difference between older and newer studies (Analysis 10.3).

2. Secondary outcomes

Choice

Of 209 studies, 165 (78.9%) studies measured the effect of patient decision aids on choice with 86 studies pooled (Analysis 11.1 ; Analysis 11.2 ; Analysis 11.3 ; Analysis 11.4 ; Analysis 11.5 ; Analysis 11.6) and 79 studies not pooled (Table 12 ; Table 13).

Choice for major elective surgery

Of 209 studies, 38 (18.2%) studies focused on choices regarding major elective surgery, defined as typically requiring general anesthetic. The effects of patient decision aids on choosing surgery over a conservative option were variable depending on the surgery type (Analysis 11.1). When two or more studies evaluated the same surgery type, fewer patients chose major elective surgery over conservative options when exposed to patient decision aids versus usual care during decision-making for implantation of left ventricular assist device (RR 0.75, 95% CI 0.60 to 0.93; 3 studies) (Analysis 11.1) or for undergoing coronary revascularization (RR 0.76, 95% CI 0.62 to 0.94; 2 studies) (Analysis 11.1). The use of patient decision aids did not have an effect on choice for other surgery types (breast cancer, joint replacement, upper extremity conditions, prostate cancer, benign prostatic hyperplasia, abdominal aortic aneurysm, renal stone treatment, bariatric surgery, and menorrhagia) (Analysis 11.1). Subanalysis without six studies rated as high risk of bias showed the same direction of effect (RR 0.91, 95% CI 0.86 to 0.97; 32 studies) (Analysis 11.4).

Choice for prostate-specific antigen screening

Of 209 studies, 13 (6.2%) studies focused on choice regarding prostate-specific antigen (PSA) screening with 11 studies pooled (Analysis 11.2) and two studies not pooled (Table 12). Fewer patients chose PSA screening when exposed to patient decision aids as compared to usual care (RR 0.89, 95% CI 0.81 to 0.99; 11 studies) (Analysis 11.2). Subanalysis without one study at high risk of bias showed the same direction of effect (RR 0.88, 95% CI 0.77 to 0.99; 10 studies) (Analysis 11.5).

Choice for colorectal cancer screening

Of 209 studies, 18 (8.6%) studies reported preferences or uptake rates for colorectal cancer screening with 17 studies pooled and one not pooled (Table 12). More patients chose colorectal cancer screening when exposed to patient decision aids as compared to usual care (RR 1.22, 95% CI 1.07 to 1.41; 17 studies) (Analysis 11.2). Subanalysis without two studies at high risk of bias showed the same direction of effect (RR 1.17, 95% CI 1.02 to 1.35; 15 studies) (Analysis 11.5).

Choice for cancer genetic screening

Of 209 studies, five (2.4%) studies reported preferences or uptake rates for breast cancer genetic screening, with four studies pooled and one not pooled (Table 12). There was no difference in screening rates among patients who used a patient decision aid as compared to those who did not (RR 1.04, 95% CI 0.77 to 1.39, 4 studies) (Analysis 11.2). None of the studies were rated as high risk of bias and all continued to be included in the subanalysis (Analysis 11.5).

Choice for breast screening

Of 209 studies, eight (3.8%) studies reported preferences or uptake rates for breast cancer screening with seven studies pooled and one not pooled (Table 12). Fewer patients chose mammography screening when exposed to a patient decision aid as compared to usual care (RR 0.97, 95% CI 0.94 to 0.99, 7 studies) (Analysis 11.2). A subgroup analysis without two studies rated as high risk of bias showed no difference in patients who chose mammography screening (RR 0.94, 95% CI 0.89 to 1.00; 5 studies) (Analysis 11.5).

Choice for prenatal screening

Of 209 studies, six (2.9%) studies reported preferences or uptake rates for prenatal screening with four studies pooled and two not pooled (Table 12). There was no difference in screening rates among patients who used a patient decision aid as compared to those who did not (RR 1.03, 95% CI 0.95 to 1.10; 4 studies) (Analysis 11.2). None of the studies were rated as high risk of bias and all continued to be included in the subanalysis (Analysis 11.5).

Choice for diabetes treatment with new medications

Of 209 studies, seven (3.3%) studies reported preferences or uptake rates for starting new medications for diabetes with six studies pooled and one not pooled (Table 12). There was no difference in preference or uptake rates for starting new anti-diabetic medications among patients who used a patient decision aid as compared to those who did not (RR 2.43, 95% CI 0.64 to 9.17; 6 studies) (Analysis 11.3). Subanalysis without two studies rated as high risk of bias showed increased preferences or uptake rates for starting new medications for diabetes (RR 1.65, 95% CI 1.06 to 2.56; 4 studies) (Analysis 11.6).

Confidence in decision-making

Of 209 studies, 27 (12.9%) studies measured the effect of patient decision aids on confidence in decision-making using the Decisional Self-efficacy Scale (n = 13), COMRADE (n = 2), or a range of other measures (see Table 14). A subanalysis of six studies that used the Decisional Self-efficacy Scale (O'Connor 2002) showed no difference between groups (MD 2.49 out of 100, 95% CI 0.03 to 4.95) (Analysis 12.1 .1). A subanalysis of six studies that used other measures showed that patient decision aids were more effective than usual care for increasing patient confidence in decision-making (MD 7.36, 95% CI 2.67 to 12.05; 6 studies) (Analysis 12.1 .2). When studies assessed as high risk of bias were removed, the findings were similar (Analysis 12.2). There was no difference between older and newer studies (Analysis 12.3).

Adherence to chosen option

Of 209 studies, 25 (12.0%) measured adherence to the chosen option using various approaches (Table 15). There were mixed results with some positive (n = 5 studies) and/or no difference (n = 20 studies). None of the studies showed a negative effect on adherence.

Preference-linked health outcomes

None of the 209 studies measured preference-linked health outcomes – that is, whether the patients experienced the outcomes they preferred and avoided the outcomes they wanted to avoid.

Impact on healthcare system

Consultation length

Of 209 studies, 23 (11.0%) examined the effects of patient decision aids on consultation length with 13 studies pooled by timing of intervention and 10 studies not pooled (Table 16). When used in preparation for consultation, there was little to no difference in consultation length for those exposed to a patient decision aid as compared to usual care (MD -2.97 minutes, 95% CI -7.84 to 1.90; 5 studies) (Analysis 13.1). When the patient decision aid was used during the consultation, the consultation length was 1.50 minutes longer compared to usual care (MD 1.50 minutes, 95% CI 0.79 to 2.20; 8 studies) (Analysis 13.1). More specifically, the consultation was 5.9 minutes longer when the added step of a decision analysis was used for prenatal diagnostic testing decision (Bekker 2004). When studies assessed as high risk of bias were removed, the findings were similar (Analysis 13.2). There was no difference between older and newer studies (Analysis 13.3 ; Analysis 13.4).

Cost

Of 209 studies, eight (3.8%) examined costs (Table 16). Three studies reported on cost-effectiveness analysis (Kennedy 2002 ; Shourie 2013 ; Stacey 2016 / Trenaman 2017) and six evaluated the effect of patient decision aids compared to usual care on total healthcare costs (Montgomery 2007 / Hollinghurst 2010 ; Murray 2001a ; Murray 2001b ; Stacey 2016 / Trenaman 2017 / Trenaman 2020 ; Van Peperstraten 2010 ; Vuorma 2003). For all three cost-effectiveness analyses, the use of a patient decision aid appeared to be more cost-effective compared to usual care. Effects of patient decision aids on total healthcare costs mostly showed little to no difference in three of the six studies (Montgomery 2007 – birth options after Cesarian, Stacey 2016 – surgery for joint replacement, Vuorma 2003 – hysterectomy for benign heavy bleeding). Two studies that used an interactive computer program (Murray 2001a - benign prostate enlargement; Murray 2001b – hormone replacement therapy) had increased costs, but when the decision aid intervention costs (interactive video disk equipment) were removed, there was little to no difference. Only one study showed significant reduced costs for the decision aid group (Van Peperstraten 2010 - embryo transfer for in vitro fertilization).

Healthcare resource use

Of 209 studies, eight (3.8%) examined healthcare resource use as related to patient decision aid use, for example outcomes such as the scheduling of initial or repeat consultations, length of hospital stay, and hospital admissions (Table 16). Studies reported little to no difference regarding healthcare resource use, except for Hess 2018 , which reported a reduced length of stay in the emergency department following exposure to the patient decision aid in the consultation (MD 23 minutes; P = 0.02).

3. Heterogeneity across studies

When comparing patient decision aids to usual care, there was statistically significant heterogeneity in the primary outcomes. It should be noted that the heterogeneity of the effect was not manifested in its direction but only in its size.

For the 2009 update (O'Connor 2009b), we explored the potential factors contributing to heterogeneity (Table 17). Overall, regardless of the subgroup analyses conducted, scores for outcomes were similar to the overall effect, as indicated by overlapping confidence intervals.

DISCUSSION

Summary of main results

In this updated review, we added 104 new studies for a total of 209 studies comparing patient decision aids to usual care on a broad range of treatment and screening decisions. Studies were conducted in 19 countries across four continents (Asia, Europe, North America, Australia/Oceania). There was moderate certainty of evidence that patient decision aids likely resulted in better congruence between participants' informed values for features of options and the choice made. There was high certainty of evidence that patient decision aids compared to usual care resulted in large increases in knowledge, accurate risk perceptions, and participation in decision-making. There was reduced decisional conflict for subscales of feeling uninformed and unclear values. Overall, these findings indicate higher certainty of evidence for these primary outcomes compared to the previous review (Stacey 2017).

For secondary outcomes, there continues to be variation in the effect of patient decision aids on patients' choosing particular options. The number of patients choosing to have major elective surgery decreases (with more patients in favor of conservative options), increases in colorectal cancer screening, and decreases in prostate cancer screening; other decisions showed no difference, or variable differences, with and without studies rated as high risk of bias. These variations may be due to some options being underused and others overused at baseline relative to choices patients would make if they were more fully informed, including increased awareness of alternative options and understanding of potential benefits and potential harms/adverse effects across options.

New for this update, we conducted meta-analysis that revealed that patient decision aids improved satisfaction with the decision-making process, increased confidence in decision-making, increased preparation for decision-making (after a high risk of bias study was removed), increased observer-reported shared decision-making, and consultations were no longer when patient decision aids were used in preparation for the consultation, and were only 1.5 minutes longer when they were used during the consultation. No studies demonstrated adverse effects in patients exposed to patient decision aids compared to usual care as indicated by no increased decision regret or emotional distress. There continues to be inadequate evidence on adherence to the chosen option, and healthcare system effects. No studies measured preference-linked health outcomes. In this update, we conducted

subanalyses of pooled data for patient decision aids by older studies published earlier than 2015 and newer studies published from 2015 onwards. We found no difference in outcomes based on publication dates.

Overall completeness and applicability of evidence

We used a highly sensitive search strategy to exhaustively identify as many papers as possible from all relevant databases and also used handsearching. Our search included studies published up until March 2022 and this update doubled the number of included studies since the last publication. It is important to note that patient decision aids are complex interventions minimally defined as including specific elements (e.g. explicit decision, information on options/benefits/harms, implicit or explicit values clarification) and although some articles reported studies of patient decision aids they did not always meet this minimal definition to be included in our review. Another difference across studies is the range of outcome measures used, with some more consistently used (e.g. Decisional Conflict Scale, Decision Regret Scale, OPTION instrument) and others being unique to individual studies (e.g. knowledge test, measure of informed values-choice concordance). Finally, the decisions and clinical settings within which the decisions are made also varied across studies.

Our review showed that few included trials (< 10%) reported engagement of patient partners. It is possible that patient partners were included on their research team, and this simply was not reported. These findings were consistent with other patient-oriented intervention trials reporting very poor engagement of patient partners (Fergusson 2018). Patient decision aid trialists should consider including patients and other knowledge user partners on their teams (and report their engagement), as early and meaningful engagement of knowledge users can facilitate and accelerate research findings into clinical practice (Bowen 2013 ; Gagnon 2009).

Despite these differences, patient decision aids improved many attributes of the decision and decision-making process across a wide variety of populations, and decisions. The largest and most consistent benefits of patient decision aids, relative to usual care, are better knowledge of options and outcomes, more accurate perceptions of outcome probabilities, feeling more informed, and clearer values. These observations are clinically important because these outcomes are important for ensuring informed decision-making and suggest that current 'usual care' may not be good enough for supporting patients in the process of making these complex, values-sensitive decisions. Patients need to comprehend the options and their associated benefits and harms in order to consider and communicate to their clinicians the personal value they place on the benefits versus the harms of the options. Furthermore, uninformed decisions indicate that these patients are not providing informed consent for the chosen option (if they proceed with it). In fact, patient decision aids make an imperfect ‘informed consent’ process better (Spatz 2016). With the recent rise of misinformation and its potential negative impact on patients (Bachtiger 2021 ; Stacey 2023), patient decision aids are a valuable tool to counter this misinformation by providing balanced, evidence-based health information on all relevant options. Patient decision aids can be of benefit to vulnerable patient populations (e.g. including those with limited health literacy, lower socioeconomic status, racial/ethnic minorities), who benefit from using patient decision aids that can lead to advanced health equity (Durand 2014 ; Grabinski 2018 ; Turkson-Ocran 2021).

Compared to usual care, patient decision aids improved patients’ perception of involvement in decision-making and observer evidence of shared decision-making. These observations continue to suggest that the IPDAS criterion of helping patients participate "in ways that they prefer" needs to be assessed after a patient has adequate information about what involvement means using interventions such as patient decision aids. Clinicians may mistakenly assume that patients’ passivity in decision-making is because they believe that the best choice relies on the expertise of the clinician (which option is medically reasonable?) rather than patients’ recognition of their own preferences for the features and outcomes of options (which outcomes matter most to me?). Yet in fact, both perspectives are necessary for achieving a quality evidence-based health decision.

This update included more studies reporting the length of consultation and showed no difference in consultation length when patient decision aids were used in the preparation for the consultation. Yet, consultations were 1.5 minutes longer when it was used in consultation. This increase may be explained by the learning curve associated with using a patient decision aid in the consultation during these effectiveness studies.

The effect of patient decision aids on patients’ choosing of particular options continues to be variable. There may be several reasons for the variable effect of patient decision aids on the outcome of choices. First, these findings reflect the nature of preference-sensitive decisions and we should expect variability in patient choices overall. Second, not enough is known about baseline rates for optimal use of specific options for specific decisions. Third, for studies reporting the outcome ‘choices’ at baseline and post-patient decision aid, some options may have been under-used and others over-used, relative to the choices individuals would make if they were more fully informed. Under these circumstances, one could expect to observe directional effects on choices once patients become better informed and more involved in decision-making.

Unknown effects of patient decision aids

Research is required to establish ways of measuring preference-linked health outcomes to better determine the effect of patient decision aids on quality of life. Given health outcomes are part of the quintuple aim (e.g. patient outcomes, patient experience, clinician experience, efficiency, equity) (Nundy 2022), and that different options can lead to different impacts on quality of life, this is an important research priority.

Other outcomes that require further research include adherence and cost-effectiveness. When examining adherence, it would be important to do so in the early phase, when presumably the issue is actually decisional in nature (e.g. filling the prescription, picking up the prescription, refilling the prescription) rather than a situation whereby patients with chronic conditions revisit their decisions that may involve choosing to change or remain with the status quo, or challenges with adding a new option to their daily routine that may require other interventions such as motivational interviewing. Our update found few new studies that reported on costs or cost-effectiveness; these findings are consistent with a previous paper reporting on this outcome (Trenaman 2014). Although there

may be additional costs involved in delivering patient decision aids, a clinical practice guideline on the patient experience reports that any increase is small relative to the benefit to patients in terms of improved decision quality and improved decision-making processes when effective patient decision aids are used (NCGC/NICE 2012).

Quality of the evidence

The certainty of evidence for key outcomes in Summary of findings 1 according to GRADE ranged from moderate to high. Most studies were judged as having minimal risk of bias. When the subanalysis was conducted by removing the few studies rated as high risk of bias, the direction of effect was consistent for primary outcomes and for most secondary outcomes. For informed values-choice congruence, the GRADE rating was downgraded for potential publication bias. It is unclear the extent to which there is publication bias for this one primary outcome. Therefore, we used a cautious approach and downgraded the certainty of evidence. In addition, given that this outcome is more challenging to measure, it is more likely that it is not measured in most studies rather than not reported.

Several of the outcomes demonstrated considerable levels of heterogeneity. This reflects differences across clinically diverse studies, interventions and comparators; therefore, the pooled effect size and confidence intervals should be interpreted as a range across conditions, which may not be applicable to a specific condition. In Gentles 2013 , three potential sources of heterogeneity were explored: type of control intervention, patient decision aid quality score using IPDAS, and participants' baseline accurate risk perception, and it was found that participants' baseline accurate risk perception was an important variable for explaining heterogeneity. For example, heterogeneity would be expected for the outcome of knowledge, given that the knowledge tests themselves were not standardized. However, we did not downgrade the certainty of evidence for inconsistency since there was a consistent direction of findings across studies.

Potential biases in the review process

We followed standard procedures for conducting the systematic review according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022). Our update showed continued poor-quality reporting of the patient decision aid intervention and comparators (Lewis 2017). However, we tried to obtain copies of patient decision aids and comparators when possible and only excluded trials if it was not possible to determine if the intervention was a patient decision aid. Other potential biases in the review process are due to limitations associated with having inadequate power to investigate any differences associated with the type of comparator used in studies. Measures for some outcomes were diverse, which may have biased those review findings. Finally, we limited the extracted study data to only two comparison groups (e.g. most intensive intervention including a patient decision aid and usual care); therefore, we did not investigate the possibility of intermediate effects with less intensive patient decision aid interventions.

Agreements and disagreements with other studies or reviews

Our results confirm many of the observations reported in the previous update (Stacey 2017), and in a comparative effectiveness review that focused on studies evaluating oncology-specific patient decision aids (Trikalinos 2014). There have also been several systematic reviews of patient decision aids for specific clinical areas (Irish 2023 ; Lin 2009 ; O'Neill 2017 ; Scalia 2019). These other clinically specific reviews typically include a broader range of study designs and some include any intervention with the title of patient decision aid without verifying that the intervention met the IPDAS definition of a patient decision aid. This makes it difficult to compare our results to other reviews. Our findings for consultation length were consistent with a systematic review focused on the duration of medical consultations for shared decision-making in 63 studies (e.g. RCTs, quasi-experimental studies, cross-sectional studies) (van Veenendaal 2022). These authors concluded that applying shared decision-making does not necessarily require longer consultations and suggested that multi-level implementation approaches can mitigate the possibility of increased consultation lengths. Furthermore, with greater opportunity for training and adaptation of work processes, clinicians get used to using them, which may eventually result in reduced or neutral time (van Veenendaal 2022). A recent large-scale implementation study titled ‘Share to Care’ included multi-level implementation interventions in 22 clinics (e.g. 80 patient decision aids, training of healthcare professionals, campaign to activate patient participation in decision-making, decision coaching) reported that consultation time initially increased and then decreased as clinicians’ skills in shared decision-making improved (Geiger 2022).

AUTHORS' CONCLUSIONS

Implications for practice

Over the last 20 years during which this review has been updated, there continue to be positive effects of patient decision aids on the quality of the decision and decision-making process across a wide variety of decisions, indicating sufficient evidence for using them in clinical practice. Findings from this latest update demonstrate that patient decision aids lead to large increases in knowledge, accurate risk perceptions, and patient participation in decision-making, enriching the evidence base for using them in clinical practice.

According to the results of this review update, patient decision aids satisfy four of five elements in the quintuple aim, including better patient experiences, better patient outcomes, reduced inequities, and improved clinician experiences. Further research is required to determine higher efficiency. As reported in this review version, there is moderate to high certainty of evidence that patient decision aids improve patient decision-making outcomes and experiences. Observer evidence reported in this update demonstrates that patient decision aids facilitate shared decision-making between patients and their clinicians and, as such, influence clinician experiences.

However, few patient decision aids were used in clinical practice as revealed in a survey of investigators of studies that were included in the previous review versions we conducted (Stacey 2014b ; Stacey 2017 ; Stacey 2019). The most common barriers reported by study authors were lack of funding or infrastructure support, outdated patient decision aids, lack of a mechanism for delivery, clinicians disagreeing with their use, and lack of a post-trial plan. Facilitators to patient decision aid use were online delivery, end users on the development team, endorsement

by organizations or clinical practice guidelines (e.g. government, charities, professional organizations), clinician awareness, training for clinicians, integration in the process of care, and leadership support.

Implications for research

Studies are needed to assess the impact of patient decision aids on adherence and downstream effects on cost and resource use. Although there is some evidence that patient decision aids can improve outcomes for patients with lower health literacy and reduce biases by race/ethnicity (Durand 2014 ; Grabinski 2018), further research is required to reduce health inequalities, with a particular focus on equity-deserving groups. National granting agencies now encourage researchers to use equity, diversity, inclusion, and social justice lenses. Having stronger data demonstrating that patient decision aids can be used to improve health equity or reduce inequities may be the evidence required to further support their use in clinical practice and healthcare systems.

Our update included new studies conducted in Denmark, France, Japan, Greece, Italy, Malaysia, New Zealand, Switzerland, and Turkey, but studies continue to be conducted across four continents. The update did not find any trials from resource-limited countries, including those in Africa (Gogovor 2022).

Research should also explore the influence of specific elements included in patient decision aids on outcomes. For example, determine if specific elements or their format minimize patients' cognitive processing, improve outcomes for individuals with lower health literacy, or improve their use in practice.

Further research needs to be conducted to tease out the reasons for heterogeneity underlying these results, including variability in study quality, comparators, independent and combined elements within patient decision aids, patient decision aid format (e.g. video, internet, paper-based booklets), decision type, and the clinical settings, health systems, and countries in which they are used.

ACKNOWLEDGEMENTS

We would like to acknowledge the contribution of Junqiang Zhao and Mandy Huang, graduate students at the University of Ottawa, who assisted with data extraction and risk of bias assessment. We thank Dean Fergusson at the Ottawa Hospital Research Institute who provided consultation on the interpretation of findings for determining GRADE ratings for the 2017 update; his guidance was applied for this update.

Editorial and peer reviewer contributions

Cochrane Consumers and Communication supported the authors in the development of this review update. Cochrane Consumers and Communication editors, and academic and consumer referees, provided advice regarding the original review methods. We would like to acknowledge the guidance and contributions of Rebecca Ryan, Anne Parkhill, and Louisa Walsh; in particular, we thank Anne Parkhill for conducting the updated searches, responding to peer review feedback, and for revising the search strategy used for this update.

The following people conducted the editorial process for this review update.

- Sign-off Editor (final editorial decision): Norio Watanabe, Department of Health Promotion and Human Behavior, Kyoto University School of Public Health, Japan;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Joey Kwong, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer reviewer comments, and supported the editorial team): Lisa Wydrzynski, Cochrane Central Editorial Service;
- Copy Editor (copy editing and production): Jenny Bellorini, Cochrane Central Production Service;
- Peer reviewers (provided comments and recommended an editorial decision): Amy C Barradell, Centre for Exercise and Rehabilitation Science, University Hospitals of Leicester NHS Trust; and Department of Respiratory Sciences, University of Leicester, UK (clinical/content review); Hector P Rodriguez, University of California, Berkeley (clinical/content review); Brian Duncan (consumer review); Clarinda Cerejo, Patient Expert and Patient Advocate (consumer review); Jennifer Hilgart, Cochrane Evidence Production & Methods Directorate (methods review); Joanne Platt, Cochrane Evidence Production & Methods Directorate (search review). One additional peer reviewer provided clinical/content peer review, but chose not to be publicly acknowledged.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Allen 2010

Study characteristics	
Methods	Cluster-randomized to decision aid vs usual care
Participants	398 + 414 men considering prostate cancer screening in the USA

Allen 2010 *(Continued)*

Interventions	DA: computer tailored program on clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision; interactive computer program: inherently guided the patient through the decision aid and decision-making process), tailored printout given to patients to promote discussion with others (practitioner, significant others). The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: no intervention
Outcomes	Primary outcomes: decisional status, knowledge, decision self-efficacy, decisional consistency Secondary outcomes: desire for involvement in decision-making, decisional conflict, preferred options Outcomes assessed pre- and postintervention
Notes	Source of funding: This study was funded by the Centers for Disease Control and Prevention (Grant 3U48DP000064-01S1, SIP 21-04 Community Intervention to Increase IDM for Prostate Cancer). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Sites were blocked on size and percent of male employees and randomly assigned by computer-generated random numbers to condition within blocks" (p 2173, Setting)
Allocation concealment (selection bias)	Unclear risk	The study does not address this criterion.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this criterion.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes measured were not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data and low rate of attrition that was consistent between groups.
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Intervention delivery: mention of money incentive to complete paperwork, but was judged to have no effect on outcomes measured (p 2175). Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Allen 2018

Study characteristics

Methods	Cluster, stepped-wedge trial, randomized to decision aid plus coaching vs usual care

Allen 2018 *(Continued)*

Participants	113 + 135 adults with end-stage heart failure considering destination therapy left ventricular assist device placement from 6 mechanical circulatory support programs across the USA
Interventions	DA: pamphlet and video used during consultation that included decision delivered by trained clinicians. DA includes information on the clinical problem, outcome probabilities, explicit values clarification, patient narratives, and guidance in communication. The DA is publicly available at https://patient-decisionaid.org/lvad/ Comparator: usual care consisting of the program's current education
Outcomes	Primary outcomes: decision quality, knowledge, and values-choice concordance Secondary outcomes: decision conflict, decision regret, control preferences, illness acceptance, perceived stress, depression, and quality of life Other outcomes reported: treatment preference, actual treatment received
Notes	Source of funding: This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (CDR-1310-06998). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors, or Methodology Committee. This work was also supported in part by the National Heart, Lung and Blood Institute (1K23HL105896-01, Allen), the Heart Failure Society of America (McIlvennan), the National Institute on Aging (1K23AG040696, Matlock), and REDCap database hosting through University of Colorado supported by NIH/NCRR Colorado CTSI (Grant Number UL1 TR001082). Conflicts of interest: Dr Allen reports consulting for Novartis, Boston Scientific, Janssen, Amgen, Duke Clinical Research Institute, and Grants from the Patient-Centered Outcomes Research Institute, National Institutes of Health, National Heart, Lung, and Blood Institute, and the American Heart Association. Dr Patel reports consulting for Abbott and Medtronic. Dr Cleveland reports consulting for Abbott. Dr Matlock reports funding from the American College of Cardiology Foundation. No other disclosures are reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	High risk	There is a high rate of attrition and it is significantly different between groups. At 6 months loss to follow-up is 42% intervention versus 33% control (P = 0.02706). Significantly lower enrolment in the control group: 228 randomized to control group but only 135 were enrolled in the full study (59%); 157 randomized to intervention but only 113 enrolled (72%) (P = 0.01015). Limitation section in paper does not indicate what effect this may have on the data, but only normalizes the dropout rates: "First, missing data were somewhat frequent and concentrated among the group of patients who did not undergo im-

Allen 2018 *(Continued)*

		plantation of DT LVAD. Death was the most common cause of missing data, followed by withdrawal from the study, both of which are common in studies targeting patients with life threatening illness. Our missing data rates are comparable to similar study types".
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02344576) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way. Outcomes related to the feasibility and acceptability of the intervention are reported elsewhere.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Aoki 2019

Study characteristics	
Methods	Randomized to decision aid + coaching vs usual care
Participants	35 (decision aid + coaching) versus 53 (usual care) undergraduate and postgraduate students aged 20 years and older who visited the outpatient services for first-time diagnosis of major depressive episode, including depressive phase of bipolar disorder in Japan
Interventions	DA: 3 decision aid booklets on depression, bipolar disorder, and medication treatment provided to patients during the initial consultation and prior to the decision coaching intervention and the decision-making consultation. The DAs contained general information on depression or bipolar disorder and their treatment options for patients undergoing psychiatric treatment for the first time, outcome probabilities, implicit values clarification, FAQs, guidance in communication, and a summary at the end of what was presented in the booklet. The DAs are available as a supplementary appendix in the article. Comparator: usual care delivered during the initial consultation
Outcomes	Primary: patient-perceived involvement in medical decisions (COMRADE) Secondary: satisfaction, consultation duration, sharing information with others, looking up information on options/treatments, persistence with treatment, severity of depressive symptoms, medication adherence
Notes	Source of funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Conflicts of interest: Author Koichiro Watanabe has received manuscript fees or speaker's honoraria from Astellas Pharma, Daiichi Sankyo, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceutical, Meiji Seika Pharma, Mitsubishi Tanabe Pharma, MSD, Otsuka Pharmaceutical, Pfizer, Shionogi, Sumitomo Dainippon Pharma, and Yoshitomi and has received research/grant support from Astellas Pharma, Daiichi Sankyo, Eisai, MSD, Mitsubishi Tanabe Pharma, Meiji Seika Pharma, Otsuka Pharmaceutical, Pfizer, Shionogi, and Sumitomo Dainippon Pharma and is a consultant of Eli Lilly, Otsuka Pharmaceutical, Pfizer, Sumitomo Dainippon Pharma, Taisho Toyama Pharmaceutical, and Takeda Pharmaceutical. Author Yoshikazu Takaesu has received speaker's honoraria from Eisai, Eli Lilly, Meiji Seika Pharma, Mitsubishi Tanabe Pharma, Otsuka Pharmaceutical, and Yoshitomi Pharmaceutical and has received research/grant support from Eisai, Meiji Seika Pharma, and Otsuka Pharmaceutical. The other authors declare no conflict of interest.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Aoki 2019 *(Continued)*

Random sequence generation (selection bias)	Low risk	"Participants were randomly assigned to one of two arms, following the restricted randomization and minimization method of item 8 in CONSORT 2010 (Moher 2012)" COMMENT: *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Allocation concealment (selection bias)	Low risk	The randomization was conducted by a research assistant not directly involved in the study.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Clinicians and nurses were not blinded because of the design of the study. Low risk because objective measures used.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A research assistant blinded to group allocation collected data at baseline, after the decision-making consultation, and at each visit during the 6-month trial period.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for attrition clearly described (see Figure 1). Missing outcome data balanced across groups: intervention 20/35 (57%), control 32/53 (60%). However, it was unclear how the high rate of missing data influenced the results.
Selective reporting (reporting bias)	Low risk	Registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN000009239) before the commencement of data collection. Outcomes reported were consistent with the study protocol.
Other bias	High risk	The numbers randomized to each arm were extremely disproportionate (35 intervention; 53 control). Recognized in limitations but no discussion on the influence on the results: "Fourth, a slight difference was observed between the samples in the two arms despite our calculation and estimation of an appropriate sample size. As a result, our trial might not have had an adequate sample size to detect a difference between the two arms."

Arterburn 2011

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	75 + 77 participants considering bariatric surgery in the USA
Interventions	DA: booklet + video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to discuss with clinician). The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: knowledge, values, values concordance Secondary outcomes: treatment preference, decisional conflict, decisional self-efficacy, proportion undecided Primary outcomes assessed at baseline, postintervention and 3 months follow-up; secondary outcomes assessed at baseline and postintervention

Arterburn 2011 *(Continued)*

Notes	Source of funding: This work was funded by the Foundation for Informed Medical Decision Making Inc., Grant nos. 0077-4 and 0094-1. The sponsor did not have any role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript. Conflicts of interest: D.E.A., E.O.W., T.A.B., and K.R.S. have support from the Foundation for Informed Medical Decision Making for the submitted work. D.E.A. receives research funding and has received salary support as a medical editor for the not-for profit (501[3]c) Foundation for Informed Medical Decision Making (http://www.fimdm.org), which develops content for patient education programs - including the bariatric surgery program that is the subject of this study. K.R.S. has also received research and salary support from the foundation. The Foundation has an arrangement with a for-profit company, Health Dialog, to coproduce and market these programs to health-care organizations. D.E.A. and K.R.S. have no relationship with any company making products for the treatment of obesity. The authors' spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and authors have no nonfinancial interests that may be relevant to the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[U]sed computer-assisted, block randomisation process to ensure balanced allocation of participants" (p 1670, Participants and randomization)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment and no mention of impact on study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]tudy was not blinded" (p 1670, Participants and randomization); no mention of impact on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Measures: mentioned 4 choices for treatment preference (surgery, drug therapy, diet and/or exercise program and unsure) but only reported on surgery and unsure options (p 1671); minimal attrition that was consistent between groups.
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration; all pre-specified outcomes included.
Other bias	Low risk	The study appears to be free of other sources of bias.

Auvinen 2004

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	103 + 100 men newly diagnosed with prostate cancer in Finland
Interventions	DA: pamphlet patient decision aid created for study on options' outcomes, outcome probability, guidance. The DA is available as an appendix in the development article (Auvinen 2001).

Auvinen 2004 *(Continued)*

	Comparator: usual care by clinical guideline
Outcomes	Primary outcome: uptake of options Secondary outcome: participation in decision-making Other outcomes (from Huang 2014): death (5 years), disease-free survival (10 years), biochemical failure (serum PSA elevation) (5 years), biochemical failure-free survival (5 years), disease progression (5 years), disease progression-free survival (5 years) (data from 104 + 106 men)
Notes	Source of funding: The study was supported financially by the Finnish Cancer Institute, Academy of Finland, Cancer Society of Finland, Pirkanmaa Cancer Society and Pohjois-Savo Cancer Fund. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Auvinen 2001, p 2: "randomized centrally, using software based on a random number generator"; no blocking used Auvinen 2004, (primary study), p 1: "randomized using a computer algorithm based on random numbers"
Allocation concealment (selection bias)	Unclear risk	Auvinen 2001, p 2, Patients and Methods: randomized centrally at the Finnish Cancer Registry Auvinen 2004, (primary study), p 1: randomized centrally Comment: central allocation confers low risk
Blinding of participants and personnel (performance bias) All outcomes	High risk	Auvinen 2001, p 3: "recognized carry-over effect because same physician in charge for intervention and control groups, diminish contrast between groups, as these physicians were more motivated to inform patients than those physicians not participating" Auvinen 2004 (primary study): no blinding but primary outcome is choice of treatment for prostate, objectively recorded. However, unsure how physicians may have influenced decisions.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but primary outcome is choice of treatment for prostate, objectively recorded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Auvinen 2001, p 3: flow chart "Imbalance in the numbers of patients between the arms within two hospitals. Not expected to affect the results in any way"; "some participants refused to give informed consent, health deterioration, not seen by urologist" (p 4) Auvinen 2004 (primary study), p 2: flow diagram and results; low attrition and consistent between groups
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry. Auvinen 2001, p 2: "The study protocol was approved by an ethical committee in each participating hospital" Auvinen 2004 (primary study), p 1: "The study protocol was approved by the institutional review board at each participating hospital"

Auvinen 2004 *(Continued)*

Other bias	Low risk	Appears to be free of other potential biases.

Bailey 2016

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	114 + 111 adults with type II diabetes considering additional antihyperglycemic medication to a metformin-containing regimen to improve glycemic control in the USA
Interventions	DA: interactive online decision aid that includes information on the clinical problem, explicit values clarification, guidance in decision-making (steps in decision-making, worksheet), and summary that can be taken to the consultation. The DA is not publicly available; a copy was provided by the author (Alicia C. Shillington: alicia.shillington@epi-q.com). Comparator: usual care (no intervention)
Outcomes	Primary outcome: knowledge Secondary outcomes: decision self-efficacy, decisional conflict
Notes	Source of funding: The trial and manuscript submission was funded by Janssen Scientific Affairs, LLC. Conflicts of interest: R Bailey is an employee of Janssen Scientific Affairs, LLC and shareholder of Johnson and Johnson. Michael Pfeifer is an employee and shareholder of Johnson and Johnson. Alicia Shillington is an employee and shareholder of EPI-Q Inc. Qing Harshaw is an employee of EPI-Q Inc. Jeffery VanWingen is in private practice and received compensation from Janssen Scientific Affairs for enrollment of subjects into this investigation. Nananda Col is a consultant to Janssen Scientific Affairs. Martha Funnell has served on advisory boards for Eli Lilly, Bristol-Myers Squibb, AstraZeneca Diabetes, Novo Nordisk, Omada Health, Sanofi US, and is a consultant to Janssen Scientific Affairs.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"All staff analyzing data were blinded to treatment group assignment. Referring clinicians were blinded to group assignment, unless they were incidentally unblinded by subjects during a clinical consultation subsequent to enrollment (e.g., subjects mentioning the PDA or its contents during an office visit)." "... subjects were not blinded to treatment assignment, and this may have impacted results due to expectations raised regarding PDA participation benefits. Unclear risk because the participants were not blinded: "subjects were not blinded to treatment assignment, and this may have impacted results due to expectations raised regarding PDA participation benefits"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"All staff analyzing data were blinded to treatment group assignment. Referring clinicians were blinded to group assignment, unless they were incidentally unblinded by subjects during a clinical consultation subsequent to enrollment (e.g., subjects mentioning the PDA or its contents during an office visit)." Outcomes were objectively measured and not subject to interpretation.

Bailey 2016 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"All subjects were followed for approximately 6 weeks after randomization except for 20 who were lost to follow-up (PDA group, n = 15; usual care group, n = 5)." 15/114 (13.2%) lost in patient DA arm versus 5/111 (4.5%) usual care arm. Additionally, another 5 from the patient DA group were "non-adherent with the PDA". Reasons for attrition are not reported.
Selective reporting (reporting bias)	Unclear risk	The trial protocol is available (NCT02110979). One of the secondary outcomes (decision self-efficacy) was not pre-specified.
Other bias	Unclear risk	One or more of the authors are industry employees. Industry funding is declared with no description of role in the study.

Barry 1997

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	104 + 123 patients considering benign prostatic hyperplasia treatment in the USA
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinion. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care using general information on the clinical problem
Outcomes	Primary outcome: knowledge Secondary outcomes: uptake of option, satisfaction with DM process, satisfaction with decision, interest in DM, general health outcomes, condition-specific health outcomes
Notes	Source of funding: This project was funded by Grant Nos. HS 06540 and 08397 from the Agency for Health Care Policy and Research. The development of the first edition of the SDP for BPH was funded by a grant from the John A. Hartford Foundation. Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Stratified by study site in concealed blocks of 10" (p 2)
Allocation concealment (selection bias)	Low risk	Study co-ordinator opened serially numbered, opaque, sealed envelopes (p 2).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of contamination.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but phase 1 eliminated risk of outcome assessor interfering with decision.

Barry 1997 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Patient accrual and follow-up reported; post-randomization withdrawals could have biased the results (more in intervention group). However, they reported no evidence of a differential effect on the study group (p 3).
Selective reporting (reporting bias)	Unclear risk	No indication that trial registered in central trials registry.
Other bias	Low risk	Appears to be free of other potential biases.

Bekker 2004

Study characteristics	
Methods	Randomized to detailed vs routine consultation
Participants	59 + 58 pregnant women who have received a maternal serum screening positive test result for Down syndrome in the UK
Interventions	DA (in consult): decision analysis plus routine consultation on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching. The DA is available as an appendix in the article. Comparator: routine consultation on options' outcomes, outcome probability
Outcomes	Primary outcome: anxiety Secondary outcomes: uptake of option, knowledge, decisional conflict, informed decision-making, satisfaction with consultation, consultation length
Notes	Source of funding: "Thank you to the MRC for funding Dr Bekker's studentship". Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "randomly allocated... using previously numbered... envelopes" Bekker 2004 (primary study), p 3: "Participants were randomly allocated by previously numbered envelopes"; does not mention how sequence was generated.
Allocation concealment (selection bias)	Low risk	Bekker 2003, p 2 - section 2.3 Sample and Procedure: "Using previously numbered, sealed, opaque envelopes" Bekker 2004 (primary study), p 3: previously numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants blinded, personnel not blinded. Same personnel did control and intervention. Tape-recorded sessions to ensure no bias.
Blinding of outcome assessment (detection bias)	Low risk	Unclear blinding but outcomes were objectively measured.

Bekker 2004 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Bekker 2003 flow diagram indicates post-randomization attrition with more attrition in decision aid group; no discussion on implications of attrition. Bekker 2004 (primary study), p 4: results/flow diagram; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	Bekker 2003: the coding frame was developed from literature. Does not mention protocol. Bekker 2004 (primary study): no information provided about central trials registry.
Other bias	Unclear risk	Bekker 2003: does not directly address baseline characteristics of participants. Bekker 2004 (primary study): appears to be free of other potential biases.

Berger-Hoger 2019

Study characteristics	
Methods	Cluster-randomized to decision aid + decision coaching + structured physician's consultation vs usual care
Participants	37 (decision aid + coaching + structured consultation) versus 30 (usual care) German women, aged 18 years or older, with primary histologically confirmed ductal carcinoma in situ facing primary treatment decisions
Interventions	Paper-based decision aid provided before nurse decision coaching and in preparation for consultation with the physician. The DA included clinical information, outcome probabilities, explicit values clarification, QR code to access more information, and guidance in decision-making and communication. The DA is not publicly available; a copy was provided by the author (Birte Berger-Höger; birte.berger-hoeger@uni-bremen.de). Comparator: usual care
Outcomes	Primary outcome: extent of informed shared decision-making Secondary outcomes: patients' and healthcare professionals' perspectives of shared decision-making, informed choice (knowledge, attitude, uptake), decisional conflict, duration of coaching sessions and physician encounters
Notes	Source of funding: The German Federal Ministry of Health funded the study within the National Cancer Action Plan (Grant No. NKP – 332 – 054). Conflicts of interest: All authors have completed the disclosure form and declare no support from any organization for the submitted work other than those listed above; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years, and no relationships or activities that could appear to have influenced the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The statistician (BH) provided a computer-generated allocation sequence. During study progress, allocation might have become predictable. Thus, we

Berger-Hoger 2019 *(Continued)*

		used a random permuted block design with block sizes of 4, 6 or 8 to randomize clusters."
Allocation concealment (selection bias)	Low risk	"The allocation was concealed. An independent external person prepared sealed opaque envelopes. After baseline assessment of the respective cluster and its professionals, two researchers (BBH, KL) opened the sealed opaque envelope and revealed the center's allocation on site. Patients were recruited by the participating physicians (electronic supplementary material S2) and kept unaware of their allocation status. After the final physician encounter, they were asked to guess whether they had received standard care or the new counselling approach."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[P]erson prepared sealed opaque envelopes"... "After baseline assessment of the respective cluster and its professionals, two researchers (BBH, KL) opened the sealed opaque envelope and revealed the center's allocation on site"... "Patients were recruited by the participating physicians (electronic supplementary material S2) and kept unaware of their allocation status. After the final physician encounter, they were asked to guess whether they had received standard care or the new counselling approach." Participants were blinded so low risk of bias for that item. Unclear if personnel blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Low risk for outcomes of interest to this review that were objectively measured and not subject to interpretation (i.e. knowledge, decisional conflict). High risk for the outcome of patient-clinician communication only: "The primary outcome was the extent of informed shared decision-making assessed by the observer-based instrument of the validated inventory Multifocal APProach to the sharing‘ IN Shared Decision-Making (MAPPIN'SDM). It assesses the mutual shared decision-making-behavior of health professionals and patients based on video-recordings." "Due to the structural inequality between intervention and control group, video raters could not be blinded."
Incomplete outcome data (attrition bias) All outcomes	Low risk	For 8 patients, missing values were imputed (5 patients with missing values in 1, 2 or 3 items, 3 patients with missing values in all 11 items).
Selective reporting (reporting bias)	Low risk	The study protocol was available and all of the study's prespecified (primary and secondary) outcomes that were of interest in the review have been reported in the prespecified way.
Other bias	Low risk	Cluster analysis on an individual level was planned; however, there were unanticipated low cluster sizes that resulted in unstable intracluster correlation coefficient estimations. As a result, cluster analysis was used as this is more robust, given the limitations of their recruitment/clusters. Free of other potential biases: no evidence of selective recruitment of cluster participants.

Bergeron 2018

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	24 + 26 families of children with obstructive sleep apnea and without tonsillar hypertrophy in the USA

Bergeron 2018 *(Continued)*

Interventions	DA: paper-based option grid decision aid used during consultation that included clinical information and outcome probabilities. The DA is not publicly available; a copy was provided by the author (Stacey Ishman; stacey.ishman@cchmc.org). Comparator: usual care
Outcomes	Decisional conflict, preferred option including undecided, communication (collaboRATE scale) Secondary article: implemented treatment (actual choice), treatment modified
Notes	Source of funding: no funding Conflicts of interest: The authors have no funding, financial relationships, or conflicts of interest to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization was carried out using a random number generator at the time of presentation to the clinic
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single-blinded (outcomes assessor): the person administering the decisional conflict measures was blinded to the method used for each patient. No mention of blinding participants. Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Single blinded (outcomes assessor): the person administering the decisional conflict measures was blinded to the method used for each patient.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, no loss to follow-up reported.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Bernstein 1998

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	65 + 53 patients with coronary artery disease considering revascularization surgery in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinion. The DA was available from the Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care (no information provided)

Bernstein 1998 *(Continued)*

Outcomes	Primary outcome: satisfaction with decision and decision-making process Secondary outcomes: uptake of option, knowledge, satisfaction with care, general health outcomes, condition-specific health outcomes
Notes	Source of funding: This research was supported in part by a grant from the University of Michigan Hospitals Small Grant Program. Kim Skarupski was supported by a postdoctoral Health Services Research and Development fellowship by the Department of Veterans Affairs. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was stratified by study site in blocks of 10" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andomization performed by a study coordinator opening opaque, sealed envelopes at study headquarters" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Neither participants nor study staff were blinded to treatment assignment - could lead to different satisfaction ratings based on knowing the treatment received.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); low attrition of eligible participants randomized and consistent between groups
Selective reporting (reporting bias)	Unclear risk	No information provided indicating trial was included in central trials registry.
Other bias	Low risk	Appears to be free of other potential biases.

Berry 2013

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	266 + 228 men considering prostate cancer treatment in the USA
Interventions	DA: interactive web-based video on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (list of questions to ask doctor and automated summary). The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcome: preferred/actual treatment choice (pre- and post-DA), proportion undecided

Berry 2013 *(Continued)*

	Other outcomes (Bosco 2012): choice concordance (6 months post-DA). (Data from 239 + 209 men).
Notes	Source of funding: NIH, R01-NR009692. The funder did not have a role in the manuscript. This material is the result of work supported with resources and use of facilities at the Charlie Norwood VA Medical Center, Augusta, GA, VA Puget Sound Healthcare System, Seattle, WA, and the South Texas Veterans Health Care System, San Antonio, TX, all of which approved the submission of the manuscript. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Methods section, second paragraph, p 3: "Participants were randomized automatically by the P3P application to study groups (1:1 using a simple randomization scheme with no blocking)"
Allocation concealment (selection bias)	Low risk	Methods section, p 3: "Participants were randomized automatically by the P3P application to study groups"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded and study does not address the effect on the results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear whether outcome assessors are blinded, but outcomes are not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis and low dropout (p 4).
Selective reporting (reporting bias)	Low risk	Protocol made available
Other bias	Unclear risk	Was a multicentre trial, which could have lead to contamination, protocol violation, and biased questionnaire completion.

Berry 2018

Study characteristics

Methods	Randomized to decision aid plus usual education vs usual education plus links to reputable websites
Participants	198 + 194 men with clinically localized prostate cancer and an upcoming consultation in the USA
Interventions	DA: online interactive decision aid plus usual care. The DA included a preliminary questionnaire including a values clarification exercise to elicit patients concerns and information was tailored based on their personal profile, guidance in communication, and an automated summary report that could be printed. Each clinician of an intervention group patient received the 1-page summary of patient-reported information to cue the provider to symptom issues, concerns, and preferences. The DA is publicly available at https://www.p3p4me.org/users/login . Comparator: usual education plus links to reputable websites
Outcomes	Primary outcome: decisional conflict

Berry 2018 *(Continued)*

	Secondary outcomes: decision regret, actual choice (reported for full sample only)
Notes	Source of funding: Supported by National Institutes of Health, National Institute for Nursing Research R01NR009692 and CTN NCT01844999. Conflicts of interest: Traci M. Blonquist, financial interest and/or other relationship with Pfizer, and Johnson and Johnson

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"participants were randomized to the intervention or the UC group in permuted blocks of 4 as stratified by clinic site via an algorithm embedded in the software"
Allocation concealment (selection bias)	Low risk	Web-based central allocation: "participants were randomized to the intervention or the UC group in permuted blocks of 4 as stratified by clinic site via an algorithm embedded in the software"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Research assistants were not blinded to study group assignment but all patient-reported outcome measures were self-administered. Outcomes were objectively measured and not subject to interpretation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate, but balanced across groups.
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT01844999). One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified. For the primary outcome of "Decisional conflict [Time Frame: Change from baseline to 6-months]" only 1-month data are reported. The primary outcome of "Preparation for decision making [Time Frame: 1-month after study entry]" is not reported.
Other bias	Unclear risk	"we excluded the lowest accruing sites from the final analytical sample, which were mainly independent or nonnetworked practices"

Beulen 2016

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	157 + 157 pregnant women aged 18 years or older in the Netherlands
Interventions	DA: online interactive decision aid (text and video) on clinical problem, outcome probabilities, explicit values clarification, guidance in decision making (systematic steps to go through), guidance in communication, and summary to take to consult. The DA is publicly available at https://www.keuzehulp.info/cz/pnt/intro/1 .

Beulen 2016 *(Continued)*

	Comparator: usual care using standard counseling and brochure
Outcomes	Primary outcome: informed decision-making Secondary outcomes: knowledge, attitudes, prenatal test utilization, value-consistency, decision conflict, decisional regret, and anxiety
Notes	Source of funding: Foundation for Prenatal Screening in the Nijmegen Region. Conflicts of interest: The authors declare no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"After obtaining informed consent, participants were allocated to the control or intervention group by a computer-generated randomisation."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	< 90% of enrolled patients are included in the analysis: the 261 remaining women (130 randomised to the control group and 131 randomised to the intervention group) were included in the analysis: 261/314 (83%). However, missing outcome data are balanced in numbers across intervention groups, with similar reasons for missing data across groups.
Selective reporting (reporting bias)	Unclear risk	The study protocol is not available and therefore there is no way to verify whether the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Bjorklund 2012

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	236 + 247 women less than 11 weeks pregnant considering Down syndrome screening in Sweden
Interventions	DA: linear video on options' outcomes, clinical problem, outcome probabilities, others' opinion, and guidance (step-by-step process for making the decision). The DA is no longer available at vimeo.com/34600615/. Comparator: usual care using pamphlet

Bjorklund 2012 *(Continued)*

Outcomes	Primary outcomes: knowledge (post-DA), attitude (post-DA), uptake of combined ultrasound and biochemical screening (post-DA) Secondary outcomes: values congruent with chosen option (post-DA)
Notes	Source of funding: This study was supported by grants from Sophiahemmet University College and from Södersjukhuset, Department of Obstetrics and Gynecology, Stockholm, Sweden. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The midwife allocated the participants randomly by sealed envelopes" (p 391) but does not state the actual sequence generation method.
Allocation concealment (selection bias)	Low risk	Used sealed envelopes, "prepared, sequentially coded and distributed to the maternity units by the research group" (p 391).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"It was not possible to blind neither [sic] the midwives nor the participants due to the characteristics of the intervention" (p 395). The study does not address the effects of this on the results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	No blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of why some participants' data were excluded in Tables 2, 3, and 4.
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	Low risk	Appears to be free of other sources of bias.

Bonner 2022

Study characteristics

Methods	Randomized to standard DA vs literacy sensitive DA vs control
Participants	293 + 301 + 299 from a national sample of people aged 45 to 74 in Australia
Interventions	DA: decision aid used independently that includes a risk calculator of having a heart attack, options to decrease their risk, probabilities of outcomes, implicit values clarification, guidance in decision-making (step-by-step process), and lifestyle action plan with summary. An example of the DA is available as a supplementary appendix in the article. Comparator: risk calculator, information plus action plan
Outcomes	Primary outcome: lifestyle intentions

Bonner 2022 *(Continued)*

	Secondary outcomes: ability to recall their risk, credibility of the risk results, emotional response to risk results, decisional conflict
Notes	Source of funding: This study was funded by a Vanguard Grant from the National Heart Foundation of Australia (ID 102215). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate and balanced across groups. Analyzed control 135 + 155 = 290/299 (missing 3%); analyzed standard DA 148 + 137 = 285/293 (missing 3%).
Selective reporting (reporting bias)	Low risk	The study protocol is registered (ACTRN12620000806965) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"A limitation is that the web-based panel sample may not be representative of the general population and may better reflect users of web-based heart age tools than patients presenting to primary care for CVD risk assessment. The study was powered by moderate effect sizes and therefore may have lacked the power to detect more subtle differences; however, these findings will be useful for informing sample size calculations for future studies"

Bourmaud 2016

Study characteristics

Methods	Randomized to decision aid vs usual information
Participants	7885 + 7959 women who were invited to participate in a population-based breast cancer screening program in France
Interventions	DA: paper-based leaflet that included information on breast cancer risk, probabilities of outcomes, implicit values clarification, and guidance in communication. The DA is publicly available as a supplementary file in the publication https://www.oncotarget.com/article/7332/text/ . Comparator: usual standard information

Bourmaud 2016 *(Continued)*

Outcomes	Primary outcome: women's attendance rate for the breast cancer screening program Secondary outcome: delay between the invitation and the date of attendance for breast cancer screening
Notes	Source of funding: This study was supported by the French National Association against Cancer (Ligue National Contre le Cancer). Conflicts of interest: PSM declares a conflict of interest through her activity, being a practitioner involved in breast cancer screening promotion at a local level. All the others authors declare no financial support for the submitted work; no relationships that might have an interest in the submitted work in the previous three years; None of their spouses, partners, or children have financial relationships that may be relevant to the submitted work; and none have non-financial interests that may be relevant to the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Women were randomly assigned in a 1:1 ratio via a computer-generated, centralized randomization sequence, which was done with a block randomization of four, to the DECIDEO or usual invitation group. The randomization was balanced through stratification according to the following hierarchy: the department, the age according to 2 classes (above or below 65), and the number of invitations already received by the women (leading or not, to participation in national screening)"
Allocation concealment (selection bias)	Low risk	"Women were randomly assigned in a 1:1 ratio via a computer-generated, centralized randomization sequence" (central allocation)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT analysis, reasons for participants excluded from analysis, low attrition rate (< 2% to 3%)
Selective reporting (reporting bias)	Low risk	The trial was registered retrospectively (NCT02093039). "This study was later registered in clinicaltrial.gov on 03/19/2014". However, it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	High risk	"imbalance in the number of women excluded from the analysis due to screening attendance before reception of the invitation (115 vs 41 in the intervention and control groups, respectively)", "Some women were excluded because there was a delay between the invitation being sent by the cancer screening association and its reception by the women; during the delay some of the randomized women had already attended breast cancer screening since they did not need to take the invitation letter with them." The difference is significant (P < 0.00001). Acknowledged in the limitations but not discussed: "One last limitation concerns the imbalance in the number of women excluded from the analysis due to screening attendance before reception of the invitation".

Bozic 2013

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	95 + 103 participants with hip and/or knee osteoarthritis considering hip/knee surgery in the USA
Interventions	DA: DVD and booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, and guidance/coaching with health coach. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. The authors have a copy of the video and booklet that was evaluated in the study. Comparator: usual care using pamphlet
Outcomes	Primary outcomes: informed decision/knowledge (pre, immediately post, and 6 weeks follow-up) Secondary outcomes: preferred treatment choice (pre and immediately post), patient and provider satisfaction (immediately post), length of consultation time
Notes	Trial registration: NCT01492257 Source of funding: This work was supported by a grant from the RobertWood Johnson Foundation (RWJF). Funds were used to pay for salaries, employee benefits, and other direct costs such as office operations, communications, meetings, travel, surveys, and contracts. The funding source did not play a role in the investigation. Conflicts of interest: One or more of the authors received payments or services, either directly or indirectly (i.e. via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The randomization was blocked with use of random permuted blocks in groups of four, six, or eight to help ensure that the groups were balanced" (p 1634)
Allocation concealment (selection bias)	Low risk	"Patients were randomized to either the intervention group or the control group with use of the sealed envelop method" (p 1634)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[S]urgeons were not blinded to the intervention" (p 1635). Knowing the allocation of participants, surgeons' favorable scoring could be due to greater investment in decision-making. Insufficient information to make a judgment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes are objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	62% (123/198) retention rate therefore high attrition rate; however, the attrition was balanced between groups.

Bozic 2013 *(Continued)*

Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Appears to be free of other sources of bias.

Brazell 2014

Study characteristics	
Methods	Randomized to DA + standard counselling vs usual care + standard counselling
Participants	53 + 51 women presenting for the management and treatment of pelvic organ prolapse in the USA
Interventions	DA: paper-based or web-based DA on clinical problem, options' outcomes, outcome probabilities, patient stories and standard counseling. The DA developed by Healthwise is available at https://decisionaid.ohri.ca/Azsumm.php?ID=1228 . Comparator: standard counseling alone
Outcomes	Primary outcomes: decisional conflict (immediately post-consultation) Secondary outcomes: choice (3 months after making decision), decisional regret (3 months after making decision)
Notes	Source of funding: The decision aid used for this study was developed by Healthwise and provided to the authors at no cost. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized 1:1 using a random numbers table in blocks of 6" (p 231)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make judgment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make judgment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High attrition but balanced between groups: "39 randomized subjects were either missed by the research assistant at their new patient visit and thus did not receive a DCS questionnaire to complete or they canceled their appointments and did not reschedule a new one" (p 233). There was a 48% (50/104) attrition rate for decisional regret measures.
Selective reporting (reporting bias)	Low risk	Trial registered

Brazell 2014 *(Continued)*

Other bias	High risk	Risk of contamination due to same physicians in both groups. Also, outcomes measured after the patient DA and physician consultation.

Brown 2019

Study characteristics	
Methods	Randomized to decision aid + coaching vs usual care
Participants	19 (decision aid + coaching) versus 22 (usual care) adults aged 70 years of age and older with advanced chronic kidney disease attending hospital-based nephrology services considering renal replacement therapy in Australia
Interventions	DA: paper-based decision aid and audio-recording that included clinical information, probabilities of outcomes, explicit values clarification, guidance in decision-making (step-by-step process), guidance in communication, with summary worksheets and examples of how to complete them, and suggested publicly available resources. Decision coaching: 1 month after receiving the DA, a trained renal nurse used the DA to support patient in active, autonomous role in decision-making in 1 or 2 sessions in person for 45 minutes at a public hospital renal program and then again 3 months later if a decision had not been made. The DA is not publicly available; a copy was provided by the author (Leanne Brown; leanne.brown2@health.qld.gov.au). Comparator: usual care (education)
Outcomes	Primary: decision regret, decisional conflict Secondary: knowledge, quality of life, participants' and nurses' perceptions of the usefulness of the patient DA (preparation for decision-making)
Notes	Source of funding: National Health and Medical Research Council; Australian Centre for Health Service Innovation (AusHSI); Queensland Health Nursing and Midwifery Research Fellowship; Chronic Kidney Disease Centre of Research Excellence; Sunshine Coast Hospital and Health Service; Wide Bay Hospital and Health Service. Conflicts of interest: No conflict of interest has been declared by the authors.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"... through a computer-generated program using block randomisation"
Allocation concealment (selection bias)	Unclear risk	"Randomisation occurred once the eligibility of the participant was confirmed, consent provided and baseline data collected. Allocation of the participant to either intervention or standard care occurred through a computer-generated program using block randomisation." Nurse not blinded.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; it is unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	To minimize bias, the outcome research assistant and the lead researcher were blinded to group allocation.

Brown 2019 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Few dropouts. All participants included.
Selective reporting (reporting bias)	Low risk	Primary outcomes as reported in study registration (ACTRN 12614001090606).
Other bias	Low risk	The study appears to be free of other sources of bias.

Carlson 2019

Study characteristics	
Methods	Randomized to DA + standard counseling vs standard counseling alone
Participants	105 + 92 women with a singleton gestation at less than 22 weeks scheduled to meet with a genetic counselor at 1 of 3 prenatal diagnosis clinics for a discussion of aneuploidy screening in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that describes clinical condition, outcome probabilities, and explicit values clarification. It is the same evaluated by Kupperman 2014 but modified to include new options. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care (genetic counseling)
Outcomes	Primary outcome: knowledge Secondary outcomes: decisional conflict, choice of testing, pursuit of invase testing
Notes	Source of funding: The project described was supported by the Clinical and Translational Science Award program of the Division of Research Resources, National Institutes of Health, through grant award no. 1UL1TR001111, by the UNC Center for Maternal and Infant Health, through the Cefalo-Bowes Young Researcher Award, and by the Eunice Kennedy Shriver National Institute of Child Health and Human Development BIRCWH K12 Grant HD001441 (N.L.V.) and K23 HD088742 (N.L.V.). Conflicts of interest: The authors declare no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Via a coin-flip algorithm within the app, women were randomly assigned to group 1 (control group) or group 2 (decision aid group).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	As it was not pragmatic for this study, randomization assignment was not blinded. Unclear if measurements could be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	As it was not pragmatic for this study, randomization assignment was not blinded. However, outcomes were objectively measured and not subject to interpretation.

Carlson 2019 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, 100% included in analysis.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02991729) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Carroll 2017

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	41 + 41 new candidates for implantable cardio-defibrillators in Canada
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, role in decision-making, SURE test, guidance in decision-making (5-step guide), and guidance in communication. The DA is not publicly available; a copy was provided by the author (Sandra L. Carroll; carroll@mcmaster.ca). Comparator: usual care (general education after decision to accept the implantable cardio-defibrillator is established)
Outcomes	Primary outcome: feasibility of conducting the RCT Secondary outcomes: knowledge, decisional conflict, SURE test, Preparation for Decision-Making Scale
Notes	Source of funding: This study was funded by the Canadian Institutes of Health Research (CIHR)—operating grant #119449. Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization took place prior to electrophysiology specialist consultations using a centralized Internet randomization service (https://www.randomize.net).
Allocation concealment (selection bias)	Low risk	The use of https://www.randomize.net ensured that the allocation sequence was concealed from the research assistant.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Due to the nature of the intervention, patients and the research assistant collecting data were not blinded to study group assignment. Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The data analyst was blinded to group assignment.

Carroll 2017 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Case 2019

Study characteristics	
Methods	Randomized to decision aid versus usual care
Participants	50 + 49 new patients over the age of 18 years being evaluated for chest pain with no known history of coronary artery disease in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that included clinical information, outcome probabilities, explicit values clarification, individualized risk calculator, and patient testimonies. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Knowledge, decisional conflict, satisfaction with the decision-making process, trust in physician, acceptability of DA, preparation for decision-making (reported for DA group only)
Notes	Source of funding: A research grant from the Lee and Juliet Folger Fund Foundation. Conflicts of interest: The authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization was performed by a random number generator with assignment blinded in a sealed folder before enrolment.
Allocation concealment (selection bias)	Low risk	Randomization was performed by a random number generator with assignment blinded in a sealed folder before enrolment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The treating health care provider was blinded to randomization, and patients were advised not to discuss randomization with the provider. "although health care providers were blinded to enrollment and randomization, some unintentional unblinding may have occurred because patients enrolled in the study may have had their study folder and iPad with them in the patient room in order to maximize their time with using the PDA and completing the questionnaires. This may have biased providers in their interaction with patients who they suspected were enrolled in the study than they otherwise would be."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.

Case 2019 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	Flow diagram, high attrition rate in the DA group 7/50 (14%) compared to the standard care group 1/49 (2%). The difference between groups is significant (P = 0.029042).
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	"selection bias was also present in our study due the fact that in general patients who are referred to outpatient clinic are overall a lower risk patient population and less likely to undergo a higher risk test such as invasive coronary angiography"

Chabrera 2015

Study characteristics	
Methods	Randomized to DA vs usual care
Participants	73 + 74 men recently diagnosed with prostate cancer considering treatment options in Spain
Interventions	DA: 2-part decision support booklet with clinical problem, options' outcomes, outcome probabilities, patient stories, explicit values clarification, and guidance. The DA is not publicly available; a copy was provided by the authors (cchabrera@tecnocampus.cat). Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict, satisfaction with decision-making process Secondary outcome: coping Outcomes assessed at 3 months postintervention
Notes	Source of funding: This project was supported by the Official Nursing College of Barcelona and the Badalona Against Cancer Foundation. Conflicts of interest: The authors have no conflicts of interest to disclose.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"[S]tudy participants were randomized into 1 of 2 arms using a computer-generated random list with unequal blocks" (p E44)
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided to make a judgment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make a judgment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make a judgment.

Chabrera 2015 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Balanced attrition in both groups
Selective reporting (reporting bias)	Unclear risk	No protocol provided; trial not registered
Other bias	Unclear risk	Prostate cancer in Catalonia is common; however, only 147 were recruited for this trial (p E44).

Chambers 2012

Study characteristics	
Methods	Randomized to DA vs usual care
Participants	74 + 77 healthcare workers who did not receive the influenza vaccine considering receiving the vaccine in Canada
Interventions	DA: web-based DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance. The DA is available at https://decisionaid.ohri.ca/Azsumm.php?ID=1562 . Comparator: usual care using pamphlet
Outcomes	Primary outcomes: confidence in decision (post-DA) Secondary outcomes: impact on immunization intent (post-DA), proportion undecided
Notes	Source of funding: This trial is funded under a three-year, Canadian Institutes of Health Research (CIHR), Institute of Population and Public Health, Team Grant: Pandemic Preparedness - Influenza Biology, Vaccines, Ethics, Legal and Social Research Grant #90189, in partnership with the CIHR Pandemic Preparedness programme. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. Conflicts of interest: none declared

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The randomization list was generated using the randomization function in Excel 2002 (version 10.6856.6856 SP3)" (p 199)
Allocation concealment (selection bias)	Low risk	"The list was imported from Excel into a Microsoft SQL Server database. The online application would sequentially assign a random identification number and their decision aid status (seeing the decision aid or not) from the randomization list when users logged into the survey." (p 199)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported whether or not they were blinded during the course of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Questionnaire scores are objective and not subject to interpretation.

Chambers 2012 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	65% completion rate in intervention arm and 77% completion rate in control arm: attrition could be different where the respondents and non-respondents are different.
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Unclear risk	Figure 1 numbers for exclusion are not logical.

Chen C 2021

Study characteristics	
Methods	Randomized to decision aid + decision coaching vs standard education material
Participants	67 + 63 patients aged ≥ 20 years with first episode of low back pain with diagnosis of low back pain, spinal stenosis, intervertebral disc disorders, spondylolisthesis, or other spondylosis in Taiwan
Interventions	DA: paper-based booklet used in conjunction with a decision coach in preparation for consultation with the physician that included clinical information, explicit values clarification, knowledge test, guidance in decision-making (5-step guide), guidance in communication (used with a decision coach), knowledge test and plan for subsequent steps. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: standard educational material
Outcomes	Primary outcome: decision self-efficacy Secondary outcomes: participation in decision-making (Control Preferences Scale), shared decision-making (SDM-Q9), decisional conflict, satisfaction with decision (SWD)
Notes	Source of funding: This study was supported by the Ministry of Science and Technology (grant number MOST-107-2314-B-038-026-MY3), Taipei Medical University– Shuang Ho Hospital, Ministry of Health and Welfare (grant numbers 107 TMU-SHH-17, 108TMU-SHH-23), and Taipei Medical University Hospital (109TMUH-H-01). Conflicts of interest: none

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Few details: randomization was performed by a research assistant with no knowledge of the trial.
Allocation concealment (selection bias)	Low risk	After completing a pretest questionnaire, each participant opened a sealed, opaque randomization envelope that informed them of their assignment to either the intervention group (decision coaching with DAs) or the comparison group (patient education by another health educator).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	This was an RCT with blinding of both patients and their physicians… The decision coaching and patient education interventions were independently conducted in an assessment room separate from the consultation room to keep the patients blinded and minimize treatment contamination between groups
Blinding of outcome assessment (detection bias)	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.

Chen C 2021 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis, small loss to follow-up (1 per group) with justification
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03679494) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Chen S 2021

Study characteristics	
Methods	Randomized to decision aid + usual care vs usual care
Participants	33 + 32 women eligible for vaginal birth after cesarean in Taiwan
Interventions	DA: paper-based booklet used in preparation for consultation that includes clinical information, probabilities of outcomes, explicit values clarification exercise with examples, glossary of terms, list of resources, guidance in decision-making (step-by-step process), and guidance in communication. The DA is not publicly available; a copy was provided by the author (Allison Shorten; ashorten@uow.edu.au). The English version of the DA is available for purchase at https://www.capersbookstore.com.au/product/birth-choices-vaginal-or-caesarean-birth/ . Comparator: education on "do's and don'ts" during pregnancy
Outcomes	Primary outcomes: decisional conflict, knowledge Secondary outcomes: birth mode preference, birth outcome, and satisfaction with decision
Notes	Source of funding: This study was funded by the Ministry of Science and Technology in Taiwan (MOST 106-2314-B-255-006). Conflicts of interest: Dr. Shorten is the author of the birth choices decision aid booklet. She does not have any financial interest in the distribution or sale of the booklet. The authors declare that they have no competing interest.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Using computer permuted block randomization, participants were allocated to control group (usual care) and intervention group (usual care plus the decision aid).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Women and providers were blinded to allocation in the study.

Chen S 2021 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis; missing outcome data are balanced across groups.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	Small sample size (randomized 33 + 32; last follow-up 29 + 30), did not attain statistical power, matched pair t-tests used

Clancy 1988

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	753 + 263 health physicians considering hepatitis B vaccine in the USA
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification (personal decision analysis), guidance/coaching. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care (no information provided)
Outcomes	Uptake of option
Notes	Source of funding: not reported Conflicts of interest: Dr. Clancy was a Henry J. Kaiser Family Foundation Fellow in General Internal Medicine at the University of Pennsylvania when this study was conducted, and Drs. Cebul and Williams were Kaiser Faculty Scholars in General Internal Medicine.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random numbers table; all incoming residents were assigned to Group 2 (non-randomized residents identified as subgroup) (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding of participants or personnel. Did not report on how this may affect their findings.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, but decisions for screening were retrieved from health records (objective data).

Clancy 1988 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow chart not included. Insufficient information to make a judgment.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	Potential selection bias - non-randomized residents were added to group 2 and therefore potential unbalanced distribution (p 287). Low response rate among those offered decision analysis.

Cox 2019

Study characteristics	
Methods	Randomized to decision aid vs control (no intervention)
Participants	138 (plus 210 surrogate decision-makers) + 139 (plus 206 surrogate decision-makers) patients aged 18 or older with no anticipation of death or liberation from mechanical ventilation within 24 hours, and ventilation for at least 10 days in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, explicit values clarification, example patient/family scenarios, individualized 1-year prognosis estimate, preferred role in decision-making, guidance in decision-making (step-by-step process), guidance in communication, and 2-page summary for discussion with family and clinician. The DA is not publicly available; a copy was provided by the author (Christopher E. Cox; christopher.cox@duke.edu). Comparator: control (no intervention)
Outcomes	Primary outcome: clinician-surrogate concordance (a measure of both the alignment of prognostic expectations and the quality of information exchange among decisional participants) Secondary outcomes: knowledge, satisfaction with clinician communication, anxiety and depression, post-traumatic stress symptom inventory, decisional conflict, patient perception of care centeredness, patient length of stay
Notes	Source of funding: Supported by grant R01 HL109823 from the National Institutes of Health. Conflicts of interest: Drs. White, Hough, Kahn, and Olsen and Mr. Jones report grants from the National Institutes of Health during the conduct of the study. Dr. Carson reports grants from the National Heart, Lung, and Blood Institute during the conduct of the study and grants from Biomarck Pharmaceuticals outside the submitted work. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M18-2335.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	A password-protected computerized system randomly assigned patients and their surrogates 1:1 to either intervention or control in blocks of 4, stratifying by site.

Cox 2019 *(Continued)*

Allocation concealment (selection bias)	Low risk	A password-protected computerized system randomly assigned patients and their surrogates 1:1 to either intervention or control in blocks of 4, stratifying by site (central allocation)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding during outcome assessment after randomization was ensured by use of a second co-ordinator at each site who was unaware of group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate for Interview 2 when outcomes of interest to the review were collected and missing data are balanced across groups. Reasons for attrition provided.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01751061) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"unmeasured physician-level effects or contamination among clinicians could have biased results toward the null hypothesis"

Coylewright 2016

Study characteristics	
Methods	Randomized to decision aid versus usual care
Participants	70 + 62 adults (aged ≥ 18 years) who were candidates for both optimal medical therapy and percutaneous coronary intervention for the treatment of stable coronary artery disease in the USA
Interventions	DA: paper-based decision aid used during consultation that includes outcome probabilities, guidance in decision-making, and communication (used during consultation). The DA is publicly available at https://carethatfits.org/pci-choice/ . Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcome: measure of shared decision-making using OPTION
Notes	Source of funding: This study was supported by the Mayo Clinic Kern Center for the Science of Healthcare Delivery. Conflicts of interest: Dr Hess's institution has received funding from the Patient Centered Outcomes Research Institute for investigator initiated research (952,12-11-4435, and 0876-SAEM).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The randomization took place on a secure study website using a computer-generated allocation sequence.

Coylewright 2016 *(Continued)*

Allocation concealment (selection bias)	Low risk	The randomization took place on a secure study website using a computer-generated allocation sequence, which randomized patients in a concealed fashion to decision aid versus usual care.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not possible for patients and involved clinicians. Unclear how lack of blinding influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Open-label according to trial registry. Low risk for outcomes that were objectively measured and not subject to interpretation (knowledge, decisional conflict). High risk for one outcome subject to interpretation (patient-clinician communication: analysis of video-recordings using the OPTION scale).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram: low attrition rates and similar across arms (< 10%); reasons for attrition recorded. Evaluable for analysis 65/70 DA and 59/62 usual care (P = 0.579774).
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01771536) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias

Crew 2022

Study characteristics	
Methods	Randomized to decision aid + standard usual care vs standard usual care
Participants	142 + 148 women aged 35 to 75 years with a 5-year invasive breast cancer risk ≥ 1.67% in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, patient scenarios, risk game, individualized breast cancer risk factors, guidance in decision-making (list of steps), and summary in the action plan that can be printed and discussed with the clinician. The DA is not publicly available; a copy was provided by the author (Katherine D. Crew; kd59@cumc.columbia.edu). All clinicians had access to the Breast cancer risk NAVigation toolbox for providing them with their patients' personalized risks and preferences prior to the clinical encounter. Comparator: usual care (education)
Outcomes	Primary outcome: choice uptake Secondary outcomes: perceived breast cancer risk, breast cancer worry, chemoprevention knowledge, self-efficacy, decision conflict, informed choice
Notes	Source of funding: none Conflicts of interest: The authors declare no potential conflicts of interest.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Crew 2022 *(Continued)*

Random sequence generation (selection bias)	Low risk	"randomized 1:1 and stratified by Hispanic ethnicity and menopausal status". The investigators describe the use of stratification (use of computer implied).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Flow diagram, missing data across groups is significantly different (complete data at 1 month were 120/148 for DA group and 133/142 for control group (P = 0.001327)). No justification for loss to follow-up provided.
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT03069742). Several outcomes of interest to the review were not pre-specified (self-efficacy, decisional conflict, informed choice).
Other bias	Low risk	The study appears to be free of other sources of bias.

Cuypers 2018

Study characteristics	
Methods	Cluster-randomized to online DA + usual care vs usual care (information + counseling)
Participants	235 + 101 patients newly diagnosed with localized prostate cancer in the Netherlands
Interventions	DA: online decision aid that included information on the clinical problem, outcome probabilities, explicit values clarification, decision-making guidance, guidance in communication, and a summary sheet to share with the urologist. The DA is not publicly available; access to the decision aid was provided by the author (Maarten Cuypers: maarten.cuypers@radboudumc.nl). Comparator: usual care that included information and counseling
Outcomes	Primary outcome: decisional conflict Secondary outcomes: patient involvement, knowledge, satisfaction with information, anxiety, depression. Decision regret measured 12 months later (Cuypers 2019).
Notes	Source of funding: This research is funded by CZ Fund, a Dutch not-for-profit health insurer (Grant 2013-00070) and Delectus Foundation, a Dutch non-profit foundation aimed to initiate and stimulate research into shared decision-making. The funding agreements ensured the authors' independence in designing, conducting, and analyzing the results. MdV obtained funding from CZ; PK is chairman of Delectus Foundation. Conflicts of interest: The authors declare that they have no further conflicts of interest.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Cuypers 2018 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	"Eighteen Dutch hospitals were randomized to the intervention or control arm." Sequence generation not reported.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Although patients were unaware of randomization at hospital level and were not informed that the DA was the subject of this study, care providers were aware that the purpose of the study was to compare the DA to usual information routines. During counseling, the novelty of the DA might have been overemphasized...In the control arm, this could have led to modifications of existing information or counseling routines due to the increased attention for SDM from this study, or in the DA group, to the creating of too high expectations as care providers could have (over-)emphasized the novelty of the DA.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Response rate at T1 (after treatment decision-making) was 235/273 (86%) in the DA group and 101/111 (91%) in the control group (Cuypers 2019). At 6 months, 214 (78%) and 94 (85%); at 12 months, 208 (76%) and 85 (77%). Low recruitment in the control groups.
Selective reporting (reporting bias)	Low risk	Dutch Trial Register (NTR4554); health-related quality of life and skills not reported, but they were secondary outcomes and not of interest to the current review.
Other bias	High risk	Usual information and counseling was not described to determine if it was also a patient decision aid. Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Davison 1997

Study characteristics	
Methods	Randomized to decision aid + audio-taped consultation vs usual care
Participants	30 + 30 men with prostate cancer considering treatment in Canada
Interventions	DA: written + audiotape consultation of options' outcomes, clinical problem, outcome probability, others' opinion. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: role in decision-making Secondary outcomes: anxiety, depression
Notes	Source of funding: Supported by a studentship from the National Cancer Institute of Canada with funds provided by the Canadian Cancer Society to the first author, and by an investigator award from the Medical Research Council of Canada and the National Health Research and Development Program to the second author.

Davison 1997 *(Continued)*

	Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The group to which subjects were assigned was predetermined by a block randomization procedure. This ensured there were an equal number of subjects in both groups for each physician." (p 5, Data collection)
Allocation concealment (selection bias)	Unclear risk	Not mentioned; group assignment predetermined by block randomization procedure (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding and whether outcomes could be affected by unblinded assessor.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No flow diagram; p 12 explains why certain men did not listen to audiotape. All men approached by study investigator agreed to participate; only 1 man refused to complete the second set of questionnaires.
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other sources of bias; similar baseline characteristics

De Achaval 2012

Study characteristics

Methods	Randomized to detailed vs simple vs usual care
Participants	70 + 70 + 71 patients diagnosed with knee osteoarthritis considering treatment in the USA
Interventions	Complex DA: video booklet + interactive joint analysis on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (list of questions) Comparator DA: video booklet on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance (list of questions) The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. The authors have a copy of the video and booklet that was evaluated in the study. Comparator: usual care receiving generic booklet
Outcomes	Decisional conflict (baseline and postintervention)
Notes	Source of funding: Supported by the Agency for Healthcare Research and Quality through the Center for Education and Research on Therapeutics (grant U18-HS016093). Dr. Fraenkel's work was supported by an NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases K23 award (AR-048826-05). Dr. Suarez-Almazor holds a K24 career award from the National Institute of Arthritis

De Achaval 2012 *(Continued)*

	and Musculoskeletal and Skin Diseases (AR-53593-06) and is the Director of the Houston Center for Education and Research on Therapeutics funded by the Agency for Healthcare Research and Quality. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated list with uneven blocks (p 231)
Allocation concealment (selection bias)	Low risk	Numbered, sealed, and opaque envelopes (p 231)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Likely not blinded, but low threat of bias in study (p 231)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were not blinded but outcome was objectively measured (p 231).
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 dropouts; missing data effect size unlikely to have significant impact on study outcome
Selective reporting (reporting bias)	Unclear risk	Protocol not available
Other bias	Low risk	Appears to be free of other sources of bias.

Dolan 2002

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	50 + 47 average risk for colorectal cancer considering screening in the USA
Interventions	DA: computer with analytic hierarchy process on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance/coaching. The DA is not publicly available. Comparator: usual care with information on options, clinical problem
Outcomes	Primary outcomes: uptake of option, decisional conflict Secondary outcomes: role in decision-making
Notes	Source of funding: This project was supported by grant number R03 HS10728 from the Agency for Healthcare Research and Quality. Conflicts of interest: not reported

Risk of bias

Dolan 2002 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomization schedules were created using a computer random number generator" (p 2, Study interventions)
Allocation concealment (selection bias)	Low risk	Computer-based (p 2, Study interventions)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants. All patient interviews in both the experimental and control groups were done by the same investigator; unclear on how this could contribute to risk of bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram - low attrition
Selective reporting (reporting bias)	Unclear risk	Nothing specifically mentioned re study protocol.
Other bias	Low risk	Appears to be free of other sources of bias.

Durand 2021

Study characteristics	
Methods	Cluster-randomized to text-only decision aid (Option Grid) vs pictorial decision aid (picture Option Grid) vs usual care
Participants	66 (text DA) + 248 (pictorial DA) + 257 (usual care) women 18 years and older with a biopsy-confirmed diagnosis of early-stage breast cancer (stages I-IIIA) eligible for breast-conserving surgery and mastectomy in the USA
Interventions	DA: option grid decision aid used during consultation that included clinical information, probabilities of outcomes, and implicit values clarification. The DAs are presented in Figure 1 of the article. Data were extracted for the text-only decision aid. Comparator: usual care, which was variable by site (e.g. information sheets, posters, video clips, etc.)
Outcomes	Primary outcomes: decision quality (3 subscales: extent to which patients are informed about treatment options (knowledge score), receive surgery aligned with their preferences (concordance score), and are involved in decision-making (decision process score)) Secondary outcomes: treatment choice, treatment intention, shared decision-making (collaboRATE and Observer OPTION-5), anxiety, quality of life, decision regret, co-ordination of care
Notes	Source of funding: The research reported in this article was funded through an award from the Patient-Centered Outcomes Research Institute (1511-32875). The University of Texas MD Anderson Cancer Center is supported by the National Institutes of Health (grant P30 CA016672). Conflicts of interest: Glyn Elwyn and Marie-Anne Durand have developed the Option Grid patient decision aids, which are licensed to EBSCO Health; they receive consulting income from EBSCO Health and may receive royalties in the future. A. James O'Malley reports grants from the National Institutes of

Durand 2021 *(Continued)*

Health, the Agency for Healthcare Research and Quality, and the Patient-Centered Outcomes Research Institute. Mary C. Politi reports grants from Merck outside the submitted work. Catherine H. Saunders holds a copyright in the consideRATE suite of tools. Karen Sepucha received salary support from 2014 to 2018 as a member of the scientific advisory board for Healthwise, a not-for-profit foundation that develops and distributes patient education and decision support materials; she also reports grants from the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute, and the Patrick and Catherine Weldon Donaghue Medical Research Foundation outside the submitted work. Richard J. Barth reports grants and other from CairnSurgical, Inc, and grants from the National Institutes of Health outside the submitted work; in addition, Barth has a patent licensed to Dartmouth College. The other authors made no disclosures.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"To minimize contamination, we randomized surgeons to 1 of 3 arms nested within 4 cancer centers. We used balanced block randomization to account for the varying number of surgeons at each site." (use of computer implied)
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single-blinded (outcomes assessor) according to the study protocol. Surgeons and participants were not blinded and therefore it is unclear how this may have affected the surgeon's performance in delivering the intervention/comparator and influence on the outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The statistical analyst was blinded to site and arm assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, high attrition rates but missing data have been imputed using appropriate methods. "At T3, the number of patients with missing data ranged from 89 (19.9%) for knowledge to 98 (21.9%) for decision process. Multiple imputation analyses suggested minimally different estimates when data were imputed for most outcomes in comparison with no imputation. We can thus be assured that current findings are very unlikely to be overturned by accounting for missing data via multiple imputation."
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03136367) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	High risk	Surgeons were randomized, patients were unit of observation (not randomized). This led to imbalanced allocation to arms due to differences in the number of patients seen by each surgeon (66 patients allocated to Option Grid and 257 patients allocated to usual care). They planned to stratify patients according to socioeconomic status in statistical analyses, but they did not enforce balance with respect to socioeconomic status when enrolling participants. Acknowledged in limitations but not discussed: "Randomization at the surgeon level led to chance imbalance between arms, with surgeons in the Option Grid arms having lower volumes of eligible patients and different distributions of the patient characteristics. Attempts to modify these patterns were unsuccessful. And lower recruitment than planned" Potential conflicts of interest: "Glyn Elwyn and Marie-Anne Durand have developed the Option Grid patient decision aids, which are licensed to EBSCO Health; they receive consulting income from EBSCO Health and may receive royalties in the future"

Durand 2021 *(Continued)*

	Selective recruitment of cluster participants: "We randomized breast surgeons to accrue patients in 1 of 3 trial arms for 18 months. We recruited English-, Spanish-, and Mandarin Chinese-speaking women (18 years old or older) with a biopsy-confirmed diagnosis of early-stage breast cancer (stages I-IIIA) eligible for breast-conserving surgery and mastectomy according to medical records and participating surgeons' judgment." (High risk) Free of other potential biases: adjustment for clustering performed.

Ehrbar 2019

Study characteristics	
Methods	Randomized to decision aid + counseling vs control (counseling alone)
Participants	40 + 39 female patients aged 18 to 40 scheduled to undergo cancer treatment that potentially endangered their fertility in Switzerland and Germany
Interventions	DA: online decision aid provided post-consultation that included clinical information, explicit values clarification, guidance in decision-making (step-by-step process), guidance in communication, and visual summary showing average values for both the pros and cons that can be printed or downloaded. The DA is publicly available at https://www.fertionco.ch/de/home/ . Comparator: standard counseling (no further details provided)
Outcomes	Primary outcome: decisional conflict Secondary objectives: knowledge (subjective), attitude and willingness regarding fertility preservation, decisional regret, final decision, satisfaction with the DA (intervention group only)
Notes	Source of funding: The study was funded by a grant from the Swiss Cancer Research (KFS-3584-02-2015). Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"After having given written informed consent, study participants were assigned with a block randomization to either the control or the intervention group by the study coordinator." The investigators describe the use of stratification or permuted blocking (use of computer implied).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding according to the study protocol. It is unclear if participants' awareness of their group allocation may have biased their responses for subjective measures (e.g. decisional conflict).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.

Ehrbar 2019 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High rate of attrition but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02404883) and all the study's pre-specified primary and secondary outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	As seen in the sample size section, only 63.71% of the patients who were asked eventually participated in the study. The small sample of the final analysis needs to be considered and the interpretation of the results therefore needs to be treated with caution.

Elliott 2022

Study characteristics	
Methods	Cluster-randomized to decision aid + clinical decision support (CDS) vs CSD alone vs usual care
Participants	34 clinics randomized in the USA: 11 DA + CDS (7807 patients), 11 CDS alone (8818 patients), 12 usual care (10,974 patients). Eligible patients were 1) aged 21 to 74 years; 2) not pregnant, cognitively impaired, or in hospice care; and 3) not up-to-date for breast, cervical, colorectal, or lung cancer screening at an index visit at a randomized clinic.
Interventions	DA: paper-based decision aids used in consultation plus web-based clinical decision support (CDS). The decision aids included clinical information, probabilities of outcomes, explicit values clarification, and guidance in decision-making. Short form versions of the decision aids notified patients and providers of the patients' eligibility for a cancer screening test, briefly presented benefits and risks, options to consider, and invited the patient to access during the clinic visit the full-length shared decision-making tool and discuss with their provider. The CDS intervention was a web-based, electronic health record-linked system that included cancer prevention algorithms and the CDS output provided personalized recommendations to both primary care providers and patients in high-literacy (provider) and low-literacy (lay person) printed and electronic formats. The DAs are available as a supplementary appendix in the article. Comparator: usual care (no details provided) Comparator: CDS alone (not extracted)
Outcomes	Primary outcome: a composite indicator of the proportion of patients overdue for breast, cervical, or colorectal cancer screening at index who were up to date on these 1 year later. Secondary outcomes: breast cancer screening, cervical cancer screening, colorectal cancer screening, lung cancer screening.
Notes	Source of funding: Financial support for this study was provided entirely by a grant from National Cancer Institute of the National Institutes of Health. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under award No. R01CA193396. Conflicts of interest: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Elliott 2022 *(Continued)*

Random sequence generation (selection bias)	Low risk	"Cluster randomization of the 34 primary care clinics was chosen to minimize contamination. Re-randomization balanced clinic attributes across 3 study groups on 2 primary factors: clinic urbanicity based on Rural-Urban Commuting Area (RUCA) codes, and the percentage of women at each clinic up to date on breast cancer screening to address clinic attentiveness to routine cancer screening." Referenced: Morgan KL, Rubin DB. Rerandomization to improve covariate balance in experiments. Ann Stat. 2012;40(2): 1263–82.
Allocation concealment (selection bias)	Low risk	"The first concealed randomization scheme meeting balance criteria was selected and resulted in n = 11 CDS, n = 11 CDS+SDM, and n = 12 UC clinics."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate and similar across arms (less than 10%), reasons for attrition recorded
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02986230) and all the study's pre-specified primary and secondary outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Evans 2010

Study characteristics	
Methods	Randomized to online decision aid vs paper decision aid vs questionnaire vs usual care
Participants	129 + 126 + 127 + 132 men considering PSA screening in Wales
Interventions	DA: online program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary). The DA is no longer available (at www.prosdex.com). The authors have screenshots of the website that was evaluated in the study. Comparator: paper version of online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer program; summary) Comparator: received a questionnaire Comparator: received nothing
Outcomes	Primary outcomes: knowledge (post-DA) Secondary outcomes: attitude (post-DA), intention to undergo PSA testing (post-DA), anxiety (post-DA), uptake of PSA test (post-DA), total decisional conflict

Evans 2010 *(Continued)*

Notes	Source of funding: The study was funded by Cancer Research UK. The researchers are entirely independent from the funders (Grant number: C6475/A7490). Cardiff University agreed to act as sponsor for the above project, as required by the Research Governance Framework for Health and Social Care (Sponsorship reference: SPON 304-06). The sponsor acted as employer of members of the research team. The sponsor and funder were not involved in the review and final approval of the manuscript. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[A] random sample of 100 men was selected from the list." "The process ensured individual level randomization" (p 4, Recruitment process)
Allocation concealment (selection bias)	Low risk	"[A]ffirmative consent forms from each practice were transferred to the research officer who allocated each participant with a number provided remotely by the trial statistician to ensure concealment" (p 4, Recruitment process)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The study does not address this outcome
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram indicating high attrition consistently across groups
Selective reporting (reporting bias)	Low risk	Registered as a trial
Other bias	Low risk	The study appears free of other sources of bias.

Fagerlin 2011

Study characteristics

Methods	Decision aid vs delayed intervention vs control
Participants	382 + 159 + 100 women with an elevated 5-year risk of breast cancer considering breast cancer prevention medication in the USA
Interventions	DA: tailored DA on options' outcomes, clinical problem, outcome probabilities, and explicit values clarification. The DA is no longer available (http://www.cbdsm.org/files/downloads/ChemopreventionDecisionAid.pdf). The authors have a word file version of the content of the website that was evaluated in the study. Comparator 1: given DA after 3-month follow-up Comparator 2: given DA after all outcome measures were taken
Outcomes	Decisional conflict (post-DA), behavioral intent (post-DA), actual behavior (post-DA), proportion undecided, perception of benefits (post-DA), perception of risk (post-DA)

Fagerlin 2011 *(Continued)*

	Other outcomes: • Banegas 2013: decisional conflict (post-DA) (data from 690 + 160 + 162 women), proportion undecided (3 months) • Korfage 2013: knowledge (immediately post and 3 months post-DA), attitudes (immediately post and 3 months post-DA), behavioral intent (post-DA), actual behavior (3 months post-DA), informed decision defined as "participants with sufficient knowledge about chemoprevention behavior, whose attitudes were concordant with their intentions or decisions to engage in chemoprevention behavior" (data from 383 + 102 + 100 women)
Notes	Primary outcome was not specified Source of funding: Financial support for this study was provided by a grant from the National Institutes for Health (P50 CA101451). Conflicts of interest: Drs. Fagerlin and Smith were supported by MREP early career awards from the U.S. Department of Veterans Affairs. Dr. Zikmund-Fisher is supported by a career development award from the American Cancer Society. Dr. Hayes received support from Fashion Footwear Charitable Foundation of New York/QVC Presents Shoes on Sale.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence generation was provided by the author.
Allocation concealment (selection bias)	Low risk	Central and web-based allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding - using an online decision aid would have avoided control participants accessing the decision aid.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not report exclusions; inadequate reporting on participant flow through the study to determine risk for attrition bias or incomplete outcome data.
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol.
Other bias	Low risk	Appears to be free of other sources of bias.

Fisher 2020

Study characteristics

Methods	Randomized to decision aid vs active control
Participants	103 + 93 participants aged 18 and older with bipolar II disorder considering treatment options for maintaining mood stability/preventing relapse in Australia

Fisher 2020 *(Continued)*

Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, patient examples, additional resources, guidance in decision-making (7 steps), and guidance in communication. The DA is publicly available at http://www.bipolardecisionaid.com.au/ . Comparator: information (publicly available website: https://www.blackdoginstitute.org.au/resources-support/bipolar-disorder/treatment/)
Outcomes	Decisional conflict, concordance between preferred and actual levels of decision-making involvement, preparedness for decision-making, knowledge, decision regret, value-based informed choice, and uptake of treatment options
Notes	Source of funding: This research was funded by an Australian Rotary Health Mental Health for Young Australians Grant (2017–2019). The funding body had no role in the design and conduct of the study, analysis and interpretation of the data, and reporting of results. Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Upon completion of T0 measures, participants were randomly allocated (1:1) to either the control or intervention group, using a website-generated randomisation sequence.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	In protocol: neither participants nor the trial researchers will be blinded to participants' group assignment. It is unclear how lack of blinding influenced the results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	In protocol: Neither participants nor the trial researchers will be blinded to participants' group assignment. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate (post-treatment decision T1: 56/103 completers DA and 56/93 completers control (P = 0.408883)) (3-month follow-up (T2): 40/103 completers DA and 44/93 control (P = 0.231112)), but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12617000840381) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Fraenkel 2007

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	47 + 40 patients with knee pain considering treatment options in the USA

Fraenkel 2007 *(Continued)*

Interventions	DA: interactive computer tool options' outcomes, outcome probability, explicit values clarification. The DA is not available. Author said the DA was never fully developed; all information about the DA is included in the article. Comparator: usual care using the Arthritis Foundation information pamphlet
Outcomes	Decisional self-efficacy, preparation for decision-making
Notes	Primary outcome was not specified Source of funding: Supported in part by a grant from the Claude D. Pepper Older Americans Independence Center at Yale University School of Medicine (P30AG21342). Dr. Fraenkel is supported by the K23 Award AR048826-01 A1. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomization sequence (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided; computer-generated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding, but study does not report if it had an impact on the outcomes measured.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low risk of attrition bias - outcome data for all 40 controls and 44 of 47 intervention (p 3, Results).
Selective reporting (reporting bias)	Unclear risk	No information provided; no indication if trial was registered centrally.
Other bias	Low risk	Appears to be free of other potential biases.

Fraenkel 2012

Study characteristics

Methods	Cluster-randomized controlled trial of clinics to decision aid versus usual care
Participants	69 + 66 patients with nonvalvular atrial fibrillation considering anticoagulation with aspirin or warfarin in the USA
Interventions	DA: computer-based tool on options' outcomes, clinical problem, options' probabilities, guidance, explicit values clarification. The DA is not publicly available; a copy was provided by the author (terri.fried@yale.edu).

Fraenkel 2012 *(Continued)*

	Comparator: control arm (no further information provided)
Outcomes	Primary outcomes: feeling informed and having clear values (baseline, immediately post) Secondary outcomes: knowledge (baseline, immediately post), accuracy of risk (baseline, immediately post), anxiety (baseline, immediately post), worry (baseline, immediately post), rationale for preferred treatment (during the encounter - DA group only), discussion of related outcomes (during the encounter as captured on audiotape), change in treatment plan (post intervention), anxiety, accurate risk expectations (stroke, bleeding)
Notes	Trial registration NCT00829478 Source of funding: The project described was supported by the Donaghue Foundation Practical Benefit Initiative DF #06-205 and by the Claude D. Pepper Older Americans Independence Center at Yale University School of Medicine (#P30AG21342 NIH/NIA). Conflicts of interest: Dr. Fried is supported by K24 AG28443. Dr. Street is supported in part by the Houston Health Services Research and Development Center of Excellence (HFP90-020) at the Michael E. DeBakey VA Medical Center.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Inadequate information on random sequence generation
Allocation concealment (selection bias)	Unclear risk	Inadequate information on allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"To avoid contamination, participants were randomized at the level of the firm so that all participants in one firm received the intervention, and all participants in the second firm were included in the control arm" (p 1435)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"An interviewer blinded to the participant's group assignment reassessed the primary and secondary outcomes after participant's primary care visit" (p 1436)
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Does not appear to be incomplete outcome data; flow diagram does not report participation beyond randomization.
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Fraenkel 2015

Study characteristics

Methods	Randomized to decision aid versus usual care
Participants	62 + 63 patients aged 18 and older with rheumatoid arthritis in the USA

Fraenkel 2015 *(Continued)*

Interventions	DA: web-based decision aid used in preparation for consultation that included clinical information, probabilities of outcomes, explicit values clarification, and knowledge tests with feedback. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care (education and counseling)
Outcomes	Change in objective knowledge, subjective knowledge and values clarity, risk communication and confidence in decision using COMRADE, decision to escalate care, and actual escalation of care
Notes	Source of funding: Supported by a Disease Targeted Innovative Research Grant from the Rheumatology Research Foundation and by the Claude D. Pepper Older Americans Independence Center at Yale University School of Medicine (through a grant from the National Institute on Aging [P30AG021342]). Dr. Fraenkel's work was supported by grant AR-060231-01 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Mr. Charpentier's work was supported by grant SES-1155924 from the National Science Foundation. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Random treatment assignments were placed in numbered, opaque envelopes. Participants were randomly assigned to the intervention or usual care control group in a 1:1 ratio.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Follow-up data were collected over the telephone by trained, blinded interviewers using a standardized script at 2 and 8 weeks.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate and similar across arms (< 10%)
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01721200) and all of the study's pre-specified outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Frosch 2008a

Study characteristics

Methods	Randomized to decision aid vs decision aid + chronic disease trajectory vs chronic disease trajectory vs usual care (Internet information)
Participants	155 + 152 + 153 + 151 men considering prostate cancer screening in the USA

Frosch 2008a *(Continued)*

Interventions	DA: information on options' outcomes, clinical problem, outcome probabilities, others' opinions. The DA is not publicly available; screenshots were provided by the author. Comparator 1: information on options' outcomes, clinical problem, outcome probabilities, others' opinions, explicit values clarification (utilities for outcomes associated with prostate cancer) Comparator 2: explicit values clarification (utilities for outcomes associated with prostate cancer) Comparator 3: usual care using public information on prostate cancer screening on American Cancer Society and Centers for Disease Control and Prevention websites 2005-2006
Outcomes	Primary outcomes: knowledge, actual option, decisional conflict Secondary outcomes: concern about prostate cancer, treatment preference if prostate cancer diagnosed
Notes	Source of funding: This study was supported by cooperative agreement U57/CCU920678 from the Centers for Disease Control and Prevention. Dr Frosch also received support from the Robert Wood Johnson Foundation Health & Society Scholars Program. Conflicts of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer algorithm randomly assigned participants to the 4 study groups.
Allocation concealment (selection bias)	Low risk	Revealed after signed consent and completed baseline measures.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Accessed a secure Internet site that hosted all study materials; participants had unlimited access to assigned intervention; unclear blinding of personnel.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were measured via questionnaires and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; imputed missing data for participants who did not complete follow-up assessments; minimal attrition.
Selective reporting (reporting bias)	Unclear risk	No indication of published protocol
Other bias	Low risk	Appears to be free of other potential biases.

Fung 2021

Study characteristics

Methods	Randomized to decision aid vs information

Fung 2021 *(Continued)*

Participants	36 + 37 participants aged ≥ 60 years with newly diagnosed obstructive sleep apnea in the USA
Interventions	Web-based decision aid + paper-based workbook used in preparation for consultation with the physician that includes clinical information, outcome probabilities, explicit values clarification, individualized sleep test results, exercise for patient to identify long-term health goals, other resources, patients narratives (hypothetical), guidance in decision-making (used with in-person support), and guidance in communication. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: general information about sleep
Outcomes	Decisional conflict, preparation for decision-making, knowledge
Notes	Source of funding: This study was funded by the National Institute on Aging of the National Institutes of Health (K23AG045937 to C.H.F., K23AG055668 to Y.S., K23AG049955 to J.D., National Center for Advancing Translational Science, UCLA CTSI Grant UL1TR001881), as well as the American Federation for Aging Research, The John A. Hartford Foundation, and The Atlantic Philanthropies (The Beeson Career Development in Aging Research Award Program to C.H.F.). R.D.H. received support from the University of California, Los Angeles Resource Centers for Minority Aging Research Center for Health Improvement of Minority Elderly under the National Institutes of Health National Institute on Aging Grant P30-AG021684. J.L.M. received support from the National Heart, Lung and Blood Institute at the National Institutes of Health (K24HL143055). Conflicts of interest: The authors have no financial or nonfinancial interests that are relevant to the submitted manuscript

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients who met inclusion criteria were randomized within each study site to receive Decide2Rest vs control. At the university site, participants were randomized using simple randomization to one of two groups (decision aid with in-person support; control with in-person support) on the day of the intervention. The Research Electronic Data Capture randomization tool was used to allocate the participants to either the Decide2Rest or control program. At the VA site, participants were randomized to one of four groups (decision aid with in-person support, decision aid with telephone support, control with in-person support, or control with telephone support) on the day of the intervention using a block randomization (block size = 4). The randomization sequence was created using Stata 13.1 (StataCorp LLC, College Station, Texas).
Allocation concealment (selection bias)	Low risk	A set of opaque, sequentially numbered envelopes was prepared during the setup phase of the study by research team member without direct contact with research participants, and at the time of randomization; the envelopes were opened sequentially by a staff member without contact with the research participants.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Decisional measures were assessed in all randomized participants postintervention at a separate in-person research visit that occurred after the sleep clinic appointment (typically, the postintervention assessment occurred on the day of the intervention). At the VA site, the assessor was blinded to study arm assignment, whereas at the university site, blinding was not possible because of staffing limitations.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Decisional measures were assessed in all randomized participants postintervention at a separate in-person research visit that occurred after the sleep clinic appointment (typically, the postintervention assessment occurred on the day of the intervention). At the VA site, the assessor was blinded to study arm assignment, whereas at the university site, blinding was not possible be-

Fung 2021 *(Continued)*

		cause of staffing limitations. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT, all participants included in analysis, no loss to follow-up
Selective reporting (reporting bias)	Unclear risk	Registered (NCT03138993). Outcomes in the article do not match outcomes identified in trial registry. In article, outcomes are: decisional conflict, preparation for decision-making, knowledge. In trial registry, outcomes are recruitment rates, enrolment rates, length of time for completing intervention session.
Other bias	Unclear risk	The two recruitment sites have different study groups: (site 1: DA vs control; site 2: decision aid with in-person support, decision aid with telephone support, control with in-person support, or control with telephone support).

Gabel 2020a

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	830 + 849 Danish citizens aged 50 to 74
Interventions	DA: online decision aid that includes information about screening, explicit values clarification, and summary page with a "choice indicator" and users answers to the values clarification exercise. The DA is not publicly available; screenshots of the web pages of the DA were obtained from the author (Mette Bach Larsen: metbacla@rm.dk). Comparator: no intervention
Outcomes	Primary outcome: informed choice based on the following proxy measures: knowledge, attitudes, and screening uptake Secondary outcomes: colorectal screening induced worries, decisional conflict
Notes	Source of funding: The trial has been funded by grants from public and private foundations: The Danish Foundation TrygFonden; The Danish Cancer Society; The Health Research Fund of Central Denmark Region; Health, Aarhus University; The Private Foundation of the Family Spogård, The Health Foundation, Denmark; Danish Cancer Research Foundation; The Private Foundation of Ringgaard-Bohn, and the Danish Health Authority. Conflicts of interest: none

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"allocation will be performed in the ratio 1:1 and will use a computer-generated algorithm for randomization, based on a simple randomization procedure. Randomization will be conducted based on the study participants' record-ID numbers." (as per published protocol Gabel 2018)
Allocation concealment (selection bias)	Unclear risk	Not reported

Gabel 2020a *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High rate of attrition but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03253822) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Gabel 2020b

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	3571 + 3571 Danish citizens aged 53 to 74
Interventions	DA: online decision aid that includes information about screening, explicit values clarification, and summary page with a "choice indicator" and users answers to the values clarification exercise. The DA is not publicly available; screenshots of the web pages of the DA were obtained from the author (Mette Bach Larsen: metbacla@rm.dk). Comparator: no intervention
Outcomes	Primary outcomes: components of informed choice assessed using 3 dimensions (knowledge about the options to choose from, attitudes towards the options, and actual behavior) Secondary outcomes: decisional conflict and stated use of the decision aid.
Notes	Source of funding: The trial has been funded by grants from: TrygFonden; The Danish Cancer Society; The Health Research Fund of Central Denmark Region Health, Aarhus University; The Private Foundation of the Family Spogárd, The Health Foundation, Denmark; Danish Cancer Research Foundation; The Private Foundation of Ringgaard-Bohn, and the Danish Health Authority. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. Conflicts of interest: The authors have declared that no competing interests exist.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"respondents were simultaneously randomised into intervention and control groups in a 1:1 ratio using a computer-generated algorithm for randomization based on a simple randomization procedure randomly assigning participant ID numbers to intervention or control group"

Gabel 2020b *(Continued)*

Allocation concealment (selection bias)	Low risk	"Respondents to the baseline questionnaire were simultaneously randomised into intervention or control group. Allocation was based on participants' record-ID numbers using a computergenerated algorithm for randomization based on a simple randomization procedure. The algorithm was generated by an administrator of the REDCap (Research Electronic Data Capture) software [32], which was otherwise not attached to the study"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High rate of attrition but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03253822) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Gagne 2017

Study characteristics	
Methods	Randomized to decision aid + education vs education alone
Participants	26 + 25 participants was aged 18 to 65 with mild to severe asthma and prescribed inhaled corticosteroids, either alone or in combination with long-acting β2-agonists in Canada
Interventions	Intervention: decision aid plus education. The decision aid included information on the clinical condition, explicit values clarification, and guidance in decision-making (step-by-step process). The education session included guidance in communication (elicited patients' concerns by asking questions and providing feedback) and participants were also provided with an individualized written action plan. The DA is publicly available at https://cts-sct.ca/wp-content/uploads/2020/10/GagneBoulet_DA_Asthma_ICS_IPDASFinalVersion_Color_English_v2015-11-04.pdf . Comparator: education that included information on the clinical condition, treatments and side effects, guidance in communication, and an individualized written action plan
Outcomes	Primary outcome: knowledge Secondary outcomes: decisional conflict, appropriate use of pharmacotherapy (adherence), and asthma control
Notes	Source of funding: LPB (principal investigator) and FL (co-investigator) received a grant from the Allergy, Genes and Environment Network for funding the research: http://allergen-nce.ca/. Conflicts of interest: Potential conflicts of interest to disclose are: 1) the Knowledge Translation, Education and Prevention Chair in Respiratory and Cardiovascular Health is supported by unrestricted grants from AstraZeneca, and 2) the Chair on Adherence to Treatments was supported by unrestricted grants from AstraZeneca, Merck Canada, Sanofi Canada, Pfizer Canada and the Prends soin de toi pro-

Gagne 2017 *(Continued)*

gram. M.G., F.L., and J.M. have no conflict of interest to declare. L.P.B. considers having no conflict of interest but wishes to declare what can be perceived as potential conflicts of interest. Advisory Boards: GlaxoSmithKline, Novartis. Conferences (honoraria): AstraZeneca, GlaxoSmithKline, Merck, Novartis. Sponsorship for investigator-generated research: AstraZeneca, GlaxoSmithKline, Merck Frosst, Schering. Sponsorship for research funding for participating in multicenter studies: AllerGen, Altair, Amgen, Asmacure, AstraZeneca, Boehringer-Ingelheim, Genentech, GlaxoSmithKline, Novartis, Ono Pharma, Pharmaxis, Schering, Wyeth. Support for the production of educational materials: AstraZeneca, GlaxoSmithKline, Merck Frosst, Boehringer-Ingelheim, Novartis. Organizational: Chair of the Global Initiative for Asthma (GINA) Guidelines Dissemination and Implementation Committee, Knowledge Translation, Education and Prevention Chair in Respiratory and Cardiovascular Health, Member of the Executive Committee of Interasma (Global Asthma Organization).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The study was designed as a prospective two-month randomized controlled parallel group trial (allocation ratio 1:1). A statistician generated a random allocation sequence of block size of four using a computer software program."
Allocation concealment (selection bias)	Low risk	"The study coordinator enrolled participants. Educators assigned participants to interventions using sequentially numbered, opaque, sealed and equally weighted envelopes."
Blinding of participants and personnel (performance bias) All outcomes	High risk	After assignment to interventions, only the study co-ordinator, who assessed the outcomes, was blinded. "the educators who were responsible for provision of patient education in both groups were not blinded to the experimental intervention and may have been more motivated to support control participants in making decisions. This may have diminished the impact of our DA on decisional conflict as well as reduced the probability to detect between-group differences"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	After assignment to interventions, only the study co-ordinator, who assessed the outcomes, was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT, all participants included in analysis, loss to follow-up similar between arms 2/26 (7.7%) for DA and 2/25 (8%) for control.
Selective reporting (reporting bias)	Unclear risk	The study was registered retrospectively in 2015 (NCT02516449) after recruitment was completed in 2013, and therefore no way to verify whether the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Gattellari 2003

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	126 + 122 men considering PSA testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification. The DA is available as an appendix in the article.

Gattellari 2003 *(Continued)*

	Comparator: usual care using brief information on screening test and chances of false-positive results
Outcomes	Preferred option, knowledge, decisional conflict, accurate risk perceptions, perceived ability to make an informed choice
Notes	Primary outcome was not specified Source of funding: Melina Gattellari was supported by an Australian Postgraduate Award at the time this study was conducted. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Pre-randomized code - no further information (p 1)
Allocation concealment (selection bias)	Low risk	Pre-randomized code unobtrusively marked on envelopes (p 1)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Consenting men were blinded to allocation, but unclear if personnel were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Pre-test characteristics included. Flow chart not included and reasons for attrition not mentioned; some attrition but balanced between groups.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Gattellari 2005

Study characteristics

Methods	Randomized to decision aid booklet vs decision aid video vs usual care
Participants	140 + 141 + 140 men considering PSA testing in Australia
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification. The DA is available as an appendix in a previously published article (Gattellari 2003). Comparator 1: video on clinical problem, outcome probability, others' opinion Comparator 2: usual care using brief information on screening test and chances of false-positive results
Outcomes	Preferred option, knowledge, decisional conflict, perceived ability to make an informed choice

Gattellari 2005 *(Continued)*

Notes	Primary outcome was not specified Source of funding: At the time of the study, Melina Gattellari was supported by a Commonwealth Department of Education, Science and Training Australian Postgraduate Award (APA) and was a doctoral candidate at the School of Public Health, University of Sydney. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Unique identification codes assigned to participants according to date and time enrolled into the interventional component of the study. Block randomization of identification codes then performed via computer software (p 2 - 2.3.1).
Allocation concealment (selection bias)	Low risk	"Allocation concealment was ensured as the interviewers, responsible for enrolling participants onto the trial, were blinded to the randomized study design while one of the authors (MG) was responsible for randomisation. Hence, it was not possible for either participants or interviewers to be aware of the randomisation sequence." (p 2 - 2.3.1)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and interviewers were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	At post-test, it was not possible to blind the interviewers but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal attrition that is consistent across groups (figure 1)
Selective reporting (reporting bias)	Unclear risk	"[S]uccess of study protocol" limitation to protocol: men not confronted with actual decision to undergo PSA screening; no indication that trial registered in central trials registry (p 13, paragraph 5)
Other bias	Low risk	"[H]igh follow-up rate and allocation concealment; study not subjected to selection bias" (p 13, paragraph 5). Appears to be free of other sources of bias.

Gokce 2019

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	60 + 59 patients aged 18 to 75 years with symptomatic non-lower pole renal stones < 20 mm in Turkey
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information and explicit values clarification. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care

Gokce 2019 *(Continued)*

Outcomes	Decision (choice), decisional conflict, knowledge
Notes	Source of funding: not reported Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer software was used to generate random allocation sequence.
Allocation concealment (selection bias)	Low risk	The patients were randomized to two study groups. Computer software was used to generate random allocation sequence. The random allocation sequence was placed in preset, numbered envelopes and a nurse opened the envelopes for each patient to perform randomization.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis, low attrition rate (97% retention rate for both groups)
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Gordon 2017

Study characteristics

Methods	Randomized to decision aid + education vs education alone
Participants	133 + 155 participants aged 21 and older who have never received a kidney from an increased risk donor in the USA
Interventions	DA: web-based decision aid used after routine education and physician consultation that includes clinical information, outcome probabilities, implicit values clarification, patient stories, and knowledge tests. The DA is publicly available at https://informme.cbits.northwestern.edu/system/ . Comparator: routine education
Outcomes	Knowledge, willingness to accept increased risk donor kidney transplant
Notes	Source of funding: This publication was supported by the NINR/NLM (Grant No. R21NR013660 to EJ Gordon). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the views of NIH.

Gordon 2017 *(Continued)*

Conflicts of interest: The authors declare no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Staff then randomized participants, using 1:1 equal allocation, to receive either routine education only (control arm) or Inform Me after attending routine education (intervention arm), using a computer-generated random number list, with individual numbers inserted into sequentially numbered, sealed envelopes concealed until study arm was assigned. Randomization was stratified by site.
Allocation concealment (selection bias)	Low risk	Using a computer-generated random number list, with individual numbers inserted into sequentially numbered, sealed envelopes concealed until study arm was assigned.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The trial was single-blinded; research team members assessing outcomes (EJG, MWS, MGI) were blinded to assignments to the intervention. Unclear how lack of blinding of participants influenced the outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The trial was single-blinded; research team members assessing outcomes (EJG, MWS, MGI) were blinded to assignments to the intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in analysis.
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT01859884). Decisional conflict was prespecified as an outcome measure but is not reported in the article.
Other bias	Unclear risk	"Although 1:1 randomization was implemented, we realized that, due to technical problems with Internet connectivity and concomitant concerns over potential data loss for the intervention arm, we needed to recruit more participants to ensure at least 100 participants per arm. We therefore generated an additional 100 random numbers, which were mostly used at the NMH site. The study stopped recruitment after reaching our initial target sample size, twelve numbers were not used (6 per site). We recovered most data and obtained a larger sample than our initial recruitment target."

Green 2001

Study characteristics

Methods	Randomized to decision aid + counseling vs counseling alone vs usual care
Participants	29 + 14 women with a first degree relative with breast cancer interested in learning about genetic testing in the USA
Interventions	DA: CD-ROM plus counseling on options' outcomes, clinical problem, others' opinions, guidance/coaching. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: counseling Comparator: usual care

Green 2001 *(Continued)*

Outcomes	Primary outcome: preferred options Secondary outcome: knowledge
Notes	Source of funding: This publication was supported by grant number 1R03 CA 70638 from the National Cancer Institute (NCI), and grant number 1 R01 CA84770 from NCI and the National Human Genome Research Institute (NHGRI). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[B]lock randomization schedule to one of three groups in a 2:2:1 ratio" (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[G]enetic counsellor blinded to randomization until just prior to the session" (p 2), unclear if participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Values do not always add up to the number of participants due to missing data"; reasons not mentioned (p 4). "Participants' baseline knowledge was reflected in the control group's answers"; participants balanced in study groups
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other sources of bias.

Hamann 2006

Study characteristics

Methods	Cluster-randomized trial of decision aid vs usual care
Participants	54 + 59 patients with schizophrenia considering treatment options (cluster-RCT with 12 wards paired and randomized) in Germany
Interventions	DA: 16-page booklet on options' outcomes, outcome probabilities, explicit values clarification, coaching/guidance. The DA is not publicly available; a copy was provided by the author (in German). Comparator: usual care
Outcomes	Knowledge, participation in decision-making (COMRADE - doctor gave me a chance to decide which treatment I thought was best for me), uptake of psycho-education, rehospitalization, adherence, satisfaction with care, severity of illness (baseline only), attitudes about drug use, decision-making preference

Hamann 2006 *(Continued)*

Notes	Primary outcome was not specified Source of funding: The trial was funded by the German Ministry of Health and Social Security (217-43794-5/9) within the funding project 'Der Patient als Partner im medizinischen Entscheidungsprozess'. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[O]ne member of each pair being randomly assigned to the control or to the interventional condition" (p 266). Sequence generation method was not stated.
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	High risk	Clustering was not accounted for in the analysis. Free of other potential biases: no evidence of selective recruitment of cluster participants.

Hanson 2011

Study characteristics

Methods	Cluster-randomized trial of decision aid vs usual care
Participants	127 + 129 patients diagnosed with advanced dementia and eating problems considering long-term feeding tube placement in the USA
Interventions	DA: booklet or audio recording on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (steps in decision-making, worksheet, summary). The DA is available at https://decisionaid.ohri.ca/AZsumm.php?ID=1652 . Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (3 months post-DA)

Hanson 2011 *(Continued)*

	Secondary outcomes: surrogate knowledge, risk perceptions, frequency of communication with providers (3 months post-DA), feeding treatment use (3, 6, and 9 months post-DA), participation in decision-making, satisfaction with the decision, decisional regret
Notes	Source of funding: The study was funded by National Institutes of Health (NIH), National Institute for Nursing Research Grant R01 NR009826. Dr. Mitchell is supported by NIH, National Institute on Aging Grant K24AG033640. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generation (p 2010, Randomization)
Allocation concealment (selection bias)	Unclear risk	No description of method used to conceal allocation (p 2010, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Cluster randomization prevented double blinding and may have introduced bias due to site effects" (p 2014, Discussion); study authors unsure of effect on study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[B]ecause of cluster randomization, data collectors were not blinded to group assignment" (p 2010, Randomization); authors believe this has little impact on study.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Intervention group missing data for 1 participant; reason for omission not reported (table 1) No explanation for number of participants in each group (n = 127), given numbers vary from those in 'recruitment and retention' figure (table 4)
Selective reporting (reporting bias)	Low risk	Registered with clinicaltrials.gov, protocol on website
Other bias	Low risk	Appears to be free of other potential biases (adjustment for clustering performed/no evidence of selective recruitment of cluster participants)

Heller 2008

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	66 + 67 breast cancer patients eligible for breast reconstruction in the USA
Interventions	DA: interactive software program on options' outcomes, others' opinions. The DA is not publicly available; a copy was provided by the author (computer disc mailed). Comparator: standard patient education
Outcomes	Knowledge, anxiety, satisfaction with treatment choice, satisfaction with decision-making ability
Notes	Primary outcome was not specified Source of funding: not reported

Heller 2008 *(Continued)*

	Conflicts of interest: There are no conflicts of interest regarding the publication of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"upon study entry, the participants were randomized (computer generated) to one of two groups" (p 2)
Allocation concealment (selection bias)	Unclear risk	Not enough information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline anxiety and knowledge included in graphs. Participant numbers between study groups are balanced (p 3). Reasons for incomplete questionnaires and study withdrawals are mentioned.
Selective reporting (reporting bias)	Unclear risk	No information provided re protocol
Other bias	Low risk	Appears to be free of other potential biases.

Hess 2012

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	103 + 105 patients in the emergency department with primary symptoms of nontraumatic chest pain, being considered for admission to the emergency department observation unit for monitoring and cardiac stress testing within 24 hours in the USA
Interventions	DA (in consultation): 1-page printout on options' outcomes, clinical problem, and outcome probabilities. The DA is presented in Figure 1 of the article. Comparator: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: risk perceptions, decisional conflict, actual choice, satisfaction with the decision-making process, patient-practitioner communication
Notes	Source of funding: The project was funded by an investigator-initiated grant from the Foundation for Informed Medical Decision Making. The study sponsor did not have any involvement in the design and conduct of the study, data analysis, interpretation of the data, or manuscript preparation or approval.

Hess 2012 *(Continued)*

	Conflicts of interest: The investigative team has not had and does not have any for-profit-seeking intentions for the Chest Pain Choice decision aid. Our decision aids are freely available at http://shareddecisions.mayoclinic.org.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion" (p 253)
Allocation concealment (selection bias)	Low risk	"Patients were randomized to either usual care or shared decision making through a Web-based, computer-generated allocation sequence in a 1:1 concealed fashion" (p 253)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded, but unclear if patients were blinded (p 253, Outcome measures). However, the primary outcome is unlikely to be biased.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Investigators assessing outcomes were blinded (p 253, Outcome measures).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Some of the numbers of patients reported in the results did not match the flow chart.
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	Appears to be free of other biases.

Hess 2016

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	458 + 455 adults aged 18 and older presenting to the emergency department with a chief complaint of chest pain who were being considered by the treating clinician for admission to the observation unit for cardiac stress testing or coronary computed tomography angiography in the USA
Interventions	DA: paper-based decision aid used during consultation that includes clinical information, outcome probabilities, and implicit values clarification. The DA is available as a supplementary file in the development article and at https://www.youtube.com/watch?v=LgOagKX_-nA . Comparator: usual care
Outcomes	Primary outcome: knowledge Secondary outcomes: uncertainty, decisional conflict, patient trust in their clinician, DA acceptability, patient engagement in decision-making, safety (major cardiac event)
Notes	Source of funding: Research reported in this publication was funded through a Patient-Centered Outcomes Research Institute (PCORI) award (contract 952). The views presented in this publication are

Hess 2016 *(Continued)*

solely the responsibility of the authors and do not necessarily represent the views of PCORI, its board of governors, or the methodology committee. The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. All involved researchers' maintained independence from the funder of the study.

Conflicts of interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: JEH has research funding from Alere, Trinity, Siemens, and Roche and has consulted for Janssen. DBD has research funding from Siemens and Roche and has consulted for Janssen. All other authors have no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation was concealed by an online password-protected randomization algorithm (Medidata Balance; Medidata Solutions, New York City, NY). Patients were randomized 1:1 and dynamically stratified by age, sex, and site because of the known associations of age and sex with cardiovascular risk, potential unmeasured differences between sites, and the availability of these data at the time of enrollment. Clinicians were not randomized.
Allocation concealment (selection bias)	Low risk	Allocation was concealed by an online password-protected randomization algorithm.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients, study co-ordinators, and treating clinicians were not masked to allocation. Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Patients, study co-ordinators, and treating clinicians were not masked to allocation. All other investigators were blinded to allocation. Primary and most secondary outcomes were objectively measured and not subject to interpretation. Five trained raters independently viewed videos of the patient-clinician discussion and assessed the degree to which clinicians engaged patients in the decision-making process using the observing patient involvement (OPTION) scale, but looks like they were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT analysis, 98% of participants included in analysis
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01969240) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"We used two versions of the decision aid in the trial—one that included the option of coronary computed tomography angiography (CCTA) and one that included only cardiac stress testing. Although this introduced a degree of heterogeneity in the intervention, the trial was intentionally pragmatic in design, and contextual fit of the decision aid to facilitate clinician-patient discussions relevant to the clinical settings enrolling patients in the trial was essential. We randomized at the patient level, increasing the risk of contamination between intervention and control groups."

Hess 2018

Study characteristics	
Methods	Cluster randomized to decision aid + risk assessment vs usual care
Participants	88 clinicians (493 patients) + 84 clinicians (478 patients) caring for children with minor head trauma younger than 18 years with non-high risk factors for clinically important traumatic brain injury in the USA
Interventions	DA: 1-page decision aid used during consultation plus personalized risk estimates. The DA included clinical information, outcome probabilities, and explicit values clarification. The DA is publicly available at https://carethatfits.org/head-ct-choice-desicion-aid/ . Comparator: usual care
Outcomes	Primary outcome: knowledge Secondary outcomes: clinician engagement of parents in the decision-making process (OPTION scale), decisional conflict, trust in physician, choice (utilization of CT scan), safety of decision aid
Notes	Source of funding: This study was funded from contract 12-11-4435 through a Patient-Centered Outcomes Research Institute Award. Conflicts of interest: Drs Hess, Tzimenatos, Nigrovic, and Kuppermann reported grants from the Patient-Centered Outcomes Research Institute during the conduct of the study. Dr Kharbanda reported grants from the Patient-Centered Outcomes Research Institute during the conduct of the study and grants from the National Institutes of Health outside the submitted work. Dr Shah reported grants from the Patient-Centered Outcomes Research Institute during the conduct of the study; and grants from the Agency for Healthcare Research and Quality, Centers for Medicare and Medicaid Innovations, US Food and Drug Administration, and National Science Foundation outside the submitted work. Mr Inselman and Dr Herrin reported personal fees from the Mayo Clinic during the conduct of the study. Dr Kuppermann reported grants from the National Institutes of Health and the Health Resources and Services Administration outside the submitted work. No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A statistician at a centralized location performed randomization to conceal allocation. Clinicians were randomized in a 1 to 1 ratio. Randomization was stratified by site and whether their primary clinical training was in a pediatric specialty (pediatrics or pediatric emergency medicine) or another clinical specialty (general emergency medicine, family medicine, or internal medicine). We used dynamic allocation to balance randomization within strata defined by site and clinician specialty.
Allocation concealment (selection bias)	Low risk	A statistician at a centralized location performed randomization to conceal allocation. Clinicians randomized to the intervention were educated separate from the Grand Rounds, and were provided information included in the decision aid and shown a video demonstrating its use. Intervention clinicians were required not to share the decision aid with other clinicians in the trial, and this was monitored by study research co-ordinators.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single-blind (participant) according to trial registration. "The main limitations were lack of blinding." Unclear how lack of blinding of study personnel may have influenced study results.
Blinding of outcome assessment (detection bias)	Low risk	Single-blind (participant) according to trial registration. "The main limitations were lack of blinding."

Hess 2018 *(Continued)*

All outcomes		Low risk for outcomes that were objectively measured (e.g. knowledge, decisional conflict, choice). High risk for observer-reported subjective outcomes (e.g. patient-clinician communication).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate and similar across arms, all patients who received DA/usual care were included in the analysis.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02063087) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Hoffman 2017

Study characteristics	
Methods	Randomized to decision aid vs attention control (education on another topic)
Participants	59 + 30 African American patients aged 49 to 75 years old scheduled for visit and due for colorectal cancer screening in the USA
Interventions	DA: video decision aid used in preparation for consultation that included clinical information, outcome probabilities, explicit values clarification, actor portrayal of real life situation, guidance in decision-making, and guidance in communication. The DA is not publicly available; a copy was provided by the author (Robert J. Volk; bvolk@mdanderson.org). Comparator: attention control (video on hypertension)
Outcomes	Knowledge, attitudes toward and perceived social normative pressure, intention to be screened, decisional conflict, self-advocacy, screening rate
Notes	Source of funding: The project was supported by grants from the National Cancer Institute (R21CA132669) and The University of Texas MD Anderson Cancer Center Duncan Family Institute for Cancer Prevention and Risk Assessment. Dr. Ashley Housten was supported by the National Cancer Institute of the National Institute of Health under Award Number R25CA057730 (Principal Investigator: Shine Chang, PhD) and by Cancer Center Support Grant CA016672 (Principal Investigator: Ronald DePinho, MD). Dr. Suzanne K. Linder was supported the Agency for Healthcare Research and Quality under Award Number R24HS022134 and by the Cancer Prevention Research Institute of Texas under Award Number RP140020. Conflicts of interest: The authors made no disclosures.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomized using computer-generated permuted blocks in a 2:1 ratio (intervention/control).
Allocation concealment (selection bias)	Unclear risk	Not reported

Hoffman 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Interviewers and participants were blinded until baseline questionnaires were completed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers and participants were blinded until baseline questionnaires were completed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis, justification for participants not included/loss to follow-up
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT01492049). Only one outcome measure was identified in the trial registry (cancer screening rate); all other outcome measures reported in the article were not identified (e.g. knowledge, decisional conflict, attitudes).
Other bias	Low risk	The study appears to be free of other sources of bias.

Ibrahim 2013

Study characteristics	
Methods	Randomized to DA alone vs DA + motivational interviewing (MI) vs motivational interviewing alone vs attention control (education)
Participants	168 (DA alone) + 163 (DA + MI) + 165 (MI alone) + 167 (control) African American patients greater than age 55 with knee OA in the USA
Interventions	DA: video decision aid that included information on the clinical condition, probabilities of outcomes of options, implicit values clarification, video clips of patient experiences, and guidance in decision-making and guidance in communication. The DA is not publicly available; the authors have a copy of the video evaluated in previous studies (Bozic 2013, De Achaval 2012, and Stacey 2014a). Comparator: attention control (education on OA but not specific to joint replacement)
Outcomes	Primary outcome: changes in patient willingness to undergo knee replacement with knowledge and expectations as possible mediating factors. Secondary outcomes: whether the patient discussed knee pain with primary care doctor, received a referral to orthopedics, saw an orthopedic surgeon within 12 months of the intervention
Notes	Source of funding: This study was supported by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development Service (IIR 05-234-2, PI: Said A. Ibrahim). Dr. Ibrahim was also supported by a K24 Award (1K24AR055259-01) from the National Institutes of Musculoskeletal and Skin Disorders. The views expressed here are those of the authors and do not represent those of the Department of Veterans Affairs or the United States Government. Conflicts of interest: not reported
Risk of bias	

Bias	Authors' judgement	Support for judgement

Ibrahim 2013 *(Continued)*

Random sequence generation (selection bias)	Low risk	"Using a 2×2 factorial design, patients at each site were randomized to one of the 4 study arms… We used permuted block randomization at the level of the patient...computer generated random assignment"
Allocation concealment (selection bias)	Unclear risk	"sealed envelope" (unclear whether envelopes were sequentially numbered, opaque)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Clinical and study staff and study participants were all blinded to assignment until after the baseline interview. The nature of the intervention meant that participants were not blind to the condition after participation in the intervention. Unclear how lack of blinding of participants may have influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinical and study staff and study participants were all blinded to assignment until after the baseline interview. The nature of the intervention meant that participants were not blind to the condition after participation in the intervention. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in analysis. "There were no losses to follow-up except for one patient in the MI arm and one patient in DA/MI arm. Over the course of the study 93% of the subjects completed at least 2 of the 3 follow-up interviews with no differences among the 4 intervention groups (p=0.62)."
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT00324857) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Ibrahim 2017

Study characteristics	
Methods	Randomized to video decision aid vs educational booklet
Participants	168 + 168 participants who self-identified as black, aged 50 years or older with chronic and frequent knee pain and radiographic evidence of osteoarthritis of the knee in the USA
Interventions	DA: video decision aid that included information on the clinical condition, probabilities of outcomes of options, implicit values clarification, video clips of patient experiences, and guidance in communication. The DA is not publicly available; the authors have a copy of the video which was evaluated in previous studies (Bozic 2013, De Achaval 2012, and Stacey 2014a). Comparator: educational booklet
Outcomes	Primary outcomes: the recommendation for total knee replacement by an orthopedic surgeon at 6 months after the intervention, receipt of total knee replacement surgery at 12 months after the intervention
Notes	Source of funding: This study was supported by grant 1R01AR059615-0 from the National Institute of Arthritis and Musculoskeletal Skin Diseases, National Institutes of Health. Dr Ibrahim reports receiving Mid-Career Development Award K24AR055259 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Ibrahim 2017 *(Continued)*

	Conflicts of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomized to one of the 2 study arms using a computer-generated assignment."
Allocation concealment (selection bias)	Low risk	"The computer-generated randomization result was sent to the study coordinator via email before the scheduled intervention session."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Owing to the nature of the intervention, participants could not have been blinded to the study arm to which they were randomized. The orthopedic surgeons were blinded to patient randomization. Research staff who were not involved in the intervention and were blinded to the study arm abstracted this information from the medical record."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Research staff who were not involved in the intervention and were blinded to the study arm abstracted this information from the medical record"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in the ITT analysis
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01851785) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Ickenroth 2016

Study characteristics

Methods	Randomized to decision aid versus information
Participants	1137 participants aged 18 and older in the Netherlands. Two participant groups: those with an intention to do a diagnostic diabetes self-test (n = 569; 285 vs 284) and those with an intention to do a diagnostic cholesterol self-test (n = 568; 284 vs 284); both groups were randomly assigned to web-based DA (intervention) vs short, non-interactive and non-test specific information on self-testing (control).
Interventions	DA: online decision aid that included general information on self-testing and personal risk factors for cardiovascular disease or developing diabetes, and an explicit values clarification exercise. The DA is no longer accessible according to the authors (Trudy van der Weijden: trudy.vanderweijden@maastrichtuniversity.nl). Comparator: general information
Outcomes	Primary outcome: knowledge Secondary outcomes: intention to take a test, attitude towards self-testing, informed choice
Notes	Source of funding: The Netherlands Organisation for Health Research and Development (ZonMw Prevention) (grant number 50-50101-96-406). Supplemental financial support has been provided by the Centraal Ziekenfonds health insurance company.

Ickenroth 2016 *(Continued)*

	Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Within each group, randomisation over experimental conditions (and invitation to view either the decision aid or the control condition) will be performed by Flycatcher using SPSS"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were blinded for randomization.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Lower response rate in the DA group "Response in the cholesterol intervention group to Questionnaire 2 (immediately after being exposed to the DA) was lower than in the control group (control 84.5% and intervention 76.4%; P = 0.020)". There was no acknowledgment or discussion in the limitations section.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NTR3149) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	People on the panel are on the whole more highly educated compared with the general population in the Netherlands, and women are over-represented. This may have led to an overestimation of the knowledge level.

Jalil 2022

Study characteristics

Methods	Randomized to decision aid + standard consultation vs control (standard consultation alone)
Participants	30 + 30 patients recently diagnosed with localized/early-stage prostate cancer in Malaysia
Interventions	DA: paper-based booklet used after standard consultation in preparation for follow-up visit to decide on treatment options. The DA included information on treatment options, benefits, harms, and an explicit values clarification exercise. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: standard consultation
Outcomes	Knowledge, decisional conflict, preparation for decision-making
Notes	Source of funding: Financial support for this study was provided entirely by a grant from University Putra Malaysia. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report.

Jalil 2022 *(Continued)*

Conflicts of Interest: The authors declare that there is no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"They were randomly assigned in a 1:1 ratio to control (standard consultation only) and intervention group (standard consultation plus PDA) using SPSS generated method of block randomization [17]. The block randomizations were structured with randomly permutated block sized by week with a minimum blocked size of 2 × 2 for each treatment group. Each hospital has different block arrangement for the selection of patients into the control or intervention group"
Allocation concealment (selection bias)	Low risk	The random allocation sequence of each center was generated and kept by one researcher who was not involved in patient recruitment and data collection. The trained recruiting nurses at each hospital will contact the researcher by phone to determine the allocation of patients (control vs intervention arm).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The trained recruiting nurses at each hospital will contact the researcher by phone to determine the allocation of patients (control vs intervention arm). The urologists were blinded to the allocation of patients. Unclear if patients were blinded to allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate but balanced across groups: 27/30 DA group and 22/30 control (P = 0.095274)
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12614000668606) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	Power calculation based on satisfaction for decision-making. This outcome is not collected in the study. Low sample size (30 + 30). Parametric statistics used even if low sample size and study does not report on homogeneity of sample.

Jibaja-Weiss 2011

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	51 + 49 women diagnosed with breast cancer considering surgical treatment in the USA
Interventions	DA: computer program on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision). The DA is no longer available (www.bcm.edu/patchworkoflife). The authors have a copy of the technical report. Comparator: usual care + breast cancer treatment educational materials normally provided to patients

Jibaja-Weiss 2011 *(Continued)*

Outcomes	Surgical treatment preference (post-DA), breast cancer knowledge (pre, post-DA, post-DA and consult), satisfaction with surgical decision (post-DA), satisfaction with decision-making process (post-DA), decisional conflict (pre, post-DA, post-DA and consult), proportion undecided
Notes	Primary outcome was not specified Source of funding: This research study was supported by the U.S. Army Medical Research and Materiel Command, under DAMD17-98-1-8022. Conflicts of interest: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients at each hospital were randomized using permuted blocks" (p 42, Methods section)
Allocation concealment (selection bias)	Unclear risk	Not addressed in the study
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not addressed in the study
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There is no way to know if the plots include all of the participants' data, since they do not specify the number of patients used to obtain these mean scores.
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Appears to be free of other potential biases.

Johnson 2006

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	32 + 35 patients considering endodontic treatment options in the USA
Interventions	DA (in consultation): decision board on options' outcomes, clinical problem, outcome probability, guidance. The DA is presented in Figure 1 of the article. Comparator: usual care
Outcomes	Primary outcomes: knowledge, satisfaction with the decision-making process, anxiety
Notes	Source of funding: This research was supported in part by a grant from the Wach Fund.

Johnson 2006 *(Continued)*

Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[F]our computerized random generation lists to assign to one of two groups" (p 3)
Allocation concealment (selection bias)	Unclear risk	Not for residents: computer-generated randomization lists (1 for each resident) were prepared by the PI (p 3-4); therefore, residents would have had pre-generated lists. Unclear for patients: "allocation was concealed from patients" (p 3) but does not explain how.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not mentioned. Allocation was concealed from patients only (p 3).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 6); all 40 patients agreed to participate in the study, but only 32 questionnaires were usable; several residents did not understand the need to enter data on the envelope and place the matched questionnaire in it (p 5).
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Unclear risk	"[B]aseline data obtained because possible that clinicians training in the EndoDB would alter usual care discussions" (p 5). Mentions taking baseline characteristics, but not included in article.

Karagiannis 2016

Study characteristics

Methods	Cluster-randomized to decision aid vs control
Participants	106 + 109 patients with type II diabetes for more than 1 year in Greece
Interventions	DA: 7 cards presented during consultation that display the benefits and harms of commonly used antidiabetic medications, which include probabilities of outcomes. The DA is publicly available at https://diabetesdecisionaid.mayoclinic.org/app/diabetes?lang=EN&v=m Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcomes: knowledge, patient-clinician communication, patient and clinician satisfaction, adherence to medication, ease of using DA and incorporating it into practice

Karagiannis 2016 *(Continued)*

Notes	Source of funding: This study was funded by a European Foundation for the Study of Diabetes (EFSD) research programme in patient education supported by an educational grant from AstraZeneca/BMS in 2012. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Eligible practices were matched based on level of care (primary or secondary) by the study statistician, and were randomly allocated within each pair, using a computer-generated allocation sequence, to either the use of the Diabetes Medication Choice Decision Aid or to usual care. Since there was more than one pair per level, the statistician paired the sites without study team input.
Allocation concealment (selection bias)	Low risk	Eligible practices were matched based on level of care (primary or secondary) by the study statistician, and were randomly allocated within each pair, using a computer-generated allocation sequence, to either the use of the Diabetes Medication Choice Decision Aid or to usual care. Since there was more than one pair per level, the statistician paired the sites without study team input.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Owing to the nature of the intervention, clinicians and patients were not blinded. It is unclear how lack of blinding influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate but balanced across groups. "... our analysis following the intention-to-treat principle, with the exception of medical adherence and clinical outcomes which were analysed based on completed data available"
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01861756) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"the addition of a ninth practice in the intervention arm in a non-random manner, after loss of one of the initially randomised practices." "we had asked study coordinators at each practice to keep a record of all patients invited to the study and of those who declined to participate. However, investigators involved did not adhere to the suggested practice (claiming it was impractical in their daily routine). Therefore, it is unknown how many patients were initially invited to each practice and how many of these declined participation." Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Kasper 2008

Study characteristics

Kasper 2008 *(Continued)*

Methods	Randomized to decision aid vs usual care
Participants	150 + 147 multiple sclerosis patients considering immunotherapy in Germany
Interventions	DA: booklet and worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification (based on IPDAS). The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: information material on immunotherapy (80 pages)
Outcomes	Primary outcomes: role in decision-making Secondary outcomes: choice, feeling undecided, helpfulness with making a decision, attitudes toward immunotherapy, expectations of side effects realized at 6 months
Notes	Source of funding: This study was supported by German Ministry of Health and Social Services (grant no. GMQQ01019401). Conflicts of interest: CH has received financial support from Biogen Elan, Bayer-Health Care, Serono and Teva, SK, JK, IM and MN have nothing to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[A]llocation using computer generated random numbers" (p 5)
Allocation concealment (selection bias)	Unclear risk	Randomization was carried out by concealed allocation, but method of concealment was not described (p 2, Assignment).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were not told whether the information they received was standard information or the newly developed DA (p 3, Masking).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were not told whether the information they received was standard information or the newly developed DA (p 3, Masking).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow of participants (p 2, Fig 1); baseline data/characteristics included
Selective reporting (reporting bias)	Low risk	"The protocol of this study has been published with the trial registration at http://controlled-trials.com/ ISRCTN25267500" (p 2)
Other bias	Unclear risk	Difference in preferred interaction style between groups at baseline (P value 0.04) (p 5)

Kennedy 2002

Study characteristics

Methods	Randomized to decision aid + coaching vs decision aid only vs usual care

Kennedy 2002 *(Continued)*

Participants	215 + 206 + 204 women considering treatment for menorrhagia in the UK
Interventions	DA: video + booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance/coaching Coaching: ~ 20 minute coaching with explicit values clarification by a registered nurse prior to seeing physician. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Primary outcomes: general quality of life Secondary outcomes: uptake of option, satisfaction, menorrhagia severity, cost-effectiveness
Notes	Source of funding: Our research was supported by a grant from the UK National Health Service (NHS) Research and Development Health Technology Assessment Programme. The Health Economics Research Group receives funding from the UK Department of Health. Dr Sculpher received a career scientist award in public health funded by the NHS Research and Development Programme. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequence was generated by computer and stratified by consultant and the age at which the woman left full-time education (p 3).
Allocation concealment (selection bias)	Low risk	"Secure randomization ensured by using a central telephone randomization system" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Possibility of contamination bias; clinicians could have applied the experience gained from consultations with the intervention groups in their consultations with the control group (p 6).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if blinding used, but most outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Table 1 and Figure 1 flow diagram (p 4-5)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free from other risks of bias.

Khalifeh 2019

Study characteristics

Methods	Randomized to decision aid vs information
Participants	26 + 25 women planning a pregnancy or ≤ 30 weeks pregnant at enrolment who had been offered to start or continue antidepressant treatment for depression by their clinician in the UK

Khalifeh 2019 *(Continued)*

Interventions	DA: online decision aid that includes information on the condition, probabilities of outcomes, explicit values clarification, guidance in decision-making (step-by-step process), guidance in communication, and an automated printable summary of the information reviewed on risks and benefits, the participant's rating of their relative importance and the participant's perception of external influences on their decision-making process. The DA is not publicly available; access to the decision aid was provided by the author (Simone Vigod: simone.vigod@wchospital.ca). Comparator: online general information
Outcomes	Decisional conflict, knowledge of depression treatment options, depressive symptoms, anxiety symptoms, feasibility, acceptability
Notes	Source of funding: This research was supported by an NIHR Research Professorship, the NIHR Clinical Research Network (CRN), and the Biomedical Research Nucleus data management and informatics facility at South London and Maudsley NHS Foundation Trust. The latter is funded by the (NIHR) Mental Health Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London, and a joint infrastructure grant from Guy's and St Thomas' Charity and the Maudsley Charity. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health and Social Care. Emma Molyneaux, Louise M Howard, and Hind Khalifeh were supported by a National Institute for Health Research (NIHR) Research Professorship to LMH (reference number: NIHR-RP-R3-12-011). Simone Vigod is supported by a Canadian Institutes for Health Research New Investigator Award and the Shirley A Brown Memorial Chair in Women's Mental Health (Women's College Research Institute, Centre for Addiction and Mental Health, University of Toronto). Conflicts of interest: The authors declare that no competing interests exist.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomised in a 1:1 ratio using a computer-generated random allocation sequence that was activated at first login to the study website, with stratification by whether they were recruited from primary care, maternity care, or psychiatric settings"
Allocation concealment (selection bias)	Low risk	"Participants were randomised in a 1:1 ratio using a computer-generated random allocation sequence that was activated at first login to the study website, with stratification by whether they were recruited from primary care, maternity care, or psychiatric settings (central allocation)"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Researchers were blind to group allocation at all data collection time points. Participants were most likely able to identify whether they had been randomised to the PDA, as this multistage interactive tool was clearly different from the single page resource sheet (control condition)."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Researchers were blind to group allocation at all data collection time points"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; low and similar attrition at first follow-up when the outcomes of interest to this review were measured (i.e. knowledge, decisional conflict).
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT02492009) and the secondary outcome of treatment decision is not reported. "Treatment Decision(s) [Time Frame: (a) Baseline (pre-randomization) and (b) 4 Weeks post-randomization and (c) 12 weeks postpartum (for participants who enrolled while pregnant) OR 6

Khalifeh 2019 *(Continued)*

		months post-randomization (for women who enrolled while planning a pregnancy)]"
Other bias	Low risk	The study appears to be free of other sources of bias.

Kleiss 2021

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	76 + 71 patients aged 18 to 89 years, presenting for a first specialist visit for a specific upper-extremity condition, for whom the choice was injection or surgery or other nonsurgical treatments, and for whom a DA was available in the USA
Interventions	DAs: online decision aids used independent of consultation that include clinical information, outcome probabilities, explicit values clarification, knowledge quiz, guidance in decision-making (5-step guide), and summary of results that can be printed or downloaded to discuss with the doctor. The decision aids are publicly available at https://www.decisionaid.info . Comparator: control (no decision aid)
Outcomes	Pain self-efficacy questionnaire, physical function, pain intensity, satisfaction with visit, understanding of received information, feeling adequately educated to make decision, choice, decision regret, satisfaction with information received
Notes	Source of funding: not reported Conflicts of interest: D.R. has received or may receive payment or benefits from Skeletal Dynamics, Wright Medical for elbow implants, Deputy Editor for Clinical Orthopaedics and Related Research, Universities and Hospitals, Lawyers outside the submitted work. No benefits in any form have been received or will be received by the other authors related directly or indirectly to the subject of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly assigned to either the intervention (viewing a DA) or the control (not viewing a DA) group in a 1:1 ratio, using a random number generator.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported for patients. Open-label according to trial registry. Unclear how lack of blinding influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate (52/76 completers DA and 49/71 completers Control) but similar across arms (P = 0.938236); reasons for withdrawals not reported

Kleiss 2021 *(Continued)*

Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03643978) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	In the flow diagram, the number of patients invited to participate is equal to the number randomized. No information on how many patients were approached and declined.

Knops 2014

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	91 + 87 patients with asymptomatic abdominal aortic aneurysm considering elective surgery vs watchful waiting in the Netherlands
Interventions	DA: interactive CD-ROM on options' outcomes, clinical problem, outcome probabilities, explicit values clarification. The DA is no longer available (www.keuzehulp.info/amc/AAA/landing-page). The authors have a PDF version of the DA content. Comparator: usual care with regular information
Outcomes	Primary outcomes: decisional conflict (baseline, 1, 4, and 10 months) Secondary outcomes: patient knowledge (baseline and 1 month), anxiety (baseline, 1, 4, and 10 months), satisfaction with conversation with the surgeon (baseline and 1 month), final treatment choice (10 months), aneurysm rupture (10 months), possible date of surgery (10 months), postoperative morbidity and mortality (10 months), physical quality of life (baseline, 1, 4, and 10 months)
Notes	Trial registration: NTR1524 Source of funding: none Conflicts of interest: none

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Allocation concealment (selection bias)	Low risk	"Computer-generated randomisation ALEA v.2.2, NKI-AVL, the Netherlands) was performed by the investigators" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and investigators could not be blinded after group assignment, a factor which is inherent to the decision aid and the design of the study. Surgeons and nurses involved in the outpatient care of the participants were blinded to the patient's allocation group, although patients were not prohibited from sharing their allocation with them." (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome measurement is not likely to be influenced by lack of blinding as all outcomes were measured objectively using validated scales and data retrieved from medical records.

Knops 2014 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Appears to have similar attrition between groups. The proportion of values missing varied from 2% to 9% per outcome measure. Missing values were completed by multiple imputation analysis. If one of the outcome measures had more than 25% missing values, that outcome measure for that patient was excluded from analysis. Therefore, missing data have been handled appropriately (p 3).
Selective reporting (reporting bias)	Unclear risk	Insufficient information to make judgment
Other bias	High risk	"Considerable number of patients could not be included, were not asked to participation, or declined to participate. Selection bias may have occured in patients that were not included" (p 6) "Both patients and surgeons were aware of the aim and subject of the study and could not be blinded to the allocation. It is possible that surgeons in the contributing centres offered more than average information to their patients" (p 6). Performance bias may have been introduced in terms of altered communication style.

Korteland 2017

Study characteristics	
Methods	Randomized to decision aid + standard care vs standard care alone
Participants	77 + 78 adult patients who were accepted for elective isolated or combined aortic valve replacement and mitral valve replacement from 5 Dutch hospitals in the Netherlands
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, explicit values clarification, knowledge quiz, guidance in decision-making, guidance in communication, and summary of patients' situation and preferences. The DA is not publicly available; access to the decision aid was provided by the author (Johanna J.M. Takkenberg; j.j.m.takkenberg@erasmusmc.nl) Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcomes: knowledge, participation in decision making, anxiety and depression, quality of life, decision regret
Notes	Source of funding: Stichting Kwaliteitsgelden Medisch Specialisten Conflicts of interest: none

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomization sequence was generated by an independent statistician using a random number generator.
Allocation concealment (selection bias)	Low risk	The randomization sequence was generated by an independent statistician using a random number generator. Allocations were placed in serially numbered, opaque, sealed envelopes by 2 independent research assistants. The investigators were unaware of the allocation sequence to ensure allocation con-

Korteland 2017 *(Continued)*

		cealment. They selected the next randomization envelope in sequence, and outcome was noted in a randomization and identification log.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded. Unclear how lack of blinding influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; low rate of attrition (loss to follow-up 9% for control and 13% for intervention) and justifications provided not related to outcomes
Selective reporting (reporting bias)	Low risk	The study protocol is available (NTR4350) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	Based on power calculation, sample size needed to detect an effect size of 0.35 on the DCS was 140 patients; 138 patients were included in analysis. Low recruitment 115/306.

Kostick 2018

Study characteristics	
Methods	Randomized to decision aid vs education
Participants	52+53 inpatients aged 30 to 85 years old considering left ventricular assist device (LVAD) treatment for advanced heart failure in the USA
Interventions	DA: paper and web-based DA provided after formal evaluation of LVAD eligibility and before receiving standard education. The DA includes clinical information, probabilities of outcomes, explicit values clarification, patient narratives, knowledge test, guidance in decision-making (step-by-step process), and guidance in communication. The DA is publicly available at www.lvaddecisionaid.com . Comparator: standard education
Outcomes	Primary outcome: knowledge. Secondary outcomes: Decision Conflict Scale, patient preparedness for decision-making, satisfaction with decision-making process, regret, shared decision-making, alignment with patent's decision-making preferences, accurate alignment of patient expectations with outcomes, satisfaction with life, perceived quality of care, preferred treatment, whether or not patients had an advance directive, and acceptability of the DA
Notes	Source of funding: PCORI award (1306-01769). Conflicts of interest: Dr Jerry Estep serves as a consultant and medical advisor for Abbott and Medtronic. Neither company was involved in the design or conduct of the study. None of the other authors report any potential conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement

Kostick 2018 *(Continued)*

Random sequence generation (selection bias)	Low risk	"a parallel design and 1:1 allocation ratio. we used an online statistical computing program (www.graphpad.com/quickcalcs) to generate our randomization schedule with the use of 1:1 “block” randomization within sites and allocation concealment during enrollment by LVAD coordinators"
Allocation concealment (selection bias)	Low risk	"Allocation concealment was accomplished by LVAD coordinators who blindly followed a predetermined allocation plan but became aware of which arm patients were assigned to after administering baseline surveys. We used an online statistical computing program (www.graphpad.com/quickcalcs) to generate our randomization schedule with the use of 1:1 “block” randomization within sites and allocation concealment during enrollment by LVAD coordinators"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Patients were not aware of which arm they were randomized to (ie, were not made aware of the difference between standard versus DA-guided education). Allocation concealment was accomplished by LVAD coordinators who blindly followed a pre-determined allocation plan but became aware of which arm patients were assigned to after administering baseline surveys, when they were enlisted to provide either standard or DA-guided education." LVAD co-ordinators who delivered the interventions were aware of treatment allocation, therefore it is unclear how they may have influenced decisions.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High rate of attrition but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02248974) and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Krishnamurti 2019

Study characteristics	
Methods	Randomized to decision aid versus usual care
Participants	60 + 60 individuals aged 8 to 80 years old with sickle cell disease considering therapeutic options or parent/legal guardian of patients (age < 18 years) who are directly involved in decision making regarding healthcare treatment in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, explicit values clarification, interactive components (e.g. voice clips, videos, patient testimonies), guidance in decision making (step-by-step process), guidance in communication, and summary comparing treatment options can be printed or saved. The DA is publicly available at http://sickleoptions.org/en_US/ . Comparator: usual care
Outcomes	Acceptability, knowledge, values, stage of decision-making, preparation for decision-making, decisional regret, self-efficacy, decisional conflict.

Krishnamurti 2019 *(Continued)*

Notes	Source of funding: This project was supported by PCORI grant CE-1304-6859 (LK). Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate (at 3 months 24/60 DA and 19/60 UC completed questionnaires) but missing data are balanced across groups, no justification for attrition
Selective reporting (reporting bias)	Low risk	The trial protocol is available (NCT03224429 & NCT02326597) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Krist 2007

Study characteristics

Methods	Randomized to decision aid booklet vs decision aid web-based vs usual care
Participants	196 + 226 + 75 patients considering prostate cancer screening in the USA
Interventions	DA: 4-page pamphlet with options' outcomes, clinical problem, outcome probability Comparator: website with same information as paper-based DA The DA is no longer available (http://www.familymedicine.vcu.edu/research/misc/psa/index.html). Comparator: usual care
Outcomes	Primary outcomes: role in decision-making Secondary outcomes: knowledge, decisional conflict, time spent discussing screening, choice (PSA test ordered)
Notes	Source of funding: This work was funded by the American Academy of Family Physicians Foundation under the Joint Grant Awards Program.

Krist 2007 *(Continued)*

	Conflicts of interest: Dr Krist is a faculty member, practicing physician, and partial owner of Fairfax Family Practice Residency, where the study was conducted.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]oordinator referred to pre-generated randomisation tables to inform the participant to which arm he was randomised" (p 2)
Allocation concealment (selection bias)	Low risk	At the time of enrolment, the allocation was concealed from the co-ordinator (p 2).
Blinding of participants and personnel (performance bias) All outcomes	High risk	Physicians were not blinded - could affect decision-making process and uptake of screening.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	p 3, Results; p 4, Flow diagram
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	Uneven groups but done intentionally; ratio of 1:3:3 but appears to be free of other potential biases.

Kukafka 2022

Study characteristics

Methods	Cluster-randomized to decision aid + standard usual care + decision support tool for clinician vs standard usual care
Participants	102 + 88 adults aged 21 to 75 years with no personal history of breast or ovarian cancer, no previous genetic counseling or testing for hereditary breast and ovarian cancer syndrome, and meeting family history criteria for BRCA1/2 genetic testing based upon family history. Participants were enrolled by 67 clinicians (physician, nurse practitioner, physician assistant, or nurse-midwife).
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification for taking breast cancer reducing pill, implicit values clarification for genetic testing, patient scenarios, risk game, individualized breast cancer risk factors, guidance in decision-making (list of steps), and summary in the action plan that can be printed and discussed with clinician. Clinicians had access to the Breast cancer risk NAVigation toolbox for providing them with their patients' personalized risks and preferences prior to the clinical encounter. The DA is not publicly available; a copy was provided by the author (Katherine D. Crew; kd59@cumc.columbia.edu). Comparator: usual care (education)
Outcomes	Primary outcome: uptake of screening within 6 months of enrolment

Kukafka 2022 *(Continued)*

	Secondary outcomes: receipt of genetic counseling at 24 months, genetic testing at 6 months, knowledge, breast cancer worry, decision self-efficacy, and decisional conflict
Notes	Source of funding: This work was funded by grant RSG-17-103-01 from the American Cancer Society to Dr Kukafka. Conflicts of interest: Dr Terry reported receiving grants from the National Institutes of Health during the conduct of the study. No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded. Unclear how lack of blinding influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high rate of attrition at 1 month (completers 82/102 DA group and 77/88 UC group) but missing data are balanced across groups (P = 0.186122).
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03470402) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Kunneman 2020

Study characteristics

Methods	Randomized to decision aid versus usual care
Participants	475 + 467 adults aged ≥ 18 years with a diagnosis of nonvalvular atrial fibrillation and at high risk of experiencing a thromboembolic event in the USA
Interventions	DA: online decision aid that was used in consultation with the physician that included information on the clinical problem, a personalized risk calculator, outcome probabilities, implicit values clarification, and a summary sheet at the end of the consultation. The DA is publicly available at https://anticoagulationdecisionaid.mayoclinic.org/ . Comparator: usual care during consultation

Kunneman 2020 *(Continued)*

Outcomes	Quality of shared decision-making (quality of communication, knowledge, accuracy of patient estimates of their own stroke risk, decisional conflict, and satisfaction), duration of the encounter, and clinician involvement of patients in the SDM process
Notes	Source of funding: The clinical trial was funded by grant RO1 HL131535-01 from the National Heart, Lung, and Blood Institute of the National Institutes of Health. Conflicts of interest: Dr Kunneman reported receiving grants from the National Heart, Lung, and Blood Institute during the conduct of the study. Ms Branda reported receiving grants from the National Heart, Lung, and Blood Institute during the conduct of the study. Dr Hargraves reported receiving grants from the National Institutes of Health during the conduct of the study. Ms Sivly reported receiving grants from Mayo Clinic during the conduct of the study and outside the submitted work. Dr Gorr reported receiving grants from the National Institutes of Health during the conduct of the study. Dr Burnett reported receiving grants and personal fees from the Mayo Clinic and the National Institutes of Health during the conduct of the study and personal fees from the Mayo Clinic outside the submitted work. Dr Jackson reported receiving grants from the Mayo Clinic during the conduct of the study and research funding from Amgen and the National Institutes of Health outside the submitted work. Dr Hess reported receiving grants from the Patient-Centered Outcomes Research Institute outside the submitted work. Dr Linzer reported receiving grants from the National Institutes of Health during the conduct of the study and grants from the American College of Physicians, the American Medical Association, and the Institute for Healthcare Improvement outside the submitted work. Dr Brito reported being the medical director of the Shared Decision Making National Resource Center at the Mayo Clinic. Dr Montori reported receiving grants from the National Heart, Lung, and Blood Institute during the conduct of the study and serving as board chair of The Patient Revolution outside the submitted work. No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization algorithm (generated within the Remote Data Capture [REDCap] software system; Vanderbilt University), which was built by the clinical trial statistician (M.E.B.), used a stratified block randomization with blocks of random size."
Allocation concealment (selection bias)	Low risk	"Encounters were randomized on a 1:1 ratio to either standard care or care that included use of the SDM tool, which allowed clinicians to participate in both study arms. The randomization algorithm (generated within the Remote Data Capture [REDCap] software system; Vanderbilt University), which was built by the clinical trial statistician (M.E.B.), used a stratified block randomization with blocks of random size. The clinical trial was stratified by medical center, cohort (start vs review), and stroke risk (CHA2DS2- VASc score of 1 for men and 2 for women vs >1 for men and >2 for women)." (Central allocation)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients were blinded, but personnel were not: "Except for patients, who will be informed that the trial will be testing different ways clinicians and patients with AF communicate about anticoagulation, all study personnel will be able to discern participant allocation." (Study protocol)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Bias may have affected the unblinded assessment of recorded encounters and the scoring of those encounters using the OPTION12 scale. Limitations acknowledged but not discussed.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT, > 90% of participants included in analysis, justifications for withdrawals reported

Kunneman 2020 *(Continued)*

Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02905032) and all of the studies original primary and secondary outcomes (submitted: 13 September 2016) have been reported in the pre-specified way.
Other bias	Unclear risk	Some authors received grants and personal fees from the Mayo Foundation, which is the developer of the DA. Selection bias could have been introduced when enrolled clinicians chose not to enroll an eligible patient encounter into the clinical trial (but this is true for any trial).

Kupke 2013

Study characteristics	
Methods	Cluster-randomized trial of 2 groups of dental students to decision board group and non-decision board group. Patients randomized to students in either group.
Participants	57 + 36 patients with defect in posterior tooth (class II defect) considering 6 treatment options, including no therapy in Germany
Interventions	DA (in consultation): options' outcomes, outcome probabilities. The DA is presented in Figure 2 of the article. Comparator: usual care with discussion of the treatment options
Outcomes	Knowledge (costs/self-payment, survival rate, characteristics, and treatment time) (postintervention); overall satisfaction with consultation (postintervention)
Notes	Primary outcome not specified Source of funding: not reported Conflicts of interest: This study did not receive financial support from manufacturers.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly assigned by a dice (selection of students and patient allocation) (p 20)
Allocation concealment (selection bias)	High risk	"The patients were assigned to the students according to common standards of the university independently and without knowing which group the student belonged to." (p 20)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were assigned to the students independently and without knowing which group the students belonged to" (p 20)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge if blinding of outcome assessment occurred
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attribution in both groups; "missing answers were treated as incorrect answers, while illegible answers were treated as missing values" (p 22)

Kupke 2013 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	No mention of study protocol or trial registration. No way to ensure the outcomes they intended to measure are fully reported.
Other bias	High risk	Did not adjust for clustering in analysis. Free of other potential biases: no evidence of selective recruitment of cluster participants.

Kuppermann 2014

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	375 + 369 11-week pregnant women who had not yet undergone prenatal screening or diagnostic testing in the USA
Interventions	DA: describes clinical condition, options, outcome probabilities, values clarification. The interactive web-based decision aid is not publicly available. Access to a video version of the DA was provided by the authors. Comparator: usual care
Outcomes	Primary outcomes: invasive prenatal diagnostic testing (3 to 6 months) Secondary outcomes: testing strategy undergone (3 to 6 months), knowledge (3 to 6 months), accurate risk perception (procedure-related miscarriage, Down Syndrome affected fetus) (3 to 6 months), decisional conflict (3 to 6 months), decisional regret (3 to 6 months)
Notes	Source of funding: This study was funded by grants from the National Institutes of Health (R01HD049686) and the March of Dimes Foundation (Social and Behavioral Sciences Research Grant 12-FY09-213). Conflicts of interest: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Kuppermann reports that she was the UCSF site primary investigator of a clinical study of cell-free DNA testing funded by Ariosa Diagnostics and receipt of unrestricted research funding from Verinata Health and Natera. Dr Caughey reports serving as a medical advisor to Ariosa and Cellscape and receipt of stock options in both companies. Dr Norton reports that she was a site primary investigator and lead coprimary investigator of a clinical study of cell-free DNA testing funded by Ariosa Diagnostics, and was site primary investigator of a clinical study of noninvasive prenatal testing funded by Cellscape; receipt of unrestricted research funding from Natera; and being an unpaid clinical advisor to Natera. No other disclosures are reported.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A computer generated random allocation sequence assigned participants to experimental groups within permuted blocks of random size, with a 1:1 allocation ratio, stratified by age, clinical site, parity, and interviewer" (p 1211)
Allocation concealment (selection bias)	Low risk	"The randomization code was not available to any study-related personnel until data analysis was complete" (p 1211)
Blinding of participants and personnel (performance bias)	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)

Kuppermann 2014 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Different research associates facilitated baseline and follow-up interviews and medical record review to ensure blinding to the randomization assignment" (p 1211)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Similar attrition in both groups. "[A]ll reported analyses were based on a modified intention-to-treat sample" (p 1211)
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Low risk	Appears to be free of other sources of bias

Kuppermann 2020

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	742 + 743 women with 1 prior cesarean delivery in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes probabilities of outcomes, explicit values clarification, risk prediction calculator, guidance in decision making (4-step guide), and summary to discuss with provider. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Primary outcome: delivery approach Secondary outcomes: vaginal birth, maternal outcomes, perinatal outcomes, neonatal outcomes, and decision quality (decisional conflict, knowledge, shared decision-making, decision efficacy, and decision satisfaction)
Notes	Source of funding: This study was supported by grant R01 HD078748 (Dr Kuppermann) from the NIH. Conflicts of interest: Dr Kuppermann reported receiving grants from the National Institutes of Health (NIH), the Patient-Centered Outcomes Research Institute, the March of Dimes, and the UCSF Preterm Birth Initiative funded by Mark and Lynne Benioff and the Bill & Melinda Gates Foundation. Dr Kaimal reported receiving grants from the NIH. Dr Gonzalez reported receiving grant funding from California Institute for Regenerative Medicine. Dr Altshuler reported receiving grants from the Society of Family Planning. Dr Bacchetti reported receiving grant funding from the NIH, the Bill and Melinda Gates Foundation, and amfAR, the Foundation for AIDS Research. Dr Grobman reported receiving grant funding from the NIH, the March of Dimes, and the Preeclampsia Foundation. No other disclosures were reported.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The computer-generated allocation sequence used randomly permuted blocks of 8, 10, and 12, stratified by language and recruitment site.
Allocation concealment (selection bias)	Unclear risk	Not reported

Kuppermann 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not masked to the intervention. Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were not masked to the intervention, but primary and secondary outcomes were assessed by study staff unaware of group assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis and similar between arms (99% included in both arms); justification for attrition reported
Selective reporting (reporting bias)	Low risk	The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Lam 2013

Study characteristics	
Methods	Randomized to decision aid or standard information booklet after initial consultation
Participants	138 + 138 women considering breast cancer surgery for early-stage breast cancer in China
Interventions	DA: take-home booklet on clinical problem, options' outcomes, outcome probabilities, guidance, explicit values clarification. The DA is not publicly available; a copy was provided by the author (wwtlam@hku.hk) Comparator: standard information booklet
Outcomes	Primary outcomes: treatment decision-making difficulties and decisional conflict scale at 1 week post consultation, knowledge at 1-week postconsultation, decision regret at 1 month after surgery Secondary outcomes: postoperative psychological distress (anxiety and depression) at 1, 4, and 10 months after surgery, decision regret at 4 and 10 months after surgery, treatment decision
Notes	Source of funding: Supported by the Health and Health Services Research Fund (Grant No. 07080651), Food and Health Bureau, and Government of Hong Kong, Special Administrative Region, People's Republic of China. Conflicts of interest: The author(s) indicated no potential conflicts of interest.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patient assignment to treatment and control arms was performed using a prior computer-generated random-number sequence" (p 2880)
Allocation concealment (selection bias)	Low risk	"A serially labeled, opaque, sealed-envelope method was used for block randomization" (p 2880)

Lam 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Two research staff members - one responsible for preintervention assessment and block allocation and the other for postintervention assessments - ensured that the researcher performing follow-up assessments was blinded regarding women's allocation status." "Blinding surgeons to allocation status proved impractical." (p 2880)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	1 research staff member was responsible for postintervention assessments to ensure that the researcher performing follow-up assessments was blinded regarding women's allocation status (p 2880).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data; similar attrition in both groups
Selective reporting (reporting bias)	Low risk	Study protocol available online with published study
Other bias	Low risk	Does not appear to be subject to other sources of bias.

Langston 2010

Study characteristics	
Methods	Randomized to decision aid + coaching vs usual care
Participants	114 + 108 women pregnant women in their first trimester considering use of contraceptives in the USA
Interventions	DA: double-sided flip chart on clinical problem, outcome probabilities, guidance (administered by a research assistant), coaching (structured, standardized, non-directive contraceptive counseling) + usual care. The DA is available at https://www.who.int/publications/i/item/9241593229 . Comparator: usual care
Outcomes	Primary outcomes: proportion of participants choosing very effective contraceptive method (post-DA and consult) Secondary outcomes: actual choice on day of procedure (post-DA and consult), adherence of very effective and/or effective methods at 3 months and at 6 months (post-DA and consult)
Notes	Source of funding: Financial support provided by a grant from an anonymous foundation. This foundation approved the study design. It did not have a direct role in the collection, analysis and interpretation of data; the writing of the manuscript; or the decision to submit the manuscript for publication. Conflicts of interest: none

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Using a random-number table, we determined the sequence for 1:1 allocation constrained by blocks of 10" (p 363, Methods - study procedures)
Allocation concealment (selection bias)	Low risk	"Randomization assignments were sealed inside numbered, opaque envelopes" (p 363, Methods - study procedures)

Langston 2010 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"No blinding of participants or coordinators was feasible due to the nature of the intervention. Physician-providers did not know the participant's allocation group, did not discuss the study with patients, and were asked not to change their counselling" (p 363, Methods - study procedures)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	For "method initiation on the day of the procedure" it is only said that the "[p]articipants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group"; possible that the results contradicted the hypothesis and were excluded for this reason.
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol; not enough information to permit judgment
Other bias	Low risk	Appears to be free of other potential biases.

Laupacis 2006

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	60 + 60 patients undergoing elective open heart surgery considering pre-operative autologous blood donation in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework). The DA is available at https://decision-aid.ohri.ca/docs/das/archive/Blood_Transfusion.pdf . Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: uptake of option, satisfaction with decision-making process, satisfaction with decision, accurate risk perceptions
Notes	Source of funding: This study was supported by the Canadian Institutes for Health Research (Grant #MT-15580). AL is a CIHR Senior Scientist and AO holds a Tier I, Canada Research Chair in Health Care Consumer Decision Support. Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomization envelopes were prepared centrally by a statistician" (p 2)
Allocation concealment (selection bias)	Low risk	"The envelopes were labeled with identification numbers and contained a card specifying the patient's group assignment. The envelopes were opened by the interviewer after completion of the baseline interview." (p 2)

Laupacis 2006 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; fig 1, flow diagram
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

LeBlanc 2015

Study characteristics	
Methods	Randomized to decision aid vs individualized score only vs usual care
Participants	32 + 33 + 14 women over 50 years diagnosed with osteopenia or osteoporosis not taking biphosphonates or other prescription medication in the USA
Interventions	DA (in consultation): clinical problem, individualized risk of condition, options' outcomes, guidance. The DA is presented in Figure 1 of the article. Comparator 1: individualized risk Comparator 2: usual care
Outcomes	Primary outcomes: knowledge (immediately post), decisional conflict (immediately post), participation in decision-making process (immediately post), decision to start (immediately post), adherence (6 months), acceptability (timing not specified), satisfaction with the decision-making process (not specified), quality of life (not specified), time (review of video consultation) Secondary outcome: decision quality (not reported)
Notes	Source of funding: This study was supported by a grant from the Foundation for Informed Medical Decision Making (Now the Informed Medical Decisions Foundation, http://www.informedmedicaldecisions.org/). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. Conflicts of interest: The authors have declared that no competing interests exist.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)

LeBlanc 2015 *(Continued)*

Allocation concealment (selection bias)	Low risk	"Patients were allocated using a computer-generated sequence that randomized them 1:1:1 in a concealed fashion" (p 5)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients and clinicians were aware of the overall objective, presented as improvement in communication between patients and clinicians during the clinical encounter, but remained blinded to the specific aims" (p 5)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, only data analysts remained blind to allocation" (p 5)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Used intention-to-treat analysis; similar attrition in both groups
Selective reporting (reporting bias)	Unclear risk	Trial registered; checklists available for CONSORT and protocol. Sample size originally calculated based on adherence but re-calculated for decisional conflict given inability to reach original target.
Other bias	High risk	"Possible contamination at the clinician level (i.e. clinician who, having used the decision aid with a prior patient, recreates elements of the decision aid with a subsequent patient allocated to receive FRAX alone or usual care) was monitored by a detailed review of the available video recorded encounters" (p 5)

LeBlanc 2015b

Study characteristics	
Methods	Cluster-randomized to decision aid vs usual care
Participants	159 + 139 patients with moderate to severe depression in the USA
Interventions	DA: decision aid used during consultation formatted as laminated cards that presented information about each antidepressant and pros and cons in terms that matter to patients: weight change, sleep, libido, discontinuation, and cost. Patients could also access a video clip and storyboard demonstrating the basic use of the decision aid and a leaflet to take home. The DA is publicly available at https://carethatfits.org/depression-medication-choice/ . Comparator: usual care
Outcomes	Decision-making quality as judged by patient knowledge and involvement in decision-making, decisional conflict, satisfaction, encounter duration, medication adherence, and depression symptoms
Notes	Source of funding: This study was funded by the Agency for Healthcare and Quality Research under the American Recovery and Reinvestment Act of 2009 (iADAPT-1 grant R18 HS019214). Conflicts of interest: AL, VMM, NDS, MDW, KJY, MEB, JWI, SRD, EMH, ML, DHB, KMDW, MRM, and KKS report no potential conflict of interest.
Risk of bias	

Bias	Authors' judgement	Support for judgement

LeBlanc 2015b *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	"The lead study statistician therefore stratified practices by their history of accrual and the presence of the DIAMOND program and centrally randomized practices within these strata to either care with or without Depression Medication Choice."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Our study is at risk of bias. Lack of blinding of participants may have affected questionnaire responses"
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Our study is at risk of bias. Lack of blinding of analysts, particularly those reviewing videos, may have biased video-based outcomes"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate but similar across arms. "There was substantial loss to follow up (~20%) for our primary endpoint, mainly due to logistical issues at the beginning of the study, where study coordinators were still adapting to the recruitment and follow up process. While these issues may increase the risk of bias in favor of the intervention, other limitations may bias it toward no difference"
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01502891) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Legare 2008a

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	45 + 45 women considering use of natural health products for managing menopausal symptoms in Canada
Interventions	DA: booklet with worksheet on options' outcomes, clinical problem, explicit values clarification, guidance/coaching (Ottawa Decision Support Framework). The DA is not publicly available; a copy was obtained from the authors. Comparator: general information brochure on the clinical problem (did not address risks and benefits)
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge of natural health products in general (not specific option outcomes), preferred choice, values-choice agreement, proportion undecided
Notes	Source of funding: This study was funded by the Canada Research Chair in Implementation of Shared Decision Making in Primary Care and the André et Lucie Chagnon Chair for an Integrated Approach to Health Promotion, Université Laval, Québec.

Legare 2008a *(Continued)*

	Conflicts of interest: FL, DS, ST, AL and SD are involved in the development of PDAs in the area of women's health. However, they receive no financial gains.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomization scheme was carried out by a biostatistician using computer-generated unequal blocks.
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes containing 1 or the other documents (a PDA in the intervention group and a general information brochure in the control group) were prepared by another individual, external to the study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The investigators were blinded but no mention of blinding of participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See Figure 1 for flow diagram; reason for loss to follow-up was described.
Selective reporting (reporting bias)	Low risk	Trial registration identifier is NCT00325923.
Other bias	Low risk	No statistically significant difference in women's characteristics between groups (Table 1)

Legare 2011

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care
Participants	245 + 214 patients with non-emergent acute respiratory infections considering using antibiotics in Canada
Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching. The DA is available at https://www.decision.chaire.fmed.ulaval.ca/outil-en/601acf01dc64b246f77888c8 . Comparator: delayed intervention
Outcomes	Primary outcomes: • Patient outcomes: actual choice (pre and post-DA), perceived decision quality (pre and post-DA), decisional conflict (pre and post-DA), decision regret (pre and post-DA), general health outcomes • Practitioner outcomes: decision, perceived decision quality, decisional conflict Secondary outcomes:

Legare 2011 *(Continued)*

	• Patient outcomes: intention to engage in future SDM (pre and post-DA), participation in decision-making • Practitioner outcomes: intention to engage in future SDM and comply with clinical practice guidelines
Notes	Source of funding: This study was funded by the Fonds de la Recherche en Santé du Québec. FL is Tier 2 Canada Research Chair in Implementation of Shared Decision Making in Primary Care. GG is Tier 1 Canada Research Chair in Health Behaviour. FL, ML, GG AOC and AL are members of Knowledge Translation Canada, a CIHR-funded national research network. A O'Connor is a Tier 1 Canada Research Chair on Decision Support for Consumers. AL holds a Doctoral Scholarship from the Canadian Institute of Health Research. Conflicts of interest: The author(s) declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician simultaneously randomised all FMGs and allocated them to groups using Internet-based software" (p 99)
Allocation concealment (selection bias)	Low risk	"Using Internet-based software" (p 99)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding of participants and personnel: only biostatistician was blinded (p 99)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Biostatistician who assesses the outcomes is blinded, outcomes were objectively measured (p 99)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear to be no missing data.
Selective reporting (reporting bias)	Low risk	No missing pre-specified outcomes
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Legare 2012

Study characteristics

Methods	Cluster-randomized controlled trial to decision aid vs usual care
Participants	239 + 210 adults and children with with a diagnosis of acute respiratory infection (e.g.,bronchitis, otitis media, pharyngitis, rhinosinusitis) in Canada
Interventions	DA (in consultation): pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance and coaching (participating physicians also received training in the form of a 2-hour online tutorial and a 2-hour on-site interactive workshop). The DA is available as a supplementary appendix in the article.

Legare 2012 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcome: use of antibiotics (immediately post consultation) Secondary outcomes: decisional conflict (immediately post), control preference scale (immediately post), quality of decision (immediately post), adherence to the decision (2 weeks post), repeat consultation (2 weeks post), decisional regret (2 weeks post), quality of life (2 weeks post) and intention to engage in SDM in future consultations regarding antibiotics for acute respiratory infections (2 weeks post)
Notes	Source of funding: This study was funded by a grant from the Conseil du médicament du Québec/Fonds de la recherche en santé du Québec. The funding organization had no role in the conception or design, conduct, analysis, interpretation or reporting of the study and no access to the data. None of the investigators received any financial compensation. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The teaching units were stratified according to rural or urban location" (p E728)
Allocation concealment (selection bias)	Low risk	"A biostatistician used internet-based software to simultaneously randomize all 12 family practice teaching units to either the intervention group or control group. The teaching units were stratified according to rural or urban location" (p E728)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients with symptoms suggestive of an acute respiratory infection were initially recruited by a RA in the waiting room before consultation with a physician" (p E728)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"The biostatistician was unaware of group allocation, the researchers and research assistants who recruited patients and collected data were not" and "Statistical analysis was performed by a statistician who was unaware of the teaching unit allocations" (p E729)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered and published
Other bias	Low risk	"To avoid contamination bias, access to the online tutorial was denied to providers in the control group during the trial" (p E728) Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Leighl 2011

Study characteristics

Leighl 2011 *(Continued)*

Methods	Randomized to DA + usual care vs usual care
Participants	107 + 100 patients diagnosed with metastatic CRC considering advanced chemotherapy in Australia and Canada
Interventions	DA: booklet and audiotape on option' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance (steps in decision making + worksheet) Comparator: usual care
Outcomes	Primary outcomes: knowledge (post-DA), satisfaction with decision (post-DA) Secondary outcomes: anxiety (pre and post-DA), satisfaction with consultation (post-DA), choice leaning (post-DA), decisional conflict (post-DA). achievement of their information preference (post-DA), participation in decision-making (post-DA), acceptability (post-DA), quality of life (post-DA)
Notes	Source of funding: Supported by the Cancer Council New South Wales (N.B.L., P.N.B., M.H.N.T.) and an American Society of Clinical Oncology Career Development Award (N.B.L.). Conflicts of interest: The author(s) indicated no potential conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomized lists (p 2078, Study design)
Allocation concealment (selection bias)	Low risk	Code concealed in sealed envelopes until time of random assignment (p 2078, Study design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients not blinded and subjective outcomes may be affected by knowing their assignment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcomes are not subjected to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	31% dropout rate, but similar losses across all groups
Selective reporting (reporting bias)	Unclear risk	Protocol not available
Other bias	Low risk	Appears to be free of other sources of bias.

Lepore 2012

Study characteristics

Methods	Randomized to decision support intervention (decision coaching by telephone + educational pamphlet) vs control

Lepore 2012 *(Continued)*

Participants	244 + 246 African American men aged 45 to 70 in the USA
Interventions	DA: condition-specific educational pamphlet on prostate cancer screening and tailored telephone education on options' outcomes, explicit values clarification, others' opinions, and guidance (decision coaching). The DA is not publicly available; a copy was provided by the author (slepore@temple.edu). Comparator: attention control (education on fruit and vegetable consumption)
Outcomes	Primary outcomes: knowledge (pretest and post-test at 8 months post-randomization), decisional conflict (post-test), physician visit to discuss testing (post-test), adherence as congruence between testing intentions and behaviors (post-test) Secondary outcomes: testing intention (post-test), benefit-to-risk ratio of testing (post-test), PSA screening (post-test), anxiety (pretest and post-test)
Notes	Trial registration NCT01415375 Source of funding: This research was supported by grant R01 CA104223 from the National Cancer Institute of the National Institutes of Health. Conflicts of interest: The authors have no conflicts of interest to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant." (p 322)
Allocation concealment (selection bias)	Unclear risk	"The principal investigator used a computer-generated randomization schedule to randomize the participant and emailed the randomization assignment to the interventionist." (p 322)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Interventionists were not blind to condition. We can assume that patients were blinded as the study design was a telephone call for both intervention and control groups (p 322).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Data collectors were blind to condition but the interventionists were not" (p 322).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Appears to have reported on all pre-specified outcomes (protocol).
Other bias	Low risk	Appears to be free of other potential sources of bias.

Lerman 1997

Study characteristics

Methods	Randomized to decision aid vs waiting list control

Lerman 1997 *(Continued)*

Participants	122 + 114 + 164 women considering BRCA1 gene testing in the USA
Interventions	DA: education and counselling on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: no intervention
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions, perceived personal risk/benefits/limitations, agreement between values and choice
Notes	Source of funding: Supported by Public Health Service grants (RO1MH/HG54435) from the National Institutes of Mental Health and the National Center for Human Genome Research, National Institutes of Health Department of Health and Human Services. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Of 440 women, 400 completed 1-month follow-up interviews; no reasons provided; baseline data/characteristics included (p 2).
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Lewis 2010

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care
Participants	211 + 232 patients considering colorectal cancer screening in the USA

Lewis 2010 *(Continued)*

Interventions	DA: web-based, DVD and VHS videotape formats + stage targeted brochures (and booster kit if patients had not been screened) on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encouraged patients to communicate with their practitioners by asking questions and sharing preferences; summary). The DA is no longer available (decisionsupport.unc.edu/CHOICE6/). The authors have screenshots of the website that was evaluated in the study. Comparator: usual care using Aetna annual reminders to obtain CRC screening
Outcomes	Knowledge of the age at which screening should begin (post-DA), completion of colorectal cancer screening (pre, post-DA), intrusive thoughts (pre, post-DA), interest in CRC screening (pre, post-DA), intent to ask provider about screening (pre, post-DA), readiness to be screened (pre, post-DA), perceived risk of colon cancer (pre, post-DA), general beliefs about colon cancer (pre, post-DA), fears about colorectal cancer screening (pre, post-DA), perceptions about whether participants had enough information (post-DA), whether participants had enough information about specific screening tests (post-DA), willingness to pay for screening tests (post), desire to participate in medical decision (post) **Practice level measures:** assess CRC screening practices (pre, post-DA), referrals (pre, post-DA), quality improvement initiatives
Notes	Primary outcome was not specified Source of funding: This study was supported by grant number PH000018 from the Centers for Disease Control and Prevention. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomisation was done using matched pairs and a blocking procedure." (p 2, Practice recruitment and randomization section)
Allocation concealment (selection bias)	Unclear risk	"Thus, purposive assignment to treatment group was used, resulting in a hybrid randomisation" (p 3, Practice recruitment and randomization section). There is no mention of the effect of this purposive assignment on the study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	As mentioned above, staff used purposive assignment and were therefore not blinded, but there is no mention of the effect on the study.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study did not address this outcome, but outcomes were objectively measured.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appear to be no missing outcome data.
Selective reporting (reporting bias)	Unclear risk	No mention of study protocol
Other bias	High risk	Unadjusted cluster analysis Free of other potential biases: no evidence of selective recruitment of cluster participants.

Lewis 2018

Study characteristics	
Methods	Randomized to decision aid vs control
Participants	212 + 212 primary care patients 70 to 84 years of age with an upcoming appointment in the USA
Interventions	DA: paper-based decision aid that includes information on the clinical problem, outcome probabilities, explicit values clarification, guidance in communication, and personalized summary to bring to consultation. The DA is publicly available at https://eprognosis.ucsf.edu/decision_aids/Colon_Male_75-79.pdf . Comparator: education on an unrelated topic (safe driving)
Outcomes	Primary outcome: a composite measure of appropriate screening behavior 6 months following the index visit Secondary outcome: screening intent immediately after the index visit Intermediate outcomes: preparedness for individualized decision-making (knowledge, unclear values), communication, proportion undecided, preparation for decision-making, screening preference
Notes	Source of funding: Agency for Healthcare Research and Quality (AHRQ) Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients were randomly assigned through a centralized computer process to the decision support intervention or attention control condition. Because our primary outcome was a combined outcome across 3 health states, we wanted to ensure adequate numbers in each health state. Therefore, we assigned participants to the intervention or control arm using permuted blocks stratified by health state"
Allocation concealment (selection bias)	Unclear risk	"Allocation was concealed from the RAs through the use of opaque, sealed envelopes." The use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Allocation was concealed from the RAs through the use of opaque, sealed envelopes. Thus, the RAs, who adminstered surveys and collected data, were blinded to the patients' assignment. Patients were also blinded to their assignment, as they did not know whether they were in the intervention or control group. Providers, however, may have been aware of patients' assignment because patients in the intervention arm brought a paper cue into the provider visit."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The RAs, who administered surveys and collected data, were blinded to the patients' assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in analysis. Screening intent 210/212 (99%) DA and 211/212 (99%) control. Screening behavior 208/212 (98%) DA and 204/212 (96%) control. Reasons for attrition are documented and balanced across groups.

Lewis 2018 *(Continued)*

Selective reporting (reporting bias)	Low risk	The trial protocol is available (NCT01575990) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way
Other bias	Low risk	The study appears to be free of other sources of bias.

Lewis 2021

Study characteristics	
Methods	Randomized to decision aid plus coaching vs usual care
Participants	15 + 15 patients ≥ 18 years approaching implantable cardioverter-defibrillator (ICD) depletion, who are deciding whether to have ICD replacement
Interventions	DA + decision coaching: paper-based decision aid that includes information on the clinical problem, outcome probabilities, explicit values clarification, self-reflection questions, knowledge test, SURE test, frequently asked questions, guidance in decision-making (step-by-step process for making the decision), guidance in communication, and summary at the end to identify needs to make a choice. Decision coaching was delivered by a trained nurse research assistant whose role was to make the decision explicit (i.e. accept vs decline), describe the options, clarify values, elicit the patient's preferred treatment option, and screen for decisional conflict. The DA is not publicly available; a copy was provided by the author (Krystina Lewis: Krystina.Lewis@uottawa.ca). Comparator: usual care consisted of a 1-page educational leaflet describing the logistics of the ICD replacement procedure
Outcomes	Primary outcomes: feasibility measures (rates of recruitment, intervention use, and completeness of data collection) Secondary outcomes: preliminary effectiveness outcomes (knowledge, decisional conflict, preferred choice, actual choice, perception of involvement in decision-making, values about ICD replacement, the Medical Outcomes Trust Short Form, acceptability and usability of decision support, survival)
Notes	Source of funding: This study was supported by a Canadian Council of Cardiovascular Nurses Research Grant. KBL's doctoral studies were supported by a Canadian Institutes of Health Research fellowship. Conflicts of interest: The authors have no conflicts of interest to disclose.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Eligible patients were randomly assigned 1:1 to the intervention or usual care by the research assistant. A clinician researcher not otherwise involved in the study prepared a randomization schedule (http://www.randomization.com/). The sequence was generated using a permuted block design with randomly varying blocks of 4 to 8."
Allocation concealment (selection bias)	Low risk	"Allocation was concealed using sequentially numbered, opaque, sealed envelopes."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	To blind patients to group allocation, they were informed that “the study was looking at a new way to support patients facing ICD battery replacement, compared to the current way we do it.” Device clinic staff and the research assistant were not blinded owing to the nature of the intervention.

Lewis 2021 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate, reasons for attrition recorded
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02668900) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	"... there is potential for selection bias as patients who required pacing or who were eligible for an upgrade to cardiac resynchronization therapy did not meet inclusion criteria. In addition, a small proportion had their ICD previously replaced."

Lin 2020

Study characteristics	
Methods	Randomized to decision aid vs information
Participants	144 + 138 families whose babies were around 1 month old and going for routine vaccination in Taiwan
Interventions	DA: paper-based decision aid used during consultation that included clinical information, probabilities of outcomes, explicit values clarification, level of understanding test, guidance in decision-making (used in consultation), and guidance in communication (prompted to discuss concerns with doctor). The DA is available as a supplementary appendix in the article. Comparator: usual care
Outcomes	Decisional conflict, decision-making difficulties, and rotavirus vaccine knowledge (perceived), and the overall rotavirus vaccination rate
Notes	Source of funding: This work was supported by a research grant from Shuang Ho Hospital, Taipei Medical University (grant no.: 108HHC-03). The sponsoring organization was not involved in the study design, data analysis, or interpretation of results. Conflicts of interest: Dr. Sheng-Chieh Lin has received research grants from Shuang Ho Hospital, Taipei Medical University. All authors including Dr. Sheng-Chieh Lin have no conflicts of interest or financial ties to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"They were randomly divided into control (non-SDM) and experimental (SDM) groups using computer-generated assignment by the outpatient clinic nurse"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	Unclear risk	The randomization result was given to the physician. Owing to the nature of the intervention, participants could not be blinded to the study arm to which they were randomized. The questionnaires were collected after the vaccina-

Lin 2020 *(Continued)*

All outcomes		tion for their babies, and were anonymous to reduce stress on the respondents. Nurses who were blinded to randomization asked and noted down the response.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor-blind: "Nurses who are blinded with randomization asked and noted down the response."
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	High rate of attrition but missing data are balanced across groups.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03804489) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	The SURE test was translated, resulting in more items (7). Selection bias: "Second, our study was performed in an urban area, so the effects of SDM in rural areas still need investigation. Third, we excluded infants whose families differed at 1 and 2 months, so we cannot assess the influence of SDM on these families"

Lin 2022

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	103 + 97 women newly diagnosed with stage 1-3 breast cancer or ductal carcinoma in situ who required breast tumor resection in Taiwan
Interventions	DA: paper-based decision aid used during consultation that includes clinical information, outcome probabilities, explicit values clarification, knowledge test, and guidance in communication. The DA is available as a supplementary appendix in the article. Comparator: usual care
Outcomes	Decisional conflict, decisional regret, psychological distress
Notes	Source of funding and conflicts of interest: All authors have no conflict of interest or financial ties to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly divided into the standard and PDA groups through computer-generated assignment by a nurse in an ambulatory care clinic.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	During preoperative hospitalization 1 day before surgery, the effect of the PDA was investigated by an outcome assessor, who was a research assistant in Shared Decision Making Resource Center of Shuang Ho Hospital and blinded to participants' group allocation. During their follow-up visit 1 month after surgery, patients' decisional regret and postoperative psychological distress

Lin 2022 *(Continued)*

		were examined by the same outcome assessor who was blinded to the allocation. Blinding of patients was not reported in the article. Unclear how lack of blinding of participants may have influenced the outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	During preoperative hospitalization 1 day before surgery, the effect of the PDA was investigated by an outcome assessor, who was a research assistant in Shared Decision Making Resource Center of Shuang Ho Hospital and blinded to participants' group allocation. During their follow-up visit 1 month after surgery, patients' decisional regret and postoperative psychological distress were examined by the same outcome assessor who was blinded to the allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rates: 76/103 DA group and 75/97 usual care group analyzed, however missing data are balanced across groups (P = 0.561491). Justifications for attrition provided.
Selective reporting (reporting bias)	High risk	The study protocol is available (NCT03105076). Knowledge was included as a primary outcome in the trial registry, but there is no mention of this outcome in the article. The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Other bias	Unclear risk	Knowledge and satisfaction with decision were used to calculate statistical power for study but did not collect/report on knowledge and satisfaction in study.

Loh 2007

Study characteristics	
Methods	Cluster-randomized to decision aid vs usual care
Participants	263 + 142 patients with physician diagnosed depression (cluster-RCT with 30 general practitioners randomized) in Germany
Interventions	DA (in consultation): options' outcomes, clinical problem, explicit values clarification, guidance/coaching. The DA is not publicly available; a copy was provided by the author (in German). Comparator: usual care
Outcomes	Participation in decision-making, adherence, satisfaction with clinical care, depression severity, consultation length
Notes	Primary outcome was not specified Source of funding: The study was funded by the German Ministry of Health (BMGS Grant 217-43794-5/6 www.shared-decision-making.org). In continuation the German Ministry of Health also supported a project concerning the methodological tasks of the research consortium (BMGS Grant 217-43794-5/11) and a project to transfer shared decision-making in medical education (BMGS Grant 217-43794-5/12, www.shared-decision-making.org). Celia E. Wills is a past recipient of a U.S. National Institute of Mental Health Mentored Clinical Scientist Career Development (K08) Award (MH01721; 2000-2005) on depression treatment decision-making of primary care patients. Conflicts of interest: not reported

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Loh 2007 *(Continued)*

Random sequence generation (selection bias)	Low risk	"[T]wo-thirds of the general practitioners were randomly assigned to the intervention group by drawing blinded lots under the supervision of the principal investigator and two researchers" (p 3)
Allocation concealment (selection bias)	Low risk	Drawing blinded lots (p 3 - 2.1)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding; not enough information provided to assess whether this contributes to bias in outcomes not measured by using a scale (e.g. consultation time was documented in minutes by the physicians following each consultation).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Further results resting on the baseline phase of this trial were already presented elsewhere" (p 5, fig); "unequal distribution of physicians was due to possibility of higher dropout rate in intervention group because of additional time and effort" (p 3).
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Appears to be free of other potential biases (p 5-6, details patient and physician baseline characteristics). Statistically significant differences were controlled for in outcome analyses. Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Love 2016

Study characteristics	
Methods	Randomized to decision aid + verbal discussion vs standard verbal discussion alone (control)
Participants	16 + 16 patients 18 years and older with an untreated, biopsy-proven, primary basal cell carcinoma in the USA
Interventions	DA: video decision aid used in preparation for consultation that includes clinical information, outcome probabilities, and implicit values clarification. The DA is available as a supplementary appendix in the article. Comparator: usual care
Outcomes	Knowledge, patient and physician satisfaction, length of time for informed consent, treatment preference
Notes	Source of funding: none Conflicts of interest: none declared
Risk of bias	

Love 2016 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated in 1:1 random sequence at each site
Allocation concealment (selection bias)	High risk	"Preprepared study packets were labeled in order (by E. M. L.), with even numbers assigned to control group and odd numbers assigned to video group. Study personnel were aware of patient cohort at the time of consent (but not at the time of recruitment). Patients were informed of study group after consent." (Alternation or rotation used)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Study personnel were aware of patient cohort at the time of consent (but not at the time of recruitment); patients were informed of study group after consent; treating physicians were blinded at 1 site and not at the other site.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Treating physicians at Emory University were blinded to patient study group; Atlanta VAMC treating physicians were not blinded because of workflow constraints." Low risk for outcomes objectively measured (i.e. knowledge). Unclear risk for informed consent time.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis in DA group (13/16 completed final knowledge test vs 16/16 for control)
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT02158650). Treatment preference (secondary outcome of interest to this review) was not pre-specified.
Other bias	Unclear risk	Small sample size (16 + 16), mean and SD but small sample size and nothing about heterogeneity (median and range may be more appropriate)

Luan 2016

Study characteristics	
Methods	Randomized to decision aid vs control (standard information)
Participants	8 + 8 new adult breast reconstruction patients of one plastic surgeon undergoing reconstruction for mastectomy indicated for breast cancer in the USA
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, and guidance in communication. The DA is not publicly available; a copy was provided by the author (Anna Luan; aluan@stanford.edu). Comparator: usual care (standard information)
Outcomes	Decisional conflict, health-related quality of life, decision regret, anxiety and depressive symptoms, utilization of any other sources of information regarding breast reconstruction, perceptions of desired level of involved, chosen option
Notes	Source of funding: none declared Conflicts of interest: none declared
Risk of bias	

Luan 2016 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A weekly block randomization structure was used.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included; insufficient reporting of attrition/exclusions (i.e. number enrolled/randomized not reported, no reasons for missing data provided)
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	"... our small sample size limits the power of our study", "distribution of surveys in the clinic setting may introduce bias into our results, as it is plausible that patients may consciously or subconsciously alter their responses"

Madden 2020

Study characteristics	
Methods	Randomized to decision aid vs control
Participants	167 + 86 women at risk for unintended pregnancy who planned to discuss reversible contraception at their scheduled appointment in the USA
Interventions	DA: tablet-based decision aid used in preparation for consultation that included clinical information, probabilities of outcomes, explicit values clarification, algorithm that identified the 3 contraceptive methods most concordant with the women's preferences, guidance in decision-making (algorithm), and printed summary of tailored information. The DA is not publicly available and we were unable to obtain a copy from the authors. The pros and cons of options were presented using information that is available on bedsider.org: https://www.bedsider.org/birth-control . Comparator: control (tablet-based education on reproductive health) with a non-tailored handout describing recommendations for reproductive health care such as screening for cervical cancer and sexually transmitted infections
Outcomes	Primary outcome: change in decisional conflict Secondary outcomes: choice of contraceptive method and satisfaction with the healthcare visit; also reports communication (discussed with provider)
Notes	Source of funding: This research was supported in part by: (1) the Society of Family Planning (SFP, grant numbers SFP3-1, SFP5-8) and (2) the Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD) (grant number K23HD070979). The funders had no role in the identification,

Madden 2020 *(Continued)*

design, conduct, and reporting on this analysis. The content is solely the responsibility of the authors and does not necessarily represent the official view of NICHD.

Conflicts of interest: Dr. Madden serves on a data safety monitoring board for phase 4 safety studies of Bayer contraceptive products. Dr. Peipert receives research funding from Bayer Healthcare Pharmaceuticals, CooperSurgical/TEVA, and Merck & Co, Inc. and serves on an advisory board for CooperSurgical Pharmaceuticals. Dr. Politi receives research funding from Merck & Co. The other authors do not have any potential conflicts of interest to report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The computer programmer who was not involved in recruitment used a random number generator to create the randomization scheme.
Allocation concealment (selection bias)	Low risk	Allocation was concealed from the research team as the tablet computer implemented the random allocation sequence.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Due to the differences in the 2 printouts provided to the study groups, which participants were encouraged to share with their healthcare provider, blinding of the participants and healthcare providers was not possible. Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis and similar attrition rate between arms (96% included for DA, 93% included for control), justification for attrition reported
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT01479985) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	One or more of the authors are industry employees: Dr. Madden serves on a data safety monitoring board for phase 4 safety studies of Bayer contraceptive products. Dr. Peipert receives research funding from Bayer Healthcare Pharmaceuticals, CooperSurgical/TEVA, and Merck & Co, Inc. and serves on an advisory board for CooperSurgical Pharmaceuticals. Dr. Politi receives research funding from Merck & Co.

Man-Son-Hing 1999

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	139 + 148 patients on atrial fibrillation trial considering continuing on aspirin vs change to warfarin in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework). The DA is no longer available (decisionaid.ohri.ca/decaids-archive.html).

Man-Son-Hing 1999 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: uptake of options, adherence Secondary outcomes: help with making a decision, knowledge, accurate risk perceptions, decisional conflict, satisfaction with decision-making process, role in decision-making
Notes	Source of funding: This study was supported by grant R01 NS 242224 from the National Institute of Neurological Disorders and Stroke, Bethesda, Md. Original development of the audiobooklet decision aids fro patients with atrial fibrillation was supported in part by DuPont Pharmaceuticals. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated scheme (p 2)
Allocation concealment (selection bias)	Low risk	Administered from a central location (p 2)
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unclear blinding however, "contamination, physicians may have provided DA information to patients receiving usual care" (p 7)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	P 4, fig 2 flow chart. Reasons for attrition not mentioned. Baseline data not included.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	No other potential risks of bias

Mann D 2010

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	80 + 70 participants diagnosed with diabetes considering the use of statins to reduce coronary risk in the USA
Interventions	DA (in consultation): healthcare provider led discussion using developed tool (Statin Choice) on options' outcomes, outcome probabilities, guidance (step-by-step process for making the decision; administered by the physician in the consultation). The website is no longer available (mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm). The authors have a PDF copy of the DA. Comparator: usual primary care visit + pamphlet

Mann D 2010 *(Continued)*

Outcomes	Knowledge (postconsult and post-DA), decisional conflict (postconsult and post-DA), risk estimation (postconsult and post-DA), beliefs (postconsult and post-DA), adherence (3 and 6 months postconsult and post-DA)
Notes	Primary outcome was not specified Source of funding: not reported Conflicts of interest: The authors have no relevant conflict of interest to disclose.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants were randomized, but there is no mention of method used (p 138, Methods section).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline data were provided.
Selective reporting (reporting bias)	Unclear risk	Only reports on improvement (i.e. decisional conflict scale); does not present outcome data to fullest (no numerical data on knowledge results between groups, only describes in words).
Other bias	Unclear risk	"We did not adjust the clustering of effects given that few participants received care by the same clinicians" (p 139, Analysis section). No mention of the magnitude of change of data due to this choice.

Mann E 2010

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	278 + 139 participants considering diabetes screening in the UK
Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification. The DA is available as a supplementary appendix in the article. Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcomes: preferred option (post-DA)

Mann E 2010 *(Continued)*

	Secondary outcomes: whether invitation type impacts on intention (post-DA), impact on knowledge (post-DA), impact on attitude (post-DA), risk perception
Notes	Source of funding: not reported Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Invitation taken from the top of a randomly ordered pile (either standard or one of two versions of an informed decision choice invitation). The materials were ordered in a way that the invitation type was hidden until the recruitment process was completed" (p 2-3, Methods, Participants section). Unclear how invitation type was hidden.
Allocation concealment (selection bias)	Low risk	"Invitation taken from the top of a randomly ordered pile; materials were ordered in a way that the invitation type was hidden until the recruitment process was completed" (p 2-3, Methods, Participants section).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Interviewers were not aware of the direction of anticipated effect of materials, and materials were dummy-coded so that no sense of intervention or control would have been communicated to interviewers or participants (p 3, Methods, Participants section).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study did not address this outcome, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Unclear risk	No mention of protocol; insufficient information to permit judgment
Other bias	Unclear risk	"Present sample was … not necessarily representative of the highest risk individuals in this age group"; "£5 incentive might have also added a selection bias"; "Lack of anonymity with verbally delivered questionnaire might encourage socially desirable responding" (p 6, Discussion section)

Manne 2020

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	47 + 46 women 18 years of age or older with a diagnosis of Stage 0-3A breast cancer without hereditary breast cancer who were considering contralateral prophylactic mastectomy in the USA
Interventions	DA: interactive, web-based decision aid used independent of consultation that included clinical information, explicit values clarification, patient experiences, patient photograph examples, glossary, knowledge test, coping strategies, and summary of key points that can be printed and emailed to participant. The DA is not publicly available and we were unable to obtain a copy from the authors.

Manne 2020 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcome: knowledge, preparation for decision-making, decisional conflict Secondary outcomes: self-efficacy to manage worry, worry, motivations, risk for contralateral breast cancer, risk for chest wall recurrence after mastectomy, DA evaluation, DA user interface
Notes	Source of funding: This study was funded by an NIH R21 grant (CA187643) to Sharon Manne and Laurie Kirstein. Conflicts of Interest: The authors declare that they have no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Few details: after the consent and survey were received, participants were randomized to B-Sure or usual care. Both sites followed the same randomization procedures.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis (44/47 (93%) in usual care, 39/46 (85%) DA group but balanced across groups P = 0.169126), no justification for dropouts provided
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Marteau 2010

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	633 + 639 patients considering diabetes screening in England
Interventions	DA: screening invitation on clinical problem, outcome probabilities, and explicit values clarification. The DA is available as a supplementary appendix in a previous article (Mann E 2010). Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcome: attendance for screening (post-DA and consult)

Marteau 2010 *(Continued)*

	Secondary outcomes: intention to make changes to lifestyle (post-DA and consult), satisfaction with decisions made among attenders (post-DA and consult)
Notes	Source of funding: This trial was funded by the Wellcome Trust (grant No 076838 “Didactic versus informed choice invitations: balancing public health benefits and individual choice” principal investigator TMM). The funding body had no role in study design, data collection, analysis, interpretation, or writing of the report. Conflicts of interest: All authors have completed the unified competing interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author). SG has received honorariums from Eli Lilly, GlaxoSmithKline, Merck, Sharp & Dohme, Colgate Palmolive, Unilever, the University of Western Ontario, and the National Health Service for undertaking lectures at educational meetings not directly related to the topic of this paper. His second class rail travel costs for attending Department of Health meetings concerning the NHS health check were reimbursed by the Department of Health.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[G]enerated simultaneously in a batch by random numbers using Excel spreadsheet software, stratifying by number of participants in household" (p 2, Randomization section)
Allocation concealment (selection bias)	Low risk	"Randomisation … was undertaken by the study statistician from a central site" (p 2, Randomization section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel were blinded and it appears that patients were unaware which arm they were in (members of the same household received the same intervention) (p 2, Randomization section).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinical and trial staff taking measurements and entering data were unaware of the study arm to which participants had been assigned (p 2, Randomization section).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Published protocol (p 2, Methods)
Other bias	Low risk	Appears to be free of other potential biases.

Mathers 2012

Study characteristics

Methods	Cluster-randomized controlled trial of 49 general practices in the UK to decision aid, healthcare professional training workshop and use of PDA in consultation, or usual care
Participants	95 + 80 participants with type 2 diabetes considering adding or changing to insulin therapy
Interventions	DA: booklet about clinical problem, treatment options, options' outcomes, outcome probabilities, explicit values clarification, structured guidance. The DA is not publicly available; a copy was provided by the author (C.Ng@sheffield.ac.uk).

Mathers 2012 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (immediately postintervention), glycemic control (glycosylated hemoglobin, HbA1c) at 6 months Secondary outcomes: knowledge (immediately post), realistic expectations (immediately post), preference option (immediately post), proportion undecided (immediately post), participation in decision-making (immediately post), regret (6 months), adherence with chosen option (6 months)
Notes	Trial registration: ISRCTN14842077 Source of funding: Funded by National Insitute for Health Research, Research for Patient Benefit. NM, CJN, MC, BC, IB and AB have support from the University of Sheffield for the submitted work. Conflicts of interest: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"All eligible and willing practices were randomly allocated by a computer" (p 3)
Allocation concealment (selection bias)	Low risk	"A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied" (p 3)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data
Selective reporting (reporting bias)	Low risk	Trial registered
Other bias	Unclear risk	Cannot make a judgment with information provided regarding cessation of recruitment at 175 (yet 320 required to allow detection of 0.5% difference in HbA1c). Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Mathieu 2007

Study characteristics

Methods	Randomized to decision aid versus usual care

Mathieu 2007 *(Continued)*

Participants	367 + 367 women aged 70 to 71 years and considering a subsequent screening mammography in Australia
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance with worksheet (Ottawa Decision Support Framework). The DA is not publicly available; a copy was provided by the author. Comparator: BreastScreen NSW brochure - includes information for women 70 + but no numeric information about the outcomes of screening
Outcomes	Primary outcomes: actual decision, informed choice Secondary outcomes: knowledge (includes 5 questions about risk perceptions), anxiety, decisional conflict, breast cancer worry, preference/intention, attitudes about screening, relationship between objective and perceived risk of breast cancer
Notes	Source of funding: This study was supported by grant 211205 from the National Health and Medical Research Council of Australia. Conflicts of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer program, which assigned allocations in accordance with a simple randomization schedule (p 2, Methods)
Allocation concealment (selection bias)	Low risk	Randomized by interview staff who accessed a previously concealed computer program (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers (at follow-up) were blinded; outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 1 flow diagram (p 2)
Selective reporting (reporting bias)	Low risk	"The trial was registered with the Australian Clinical Trials Registry and the Clinical Trials Registration System" (p 5)
Other bias	Low risk	Appears to be free of other potential biases.

Mathieu 2010

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	189 + 223 women considering mammography screening in Australia

Mathieu 2010 *(Continued)*

Interventions	DA: Internet program + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (worksheet with questions relevant to decision-making process; one or more questions that asked patients to clarify their preferences; summary). The DA is no longer available (http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml). The Internet-based decision aid was based on a previously developed and evaluated paper-based decision aid (Mathieu 2007), modified to provide age-appropriate data. Comparator: delayed intervention
Outcomes	Primary outcomes: knowledge (post-DA), risk perception Secondary outcomes: intention (post-DA), values (post-DA), informed choice (post-DA), proportion undecided
Notes	Source of funding: This study was supported by grant 211205 from the National Health and Medical Research Council of Australia. The funding source had no role in the design or conduct of the study, the collection, analysis, or interpretation of the data or the preparation of the manuscript. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputer generated simple randomization schedule" (p 66, Randomization and baseline questions section)
Allocation concealment (selection bias)	Unclear risk	"[R]andomization was conducted in a concealed manner" (p 66). Method of allocation concealment not stated.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes mentioned in Outcome measures section were reported in the results section (p 68, Table 2; information for intention as well as anxiety and acceptability can be found in text format in the secondary outcomes section on p 67-8).
Selective reporting (reporting bias)	Unclear risk	No mention of protocol
Other bias	Low risk	Appears to be free of other potential sources of bias.

McAlister 2005

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care

McAlister 2005 *(Continued)*

Participants	219 + 215 patients considering antithrombotic therapy for nonvalvular atrial fibrillation (cluster-RCT with 102 primary care practices randomized) in Canada
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework). The DA is no longer available (https://decisionaid.ohri.ca/decaids-archive.html). Comparator: usual care
Outcomes	Primary outcomes: uptake of (appropriate) option Secondary outcomes: knowledge, decisional conflict, accurate risk perceptions
Notes	Source of funding: The DAAFI Trial was funded by the Canadian Stroke Network, the Alberta Heritage Foundation for Medical Research (AHFMR), and the University Hospital Foundation, Edmonton. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]luster randomization at level of primary care practice to minimize contamination; randomization was done centrally to preserve allocation concealment using a computer generated sequence" (p 2)
Allocation concealment (selection bias)	Low risk	Randomization was done centrally to preserve allocation concealment (p 2, Methods).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded, but not sure whether the lack of blinding would affect the outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessors blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results and Fig 1 - flow diagram (p 3)
Selective reporting (reporting bias)	Low risk	DAAFI trial protocol, including copies of the various questionnaires employed, has been published (p 1, Methods).
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

McBride 2002

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	289 + 292 perimenopausal women considering hormone replacement therapy in the USA

McBride 2002 *(Continued)*

Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: delayed intervention
Outcomes	Primary outcome: accurate risk perceptions Secondary outcomes: satisfaction with decision, confidence with knowledge, and making/discussing decision
Notes	Source of funding: This work was supported by a grant from the National Cancer Institute (PO1-CA-72099-05). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Allocation concealment (selection bias)	Unclear risk	No information provided; Bastian 2002, no information provided - Study design is described elsewhere (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Complete data are available for 520 (90%) of the women (p 2). Reasons why not mentioned (Bastian 2002, p 5, Results; p 6, Baseline characteristics/data included).
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Appears to be free of other potential biases; Bastian 2002, p 8 - Eligible participants were willing to consider HRT and this may have favored recruitment of women with higher SES and those who had prior experience with HRT.

McCaffery 2010

Study characteristics

Methods	Randomized to decision aid + informed choice vs HPV testing vs repeat smear
Participants	104 + 104 + 106 women screened as HPV indeterminate considering HPV testing in Australia

McCaffery 2010 *(Continued)*

Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (worksheet). The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator 1: no decision support, received immediate HPV testing Comparator 2: no decision support, received a repeat cervical smear at 6 months
Outcomes	Primary outcomes: quality of life (post-DA) Secondary outcomes: waiting time anxiety (post-DA), perceived risk (post-DA), perceived seriousness of cancer (post-DA), worriedness (post-DA), intrusive thoughts (post-DA), satisfaction with care (post-DA), anxiety (post-DA), distress and concerns (post-DA), self-esteem (post-DA), effect on sexual behavior (post-DA), help-seeking behavior (post-DA), knowledge (post-DA)
Notes	Source of funding: This work was supported by an Australian National Health and Medical Research Council (NHMRC) Grant 402764 to the Screening and Test Evaluation Program. KM is supported by a NHMRC Career Development Award 402836. The NHMRC has played no role in the writing of this paper. Conflicts of interest: KM has received a speaker's fee from CSL (producers of the HPV quadrivalent vaccine Gardasil) and a consultancy fee from GlaxoSmithKline (producers of the bivalent HPV vaccine, Cervarix). EW has received honoraria and research funding from GSK and CSL for her research in the area of HPV vaccination. All other authors have no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
Allocation concealment (selection bias)	Low risk	"Participants were randomised centrally by the research team within each clinic in blocks of three" (p 2, Design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients and staff were unblinded, but objective outcomes were used.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcomes are on questionnaires; not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Figure 3: sensitivity analysis was done to include most of the patients.
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Low risk	Appears to be free of other sources of bias.

McGrath 2017

Study characteristics

McGrath 2017 *(Continued)*

Methods	Randomized to decision aid vs control (no decision aid)
Participants	38 + 41 women with epilepsy of childbearing age (18 to 45) in Australia
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, patient narratives, guidance in decision-making (5-step process), and guidance in communication. The DA is available as a supplementary appendix in the article. Comparator: control (no intervention)
Outcomes	Primary outcomes: knowledge, decisional conflict, decisional self-efficacy Secondary outcomes: certainty, patient-practitioner communication, depression, anxiety
Notes	Source of funding: none Conflicts of interest: none of the authors has any conflict of interest to disclose

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomly allocated to either receive the DA or the control group using a 1:1 allocation schedule. Random numbers corresponding to intervention vs control group were generated through www.randomizer.com.
Allocation concealment (selection bias)	Low risk	Random numbers corresponding to intervention vs control group were generated through www.randomizer.com. These numbers were linked in advance to participant identification numbers and concealed until allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate in the intervention arm 8/38 (21%) compared to the control arm 4/41 (9.7%), however the difference in missing data is not significant (P = 0.162203). Reasons for attrition are provided.
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12613001082796). Low risk for all outcomes except for patient-clinician communication and values congruence with chosen option, which were not included as an outcomes in the trial registry (high risk).
Other bias	Low risk	The study appears to be free of other sources of bias.

McIlvennan 2018

Study characteristics

Methods	Cluster-randomized, stepped-wedge trial, decision aid vs usual care

McIlvennan 2018 *(Continued)*

Participants	71 + 111 informal caregivers of patients with end-stage heart failure eligible for a destination therapy left ventricular assist device implantation in the USA
Interventions	DA: booklet and video decision aid integrated with consultation that includes clinical information, outcome probabilities, explicit values clarification, patient narratives, guidance in communication, and summary page that can be shared in consultation. The DA is publicly available at https://patientdecisionaid.org/lvad/ . Comparator: usual care (education)
Outcomes	Primary outcome: decision quality (informed values-choice congruence) Secondary outcomes: decision, decisional conflict, decision regret, perceived stress, preparedness for caregiving, satisfaction with care, depression, acceptability of the educational materials
Notes	Source of funding: This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (CDR-1310-06998). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors, or Methodology Committee. This work was also supported in part by the National Heart, Lung and Blood Institute (1K23HL105896-01, Allen), the Heart Failure Society of America (McIlvennan), the National Institute on Aging (1K23AG040696, Matlock), and REDCap database hosting through University of Colorado supported by NIH/NCRR Colorado CTSI (Grant Number UL1 TR001082). Conflicts of interest: Dr. Blue has received personal fees from Abbott and Medtronic. Dr. Patel has received personal fees from Abbott and Medtronic. Dr. Allen has received personal fees from ACI Clinical, Janssen, Cytokinetics, Novartis, Boston Scientific, Amgen, and Duke Clinical Research Institute. All other authors have reported that they have no relationships relevant to the contents of this paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition; however, missing data for 1- and 6-month outcomes is balanced across groups (1 month 53/71 completers DA group 89/111 completers control group (P = 0.379326); 6 months 50/71 completers DA group 78/111 completers control group (P = 0.9825)).
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02344576) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	One or more of the authors received industry funding with no description of role in the study: "Dr. Blue has received personal fees from Abbott and Medtronic. Dr. Patel has received personal fees from Abbott and Medtronic. Dr.

McIlvennan 2018 *(Continued)*

	Allen has received personal fees from ACI Clinical, Janssen, Cytokinetics, Novartis, Boston Scientific, Amgen, and Duke Clinical Research Institute." Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

McLean 2020

Study characteristics	
Methods	Randomized to decision aid versus information
Participants	21 + 19 participants aged > 16 years with a diagnosis of hidradenitis suppurative diagnosis in Canada and the USA
Interventions	DA: online decision aid that included information about the condition, explicit values clarification, guidance in decision-making (step-by-step process), and printable summary of results. The DA is publicly available at https://www.informed-decisions.org/hidradenitispda.php . Comparator: website that included information about the condition, treatment options, and guidance in communication (e.g. basic questions to ask your doctor)
Outcomes	Primary outcomes: difference in knowledge and decisional conflict as well as preparation for decision-making Secondary outcomes: resource acceptability, decisional conflict, and decision regret
Notes	Source of funding: Supported by an Advancing Science Through PfizereInvestigator Research Exchange (ASPIRE) grant (Dr Dellavalle). Conflicts of interest: Dr Sisic and Authors McLean and McBride received salaries from Windsor Clinical Research Inc. Dr Dellavalle is a member of Cochrane Council, received other independent peer-reviewed grants from Pfizer, and has been a medical consultant for Altus Labs and ParaPRO. Dr Tan is the president of Windsor Clinical Research Inc. He has been a speaker and consultant fordor received honoraria, grants, and research support from Almirall, Bausch, Boots/Walgreens, Botanix, Cipher, Galderma, Incyte, L'Oreal, Novartis, Pfizer, Promius, SUN, and UCB. Author Samardzic has no conflicts of interest to declare.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"1:1 randomization. Hidradenitis suppurativa patient decision aid and Mayo groups were randomly labeled as group A or B by one researcher (O.M.) via a coin toss, and allocation was concealed from another researcher (D.M.). D.M. performed simple block randomization using http://www.randomization.com with a fixed block size of 2 (group A or B) to generate a random sequence"
Allocation concealment (selection bias)	Low risk	"Hidradenitis suppurativa patient decision aid and Mayo groups were randomly labeled as group A or B by one researcher (O.M.) via a coin toss, and allocation was concealed from another researcher (D.M.). D.M. performed simple block randomization using http://www.randomization.com with a fixed block size of 2 (group A or B) to generate a random sequence that was concealed from O.M., and informed O.M. of participants' allocation group. O.M. was responsible for enrollment and administration of surveys."

McLean 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Content sources were deidentified, and both the hidradenitis suppurativa patient decision aid and Mayo were hosted on an independent website to ensure blinding. Only O.M. was aware of participants' allocated group. outcomes were objectively measured and not subject to interpretation"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Content sources were deidentified, and both the hidradenitis suppurativa patient decision aid and Mayo were hosted on an independent website to ensure blinding. Only O.M. was aware of participants' allocated group. outcomes were objectively measured and not subject to interpretation"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% of participants included in analysis (71.4% decision aid and 68.4% control but higher loss to follow-up expected for online survey study), similar loss to follow-up between arms and provided justification.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	Small sample size (21 versus 19)

Meade 2015

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	107 + 81 women aged within their childbearing and rearing years that had been clinically diagnosed with rheumatoid arthritis and currently under the care of a rheumatologist, and contemplating having children or more children in Australia
Interventions	DA: online printable decision aid that includes information on the clinical problem, outcome probabilities, explicit values clarification, patient narratives, checklists, information resources, guidance in decision-making (step-by-step process for making the decision, checklist to identify decisional needs), and guidance in communication. The DA is publicly available at https://www.westernsydney.edu.au/__data/assets/pdf_file/0007/1541527/RAandmotherhooddecisiontool_PDF_DA.pdf . Comparator: no intervention
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: anxiety, depression, perceived self-efficacy
Notes	Source of funding: This work was supported by the Australian Research Council, [grant number LP0989906] titled 'Motherhood choices: a decision aid for women with Rheumatoid Arthritis' in partnership with Arthritis NSW. Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	As women provided consent, a member of the research team randomly allocated them to either the DA or control group, using the Bernoulli function in Excel.

Meade 2015 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, "A total of 188 women consented to participate in the study. Forty-four (28 out of 107 DA; 16 out of 81 Control) participants did not complete pre or post questionnaire and after a number of efforts to contact them, were assumed to have withdrawn from the study." High attrition rate for intervention arm (27%) vs control (19%), but difference is not significant (P = 0.168634).
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12615000523505) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"As a consequence of the random allocation, the control and intervention groups were not balanced for parity or gravity"

Meier 2019

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	51 + 48 parents considering adenotonsillectomy for their children, under 6 years of age, and presenting with sleep-disordered breathing in the USA
Interventions	DA: paper-based decision aid used during consultation that includes clinical information, outcome probabilities, and explicit values clarification. The DA is presented in Figure 1 of the article. Comparator: usual care
Outcomes	Decisional conflict, shared decision-making, patient-clinician communication (OPTION scale)
Notes	Source of funding: This study was supported by a Triological Society Career Development Award (J.D.M.). Conflicts of interest: The authors have no financial relationships, or conflicts of interest to disclose.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Simple randomization with opaque envelopes containing assignment to either receive the DA prototype during the visit (study group) or undergo the usual surgical consultation (control group).

Meier 2019 *(Continued)*

Allocation concealment (selection bias)	Low risk	Simple randomization with opaque envelopes containing assignment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Study reports that parents were blinded, however participants were told in advance of randomization that they were either going to have consultation only or use a tool + consultation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported. Low risk of bias for decisional conflict and Shared Decision-Making Questionnaire–Parent Version (SDM-Q-9). High risk for one outcome subjective to interpretation (video-recordings coded with OPTION).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included; no reasons for missing data; no information about how many patients were initially invited for intervention and control groups.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Metcalfe 2017

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	76 + 74 women with a BRCA mutation with no previous diagnosis of cancer recruited from 4 clinics in Canada and an online support network in the USA
Interventions	DA: paper-based decision aid used in preparation for consultation that included clinical information, outcome probabilities, explicit values clarification, guidance in decision-making (step-by-step), and guidance in communication. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care (genetic counseling)
Outcomes	Primary outcome: decisional conflict Secondary outcomes: cancer-related distress, knowledge, choice predisposition (undecided)
Notes	Source of funding: not reported Conflicts of interest: The authors declared no conflict of interest.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"If all eligibility criteria were met, then the women were randomized centrally with a secure Web-based randomization service (http://www.randomized.net)"
Allocation concealment (selection bias)	Low risk	The women were randomized centrally with a secure web-based randomization service (http://www.randomize.net).

Metcalfe 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It is unclear if participants were blinded; personnel were blinded. Unclear how lack of blinding may have influenced the results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A research assistant blinded to group allocation telephoned all study participants at 3, 6, and 12 months post-randomization to determine trial outcomes.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No flow diagram, low attrition rate (response rates were 94% at 3 months, 94% at 6 months, and 93% at 12 months). There was no difference in the response rate by group allocation.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Miller 2005

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	279 women considering BRCA1-BRCA2 gene testing in the USA
Interventions	DA: educational intervention on options' outcomes, personal family cancer history; clinical problem, outcome probability, explicit values clarification, others' opinions, guidance/coaching. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: provision of general information about cancer risk
Outcomes	Preferred option, knowledge, perceived risk, satisfaction
Notes	Primary outcome was not specified Source of funding: This research was supported in part by the Department of Defense DAMD17-98-1-8306, DAMD17-01-1-0238, and DAMD17-02-1-0382 grants, the Fox Chase Cancer Center's Behavioral Research Core Facility (P30CA06927), and NIH grant R01HG01766. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomized by the CATI system" (p 4) after self-initiated telephone contact
Allocation concealment (selection bias)	Low risk	"[C]omputerized assisted telephone interview system (CATI)" (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not addressed

Miller 2005 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reasons stated for initial dropout of study participants (p 8). Patients contacted offered reasons for dropping out. Study protocol allowed patients to be reached up to 13 times at follow-up, but still could not be reached.
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Appears to be free of other sources of bias.

Miller 2011

Study characteristics	
Methods	Decision aid vs attention placebo
Participants	132 + 132 participants considering colon cancer screening in the USA
Interventions	DA: computer-based web program on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encourages patient-practitioner communication, summary). The DA is no longer available (intmedweb.wakehealth.edu/choice/choice.html) Comparator: computer-based web program on prescription drug refills and safety
Outcomes	Primary outcomes: receipt of CRC screening (post-DA) Secondary outcomes: ability to state a preference, change in readiness to receive screening (pre and post-DA), CRC test ordering (post-DA), proportion undecided
Notes	Source of funding: This study was funded by a Cancer Control Career Development Award (DPM) from the American Cancer Society (CCCDA-05-162-01). Conflicts of interest: MPP was supported by a National Cancer Institute Established Investigator Award (K05 CA129166). No other financial disclosures were reported by the authors of this paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block-randomized, stratified by literacy level (p 609, Methods)
Allocation concealment (selection bias)	Unclear risk	Study does not address this domain
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Health care providers were not notified of patients' enrolment in the study at any time (p 609, Methods). RAs that administered post-DA questionnaire were not blinded but believed to be a low risk of bias (p 613, Discussion).
Blinding of outcome assessment (detection bias)	Low risk	"[C]linical outcome assessors were [blinded]" (p 613, Discussion)

Miller 2011 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol on ClinicalTrials.gov
Other bias	Unclear risk	USD 10 gift card for participation could affect the participant pool.

Miller 2018

Study characteristics	
Methods	Randomized to decision aid vs control
Participants	223 + 227 individuals aged 50 to 74 years who were scheduled to see a primary care provider and due for colorectal cancer screening in the USA
Interventions	DA: video decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, implicit values clarification, and patient narratives. The DA is not publicly available; a copy was provided by the author (David P. Miller Jr.; dmiller@wakehealth.edu). Comparator: attention control (education on another topic)
Outcomes	Primary outcome: chart-verified completion of CRC screening within 24 weeks Secondary outcomes: ability to state a screening preference, intention to receive screening, screening discussions, and orders for screening tests
Notes	Source of funding: The study received funding and support from the National Cancer Institute (R01CA178941), the Wake Forest Clinical and Translational Science Institute study coordinator pool (UL1TR001420), and the shared resources provided by the Wake Forest Comprehensive Cancer Center (CCSG P30CA012197). No funding organization played a role study conduct, manuscript preparation, or decision to submit for publication. Conflicts of interest: Dr. Miller reports grants from the National Cancer Institute during the conduct of the study. Drs. Miller, Weaver, and Troyer report grants from the National Institutes of Health during the conduct of the study. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M17-2315.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The study program randomly assigned participants, stratified by site, to either the mPATHCRC or Control Program with equal probability using variably sized permuted block randomization with random block sizes of 2 or 4.
Allocation concealment (selection bias)	Low risk	The random allocation sequences were generated by the study statistician using nQuery Advisor 7.0 and stored on the iPads used at each site in files accessible only by the study programmer. Two iPads were used at the largest clinic, each with its own allocation sequence.

Miller 2018 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Study interviewers and outcome assessors were blinded to participant allocation. Not reported for patients but outcomes of interest were objectively measured.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study interviewers and outcome assessors were blinded to participant allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; all participants randomized were included in analysis.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02088333) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"Selection bias could also have affected our results because recruited patients had to agree to arrive at the clinic early to enroll. In addition, the postprogram survey assessing preferences may have triggered some patients to discuss CRC screening with their providers."

Moin 2019

Study characteristics	
Methods	Cluster-randomized to decision aid + shared decision-making intervention vs usual care (using propensity score matched controls)
Participants	351 + 1028 overweight/obese patients with prediabetes in the USA
Interventions	DA: web-based interactive decision aid used during consultation that included clinical information, probabilities of outcomes, explicit values clarification, patient narratives, quiz section, guidance in decision-making (step-by-step process), guidance in communication, and printed copy of a summary report with their decision and plan at the end of the visit. The DA is publicly available at https://decisionaid.ohri.ca/AZsumm.php?ID=1654 . Comparator: usual care (no details provided)
Outcomes	Primary outcome: diabetes prevention program (≥ 9 sessions attended) and/or metformin uptake at 4-month follow-up Secondary outcome: weight change at 12 months
Notes	Source of funding: National Institute of Diabetes and Digestive and Kidney Diseases (R18 grant number DK105464). Conflicts of interest: Dr. Duru is on the Healthwise scientific board. None of the other authors disclosed any potential conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"We stratified 20 primary care clinics by clinic size and mean patient age, randomizing 10 clinics to the SDM intervention and 10 to usual care (we launched in 16 clinics [8 intervention and 8 control] and subsequently added the last 4)."

Moin 2019 *(Continued)*

		The investigators describe the use of stratification or permuted blocking (use of computer implied).
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram for intervention clinics only
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02384109) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	High risk	Concerns regarding the ethical implications of usual care participants not consenting to participate. Actual choice for the usual care group subject to bias (results extremely low compared to the DA group). Article reported that: "Because it was not feasible to collect informed consent from matched controls, DPP suppliers could not share DPP participation data from controls. Therefore, we conducted natural language queries of all EMR progress notes between 2015 and 2018 to capture participation in DPP or any other structured weight loss program". Selection bias: "this trial was conducted at UCLA Health where pharmacists were integrated in a large network of primary care clinics, which may limit generalizability...". Confirmation bias: "the intervention patients who chose to participate may have been more motivated than others to lower their diabetes risk." Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Montgomery 2003

Study characteristics	
Methods	Randomized to decision aid + decision analysis vs decision analysis vs decision aid vs usual care
Participants	51 + 52 + 55 + 59 newly diagnosed hypertensive patients considering drug therapy for blood pressure in the UK
Interventions	DA: decision analysis plus information video and leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: decision analysis on options' outcomes, outcome probability, explicit values clarification Comparator: video and leaflet on options' outcomes, clinical problem

Montgomery 2003 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: uptake of option, knowledge, anxiety
Notes	Source of funding: The Medical Research Council provided funding for the study and support for Dr Montgomery with a Training Fellowship in Health Services Research (G106/912). Professor Fahey was supported by a National Health Service Primary Care Career Scientist Award at the time of the research. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation schedule was computer-generated by an individual not involved in the study (p 2)
Allocation concealment (selection bias)	Low risk	"[A]llocation was concealed to the author in advance by the nature of the minimization procedure" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to the outcome assessed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Montgomery 2007

Study characteristics

Methods	Randomized to decision aid with values clarification vs decision aid without values clarification vs usual care
Participants	245 + 250 + 247 women with previous cesarean section in the UK
Interventions	DA: options' outcomes, clinical problem, outcome probability, explicit values clarification. The DA is no longer available (http://www.computing.dundee.ac.uk/acstaff/cjones/diamond/Information.html). Comparator: options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: decisional conflict

Montgomery 2007 *(Continued)*

	Secondary outcomes: choice, anxiety, knowledge, satisfaction with decision, costs (Hollinghurst 2010)
Notes	Source of funding: BUPA Foundation. AAM was part supported by a postdoctoral fellowship from the UK Department of Health National Coordinating Centre for Research Capacity Development. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked by using randomly permuted and selected blocks of sizes 6, 9, 12, and 15 generated by computer (p 2 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	1 member of the study team generated the randomization sequence by computer, and another member of staff with no other involvement in the trial performed the allocation (p 2 Methods, Randomization).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow of women through the study
Selective reporting (reporting bias)	Low risk	Trials registry ISRCTN84367722
Other bias	Low risk	Recruited more than planned to account for lost data (p 4, Sample size); baseline characteristics were balanced.

Montori 2011

Study characteristics

Methods	Randomized to decision aid vs usual care + booklet
Participants	52 + 48 women with low bone mass or osteoporosis considering taking bisphosphonates in the USA
Interventions	DA (in consultation): worksheet on options' outcomes, clinical problem, outcome probabilities, guidance (administered by physician). The DA is no longer available (shareddecisions.mayoclinic.org/decision-aids-for-diabetes/other-decision-aids/). The authors have a PDF copy of the DA. Comparator: usual care + general information booklet on osteoporosis
Outcomes	Patient knowledge (post-DA), satisfaction with knowledge transfer (post-DA), decisional conflict (post-DA), patient-clinician communication (OPTION), trust with physician (during intervention), clinician's perception of decision quality (post-DA), clinician's satisfaction with knowledge transfer (post-DA), uptake (post-DA), adherence (post-DA), fidelity (post-DA), contamination (post-DA), risk perception
Notes	Primary outcome was not specified

Montori 2011 *(Continued)*

Source of funding: The trial was funded by the Mayo Clinic Foundation for Medical Education and Research. The funding source had no role in the design, conduct, or decision to publish results of this trial.

Conflicts of interest: The authors of this article disclose no financial conflicts of interest pertinent to this trial. In particular, the decision aid described in this article is in the public domain and can be obtained from the authors without charge. The authors, their relatives, or other associates have not initiated any business to profit from this decision aid (or any other decision aid they have developed and studied) or the dissemination of the results of this trial, beyond the usual benefits of academic recognition. The authors or any member of the team who participated in the development or evaluation of the decision aid have not received financial support from pharmaceutical companies that market bisphosphonates or their competitors. The KER UNIT, a laboratory within the Mayo Clinic where the study was conceived, run, and analyzed, and this report was prepared, had explicit rules in place before, during, and at the time of writing this note against receiving any funding from for-profit pharmaceutical or device manufacturers.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"computer generated allocation" (p 551, Randomization)
Allocation concealment (selection bias)	Low risk	Patients randomized "in a concealed fashion (using a secure study website)" (p 551, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No mention of participants being blinded to their allocation; only mention of data collectors and analysts blinding (p 551, Randomization).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"After randomization, data collectors and data analysts were blind to allocation" (p 551, Randomization); outcomes were not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	"The protocol for this trial has been reported in full" (p 550, Design)
Other bias	Unclear risk	Appears to be free of other potential biases.

Montoya 2019

Study characteristics

Methods	Randomized to decision aid plus standard care vs standard care alone
Participants	15 + 15 women 18 years and older referred for initial evaluation of primary symptomatic pelvic organ prolapse in the USA
Interventions	DA: video decision aid used in preparation for consultation that included clinical information, implicit values clarification, and guidance in communication. The DA is not publicly available; a copy was provided by the author (T. Ignacio Montoya; teodoro.montoya@ttuhsc.edu)

Montoya 2019 *(Continued)*

	Comparator: usual care
Outcomes	Knowledge, satisfaction with initial treatment decision, decisional conflict
Notes	Source of funding: Supported by Texas Tech University Health Sciences Center El Paso institutional seed grant. Conflicts of interest: The authors have declared they have no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A block randomization technique was performed using blocks of 6 (use of computer implied).
Allocation concealment (selection bias)	Low risk	Group assignments were predetermined and concealed in sealed envelopes, which were sequentially opened at the time of each participant's inclusion into the study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Providers were not blinded to the group allocation of the patients, potentially introducing bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; one participant from each group was lost to follow-up (Fig. 1).
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02850835) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Morgan 2000

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	120 + 120 patients with ischemic heart disease considering revascularization surgery in Canada
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinions. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care
Outcomes	Primary outcome: satisfaction with the decision-making process Secondary outcomes: uptake of option, knowledge

Morgan 2000 *(Continued)*

Notes	Source of funding: This research was funded in part by the Ontario Ministry of Health and the Heart and Stroke Foundation of Ontario (Grant NA3039). Dr. Llewellyn-Thomas is a National Health Scholar supported by the National Health Research & Development Program of Health Canada. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Morgan 1997, p 29: all randomization enrolment was performed by telephone at which time the participant was assigned. Morgan 2000 (primary study), p 2, Methods, Patient Population: "Only the statistician was privy to the two randomisation schedules and blocking factor used"
Allocation concealment (selection bias)	Low risk	Morgan 1997, p 29: only the statistician was privy to the two randomization schedules and blocking factor Morgan 2000, (primary study), p 2, Methods, Patient Population: "only the statistician was privy to the two randomisation schedules and blocking factor used. All randomization enrolment was performed by telephone"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[D]ue to nature of trial, neither patients or investigators were blinded to the study" - may introduce bias to subjective outcomes such as satisfaction.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Morgan 1997, p 39, Patient accrual and follow-up: baseline characteristics included Morgan 2000 (primary study): 78% completed follow-up (90 of 120 in the intervention; 97 of 120 in the control). Reasons for attrition were provided.
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Unclear risk	Morgan 1997, p 56: significant number of patients were lost to follow-up (25%); Morgan 2000 (primary study): baseline data imbalance (high school grad, income, no. of diseased arteries). Dropout group reported lower incomes; may have affected results. (Discussion par. 6) "Selection bias was minimized by enrolling available consecutive patients"

Mott 2014

Study characteristics

Methods	Randomized to shared decision-making process with DA versus usual care
Participants	13 +14 military veterans in USA diagnosed with PTSD and had served in Iraq or Afghanistan

Mott 2014 *(Continued)*

Interventions	DA: booklet on clinical problem, options' outcomes, structured guidance. The DA is not publicly available; a copy was provided by the author (juliette.mott@va.gov). Comparator: usual care
Outcomes	Satisfaction with SDM qualitatively (postintervention), perceived advantages and disadvantages of SDM qualitative (postintervention), treatment preferences (4 months), adherence using treatment engagement (4 months)
Notes	Not reported as registered in trials database; no primary outcome reported Source of funding: This research was supported by the Office of Academic Affiliations VA Advanced Fellowship Program in Mental Illness Research and Treatment, the Department of Veterans Affairs South Central Mental Illness Research Education and Clinical Center (MIRECC), and the VA HSR&D Houston Center of Excellence (HFP90-020). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomized to SDM or UC using a computer-generated randomization sequence" (p 146)
Allocation concealment (selection bias)	Low risk	"[R]andomization envelopes were prepared by the study statistician to ensure that study staff remained masked to randomization sequence" (p 146)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided to make judgment.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff not blinded but because outcomes were taken from medical records. "At 4-month follow-up, study staff reviewed participants' medical records to extract information on treatment preferences and engagement. Medical-record reviews were conducted by a single rater trained in use of the dataextraction form. A second rater, masked to initial ratings, reextracted data from 20% of patients" (p 146).
Incomplete outcome data (attrition bias) All outcomes	High risk	27 participants were consented and enrolled, yet only 20 (usual care = 11; SDM = 9) completed the study (p 146-7). Only 5 participants in the SDM arm completed the exit interview. No mention of missing data.
Selective reporting (reporting bias)	Low risk	No protocol available but all expected outcomes are reported on.
Other bias	Low risk	Does not appear to be any other sources of bias.

Mullan 2009

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care

Mullan 2009 *(Continued)*

Participants	48 + 37 patients with type 2 diabetes considering treatment options (cluster-RCT with 40 clinicians randomized) in the USA
Interventions	DA (in consultation): decision cards with information on options, outcomes, outcome probability, explicit values clarification. The DA is presented in Figure 1 of the article. Compare: 12-page pamphlet on oral anti-hyperglycemic medications
Outcomes	Knowledge, decisional conflict, participation in decision-making, acceptability of the information, change in medication, adherence, HbA1C levels, trust in physician, OPTION to analyze audio-taped encounters
Notes	Primary outcome was not specified Source of funding: The American Diabetes Association, through its competitive peer-reviewed granting process, funded this study. Novo Nordisk, a maker of insulin, subsidized the American Diabetes Association granting program but did not have direct contact with the investigators and did not play any role in the awarding of the grant to the research team. Conflicts of interest: none reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated
Allocation concealment (selection bias)	Low risk	Central allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients were blinded, the clinicians were not, but each session was recorded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reasons for attrition not included
Selective reporting (reporting bias)	Low risk	Trial registration no. at clinicaltrials.gov reported
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Murphy 2020

Study characteristics	
Methods	Randomized to decision aid vs usual care

Murphy 2020 *(Continued)*

Participants	21 + 56 men with prostatectomy in the UK
Interventions	DA: web-based decision aid that includes initial step to help customize grid of recommended products and implicit methods to clarify values. The DA is publicly available at https://www.continenceproductadvisor.org . Comparator: usual care (supplied with incontinence pads and advised to buy more as needed)
Outcomes	Decisional conflict
Notes	Source of funding: This work was funded by the Movember Foundation in partnership with Prostate Cancer UK as part of True NTH programme. Conflicts of interest: No conflicts of interest to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	"After providing consent, men were randomised by the research nurse (using sealed brown paper envelopes to conceal allocation)"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"it was not possible to blind participants as to the intervention". Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	“Twenty-one were randomly assigned to Arm A (usual care) and n = 56 to Arm B or C (which included giving patients additional chosen products). After catheter removal, 27 men (five from Arm A and 22 from Arm B or C) did not have urinary leakage and therefore did not need to use the CP-PDA”. No flow diagram; participants excluded after randomization because did not have urinary leakage. High rate of attrition: 22/56 (39%) DA and 5/21 (24%) usual care, but difference across groups is not significantly different (P = 0.204978).
Selective reporting (reporting bias)	Unclear risk	Registered (NIHR CPMS 31077) but unable to retrieve record.
Other bias	Low risk	The study appears to be free of other sources of bias.

Murray 2001a

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	57 + 55 men considering treatment for benign prostatic hypertrophy in the UK

Murray 2001a *(Continued)*

Interventions	DA: Health Dialog interactive videodisc on options, outcomes, clinical problem, outcome probability, others' opinions. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care
Outcomes	Primary outcomes: uptake of option, prostate symptoms, costs, anxiety Secondary outcomes: decisional conflict, role in decision-making, general health status, utility
Notes	Source of funding: NHS national research and development programme, the BUPA Foundation, and the Kings's Fund. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 4)
Allocation concealment (selection bias)	Low risk	"Allocation were sealed in opaque numbered envelopes, opened by the study nurse" (p 4)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded but not sure how this would introduce bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 5); baseline data/characteristics included and balanced
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Appears to be free of other sources of bias.

Murray 2001b

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	102 + 102 women considering hormone replacement therapy in the UK
Interventions	DA: Health Dialog interactive videodisc on options outcomes, clinical problem, outcome probability, other's opinion. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care

Murray 2001b *(Continued)*

Outcomes	Primary outcomes: preferred option Secondary outcomes: help with making a decision, decisional conflict, role in decision-making, anxiety, menopausal symptoms, costs, utility, general health status
Notes	Source of funding: BUPA Foundation and the King's Fund Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomisation schedule, stratified according to recruitment centre, was generated by computer" (p 3 Methods, Randomization)
Allocation concealment (selection bias)	Low risk	"Allocations were sealed in opaque numbered envelopes, opened by the study nurse after collection of the baseline data" (p 3 Methods, Randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See page 3 figure for progress of patients through trial
Selective reporting (reporting bias)	Unclear risk	Protocol is not mentioned
Other bias	Low risk	Similar baseline characteristics; appears to be free of other potential biases. Educational achievement was higher in control group. Quote "Subsequent analysis showed that educational level not related to use of HRT nor was there an interaction between educational attainment and the intervention".

Nagle 2008

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care
Participants	167 + 172 women in early pregnancy considering genetic testing (26 + 29 general physicians) (cluster-RCT with 60 general practitioners randomized) in Australia
Interventions	DA: 24-page booklet and worksheet on options, benefits and risks, test limitations, outcomes; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework). The DA is available at https://www.mcri.edu.au/images/documents/migrate/prenatal-screening-decision-aid.pdf . Comparator: standard pamphlet on prenatal testing

Nagle 2008 *(Continued)*

Outcomes	Primary outcomes: informed choice, decisional conflict Secondary outcomes: anxiety, depression, attitudes toward pregnancy, acceptability of the intervention, choice
Notes	Source of funding: This project was funded by the National Health and Medical Research Council (Project Grant 237124). J.H. and B.M. are both supported by Career Development Awards (ID 350989 and 216741, respectively). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers (p 3)
Allocation concealment (selection bias)	Low risk	Computer-generated random numbers by an independent statistician; allocation concealment was achieved (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Due to the nature of the intervention, it was not possible to blind women, GP's or researchers" (p 3); unclear if this would introduce bias to outcome assessed
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were not blinded, but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results, p 4; Fig 1 - flow diagram, p 5
Selective reporting (reporting bias)	Low risk	Trial Registration - The ADEPT trial was registered in the UK with Current Controlled Trials [ISRCTN22532458] and with the Australian Clinical Trials Registry (No: 012606000234516) (p 4).
Other bias	Low risk	Appears to be free of other potential biases (p 8); selection bias but was adjusted for in analysis. Free of other potential biases: adjustment for clustering performed.

Nassar 2007

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	102 + 98 women diagnosed with a breech presentation from 34 weeks gestation considering external cephalic version in Australia
Interventions	DA: 24-page booklet, 30-minute audio-CD and worksheet; clinical problem, outcome probability, explicit values clarification, opinions of others', guidance (Ottawa Decision Support Framework). The DA is no longer available (http://sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php).

Nassar 2007 *(Continued)*

	Comparator: usual care counseling and information on the management of breech presentation
Outcomes	Primary outcomes: knowledge, decisional conflict, anxiety, satisfaction with the decision Secondary outcomes: preferred role in decision-making, preferred choice
Notes	Source of funding: This study was supported by an Australian National Health and Medical Research Council project grant (211051). Natasha Nassar is funded by an Australian National Health and Medical Research Council Public Health Postgraduate Research Scholarship. Christine Roberts is funded by an Australian National Health and Medical Research Council Public Health Practitioner Fellowship. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[R]andomly generated using computer and stratified by parity and center using random variable block sizes" (p 2)
Allocation concealment (selection bias)	Low risk	"[P]articipants were randomized by telephoning a remote, central location" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Womens were not blinded - unclear if this would introduce bias to the outcome assessed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up because of onset of labor or incomplete data forms (p 3). Baseline characteristics are included and equal. Minimum of 84 participants in each study group achieved; p 4 - flow diagram.
Selective reporting (reporting bias)	Low risk	ISRCTN14570598
Other bias	Low risk	"Maternal characteristics and baseline measures of cognitive and affective outcomes were comparable between groups" (p 3 Results, Table 1) "Blinding clinicians and employment of a research midwife to interact with women" (p 6)

Oakley 2006

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	16 + 17 postmenopausal women with osteoporosis considering treatment options to prevent further bone loss in the UK
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinions, guidance (Ottawa Decision Support Framework). The DA is no longer available (decisionaid.ohri.ca/decaids-archive.html). The authors have a PDF copy.

Oakley 2006 *(Continued)*

	Comparator: usual care
Outcomes	Satisfaction with information, decisional conflict (intervention group only), improvement in adherence
Notes	Primary outcome was not specified Source of funding: Unrestricted educational grants to support this work were provided by Eli Lilly & Co Ltd, Merck Sharp & Dohme Ltd, and Starakan. The Medicines Partnership provided practical support and funded production of the decision aid. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Low risk	Group allocation was done by a third party, unconnected to the study and blinded to the identity of the patients (p 1).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear blinding; some outcomes were assessed by open-ended questions; do not know whether this contributes to risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Sample characteristics not included; baseline satisfaction score included. "No evaluation was carried out to determine the reasons for non-participation" (p 2)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	No baseline characteristics (p 2). Only 16 patients in the intervention group and 17 in the control group; small sample size.

Omaki 2021

Study characteristics

Methods	Randomized to decision aid vs attention matched health risk assessment
Participants	65 + 59 individuals aged 18 and older visiting the emergency department for an injury or pain-related complaint in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that included clinical information, explicit values clarification, guidance in decision-making (step-by-step process), guidance in communication, tailored summary based on the patient's risk assessment and self-identified priorities that is emailed to the patient, and other elements (e.g. SURE test, knowledge test, feedback on doctor visit). **Note: the DA was previously illustrated via https://myhealthychoices.nursing.jhu.edu but is no longer available.*

Omaki 2021 *(Continued)*

	Comparator: attention matched health risk assessment
Outcomes	Comfort level with pain medication options, knowledge, decisional conflict, and shared decision-making. Actual choice also reported.
Notes	Source of funding: This work was supported by a grant from the National Center for Injury Control and Prevention, Centers for Disease Control and Prevention (grant number 1R49CE002466). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated roster in a 1:1 ratio
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate but missing data similar across arms (P = 0.942989)
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT03012087) and one or more outcomes relevant to the review were not pre-specified (decisional conflict, shared decision-making).
Other bias	Low risk	The study appears to be free of other sources of bias.

Oostendorp 2017

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	83 + 45 patients considering second-line palliative chemotherapy for advanced breast or colorectal cancer in the Netherlands
Interventions	DA: decision aid used during consultation with the nurse that included clinical information, outcome probabilities, explicit values clarification, guidance in communication, and a summary of all the information provided. A booklet with information tailored to the patient's desire was available to take home. The DA is available as a supplementary appendix in the article. Comparator: usual care (information about the treatment choice from their oncologist)
Outcomes	Primary outcome: well-being (anxiety, depression, general health, cancer worries, health-related quality of life)

Oostendorp 2017 *(Continued)*

	Secondary outcomes: coping (including perceived participation, perceived involvement), information-related measures (e.g. amount of information, satisfaction with quality of information, balanced presentation), knowledge (objective and subjective), risk perception (objective and subjective), decision-related measures (decision satisfaction-uncertainty, decision control, weighing pros and cons, treatment choice, strength of treatment preference), and treatment attitudes
Notes	Source of funding: This work was supported by the Dutch Cancer Society (grant number KUN 2006-3465). Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Unequal randomisation (using a 1:2 ratio) was used because the sample size of the control group was based on the current evaluation of the DAs, while the sample size of the intervention group was based on more detailed analyses of patients' desire for information. Randomisation lists were computer generated per hospital and tumour type, using a block size of 3."
Allocation concealment (selection bias)	Low risk	"When a patient included in the study experienced disease progression and was offered second-line chemotherapy, randomisation was performed. A nurse would open a sealed envelope to find out whether the patient would either:…oncologists were not aware of the allocation prior to randomisation"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Another limitation inherent to the nature of DAs is that complete blinding was not possible." In protocol: "Blinding of the medical oncologists and the patients is not feasible in this type of research, because patients may want to discuss the information from the decision aid with their oncologist. However, patients are blinded to the intervention in that they are not aware of the exact content of the decision aid; they are only informed that a new method of information giving is investigated. Nevertheless, oncologists were not aware of the allocation prior to randomisation." It is unclear how the knowledge of which group patients were allocated to influenced the oncologists and nurses in their delivery of the intervention and control.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Substantial proportion of patients withdrew from the study; however, difference is not significant across groups: 1-week missing data 15/83 (18%) in the DA group and 5/45 (11%) in the control P = 0.300373; 8-week missing data 25/83 (30%) in the DA group and 12/45 (27%) in the control (P = 0.680666). Reasons for loss to follow-up not reported.
Selective reporting (reporting bias)	Low risk	Netherlands Trial Registry (NTR): NTR1113; protocol published; provides in appendix changes from published study and protocol
Other bias	Low risk	The study appears to be free of other sources of bias.

Osaka 2017

Study characteristics

Osaka 2017 *(Continued)*

Methods	Randomized to DA with patient narratives vs DA without patient narratives vs standard information booklet (provided to all arms)
Participants	70 + 70 + 70 women newly diagnosed with early-stage breast cancer in Japan
Interventions	DA: paper-based decision aid that included clinical information, probabilities of outcomes, explicit values clarification, patient narratives, guidance in decision-making (step-by-step process), and guidance in communication. The decision aid is publicly available at https://www.healthliteracy.jp/decision-aid/decision/breast-surgery.html . Comparator: standard information booklet about the condition and options
Outcomes	Primary outcome: decisional conflict Secondary outcomes: satisfaction with decision-making, anxiety
Notes	Source of funding: This work was supported by the Japan Society for the Promotion of Science Grants-in-Aid for Scientific Research (KAKENHI) Grant Number JP25670928. Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Women were randomly assigned to one of two intervention groups or a control group using a prior computer-generated random-number sequence. Block randomization was performed with a randomly selected block of six."
Allocation concealment (selection bias)	Low risk	"Allocation was performed in a different order in each block to ensure the investigators were blinded. A serially labeled opaque sealed-envelope method was used for block randomization."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"It was impossible to blind the participants to whether they had been allocated to an intervention or a control group; however, participants in the intervention groups were blinded to the difference between the two intervention groups. Health care professionals were blinded to the groups to which participants had been allocated." It is unclear how knowledge of their allocation could have influenced participant's responses to subjective measures (e.g. satisfaction with decision-making).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram. High rate of attrition post-intervention but balanced across groups: DA with narratives 13/70 (18.6%); control 16/70 (22.9%). Primary and secondary variables with > 25% missing responses or patients lost to follow-up were managed by the last observation carried forward imputation method.
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	Exclusion criteria include: "answered questionnaire inconsistently". Potential selection bias: "Our subjects were more highly educated and younger than those in previous studies of Japanese women with breast cancer. However, their staging was similar to that of population-based breast cancer data in Japan. Our single-center setting in a metropolitan area may have introduced selection bias."

Ozanne 2007

Study characteristics	
Methods	Randomized to decision aid + standard counseling vs usual care (standard counseling)
Participants	15 + 15 women considering breast cancer prevention in the USA
Interventions	DA (in consultation): interactive computer decision aid on options outcomes, outcome probability. The DA is not publicly available. A demo copy was obtained from the author. Comparator: standard counseling
Outcomes	Primary outcomes: consultation length Secondary outcomes: knowledge, decisional conflict, satisfaction with the decision, acceptability of the decision aid, physician satisfaction with the consultation
Notes	Source of funding: Pell Family Foundation Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Patients were randomized evenly between groups; no information provided about generation (p 149)
Allocation concealment (selection bias)	Unclear risk	No information provided (p 149)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Demographic data included; reasons for attrition mentioned
Selective reporting (reporting bias)	Unclear risk	No reference to study protocol
Other bias	Unclear risk	Small sample size; does not say how many physicians participated in study; mentions that there were observed changes in physician behavior (based on doing both intervention and control).

Partin 2004

Study characteristics

Partin 2004 *(Continued)*

Methods	Randomized to decision aid with others' opinions vs decision aid without others' opinions vs usual care
Participants	384 + 384 + 384 men considering PSA testing in the USA
Interventions	DA: Health Dialog video on options' outcomes, clinical problem, outcome probability, others' opinions. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator 1: pamphlet on options' outcomes, clinical problem, outcome probability Comparator 2: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: preferred option, help with making a decision, decisional conflict
Notes	Source of funding: Funded by VA Health Services Research and Development Service grant #IIR 99 277–1 to the Center for Chronic Disease Outcomes Research, Veterans Affairs Medical Center, Minneapolis, Minn. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a computer-generated algorithm (p 2)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"[P]roviders were blinded to the fact that their patients were participating in a trial", "coordinator did not have direct contact with subjects" (p 5)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[F]ollow-up interviewers blinded, statisticians were not". Outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reasons for attrition mentioned and participants balanced across study groups. Sample characteristics included.
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Appears to be free of other potential biases.

Patzer 2018

Study characteristics

Methods	Randomized to decision aid + education (standard of care) vs education alone (standard of care)

Patzer 2018 *(Continued)*

Participants	238 + 232 patients 18 to 70 years with end-stage renal disease in the USA
Interventions	DA: mobile and web-based application decision aid used during consultation that includes information on the clinical condition, probabilities of outcomes, implicit values clarification, individualized risk prediction tool, and risk report that can be printed. The DA is publicly available at https://ichoosekidney.emory.edu/ . Comparator: education
Outcomes	Primary outcome: knowledge Secondary outcomes: access to transplant, decisional conflict, patient treatment preferences, provider opinions
Notes	Source of funding: Norman S. Coplon Satellite Healthcare Foundation Conflicts of interest: The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"... research assistants obtained informed consent and randomized patients 1:1 with a random number generator application via iPad"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Given the nature of the intervention, neither patients nor providers were blinded to the study group assignment." "Additional limitations included the inability to blind patients to the intervention, which could have confounded study results, and the inability to examine long-term effects of iChoose Kidney use on patient transplant knowledge."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low attrition rate and similar across arms (less than 10%), reasons for attrition recorded
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT02235571) and the secondary outcome of decisional conflict was not prespecified.
Other bias	Low risk	The study appears to be free of other sources of bias.

Perestelo-Perez 2016

Study characteristics

Methods	Cluster-randomized to decision aid vs usual care
Participants	15 physicians (86 patients) + 14 physicians (82 patients) of patients aged 18 and older with type 2 diabetes in Spain

Perestelo-Perez 2016 *(Continued)*

Interventions	DA: online decision aid used during consultation that includes clinical information, probabilities of outcomes, implicit values clarification, an individualized risk prediction tool, and summary report. The DA is publicly available at https://statindecisionaid.mayoclinic.org/ . Comparator: usual care (no details provided)
Outcomes	Knowledge about statins, perception of cardiovascular risk, decisional conflict, satisfaction with the decision-making process, taking statins at 3 months, adherence at 3 months, consultation time, anxiety, diabetes-related stress
Notes	Source of funding: This study was supported by the Spanish Ministry of Health, Social Services and Equality (grant number: EC10-005). Conflicts of interest: The authors have no conflict of interest to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Physicians who consented to participate were randomized to intervention or usual care by means of a computer-generated list."
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Open-label according to trial protocol. Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram with high attrition rate of 22% for both groups. Reasons for loss to follow-up not provided.
Selective reporting (reporting bias)	Low risk	The study protocol is available (EudraCT: 2010-023912-14) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	High risk	Clustering was not accounted for in the analysis. Selective recruitment of cluster participants: physicians were encouraged to recruit at least 13 patients each (high risk).

Perestelo-Perez 2017

Study characteristics

Methods	Randomized to decision aid vs no intervention
Participants	68 + 79 adults 18 years and older with a major depressive disorder in Spain
Interventions	DA: web-based decision aid that was reviewed in the company of a researcher that included clinical information, probabilities of outcomes, explicit values clarification, guidance in decision-making (8-step

Perestelo-Perez 2017 *(Continued)*

	process), and summary of preferences, concerns, and decision certainty that can be used to ask questions to healthcare professionals. The DA is publicly available at https://pydesalud.com/depresion/ . Comparator: no intervention
Outcomes	Primary outcome: decisional conflict Secondary outcomes: knowledge, treatment intention, decisional control preferences, concordance between patients' goals/concerns
Notes	Source of funding: Canary Islands Agency for Research, Innovation, and Society of Information, Grant/Award Number: ProID20100251 Conflicts of interest: The authors have no conflict of interest to declare.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A simple randomization schedule (ratio 1:1) to intervention (web-based DA) or control group (usual care) was performed by an independent researcher, by means of computer software.
Allocation concealment (selection bias)	Low risk	Both physicians and the researcher who informed and recruited the patients were unaware of patients' allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not explicitly reported: a second limitation is that blinding of participants is difficult with these interventions, and therefore, a "novelty" or "attention" effect cannot be ruled out.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Statistical analyses were performed by a researcher blinded to participants' allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, none lost to follow-up
Selective reporting (reporting bias)	Unclear risk	Trial registered with the European Union Clinical Trials Register (EudraCT: 2012-001673-9), unable to locate registration.
Other bias	Low risk	The study appears to be free of other sources of bias.

Perestelo-Perez 2019

Study characteristics	
Methods	Randomized to decision aid vs control (no decision aid)
Participants	53 + 54 adults aged 50 to 69 with no previous colorectal cancer screening in Spain
Interventions	DA: web-based decision aid that was reviewed in the company of a researcher that included clinical information, probabilities of outcomes, explicit values clarification, guidance in decision-making (8-step process), and summary document including content explored and participant responses regarding their preferences. The DA is publicly available at https://pydesalud.com/cancer-colorrectal/ .

Perestelo-Perez 2019 *(Continued)*

	Comparator: no decision aid
Outcomes	Primary outcome: decisional conflict Secondary outcomes: knowledge, intention to undergo screening, congruence between values and intention to be screened
Notes	Source of funding: This study was supported by the Spanish Ministry of Economy, Industry and Competitiveness (Carlos III Institute, Spain) (Grant number: PI12/00509). Funders have had no role in the study design, the collection, analysis, and interpretation of data, the writing of the article or the decision to submit it for publication. Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-based simple randomization was performed by a statistician not involved in the study.
Allocation concealment (selection bias)	Low risk	Computer-based simple randomization was performed by a statistician not involved in the study, and the researcher who recruited participants and established an appointment by phone was blinded to allocation (used a centralized off-site computer allocation process).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"the researcher who recruited participants and established an appointment by phone was blinded to allocation". There is no mention of blinding the participants.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses to follow-up, ITT analysis
Selective reporting (reporting bias)	Unclear risk	Retrospectively registered, ISRCTN98108615; outcome identified matches outcomes in main article. However, unclear bias from retrospective registration.
Other bias	Unclear risk	The absence of intervention in the control group may introduce a “novelty effect” in favor of the DA…Regarding external validity, a selection bias could be present since they recruited participants in primary care centers, who might not be completely representative of the population targeted for CRC screening.

Perez-Lacasta 2019

Study characteristics

Methods	Randomized to decision aid vs control (standard leaflet)
Participants	260+264 woman aged 49 to 50 that in 2 to 4 months were going to be invited to participate in a breast cancer screening program for the first time in Spain

Perez-Lacasta 2019 *(Continued)*

Interventions	DA: paper-based leaflet that included clinical information, implicit values clarification, and probabilities of outcomes. The DA is available as a supplementary appendix in the article. Comparator: standard leaflet that recommended accepting the invitation to participate in the breast cancer screening program
Outcomes	Primary outcome: informed choice (knowledge and intentions consistent with attitudes) Secondary outcomes: attitudes towards breast screening, intentions about breast screening, decisional conflict, confidence, anxiety, anticipated regret, temporal orientation, perceived risk, participated in screening program, opinions about the DA and control leaflets
Notes	Source of funding: “Women participation in decisions and strategies on early detection of breast cancer” (PI14/00113) from the Instituto de Salud Carlos III and cofunded by Fondo Europeo de Desarrollo Regional (FEDER)“Una manera de hacer Europa.” Anna Pons received a grant for PhD students from the Lleida Biomedical Research Institute. Conflicts of interest: The authors have declared that no competing interests exist.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The study was designed as a parallel two-stage randomised 1:1 controlled trial (RCT). In the first stage, elementary territorial units of the healthcare system named Basic Health Areas (BHAs) were stratified by socioeconomic level [14] and 40 of them were selected and randomised to intervention or control using computer-generated blocks of size two. In the second stage, random samples of 30 to 50 women within each BHA were obtained."
Allocation concealment (selection bias)	Low risk	"The random allocation sequence was generated by a statistician with no contact with the participants (MR)"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported in the main article. In the published protocol: "It will not be possible to blind the intervention to the interviewers and participants". Study does not report on how the results could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high attrition rate but balanced across groups: 57/260 (22%) in the decision aid group and 67/264 (25%) in the control group (P = 0.352074).
Selective reporting (reporting bias)	Low risk	The trial protocol is available (NCT03046004) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	"only 56% of women in the initially selected sample could be reached and only around 38% of those invited completed the study. Thus, recruitment or dropout biases may limit, to some extent, the generalisation of our results to the target screening population"

Pignone 2000

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	125 + 124 adults considering colon cancer screening in the USA
Interventions	DA: video of options' outcomes, clinical problem, others' opinion. The DA is no longer available (http://www.med.unc.edu/medicine/edusrc/colon.htm). Comparator: video on car safety
Outcomes	Primary outcome: uptake of options
Notes	Source of funding: By the National Cancer Institute, Robert Wood Johnson Foundation Clinical Scholars Program, and University of North Carolina–Lineberger Comprehensive Cancer Center. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2, Methods, Group assignment)
Allocation concealment (selection bias)	Low risk	"[R]andomization was performed centrally and was not balanced among centers. Assignments were placed in sealed, opaque, sequentially numbered envelopes and were distributed to the three sites" (p 2, Methods, Group assignment)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"The providers and staff were not blinded to intervention status", "3 to 6 months after, different RA blinded to participant intervention examined clinic records" (p 2) Does not mention whether patients were blinded; unclear if lack of blinding contributed to potential risk of bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	A different research assistant who was blinded to participants' intervention status examined participants' clinic records in a standardized and validated manner to determine whether colon cancer screening tests were actually completed within 3 months of the index visit.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Because of an administrative error, 18 controls did not complete the second and third questionnaires (p 4).
Selective reporting (reporting bias)	Unclear risk	Protocol was not mentioned.
Other bias	Low risk	Baseline characteristics similar; appear to be no other potential sources of biases. Minimized bias from repeated measurements by administering the same questionnaires to the intervention and control participants.

Politi 2020a

Study characteristics

Politi 2020a *(Continued)*

Methods	Randomized to decision aid vs information
Participants	60 + 60 women aged 18+, English-speaking with stages 0–III breast cancer, who were considering a referral or were referred to 1 of 4 plastic/reconstructive surgeons in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, explicit values clarification, patient narratives, guidance in decision-making (step-by-step process), guidance in communication, and summary that includes risks, personal values, and things to think about to discuss with the doctor. The DA is not publicly available; a copy was provided by the author (Mary C. Politi; mpoliti@wustl.edu). Comparator: information pamphlet
Outcomes	Primary outcomes: knowledge, decisional conflict, decision process quality Secondary outcomes: treatment preferences and preference concordance, quality of life, patient activation, shared decision-making, treatment received, implementation outcomes (time spent using DA, consultation time, usability of DA)
Notes	Source of funding: This work was supported by Siteman Cancer Center through a Siteman Investment Program Pre-R01 Award, funded by the Cancer Frontier Fund through the foundation for Barnes-Jewish Hospital and Siteman Cancer Center, to Drs TMM and MCP. Conflicts of interest: MCP has a research contract (2017–2019) from Merck & Co. on a topic unrelated to the content of this article. MAO has grant funding from Pfizer, Merck, and Sanofi Pasteur, and is a consultant for Pfizer on topics unrelated to the content of this article. TMM is a consultant for, received advisory board remuneration, and received investigator-initiated grant funding from Allergan Medical and RTI Surgical, on topics unrelated to the content of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomized via computer random number generator, block size of 4, to 1 of 2 study conditions.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (all randomized included in analysis as per figure), "The percentage of missing data on items in analyses ranged from 1% to 6.7%. Missing data were considered missing at random and excluded, except missing BREAST-Q data which were imputed according to guidelines"
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03346161) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Protheroe 2007

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	60 + 56 women considering treatment options for menorrhagia in the UK
Interventions	DA: interactive computerized DA on options' outcomes, clinical problem, outcome probability, explicit values clarification, guidance. The computerized decision aid and Clinical Guidance Tree is no longer in existence; author sent chapter in thesis. Comparator: information leaflet
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, anxiety, condition-specific health outcomes, treatment preference, undecided
Notes	Source of funding: Financial support for this study was provided entirely by a grant from the Medical Research Council to Dr Protheroe with a Training Fellowship in Health Services Research G106/1048. The funding agreement ensured the author's independence in designing the study, interpreting the data, and writing and publishing the report. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomization, stratified by practice and minimized according to age (p 2, Methods)
Allocation concealment (selection bias)	Unclear risk	Random allocation was concealed from the individual who was making judgments of eligibility, but the method of concealment was not stated (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig 6 flow diagram (p 5); baseline data/characteristics included and balanced (p 4)
Selective reporting (reporting bias)	Low risk	ISRCTN72253427
Other bias	Low risk	Appears to be free of other potential biases.

Reuland 2017

Study characteristics	
Methods	Randomized to decision aid + navigation vs control
Participants	133 + 132 participants aged 50 to 75 with average colorectal cancer risk in the USA
Interventions	DA: video decision aid used in preparation for consultation that included clinical information, explicit values clarification, patient testimonies, and a 1-page summary about the decision. Navigators met participants immediately after their clinician encounter and assisted in carrying out the screening plan. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: attention control (education on another topic)
Outcomes	Primary outcome: completion of screening test Secondary outcomes: knowledge, self-efficacy (data not reported), intention to be screened
Notes	Source of funding: This study was funded by the American Cancer Society (grant RSG-13-165-01–CPPB). Dr Brenner was supported by the Agency for Healthcare Research Quality's National Research Service Award (grant No. 5-T32HSHS000032). Dr Weaver was also supported by the National Center for Advancing Translational Sciences, National Institutes of Health (grant No. 1UL1TR001111-01). Pilot work for this study was funded by University of New Mexico Clinical and Translational Science Center (grant No. 8UL1TR000041) and the North Carolina Translational and Clinical Sciences Institute at the University of North Carolina (grant No. 1UL1TR001111) and the UNC Lineberger Comprehensive Cancer Center. This study was supported in part by a grant from NIH (DK056350) to the University of North Carolina Nutrition Obesity Research Center OR from NCI (P30-CA16086) to the Lineberger Comprehensive Cancer Center. Conflicts of interest: Dr Pignone is a member of the US Preventive Services Task Force. The views presented herein are not necessarily those of the Task Force.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomized 1:1 to intervention or control groups using sequentially numbered, opaque, sealed envelopes generated by the study biostatistician (use of computer implied).
Allocation concealment (selection bias)	Low risk	Participants were randomized 1:1 to intervention or control groups using sequentially numbered, opaque, sealed envelopes generated by the study biostatistician.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"... research assistant conducting the enrollment and index visit data collection will also be the patient navigator, and therefore it is not feasible to blind the research assistant to treatment assignment after randomization occurs. However, a separate, blinded member of the research team will determine the primary study outcome of CRC screening test completion (based on medical record review at six months). In addition, the study biostatistician will program the primary models for addressing each of the aims using dummy treatment assignments and will remain blinded to actual treatment assignments until the models, along with any related assumptions, have been assessed and finalized."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"... research assistant conducting the enrollment and index visit data collection will also be the patient navigator, and therefore it is not feasible to blind the research assistant to treatment assignment after randomization occurs. However, a separate, blinded member of the research team will determine the primary study outcome of CRC screening test completion (based on medical

Reuland 2017 *(Continued)*

		record review at six months). In addition, the study biostatistician will program the primary models for addressing each of the aims using dummy treatment assignments and will remain blinded to actual treatment assignments until the models, along with any related assumptions, have been assessed and finalized." Also, outcomes objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, all included in analysis
Selective reporting (reporting bias)	Unclear risk	Registered (NCT02054598) and protocol published. Outcomes across article, registry, and protocol are similar except for self-efficacy not being reported in main article or intermediate outcome analysis.
Other bias	High risk	There is a mismatch of randomized participants between the main article (DA 133, control 132) vs intermediate outcomes analysis paper (DA 134, control 133).

Rivero-Santana 2021

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	97 + 96 adults with knee OA who are candidates for total knee replacement in Spain
Interventions	DA: online decision aid used in preparation for consultation that includes clinical information, probabilities of options, explicit values clarification, knowledge test, and a summary of patient's responses and comparison tables that is automatically generated and sent to her/his email. The DA is not publicly available; a copy was provided by the author (A. Rivero-Santana; amado.riverosantana@sescs.es) Comparator: usual care (no details provided)
Outcomes	Primary outcome: decisional conflict Secondary outcomes: knowledge, satisfaction with the decision-making process, treatment preference, having undergone surgery at 6 months follow up, decision regret
Notes	Source of funding: This work was funded by the Instituto de Salud Carlos III, Ministry of Health, Spain (grant number PI15/01264). The funding source had no role in the design, execution, analyses, interpretation of the data, or the decision to publish the results. Conflicts of interest: Authors have no competing interests to declare.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Patients with knee OA were randomized to intervention (i.e. reviewing the patient DA accompanied by a researcher) or usual care (ratio 1:1). Computer-based simple randomization, stratified by recruitment setting (hospital/primary care), was performed centrally by a statistician not involved in the study.
Allocation concealment (selection bias)	Low risk	Computer-based simple randomization, stratified by recruitment setting (hospital/primary care), was performed centrally by a statistician not involved in the study. Patients' allocation to intervention (patient DA) or usual care was

Rivero-Santana 2021 *(Continued)*

		concealed by means of sealed envelopes, which were open only after patients signed informed consent.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Due to the nature of the intervention, researchers and patients could not be blinded. The researchers who assessed 6-month outcomes by telephone were also non-blinded. The impossibility of blinding patients and researchers to the intervention introduces an inherent risk of performance bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in analysis; loss to follow-up similar between arms; justifications provided for loss to follow-up.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03254771). "Another modification of the protocol was carried out, after the beginning of the trial: the follow up was increased as much as possible within the time limits of the project (from 3 to 6 months), in order to assess TKR rates, not included previously as an outcome measure."
Other bias	Low risk	The study appears to be free of other sources of bias.

Roberto 2020

Study characteristics	
Methods	Randomized to decision aid vs control (standard brochure)
Participants	1073 + 1046 women aged > 45 with no history of breast cancer in Italy
Interventions	DA: web-based decision aid that includes clinical information, probablilities of options, explicit values clarification with a summary of answers that can be printed. The DA is publicly available at: https://www.donnainformata-mammografia.it/en/ . Comparator: web-based brochure that includes clinical information, probabilities about repeat or more in-depth exams and false positives
Outcomes	Primary outcome: informed choice (knowledge and consistent attitude and intention) Secondary outcomes: participation rate, satisfaction with information, decisional conflict, time spent on the platform, DA acceptability
Notes	Source of funding: This project won a competitive grant of Italian Association for Cancer Research IG2015-17274. Conflicts of interest: A.R., C. Colombo and P. Mosconi report grants from Italian Association for Cancer Research, competitive grant no. IG2015–17274, during the conduct of the study; G.C., R.S. and E.P. report grants from Mario Negri IRCCS Institute, during the conduct of the study; L.G. reports grants from Mario Negri IRCCS Institute and Gisma (Italian group that organised mammography screening) during the conduct of the study; P. Mantellini and M.V. report grants from Gisma (Italian group that organised mammography screening) during the conduct of the study. Authors not named here have disclosed no conflict of interest.
Risk of bias	

Roberto 2020 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study protocol: the random allocation will be on a 1:1 basis, provided by a computer-generated allocation sequence.
Allocation concealment (selection bias)	Unclear risk	Not enough details (from protocol): "Women of this age in each screening center, will receive an invitation letter to the trial with a personal code number for registering on the platform. All code numbers will be extracted and transferred from the screening centers to the platform."
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding, unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Flow diagram; a high rate of attrition and numbers are not balanced across groups: 472/1073 in the DA group and 529/1046 in the control group analyzed (P = 0.002401).
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03097653) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	Potential selection bias: "Participating women had a high level of education, which limits the generalisability of findings, in agreement with other studies. Most of the participants had already had a mammography before the invitation to the organised screening programme. This suggests that many had already received information that could have fostered the attitude and intention reported in this study. Finally, in order to participate, women had to have basic information technology skills. It is likely that technical developments will offer more user-friendly tools for sharing information, increasing users' knowledge and facilitating decision-making in complex healthcare areas, such as mammography screening."

Rubel 2010

Study characteristics	
Methods	Randomized to pretest + decision aid + post-test vs decision aid + post-test vs pretest + posttest vs posttest
Participants	50 + 50 + 50 + 50 men considering prostate cancer screening in the USA
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + pretest and post-test. The DA is no longer available; a copy was obtained from the authors. Comparator: booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + post-test Comparator: pretest + post-test Comparator: post-test

Rubel 2010 *(Continued)*

Outcomes	Knowledge (pre, post-DA), decisional anxiety (post-DA), decisional conflict (post-DA), participation in decision-making (pre, post-DA), schema for PSA testing (pre, post-DA), perception of quality and interpretation of recommendation (post-DA)
Notes	Primary outcome was not specified Source of funding: This study was funded by the Centers for Disease Control and Prevention (CDC) Contract No. 200-2002-00574, Task 18. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Electronically generated random number sequence (p 309, Study design section)
Allocation concealment (selection bias)	Low risk	They were given sealed, sequentially numbered packets (p 309, Study design section).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No mention of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, but the outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol followed CONSORT checklist (p 310, Study design section).
Other bias	Low risk	Appears to be free of other potential biases.

Ruffin 2007

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	87 + 87 community-dwelling adults not previously screened for CRC in the USA
Interventions	DA: interactive website with information on options' outcomes, clinical problem, outcome probability, explicit values clarification, others' opinion, guidance. The DA is no longer available (colorectalweb.org). Comparator: non-interactive website with information on clinical problem
Outcomes	Primary outcome: uptake of option

Ruffin 2007 *(Continued)*

Notes	Source of funding: Michigan Department of Community Health and the National Cancer Institute provided funding for this research. Dr. Ruffin's participation was also made possible by support from the National Cancer Institute (K24-CA80846-010). Dr. Fetters' participation was also made possible in part by the generous support of the Robert Wood Johnson Foundation Generalist Physician Faculty Scholars Program. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A block randomisation process programmed by the study computer support staff and verified by a statistician was used including two strata, race and gender" (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Both blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The investigators, data collectors, data entry, and data analyst were all blinded to study arm assignment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Saunier 2020

Study characteristics

Methods	Cluster-randomized to decision aid vs control
Participants	41 + 42 hospital departments including 3547 hospital healthcare workers in France
Interventions	DA: paper-based leaflet that included clinical information, outcome probabilities, explicit values clarification, knowledge test, SURE test, and guidance in decision-making (4-step process). The DA is not publicly available; a copy was provided by the author (Amandine Gagneux-Brunon; amandine.gagneux-brunon@chu-st-etienne.fr). Comparator: control (no details provided)
Outcomes	Vaccine coverage Decisional conflict and knowledge assessed in DA group only

Saunier 2020 *(Continued)*

Notes	Source of funding: This work was supported by a grant dedicated to research on vaccine of the group ‘‘Prevention vaccination” of la Société de Pathologie Infectieuse de Langue Française (SPILF). Conflicts of interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The block randomization was centralized and stratified on the number of HCWs in the departments, and on the vaccine coverage during the 2017–2018 Flu season". The investigators describe the use of stratification or permuted blocking (use of computer implied).
Allocation concealment (selection bias)	Low risk	"The block randomization was centralized and stratified on the number of HCWs in the departments, and on the vaccine coverage during the 2017–2018 Flu season" (Central allocation)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No flow diagram; difficult to understand flow of participants in both study groups
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	High risk	No information about procedures for the control group. Clustering was not accounted for in the analysis. Selective recruitment of cluster participants is not addressed. There does not seem to be any formal process for recruiting participants: "One thousand leaflets were distributed in all the departments included in the intervention group". Unclear how many in each group actually received intervention or control.

Sawka 2012

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	37 + 37 individuals with early-stage papillary thyroid cancer in Canada
Interventions	DA: web-based decision aid with clinical problem, options' outcomes, outcome probabilities, guidance, printout summary. The DA is not publicly available; a copy was obtained from the authors. Comparator: usual care (consultation with a specialized head and neck surgeon, and with 1 or more medical specialist)

Sawka 2012 *(Continued)*

Outcomes	Primary outcomes: knowledge (baseline and immediately post intervention) Secondary outcomes: decisional conflict, undecided, treatment decision (baseline, immediately post intervention, 6 to 12 months), individual primarily responsible for the treatment decision (6 to 12 months)
Notes	Trial registration: NCT01083550 Source of funding: Supported by a grant from the Ontario Ministry of Health and Long-term Care (Alternate Funding Plan Innovation Fund) and by New Investigator Grant No. CNI-80701 from the Canadian Institutes of Health Research (A.M.S.). A.M.S. holds a Chair in Health Services Research from Cancer Care Ontario, funded by the Ontario Ministry of Health and Long-term Care. S.S. holds a Tier 1 Canada Research Chair. Conflicts of interest: The author(s) indicated no potential conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Central computerized randomization in a 1:1 ratio was performed at a patient level by using variable block sizes of 2 and 4 (allocation designed by a study statistician)" (p 2908)
Allocation concealment (selection bias)	Low risk	"Before the random assignment/testing visit, neither the participant, study staff, investigators, nor treating physicians were aware of the allocation, because it had not yet been assigned" (p 2908)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed" (p 2908), but it is unlikely that the outcomes are affected by the lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"There was no blinding of participants, study staff, or treating physicians after random assignment was completed. However, the statistician was blinded to the allocation of groups at the time of data analysis." (p 2908)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any missing outcome data.
Selective reporting (reporting bias)	Unclear risk	Authors state the trial is registered, but no link to trial number.
Other bias	Low risk	Appears to be free of other potential sources of bias.

Schapira 2019

Study characteristics

Methods	Randomized to decision aid + risk assessment vs usual care
Participants	104 + 103 women aged 39 to 48 with no prior mammogram in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, probabilities of outcomes, individual risk estimates, explicit values clarification, exemplars of other women considering screening, guidance in decision-making (8-step guide), guidance in communica-

Schapira 2019 *(Continued)*

	tion, and an interactive summary sheet that could be printed or emailed and sent to a mobile device. The link to the DA is no longer functional and we were unable to obtain a copy from the authors. Comparator: risk assessment + usual care
Outcomes	Primary outcomes: strength of association between breast cancer risk and mammography uptake at 12 months, knowledge, and decisional conflict. Secondary outcomes: breast cancer worry, anticipated regret, accuracy of risk perception, and breast cancer screening intentions.
Notes	Source of funding: Financial support for this study was provided the National Cancer Institute–funded consortium, Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) U54CA 163313. The funding agreement ensured the authors' independence in designing the study, interpreting the data, writing, and publishing the report. Conflicts of interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Randomization occurred by concealed assignment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants that were conducting the chart review to assess outcomes were blinded to group assignment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram; < 90% included in analysis but balanced across groups (DA 54/104 (53%) included, control 59/103 (58%) included (P = 0.438807)), no justification for attrition
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Schonberg 2020

Study characteristics

Methods	Cluster-randomized to decision aid vs control
Participants	283 + 262 women aged 75 to 89 years scheduled for a routine or physical examination with their primary care provider in the USA

Schonberg 2020 *(Continued)*

Interventions	DA: paper-based decision aid that includes clinical information, probabilities of outcomes, explicit values clarification, and a health questionnaire to assess individualized benefits for having a mammogram. The DA is available as a supplementary appendix in the article. Comparator: attention placebo control (pamphlet on home safety)
Outcomes	Primary outcome: receipt of mammography screening Secondary outcomes: knowledge, decisional conflict, preferred decision-making role, discussion of mammography with primary care provider, changes in screening intentions.
Notes	Source of funding: This research was supported by the NIH/NCI (R01CA181357) (Dr Schonberg). Dr Marcantonio was supported by a Midcareer Investigator Award in Patient-Oriented Research from the National Institute on Aging (K24 AG035075). Conflicts of interest: Dr Schonberg reported receiving grants from the National Cancer Institute (NCI) and receiving royalties for reviewing an UpToDate page on geriatric health maintenance. Drs Wee, Marcantonio, and Davis reported receiving grants from the National Institutes of Health (NIH). No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomization assignments were determined using a permuted block randomization scheme with randomly varying block sizes.
Allocation concealment (selection bias)	Low risk	Randomization assignments were determined using a permuted block randomization scheme with randomly varying block sizes and were placed in sequentially numbered, sealed envelopes by the statistician (R.B.D.), stratified by site and panel size.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"After the first patient participating for each PCP, RAs were not blinded to patient randomization assignment; however, RAs attempted to recruit all eligible patients".
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research assistants were not blinded to patient randomization assignment, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; > 90% of participants included in analysis; provide justifications for loss to follow-up, similar rate between arms
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02198690) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Schott 2021

Study characteristics

Schott 2021 *(Continued)*

Methods	Cluster-randomized to decision aid vs usual care
Participants	33 + 33 adults aged ≥ 18 years with atrial fibrillation and elevated stroke risk in the USA
Interventions	DA: web-based decision aid used during consultation that includes a personalized risk calculator, clinical information, outcome probabilities, implicit values clarification, guidance in decision-making (step-by-step process), and printable summary of results. **Note: the DA was previously illustrated via* https://www.healthdecision.org/tool#/tool/afib *but is no longer available.* Comparator: usual care
Outcomes	Primary outcome: knowledge Secondary outcomes: decisional conflict, value concordance, shared decision-making, trust in clinician, time spent on each DA page
Notes	Source of funding: This research was supported by the Cardiovascular Fellowship Award from the Dartmouth-Hitchcock Heart and Vascular Center. Conflicts of interest: Dr Coylewright reports honoraria and research funding from Edwards LifeSciences and Boston Scientific, and honoraria from W.L. Gore. The other authors report no conflicts.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A random number generator was accessed online for assignments by study personnel.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded to allocation, yet those in the control arm did not have access to the decision aid; research staff were not blinded to allocation. Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding was not possible with the study design. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram; > 90% included in analysis; justification for participants not included/loss to follow-up; missing data balanced across groups
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	High risk	"Clinicians involved in the usual care arm confirmed they did not use pDAs in their practice." Might contaminate control group if clinicians are aware of intervention being conducted (unclear risk). Selective recruitment of cluster participants: "Final patient selection was based on whether the clinician was planning a real-world discussion of the treatment options surrounding stroke prevention" (high risk). Free of other potential biases: adjustment for clustering performed.

Schroy 2011

Study characteristics	
Methods	Randomized to detailed vs simple decision aid vs control
Participants	223 + 212 + 231 average-risk patients considering CRC screening in the USA
Interventions	Detailed DA: CRC risk assessment + web-based interactive audiovisual DA on options' outcomes, clinical problem, outcome probabilities, others' opinion, and guidance. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator 1: web-based decision aid only Comparator 2: usual care using pamphlet
Outcomes	Knowledge (pre and post-DA), satisfaction with decision-making process (pre and post-DA), preferred choice (pre and post-DA)
Notes	Primary outcome was not specified Source of funding: Agency for Healthcare Research and Quality grant R01HS013912 (PCS) Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No mention of randomization process
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Providers were not blinded, subjective outcomes such as satisfaction with decision-making process could have been affected; unclear if participants were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors not blinded, but outcome measures not believed to be influenced by it.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No data appear to be missing.
Selective reporting (reporting bias)	Unclear risk	No mention of examination of selective outcome reporting or study protocol.
Other bias	Low risk	Appears to be free of other sources of bias.

Schwalm 2012

Study characteristics	

Schwalm 2012 *(Continued)*

Methods	Randomized to decision aid vs usual care
Participants	76 + 74 patients undergoing coronary angiography in Canada
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, and guidance. The DA is no longer available (http://www.phri.ca/workfiles/studies/presentations/PtDA Vascular Access 23-May.2012.pdf). The authors have a copy of the DA on file. Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, risk perception, value congruent with chosen option
Notes	Source of funding: Support for this study provided by (1) McMaster University, Department of Medicine, Internal Career Research Award; and (2) McMaster University, Department of Medicine, Division of Cardiology, AFP research competition grant. Conflicts of interest: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerized random number generator (p 261, Study design)
Allocation concealment (selection bias)	Low risk	Sealed envelopes (p 261, Study design)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Patients and physicians were not blinded to the allocation (p 261, Study design)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear if DCS score assessed by unblinded individuals, but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Did not seem to have incomplete data.
Selective reporting (reporting bias)	Low risk	Protocol is available
Other bias	Low risk	Appeared to be free of other biases.

Schwartz 2001

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	181 + 190 Ashkenazi Jewish women considering genetic testing in the USA

Schwartz 2001 *(Continued)*

Interventions	DA: 16-page booklet on genetic testing with options' outcomes, clinical problem. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: general information on breast cancer, *Understanding Breast Changes: A Health Guide for all Women,* published by the National Cancer Institute
Outcomes	Primary outcome: preferred option Secondary outcomes: knowledge, accurate risk perceptions
Notes	Source of funding: Supported by grants P30 CAS1008-07 and KO7 CA65597 from the National Cancer Institute. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated (p 3)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	High retention rate, baseline data and reasons for lost to follow-up were provided (p 2, Participants section).
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Schwartz 2009a

Study characteristics

Methods	Randomized to decision aid + genetic counseling vs genetic counseling alone
Participants	100 + 114 women considering prophylactic mastectomy for being BRCA1/2 mutation carriers in the USA
Interventions	DA: CD-ROM on options' outcomes, clinical problem, risk communication with individually tailored risk graphs, explicit values clarification, others' opinion; guidance/counseling - genetic counseling as usual care (Ottawa Decision Support Framework). The DA is not publicly available and we were unable to obtain a copy from the authors.

Schwartz 2009a *(Continued)*

	Comparator: genetic counseling on benefits and risks of testing, clinical problem (risk assessment, cancer risks associated with mutations, process of testing and interpretation of results) plus written letter outlining all guidelines and recommendations
Outcomes	Primary outcomes: decisional conflict, satisfaction with decision, actual choice (risk reduction mastectomy) Secondary outcomes: remaining undecided
Notes	Source of funding: National Cancer Institute Grant RO1 CA01846. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomized via computer-generated random number in a 1:1 ratio (p 3, Procedure)
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding, but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Fig. 1 - flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other sources of bias (p 8), "when variable for not watching DA cd was considered in multivariate models, the results did not change substantively (data not shown)".

Sheridan 2006

Study characteristics

Methods	Randomized to decision aid vs usual care (list of risk factors)
Participants	49 + 38 adults with no history of cardiovascular disease in the USA
Interventions	DA: computerized decision aid on options' outcomes, outcome probabilities. The DA is no longer available (www.med-decisions.com/cvtool/). Comparator: list of CHD risk factors to present to doctor

Sheridan 2006 *(Continued)*

Outcomes	Patient-practitioner communication (e.g. discussion with doctor, specific plan to reduce risk discussed with doctor)
Notes	Primary outcome was not specified Source of funding: Our work was funded by the Department of Medicine at the University of North Carolina, who had no role in the design, conduct, or interpretation of the study. Conflicts of interest: Dr. Sheridan and Dr. Pignone have received consulting and licensing fees from Bayer, Inc. Dr. Simpson has received honoraria and consulting fees from Merck, Pfizer, and Galaxo Smith Kline and has received honoraria and grant funding from Schering Plough.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputerized random number generator" (p 2)
Allocation concealment (selection bias)	Low risk	"[S]ealed in security envelopes" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded but the doctors who saw both groups were not.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcome was patient-reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Results (p 5); flow diagram (p 10); baseline characteristics/data included
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov NCT00315978
Other bias	Low risk	Appears to have no other potential risk of bias.

Sheridan 2011

Study characteristics

Methods	Randomized to decision aid + tailored messages vs usual care
Participants	81 + 79 patients with moderate or high risk for CHD considering CHD prevention strategies in the USA
Interventions	DA: web-based decision aid on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, and guidance. The DA is no longer available (www.med-decisions.com/h2hv3/). Comparator: usual care using computer program
Outcomes	Preferred choice (post-DA), adherence

Sheridan 2011 *(Continued)*

	Other outcomes (Sheridan 2014): patient-provider communication (post-DA), patient participation (post-DA), patient's perceptions of discussions and the healthcare visit (post-DA), preferred choice (baseline and post-DA) (data from 81 +79 patients)
Notes	Primary outcome was not specified Source of funding: The research reported in this publication was supported in part by a grant from the American Heart Association (grant number 0530164N), the National Heart Lung and Blood Institute (grant number 1 K23 HL074375), and the National Cancer Institute (grant number K05 CA129166). Conflicts of interest: The authors declare that they have no competing interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2). Sequence generation method not stated.
Allocation concealment (selection bias)	Low risk	"Patients were randomised by study staff who accessed an online randomised schedule" (p 2).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patients blinded and physicians unblinded, but objective outcomes are not likely to be affected by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes deemed objective, therefore lack of blinding did not influence assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There appears to be no missing data.
Selective reporting (reporting bias)	Low risk	Protocol made available
Other bias	Low risk	Appears to be free of other sources of bias.

Shorten 2005

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	85 + 84 pregnant women who have experienced previous cesarean section considering birthing options in Australia
Interventions	DA: decision aid booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (Ottawa Decision Support Framework). The DA is available from the author (ashorten@uow.edu.au) or www.capersbookstore.com.au/product.asp?id=301. Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict

Shorten 2005 *(Continued)*

	Secondary outcomes: preferred option, help with making a decision
Notes	Source of funding: This project is supported by an MBF Research Grant, Sydney, The University of Wollongong New Researcher Grant Scheme, Wollongong, and NSW Midwives Association Research Scholarship, Sydney, New South Wales, Australia. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-based randomized generation (p 3, Procedure)
Allocation concealment (selection bias)	Low risk	"[O]paque envelopes containing a random allocation for each participant code number" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants/midwives/doctors were blinded to patients' allocation. However, women who used the decision aid as specified and in a process of consultation with their midwife or doctor would have negated the blinding of their clinicians, and perhaps of the women themselves. For the intervention group, this may have affected the level and type of information exchanged between them and their caregivers.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16 women were lost to follow-up from the intervention group and 18 from the control group (no reasons listed) (p 4, Results).
Selective reporting (reporting bias)	Low risk	Reference to published protocol
Other bias	Low risk	Appears to be free of other potential biases.

Shourie 2013

Study characteristics

Methods	Cluster-randomized controlled trial of GP practices to web-based MMR DA + usual care, MMR leaflet + usual care, versus usual care
Participants	50 + 93 + 77 parents of children facing their first dose MMR vaccination in the UK
Interventions	Web-based DA: clinical problem, options' outcomes, explicit values clarification, guidance. The DA is no longer available (www.leedsmmr.co.uk). MMR leaflet: Health Scotland leaflet, 'MMR: your questions answered' Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (baseline and 2 weeks postintervention)

Shourie 2013 *(Continued)*

	Secondary outcomes: choice uptake of first dose MMR (when child was 15 months), knowledge (baseline and 2 weeks; results not provided), MMR immunization cognitions (baseline and 2 weeks post; results not provided), immunization trade-off beliefs (baseline and 2 weeks post; results not provided), anxiety (baseline and 2 weeks post; results not provided), use of the intervention (baseline and 2 weeks post) Follow-up article (Tubeuf 2014): cost-effectiveness
Notes	Trial registration: UK Clinical Research Network - UKCRN ID 4811 Source of funding: The study was funded by the National Institute for HealthResearch, Research for Patient Benefit Programme (ref. PB-PG-0107-12048). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Simple randomisation using a computer-generated random list allocated GP practices on a 1:1:1 basis" (p 3)
Allocation concealment (selection bias)	Low risk	"An independent researcher who had no contact with participants generated the allocation sequence and assigned the GP practices to their allocated arm" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"On receipt of the completed baseline questionnaire and consent form, the appropriate intervention was delivered. At this point the researchers and participants were no longer blind to allocation" (p 3). We do not know if receiving the intervention had an effect on the ultimate decision that was made.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome data assessment does not depend on the assessor. It is an objective questionnaire.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing primary outcome data.
Selective reporting (reporting bias)	Unclear risk	Protocol registered. Primary outcome reported as stated. Secondary outcomes are not reported (p 3).
Other bias	Unclear risk	Difference in allocation to groups (50 + 93 + 77). Unclear what effect this difference had on the results. Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Singh 2019

Study characteristics

Methods	Randomized to decision aid vs information
Participants	153 + 148 women aged 18 and older having a lupus nephritis flare and considering change or initiation of an immunosuppressive medication (current flare) or who had a prior lupus nephritis flare and were at risk for a future lupus nephritis flare (at risk for nephritis flare) in the UK

Singh 2019 *(Continued)*

Interventions	DA: online decision aid used in preparation for consultation that includes clinical information, outcome probabilities, implicit values clarification, frequently asked questions, and guidance in communication. The DA is not publicly available; a copy was provided by the author (Jasvinder A. Singh; Jasvinder.md@gmail.com). Comparator: information pamphlet
Outcomes	Primary outcome: decisional conflict, informed value-concordant choice Secondary outcomes: preferred role in decision-making, patient-physician communication and care processes, patient participation, acceptability of the intervention
Notes	Source of funding: This study was funded by the Patient Centered Outcomes Research Institute (https:// www.pcori.org/), contract number PCORI CE-1304-6631, to JAS. No funding bodies had any role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. Conflicts of interest: JAS has received research grants from Takeda and Savient Pharmaceuticals and consultant fees from Savient, Takeda, Regeneron, Merz, Iroko, Bioiberica, Crealta/Horizon, Fidia, and Allergan Pharmaceuticals and WebMD, UBM LLC, Medscape, and the American College of Rheumatology. JAS served as the principal investigator for an investigator-initiated study funded by Horizon Pharmaceuticals through a grant to DINORA, Inc., a 501 (c)(3) entity. JAS is a member of the executive of OMERACT, an organization that develops outcome measures in rheumatology, and receives arms-length funding from 36 companies; a member of the American College of Rheumatology's (ACR) Annual Meeting Planning Committee (AMPC); Chair of the ACR Meet-the-Professor, Workshop and Study Group Subcommittee; and a member of the Veterans Affairs Rheumatology Field Advisory Committee. JAS is the editor and the Director of the UAB Cochrane Musculoskeletal Group Satellite Center on Network Meta-analysis. MD serves on an Independent Data Monitoring Committee for Biogen, Genentech, and Janssen Pharmaceuticals and as a consultant to Abbvie, Kezar, and AstraZeneca. KLW reports grants and personal fees from Pfizer, grants and personal fees from BMS, personal fees from Abbvie, grants and personal fees from UCB, personal fees from Lilly, personal fees from Galapagos, and personal fees from GSK, outside the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Patients with lupus nephritis were randomized in a 1:1 ratio to the provision of the decision aid or the ACR lupus paper pamphlet. After obtaining written informed consent, we randomized participants using a computer-generated randomization process based upon a permuted variable block design, stratified by study site and language (English versus Spanish), and designed by a biostatistician"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	All outcomes were patient-assessed and patient-reported, and neither patients nor assessors were blinded. Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	All outcomes were patient-assessed and patient-reported, and neither patients nor assessors were blinded. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, ITT, > 90% of participants included in the analysis with justification for the ones not included; missing data balanced across groups

Singh 2019 *(Continued)*

Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02319525) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Smallwood 2017

Study characteristics	
Methods	Randomized to decision aid vs attention control (education on another topic)
Participants	29 + 21 women aged ≥ 55 years of age with osteopenia or osteoporosis in the USA
Interventions	DA: web-based decision aid used in preparation for consultation that included clinical information, personalized risk calculator, explicit values clarification, and 2 printouts at the end of the decision aid that contained extensive information about treatments and a personalized summary of risk information and values. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: attention control (education on another topic)
Outcomes	Primary outcomes: decision quality (preparation for decision-making scale and the decisional conflict scale), feasibility. Secondary outcomes: treatment decisions, patient-reported shared decision-making.
Notes	Source of funding: This study was funded by the Clinical and Translational Science Institute of Southeast Wisconsin (project number 5,520,204). Conflicts of interest: none

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Two predetermined block randomization schedules for osteoporosis and osteopenia were created using a computer random number generator and maintained electronically.
Allocation concealment (selection bias)	Low risk	The study co-ordinator was responsible for randomization and blinded to allocation until after consent was obtained.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Neither patients nor physicians could be adequately blinded to their treatment arm. Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, all participants included in the analysis
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified

Smallwood 2017 *(Continued)*

Other bias	Unclear risk	Small sample size (29 + 21) and parametric tests used, no mention of sample homogeneity. This study was underpowered for treatment decisions, limiting the power to detect differences between groups, which may have prevented statistically significant results like shared decision making at 3 months and durability of results for decisional conflict...sample of patients included some with prior treatment experience or FRAX scores that did not reach guideline recommendations.

Smith 2010

Study characteristics

Methods	Randomized to detailed vs simple decision aid vs usual care
Participants	196 + 188 + 188 socioeconomically disadvantaged participants diagnosed with average or slightly above average risk of bowel cancer considering bowel cancer screening in Australia
Interventions	DA: booklet + DVD + worksheet + question prompt list on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary). The DA is no longer available (sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php). The authors have a PDF version. Comparator: booklet + DVD + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making the decision; worksheet; encourages patients to communicate with practitioners by asking questions; summary) Comparator: usual care using standard information booklet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA), participation in decision-making (pre, post-DA) Secondary outcomes: knowledge (pre, post-DA), attitude, actual choice (post-DA), decisional conflict (post-DA), decision satisfaction (post-DA), confidence in decision-making (post-DA), general anxiety (post-DA), worry about developing bowel cancer (pre, post-DA), risk perception Other outcomes (Smith 2014): screening participation (357 + 173 participants)
Notes	Source of funding: This work was supported by a grant from the National Health and Medical Research Council of Australia (No 457381). The funder had no role in the design or conduct of the study, in the collection, analysis and interpretation of data, or in the preparation or approval of the manuscript. Conflicts of interest: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that all authors had: no financial support for the submitted work from anyone other than their employer; no financial relationships with commercial entities that might have an interest in the submitted work; and no non-financial interests that may be relevant to the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants who verbally consented to take part were then randomised to one of the three groups using random permutated blocks of size 6 and 9 for each sex stratum" (p 3, Participants and recruitment section)
Allocation concealment (selection bias)	Low risk	Central allocation; "interviewers responsible for recruiting participants were not aware of the randomization sequence or allocation and therefore did not

Smith 2010 *(Continued)*

		know which intervention respondents would receive" (p 3, Participants and recruitment section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"It was not possible for the reviewers to be blinded to the group allocation. However, all questions used standardised wording with pre-coded responses and were asked within a supervised environment, where interviewer performances were regularly monitored to ensure scripts were read as written" (p 3, Outcome measures section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"[A]nalyses were by intention to treat and carried out blinded to intervention" (p 5, Statistical analysis section); outcomes measured were not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Explanation for the missing data reported at base of tables.
Selective reporting (reporting bias)	Low risk	Study protocol available (ClinicalTrials.gov NCT00765869 and Australian New Zealand Clinical Trials Registry 12608000011381)
Other bias	Low risk	Appears to be free of other potential sources of bias.

Stacey 2014a

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	71 + 71 adults diagnosed with knee osteoarthritis considering joint replacement in Canada
Interventions	DA: DVD + booklet + worksheet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (1 page summary for the surgeon). The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. The authors have a copy of the video and booklet that was evaluated in the study. Comparator: usual care
Outcomes	Primary outcomes: feasibility (including recruitment, data collection), preliminary effectiveness Secondary outcomes: knowledge (post-DA, pre-surgeon consult), informed values-congruent with chosen option (post-DA, pre-surgeon consult), uptake of chosen option at 1 year; decisional conflict (SURE test), preparation for decision-making (4 items), wait times
Notes	Trial registration: NCT00743951 Source of funding: The study was funded using D Stacey's research start-up funds from the University of Ottawa, in Ottawa, Canada. The PtDAs were provided free of charge by the Informed Medical Decisions Foundation. Conflicts of interest: The authors (DS, GH, PT, IT, LB, MPP, AC, MT) declare that they have no competing interests. GFD is a paid consultant for Stryker Corporation advising on total and partial knee replacement.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Stacey 2014a *(Continued)*

Random sequence generation (selection bias)	Low risk	"The allocation schedule was computer-generated centrally by a statistician using a permuted block design with randomly varying block lengths of 4, 6, or 8." (p 3)
Allocation concealment (selection bias)	Low risk	"Allocations were concealed in numbered opaque sealed envelopes" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Patients were not informed of the intervention characteristics" (p 3)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"Although the research assistant was not blinded to group allocation, study outcomes for effectiveness were objective and obtained from clinic data (e.g. date of surgery or wait list status)" (p 3).
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Protocol registered on ClinicalTrials.gov
Other bias	Low risk	Appears to be free of other potential sources of bias.

Stacey 2016

Study characteristics	
Methods	Randomized to decision aid + usual education + preference report for surgeon vs usual education alone
Participants	174 + 169 adults aged 18 and older with moderate or severe hip or knee osteoarthritis and were determined at the orthopedic screening clinic to be appropriate for surgical consultation about joint arthroplasty in Canada
Interventions	DA: video decision aid plus booklet used in preparation for consultation that included information on the clinical condition, probabilities of outcomes of options, implicit values clarification, video clips of patient experiences, guidance in communication, and preference report for the surgeon. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. The authors have a copy of the video and booklet that was evaluated in the study. Comparator: education and half page of clinical assessment findings for surgeon
Outcomes	Primary outcome: wait times Secondary outcomes: decision quality (knowledge + values + actual choice), realistic expectation of outcomes, surgical rates, perceptions of decision-making process, costs (Trenaman 2017 ; Trenaman 2020)
Notes	Source of funding: This work was supported by funding and access to the PtDA from the not-for-profit Informed Medical Decisions Foundation (Grant #0099-1). Funding for graduate students was from the Faculty of Health Sciences, University of Ottawa. Conflicts of interest: The authors (DS, MT, PT, IT, AO, MPP, LB, SB, DM, GH) declare that they have no conflict of interests. GFD is a paid consultant for Stryker Corporation advising on total and partial knee replacement. At the time of the study, the Informed Medical Decisions Foundation that provided funding for the study had a licensing agreement with Health Dialog, a commercial company who markets

Stacey 2016 *(Continued)*

PtDA and health coaching. The funders were not involved in the study design, data collection, analysis, interpretation of data, or writing of the report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The allocation schedule was computer-generated centrally by a statistician, using block randomization, with randomly varying block lengths of 4, 6, or 8."
Allocation concealment (selection bias)	Low risk	"To ensure concealment, call-in telephone software was used to obtain randomized allocation."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"To minimize bias after allocation, patients reviewed the information (i.e., PtDA plus usual education or usual education only) at home, were not informed of the other intervention, and did not have contact with orthopedic screening clinic practitioners during the 2 weeks post clinic visit when measures were collected. Although the research assistant was not blinded to group allocation, the primary outcome was objective and used clinic data." Low risk because objective measures used.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"343 participants were randomized to the intervention (n = 174) or usual care (n = 169) and followed for 2 years"..."At the end of the 2-year follow-up (October 2011), there were 165 intervention group participants and 163 controls included in the primary outcome analysis." Loss to follow-up was 5% and 4% respectively.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT00911638) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Stamm 2017

Study characteristics

Methods	Randomized to decision aid alone vs decision aid + SDM vs usual care
Participants	106 + 113 + 110 men aged 50 to 75 years who were being evaluated by one of 2 primary care providers at Virginia Mason Medical Center, USA
Interventions	DA: paper-based decision aid that includes outcome probabilities and values clarification. The DA is not publicly available; a copy was provided by the author (Dr. John M. Corman; John.corman@virginiamason.org). Comparator: usual care
Outcomes	Knowledge of prostate cancer screening and the decision regarding screening
Notes	Source of funding: not reported

Stamm 2017 *(Continued)*

	Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% of participants included in analysis, similar between arms (included in usual care 85%, DA 87%, DA + SDM 83%) (P = 0.699405); provides justification for not including participants (loss to follow-up or returning survey late)
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	There is no mention of the funding source.

Steckelberg 2011

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	785 + 792 patients with no CRC history considering CRC screening in Germany
Interventions	DA: brochure on options' outcomes, clinical problem, and outcome probabilities. The DA is no longer available (www.gesundheit.uni-hamburg.de/upload/AltDarmkrebsinternet.pdf). The authors have a PDF version. Comparator: usual care using pamphlet
Outcomes	Primary outcomes: values congruent with chosen option (post-DA) Secondary outcomes: knowledge (post-DA), combination of actual and planned uptake (post-DA), risk perception
Notes	Source of funding: German Federal Ministry of Education and Research Conflicts of interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that

Steckelberg 2011 *(Continued)*

might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence (p 2, Randomization and blinding)
Allocation concealment (selection bias)	Low risk	Allocation was concealed. Identity numbers were independent of allocation, and study members did not have access to the data (p 2, Randomization and blinding).
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Trial staff who sent out questionnaires and reminders were not aware of study arm; unclear if participants were blinded (p 2, Randomization and blinding).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Trial staff and statistician who entered data were blinded (p 2, Randomization and blinding).
Incomplete outcome data (attrition bias) All outcomes	Low risk	12% missing one or both questionnaires in intervention group vs 9.2% in control group; judged to have low impact on study outcome (p 2)
Selective reporting (reporting bias)	Low risk	Protocol available
Other bias	Unclear risk	Participants who completed the trial do not add up.

Stephenson 2020

Study characteristics

Methods	Randomized to decision aid vs control (waiting list)
Participants	464 + 463 women aged 15 to 30 years with a current or future need for contraception, attending one of the study sites in the UK
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, and summary of the 3 methods most consistent with the individual's preferences are displayed and compared side-by-side, and the user can export their results by email or text message. The DA is publicly available at https://www.contraceptionchoices.org . Comparator: control (no intervention)
Outcomes	Primary outcomes: use of long-acting reversible contraception at 6 months and satisfaction with contraceptive method at 6 months Secondary outcomes: effectiveness of contraceptive method at 6 months; change in method from baseline to 6 months; pregnancy by 6 months and diagnosed sexually transmitted infection reported at 3 or 6 months

Stephenson 2020 *(Continued)*

Notes	Source of funding: National Institute for Health Research Health Technology Assessment Programme Commissioned call to increase the uptake of long-acting contraception in young women. Study registration ISRCTN 13247829. Conflicts of interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Automated, computerized randomization occurred immediately after baseline data collection. A randomization list was generated by a random number based algorithm in the computer software Stata25 and incorporated into the trial software program to allocate all participants to either the intervention or control group. The randomization list was stratified by setting and used varying block sizes.
Allocation concealment (selection bias)	Low risk	Allocation was immediate (online) and concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single-blind (outcome analysis). Unclear how lack of blinding of participants may have influenced outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The analysis of the primary outcomes was conducted blinded to allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, "modified ITT", < 90% of participants included in analysis (loss to follow-up similar between arms; 84% and 86% included)
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (ISRCTN13247829). All outcomes of interest to the current review are reported except for "health service and out-of-pocket costs".
Other bias	Low risk	The study appears to be free of other sources of bias.

Stubenrouch 2022

Study characteristics

Methods	Cluster-randomized to decision aid + consultation cards (Option grids) + decision cards vs usual care
Participants	247 + 197 patients visiting the outpatient clinics for their abdominal aortic aneurysm, varicose veins, carotid artery stenosis, or intermittent claudication and for whom more than one treatment option was possible (including the option not to treat) in the Netherlands
Interventions	DA: web-based decision aids used in preparation for consultation that include clinical information, outcome probabilities, explicit values clarification, guidance in decision-making (step-by-step guide), and summary. Consultation cards (option grids) and decision cards were used during consultation to support patient involvement in decision-making. The DAs are publicly available at: https://keuzehulp.medify.eu/KeuzehulpMedify/keuzehulp_medify.html .

Stubenrouch 2022 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcome: level of SDM during consultation (OPTION scale) Secondary outcomes: factors influencing SDM level, SDM as perceived by patients (SDM-Q-9; Collabo-RATE), and by clinicians (SDM-Q-Doc), the degree of desired patient involvement (Control Preferences Scale), knowledge, treatment choice, consultation duration, decisional conflict, and patient's quality of life
Notes	Source of funding: none to declare Conflicts of interest: none

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Patients were included consecutively and were unaware of group allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Due to the nature of this study, it is not possible to blind patients or vascular surgeon, since they actively use the intervention. However, the cluster-randomization design does reduce potential contamination of information among the participating vascular surgeons.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not blinded. Low risk for outcomes that were objectively measured (knowledge, decisional conflict, treatment choice, consultation duration). Unclear risk for patient-reported subjective measures (shared decision-making as perceived by patients, degree of desired patient involvement). High risk for observer-reported subjective measures (level of shared decision-making using OPTION scale).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis but missing data are balanced across groups (77% included in control group, 77% included in DA group), justifications provided
Selective reporting (reporting bias)	Low risk	The study protocol is available (NTR6487) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	High risk	Clustering not accounted for in the analysis of data (high risk of bias). Free of other potential biases: no evidence of selective recruitment of cluster participants.

Subramanian 2019

Study characteristics

Methods	Randomized to decision aid vs control (no intervention)
Participants	116 + 118 adults with advanced chronic kidney disease in the USA

Subramanian 2019 *(Continued)*

Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, explicit values clarification, patient testimonies, guidance in decision-making (step-by-step process), and guidance in communication. The version of the DA tested in the trial was provided by the author (Jarcy Zee; jarcy.zee@pennmedicine.upenn.edu). **Note: the DA was previously illustrated via https://choosingdialysis.org/ but is no longer available.* Comparator: no intervention
Outcomes	Treatment preference, decisional conflict, decision self-efficacy, preparation for decision-making (intervention group only), knowledge
Notes	Source of funding: Research reported in this article was funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (1109) to Dr Tentori. Dr Tentori was supported in part by National Institute of Diabetes and Digestive and Kidney Diseases grant K01DK087762. The funders did not have a role in study design, data collection, analysis, reporting, or the decision to submit for publication. Conflicts of interest: Dr Tentori is an employee of DaVita HealthCare Partners, Inc. She was employed by Arbor Research Collaborative for Health, which administers the Dialysis Outcomes and Practice Patterns Study (DOPPS) Program, which is funded by a consortium of private industry, public funders, and professional societies. Principal funders: Amgen, Kyowa Hakko Kirin, and Baxter Healthcare. Additional support for specific DOPPS projects and/or program activities in specific countries provided by: Amgen, Association of German Nephrology Centres (Verband Deutsche Nierenzentren e.V.), AstraZeneca, European Renal Association-European Dialysis and Transplant Association, German Society of Nephrology, Hexal AG, Janssen, Japanese Society for Peritoneal Dialysis, Keryx, Proteon, Relypsa, Roche, Societa Italiana di Nefrologia, Spanish Society of Nephrology, and Vifor Fresenius Medical Care Renal Pharma. Public funding and support is provided for specific DOPPS projects, ancillary studies, or affiliated research projects by: Australia: National Health & Medical Research Council; Canada: Canadian Institutes of Health Research and Ontario Renal Network; France: Agence Nationale de la Recherche; Thailand: Thailand Research Foundation, Chulalongkorn University Matching Fund, King Chulalongkorn Memorial Hospital Matching Fund, and the National Research Council of Thailand; United Kingdom: National Institute for Health Research via the Comprehensive Clinical Research Network; and United States: National Institutes of Health and PCORI. All support is provided without restrictions on publications. The remaining authors declare that they have no relevant financial interests.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study co-ordinator provided the participant with a unique user login and study ID. The list of IDs provided to each recruiter was randomly generated by an independent study programmer and each ID appeared as a random sequence of letters. The list alternated between the intervention and control arms to ensure parallel assignment to the intervention or control arms of consented participants.
Allocation concealment (selection bias)	Low risk	Neither the study co-ordinator nor the participant could discern the assignment based on the ID and both were therefore blinded to treatment assignment before consent and before the study started.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Neither the study co-ordinator nor the participant could discern the assignment based on the ID and both were therefore blinded to treatment assignment before consent and before the study started. The study co-ordinator also remained blinded to treatment assignment throughout the study because participants engaged in the study on their own time.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Neither the study co-ordinator nor the participant could discern the assignment based on the ID and both were therefore blinded to treatment assignment before consent and before the study started. The study co-ordinator also

Subramanian 2019 *(Continued)*

		remained blinded to treatment assignment throughout the study because participants engaged in the study on their own time.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, high rate of attrition but balanced across groups. Completers: 63/118 (53%) DA group and 70/116 (60%) control group (P = 0.28284). Justification for attrition reported.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02488317) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Taylor 2006

Study characteristics	
Methods	Randomized to print DA versus video DA versus wait list control
Participants	98 + 95 + 92 African American men with no history of prostate cancer to consider prostate cancer screening in the USA
Interventions	Print DA: clinical problem; outcome probabilities; guidance (list of questions to ask at next appointment); others' opinions. The DA is not publicly available; a copy was provided by the author (taylorkl@georgetown.edu). Video DA: clinical problem; others' opinions Wait list comparator: no information provided until 1 month post-randomization (baseline assessment for this group coincided with 1-month assessment of print and video arms)
Outcomes	Prostate cancer screening intention (baseline and 1 month; not reported), prostate screening uptake (1 year; not included because wait list received intervention before 1 year) process variables including use and perception of the intervention materials (1 month), prostate cancer knowledge (baseline and 1 month post), decisional conflict (baseline and 1 month post), satisfaction with screening decision (baseline and 1 month post)
Notes	No primary outcome reported; not found in trials registry Source of funding: Centers for Disease Control and Prevention grant TS290 and National Cancer Institute grant K07 CA72645-01 Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient information related to random sequence generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Insufficient information to judge blinding; however, participants were requested not to share intervention materials with others to prevent contamination between groups (p 2180).

Taylor 2006 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Does not appear to be missing any outcome data.
Selective reporting (reporting bias)	Unclear risk	No protocol registered or published
Other bias	Unclear risk	"All participants were mailed $25 for their participation following completion of the 1-month interview" (p 2181) "Men who reported that they had not yet had a chance to read/watch the materials were given an additional week to do so and called again to complete the follow-up assessment" (p 2181)

Tebb 2021

Study characteristics	
Methods	Cluster randomized to decision aid vs control
Participants	693 + 667 Hispanic/Latina females aged 14 to 18 years who were sexually active, not currently pregnant, and not currently using long-acting reversible contraception in the USA
Interventions	DA: web-based decision aid that includes clinical information, outcome probabilities, explicit values clarification, quiz, individualized recommendations based on questions answered, patient testimonies, and guidance in communication. The DA is publicly available at https://health-eyou.ucsf.edu/#eq_wellness_center . Comparator: control (no intervention)
Outcomes	Knowledge (only reports change from baseline for total sample), self-efficacy, contraceptive use, effectiveness of clinical encounter (discussed birth control), satisfaction with DA
Notes	Source of funding: This study was funded by a Patient-Centered Outcomes Research Institute (PCORI) research award [AD-1502-27481]. Additional support was also provided by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS), Maternal and Child Health Bureau: Dr. Ozer (Adolescent and Young Adult Health Research Network, Cooperative Agreement: #UA6MC27378)); Dr. Brindis and Dr. Adams: (Adolescent and Young Adult Health Capacity Building Program: # U45MC27709); Ozer, Brindis and Adams also received funding from # T7IMC00003. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement of the funders. The funders mentioned above did not participate in the study design; in the collection, analysis and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication. This information or content and conclusions are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, or the U.S. Government. Conflicts of interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
Risk of bias	

Tebb 2021 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Clinics were randomized to the control (n = 9) or intervention group (n = 9) using computer-generated random assignment.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Flow diagram, high loss to follow-up and missing data are significantly higher in DA arm (completers at 48 hours: 335/693 DA and 443/667 control (P < 0.00001)); "attrition was higher in the intervention group and dropouts tended to be younger", used multiple imputation using chained equations for attrition, no justification provided for attrition.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02847858) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	High risk	At baseline, the intervention group had significantly higher knowledge scores. Another major limitation was that, despite randomization, intervention participants, compared to controls, had significantly higher rates of sexual activity and the recruitment visit was more likely to be for a pregnancy test, EC, birth control, or birth control/pregnancy counseling. (Unclear risk). Selective recruitment of cluster participants (Low risk of bias): "All adolescent girls were offered an iPad Air upon clinic checkin (between August 2016 and May 2018). The "user" selected their preferred language and completed an online survey that obtained consent and assessed eligibility (i.e. female; 14 to 18 years; Hispanic/Latina2; sexually active; not currently pregnant; and not currently using long-acting reversible contraception (LARC))." Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Thomson 2007

Study characteristics	
Methods	Randomized to decision aid vs usual care by clinical guidelines
Participants	69 + 67 patients with atrial fibrillation considering treatment options in the UK
Interventions	DA (in consultation): computerized decision on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance/coaching by physician. The DA is not publicly available; a copy was provided by the author (computer disc sent by mail). Comparator: guidelines applied as direct advice
Outcomes	Primary outcome: decisional conflict

Thomson 2007 *(Continued)*

	Secondary outcomes: anxiety, knowledge, resource use, choice, health outcomes (stroke, transient ischemic attack, bleeding events)
Notes	Source of funding: Wellcome Trust Health Services Research Project Grants. All authors are independent of the funding bodies. Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)
Allocation concealment (selection bias)	Low risk	"[E]lectronically-generated random permuted blocks via a web-based randomisation service" (p 2, Recruitment and randomization)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Physicians were blinded. Unclear if patients are blinded and how that may affect the outcome.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See flow diagram
Selective reporting (reporting bias)	Low risk	ISRCTN24808514
Other bias	Low risk	Baseline characteristics similar, sample size similar, not stopped early

Tilburt 2022

Study characteristics

Methods	Cluster randomized to 1) pre-visit DA + within visit DA vs 2) pre-visit DA only vs 3) within-visit DA only vs 4) usual care
Participants	5 sites (44 participants who received during consultation DA) + 5 sites (50 participants who received usual care) aged ≥ 18 years with a positive prostate cancer biopsy within the previous 4 months in the USA
Interventions	DA: web-based decision aid used during consultation that includes explicit values clarification, individualized estimates of prostate cancer risk stratification, quality of life compared to average population, guidance in decision-making (5-step guide), and summary page including prostate cancer risk stratification, life expectancy, existing quality of life, and values. The within-visit DA is available at: http://prostatecancer.takethewind.com/web/index.php . The pre-visit DA is no longer available, therefore we only extracted data on the group that received the within-visit DA alone vs usual care. Comparator: usual care (no details provided)
Outcomes	Primary outcome: knowledge

Tilburt 2022 *(Continued)*

	Secondary outcomes: clinical time, decisional regret, health-related quality of life. The latter 2 outcomes will be reported in a 1-year follow-up article.
Notes	Source of funding: Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under award numbers UG1CA189823 (Alliance for Clinical Trials in Oncology NCI Community Oncology Research Program grant); UG1CA189848, UG1CA233270, UG1CA233290, UG1CA233329, UG1CA233331, UG1CA233373, UG1CA232760, and R01 MD008934 (Jon C. Tilburt, Joel E. Pacyna, Judith S. Kaur, and Simon P. Kim); and U10CA180820, UG1CA189830, and UG1CA189854 (ECOG-ACRIN). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health (https://acknowledgments.alliancefound.org. Conflicts of interest: Daniel G. Petereit reports grant support from the Bristol-Myers Squibb Foundation, the Irving A. Hansen Foundation, the Ralph Lauren Pink Pony Foundation, and the National Institutes of Health (1R01CA240080-01); consulting fees from Boston Scientific; payments or honoraria from Boston Scientific, the University of California San Francisco, the Mayo Clinic, and the University of Pennsylvania; legal consultancy for brachytherapy cases; and a leadership role with the American Brachytherapy Society. George J. Chang reports consulting fees from Medicaroid and participation on boards for J&J and 11 Health. Ethan M. Basch reports consulting fees from AstraZeneca, Carevive Systems, Navigating Cancer, and Sivan Healthcare. Michael J. Morris is an uncompensated consultant for Bayer, Novartis, Advanced Accelerator Applications, Janssen, and Lantheus; is a compensated consultant for ORIC, Curium, Athenex, the National Comprehensive Cancer Network, and Exelixis; reports participation on boards for Curium, Athenex, Exelixis, AstraZeneca, and Amgen; and receives institutional funding for clinical trials from Bayer, Endocyte, Progenics, Corcept, Roche/ Genentech, Celgene/Bristol-Myers Squibb, and Janssen. None of his disclosures are related to this work. Electra D. Paskett is a multiple principal investigator on a grant to her institution from the Merck Foundation and on another grant from Pfizer, and she also receives grant funding to her institution from the Breast Cancer Research Foundation. None of her disclosures are related to this work. Victor M. Montori reports that he works at the Knowledge and Evaluation Research Unit of the Mayo Clinic and conducts research into shared decision-making; often, shared decision-making tools are produced that are placed in the public domain and are free to use and that produce no income to the research unit or to him personally. Dominick L. Frosch reports consulting fees paid to his former employer (Sutter Health) by the Mayo Clinic/National Institutes of Health. The other authors made no disclosures.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Few details: "We used a cluster randomized trial with a 2×2 factorial design. With such a design, clinical practices were identified up front and randomized with equal allocation to 1 of 4 arms receiving both previsit and within-visit DAs, a previsit DA only, a within-visit DA only, or no DA (usual care; Fig. 1)"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% included in analysis, attrition similar between arms, no justification for attrition

Tilburt 2022 *(Continued)*

Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03103321) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way. "The latter 2 secondary outcomes are not reported in this article because they are planned for a subsequent article devoted to 1-year outcomes."
Other bias	Unclear risk	One or more of the authors are industry employees (unclear risk). Selective recruitment of cluster participants: "Because our underlying scientific question included a desire to understand the effects of DAs in minority men, particularly Black or African American men, we set aside half of all trial slots for Black or African American men to ensure a prespecified effect size analysis in this subgroup while also hoping to attract a diverse overall demographic mix of participants" (unclear risk). Few details on recruitment approaches (in article and in protocol); in protocol: "Participant recruitment will remain flexible to accommodate each site's workflow for notifying patients about new cancer diagnoses and providing consultation about treatment choices. Some sites disclose positive cancer diagnoses by phone, with the treatment consultation occurring days later. Other sites combine notification and treatment discussion into a single consultation with the physician provider. In all cases, participating sites will need to ensure that registration and intervention (in applicable study arms) occur after diagnosis notification and prior to the specialist consultation. Each site will develop methods for identifying eligible patients ahead of visits and for recruiting patients in a way that avoids the possibility of inadvertent diagnosis disclosure by study staff" (unclear risk). Free of other potential biases: adjustment for clustering performed.

Trevena 2008

Study characteristics	
Methods	Randomized to decision aid vs usual care by consumer guidelines
Participants	157 + 157 patients not previously screened for colorectal cancer in Australia
Interventions	DA: age-gender-family history specific DA booklet with information on options, outcome probabilities, explicit values clarification, guidance (personal worksheet with steps in decision-making) (Theory of planned behavior). The DA is no longer available (sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php). Comparator: consumer guidelines recommending fecal occult blood testing
Outcomes	Primary outcome: informed choice Secondary outcomes: knowledge, values, screening intention (choice); test uptake, anxiety, acceptability of the intervention, satisfaction with the decision
Notes	Source of funding: National Health and Medical Research Council (NHMRC) Program Grant Conflicts of interest: not reported

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Trevena 2008 *(Continued)*

Random sequence generation (selection bias)	Low risk	"Sequential ID numbers were randomly assigned by computer program to DA or Guidelines (G) in blocks of four" (p 3)
Allocation concealment (selection bias)	Low risk	"Allocation was concealed via the password-protected program" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded to the intervention type - not sure about GPs.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were blinded to allocation for all telephone interviews, outcomes were objectively measured.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics included (p 3). Fig 2 flow chart (p 5). Reasons for loss to follow-up not mentioned.
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov - NCT00148226
Other bias	Low risk	Appears to be free of other potential biases.

van Dijk 2021

Study characteristics	
Methods	Randomized to decision aid + usual care vs usual care
Participants	69 + 76 adults 18 years or older newly diagnosed with OA of the knee or hip in the Netherlands
Interventions	DA: online decision aid provided after the first consultation when patients received the diagnosis of osteoarthritis of the knee or hip that included clinical information, outcome probabilities, explicit values clarification, knowledge test, and guidance in decision-making (5-step guide). The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcomes: satisfaction, anxiety, knowledge, stage of decision-making, preferred treatment, health outcomes, quality of life
Notes	Source of funding: none declared Conflicts of interest: There is no conflict of interest.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The patients were randomized by a computer generated randomization sequence by one of the research fellows into the control group or intervention group.

van Dijk 2021 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"unblinded randomized controlled trial". Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"unblinded randomized controlled trial", but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis but balanced across groups (36/69 (52%) included in usual care group, 39/76 (51%) included in DA group (P = 0.917747)); justification for attrition reported
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NL4291; old trial number: NTR4435), and 2 outcomes of interest to the review (knowledge, stage of decision-making) were not pre-specified; https://trialsearch.who.int/Trial2.aspx?TrialID=NTR4435
Other bias	Low risk	The study appears to be free of other sources of bias.

Van Peperstraten 2010

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	152 + 156 infertile women on wait list for in vitro fertilization in the Netherlands
Interventions	DA: self-administered booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, guidance (step-by-step process for making decision, worksheet with questions relevant to decision-making process; 1 or more questions that asked patients to clarify their preferences; summary to be shared with practitioner), coaching (by trained in vitro fertilization nurse) + standard in vitro fertilization care. The DA is no longer available online (www.umcn.nl/ivfda-en). The authors have a PDF version. Comparator: standard in vitro fertilization care, including a session in which the number of embryos transferred was discussed
Outcomes	Primary outcomes: actual choice (postintervention and consultation) Secondary outcomes: knowledge (pre, post-DA and consultation), empowerment (pre, post-DA and consultation), participation in decision-making, decisional conflict (post-DA and consultation), levels of anxiety (pre, post-DA and consultation), depression (pre, post-DA and consultation), cost evaluation of empowerment strategy (post-DA and consultation), condition-specific health outcomes (pregnancies) (post-DA and consultation)
Notes	Source of funding: This study was funded by the Netherlands Organisation for Health Research and Development (grant No 945-16-105). All researchers are independent from this source of funding. The study sponsor had no role in the study design, collection, analysis, and interpretation of data, the writing of the article, and the decision to submit it for publication. Conflicts of interest: All authors have completed the unified competing interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare (1) no financial support for the submitted work from anyone other than their employer; (2) no financial relationships with commercial entities that might have an interest in the submitted work; (3) no spouses,

Van Peperstraten 2010 *(Continued)*

	partners, or children with relationships with commercial entities that might have an interest in the submitted work; and (4) no non-financial interests that may be relevant to the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated list (p 2, Methods section)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2, Methods section)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Because of the nature of the intervention it was not possible to blind the participants or in vitro fertilisation doctors to the allocation. Participation in our trial did not change the normal in vitro routine." (p 2, Methods section)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes assessed were not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are categories in each column of table 1 (p 3) where the denominators do not match the number of people in the group and no reason was given to explain why this would be or if this affects the study.
Selective reporting (reporting bias)	Low risk	Outcomes are the same as those registered with ClinicalTrials.gov.
Other bias	Low risk	The study appears to be free of other sources of bias.

van Tol-Geerdink 2013

Study characteristics	
Methods	Randomized to decision aid + usual care vs usual care
Participants	163 + 77 patients with primary localized prostate cancer eligible for both radical prostatectomy and radiotherapy in the Netherlands
Interventions	DA: paper-based decision aid used after initial consultation and in preparation for decision-making during second consultation that includes clinical information, probabilities of outcomes, implicit values clarification, and guidance in communication (space to write personal notes and questions for doctor). The DA is not publicly available; a copy was provided by the author (Julia J. van Tol-Geerdink; Julia.vanTol-Geerdink@radboudumc.nl). Comparator: usual care
Outcomes	Treatment preference, treatment received, decision regret, perceived participation
Notes	Source of funding: Financial support for this study was provided by a grant (2007-3809) from the Dutch Cancer Society, Amsterdam, the Netherlands. Conflicts of interest: none declared
Risk of bias	

van Tol-Geerdink 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Enrolled patients were individually randomized to (i) the usual care group, which discussed the treatment choice with their specialist, or (ii) the decision aid group, which, in addition, had the decision aid presented by the researcher (JvTG). Randomization was imbalanced (1: 2) to have a large enough decision aid group to answer separate research questions, reported elsewhere.20 Randomization was centralized to avoid allocation bias and was blocked in groups of 3 per hospital, thus stratifying for hospital site." The investigators describe the use of stratification or permuted blocking (use of computer implied).
Allocation concealment (selection bias)	Low risk	Randomization was centralized to avoid allocation bias and was blocked in groups of 3 per hospital, thus stratifying for hospital site.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Patients and caregivers could not be blinded to the intervention." Unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, loss to follow-up at t2 (pre-treatment assessment) was 10/163 (6%) DA group and 7/77 control group(9%). Justification for attrition reported.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NTR1334) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Vandemheen 2009

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	70 + 79 patients with cystic fibrosis considering referral for lung transplantation in Canada
Interventions	DA: self-administered booklet with clinical problem, outcome probability, explicit values clarification, guidance (Ottawa Decision Support Framework). The DA is available at https://decisionaid.ohri.ca/decaids-archive.html . Comparator: blank pages
Outcomes	Primary outcomes: knowledge, accurate risk perceptions, decisional conflict Secondary outcomes: preparation for decision-making, choice, durability of decision, undecided
Notes	Source of funding: Funded by The Ontario Thoracic Society, The Physicians' Services Incorporated Foundation and The Australian Cystic Fibrosis Research Trust. Conflicts of interest: not reported

Vandemheen 2009 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"[C]omputer-generated random listing of two treatment allocations blocked in blocks of 2 or 4, stratified by site and infection status of Burkholderia cepacia" (p 2)
Allocation concealment (selection bias)	Low risk	Central allocation (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Single blinded RCT; patients and researchers were blinded but physicians were not because they were involved with patients before being randomized.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research staff, who were blinded to treatment allocation, telephoned each patient and had them complete a follow-up questionnaire; other outcomes reported are objectively measured.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Baseline characteristics included (Flow diagram, p 2)
Selective reporting (reporting bias)	Low risk	Clinical trial registered with www.clinicaltrials.gov (NCT00345449)
Other bias	Low risk	Appears to be free of other potential biases.

Varelas 2020

Study characteristics	
Methods	Randomized to decision aid + standard consultation vs standard consultation alone
Participants	22 + 25 women aged > 18 years diagnosed with breast cancer (stage I or II only) and advised to undergo or had already undergone a mastectomy
Interventions	DA: tablet-based decision aid used in preparation for consultation that includes clinical information, and methods to clarify values. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: standard consultation
Outcomes	Primary outcomes: patient satisfaction using the Decisional Conflict Scale, knowledge Secondary outcomes: psychological status, surgeon satisfaction, time of consultation
Notes	Source of funding: none Conflicts of interest: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Risk of bias

Varelas 2020 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Using a random number generator with a 1:1 ratio allocation
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Patients were blindly assigned to one of the two arms. The study's surgical team were blinded to patient allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The study's surgical team were blinded to patient allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis but missing data are balanced across groups (data for 13/22 (59%) control group and 13/25 (52%) DA group (P = 0.625617)), justification for attrition provided
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Unclear risk	Small sample size (randomized 22 + 25); used parametric tests (student paired t-test) to compare groups when only 13 + 13 included in the analysis.

Vigod 2019

Study characteristics	
Methods	Randomized to decision aid vs control
Participants	48 + 48 women aged 18 years or older diagnosed with major depressive disorder who were planning a pregnancy or pregnant (less than 30 weeks gestation at enrolment) and for whom starting or continuing an antidepressant had been recommended as a treatment option for depression by their clinical provider in Canada
Interventions	DA: web-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, guidance in decision-making (systematic steps), guidance in communication, and printable automated summary of the information reviewed on risks and benefits, the participant's rating of their relative importance, and the participant's perception of external influences on their decision-making process. The DA is not publicly available; temporary access was provided by the author (Simone N. Vigod; simone.vigod@wchospital.ca). Comparator: control (list of publicly available websites)
Outcomes	Primary outcome: feasibility, acceptability, adherence to trial protocol, DA acceptability Secondary outcomes: decisional conflict, depression, anxiety, knowledge
Notes	Source of funding: This pilot trial was funded by the Canadian Institutes for Health Research (CIHR). Conflicts of interest: DS is a Member of the Scientific Advisory Committee of the Duloxetine Pregnancy Registry. VT has done consulting work for Sunovion, Shire, NovoNordisk and Valeant. SG has received personal fees from Eli Lilly, personal fees from Psychotherapy to go, and personal fees from Compendi-

Vigod 2019 *(Continued)*

	um of pharmaceuticals over the last year, outside the submitted work. The other authors have no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The allocation sequence was generated by QoC using a random permuted block randomization. QoC provided a randomization identification number list with associated unique logins/passwords to sequentially assign to enrolled participants (within strata).
Allocation concealment (selection bias)	Low risk	The allocation sequence was generated by QoC using a random permuted block randomization. QoC provided a randomization identification number list with associated unique logins/passwords to sequentially assign to enrolled participants (within strata). When a participant logged in to the study website, she would automatically be directed to her allocated condition.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not possible to blind participants, but they were not explicitly informed whether they were allocated to the intervention or control group. It is unclear how lack of blinding may have influenced outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome data were recorded by research staff who were blind to participant allocation until the final set of questions querying women's views of the PDA.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, low rate of attrition, loss to follow-up similar between arms (10% control, 12% DA), no reasons for loss to follow-up
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02308592) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	One or more of the authors are industry employees: DS is a Member of the Scientific Advisory Committee of the Duloxetine Pregnancy Registry. VT has done consulting work for Sunovion, Shire, NovoNordisk and Valeant. SG has received personal fees from Eli Lilly, personal fees from Psychotherapy to go, and personal fees from Compendium of pharmaceuticals over the last year, outside the submitted work.

Vina 2016

Study characteristics

Methods	Randomized to video decision aid + motivational interviewing vs educational booklet
Participants	240 + 253 patients with moderate to severe knee OA, self-identified as black, aged 50 years and older, with chronic and frequent knee pain, WOMAC score of 39 or greater, and x-ray evidence of knee OA in the USA
Interventions	DA: video decision aid that included information on the clinical condition, probabilities of outcomes of options, implicit values clarification, video clips of patient experiences, and guidance in communication, plus motivational interviewing. The DA is not publicly available; the authors have a copy of the video evaluated in previous studies (Bozic 2013; De Achaval 2012; Stacey 2014a).

Vina 2016 *(Continued)*

	Comparator: educational booklet
Outcomes	Primary outcome: receipt of a referral to orthopedic surgery based on a patient's self-report at the 12-month post-intervention follow-up Secondary outcome: change in patient preference/ willingness to undergo total knee replacement
Notes	Source of funding: Funding was received from the NIH/National Institute of Arthritis and Musculoskeletal Skin Diseases Grant# 1-RO1-AR-054474-5 (SI) and K24AR055259 (SI). Conflicts of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might post a conflict of interest in connection with the submitted article. All ICMJE Conflict of Interest Forms for authors and Clinical Orthopaedics and Related Research editors and board members are on file with the publication and can be viewed on request.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomized to one of the two study arms using a computer-generated random assignment. The computer-generated randomization result was sent to the study coordinator via email before the scheduled intervention session"
Allocation concealment (selection bias)	Low risk	"The computer-generated randomization result was sent to the study coordinator via email before the scheduled intervention session"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Owing to the nature of the intervention, participants could not have been blinded to the study arm they were assigned to. Primary care providers were blinded from the study arm participants were assigned to."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors of outcomes were blinded to which study arm the patients were assigned.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in the analysis. Attrition similar between arms (2 vs 1) and reasons for withdrawals recorded. Missing data for some outcomes, reported in limitations (there were patients with missing willingness data at different times).
Selective reporting (reporting bias)	Unclear risk	The study protocol is available (NCT02413411) and the secondary outcome in the trial registry is actual receipt of knee replacement, whereas the manuscript states the secondary outcome is change in patient willingness to undergo knee replacement surgery.
Other bias	Low risk	The study appears to be free of other sources of bias.

Vodermaier 2009

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	74 + 78 women with breast cancer considering treatment options in Germany

Vodermaier 2009 *(Continued)*

Interventions	DA: decision board administered by research psychologists and booklet on options' outcomes, clinical problem, outcome probability. The DA is not publicly available; a copy was provided by the author (in German). Comparator: booklet on clinical problem
Outcomes	Primary outcome: decisional conflict Secondary outcomes: choice, length of consultation, satisfaction with decision-making, participation in decision-making
Notes	Source of funding: This work was supported by the German Ministry of Health as a pre-operating study in the focus programme 'The Patient as a Partner in the Medical Decision Making Process' under Grant no. 217-43794-5/2 (Professor Dr Michael Untch, PI) and by a stipend from the Dr-Werner-Jackstaedt-Stiftung in the Founder Association of the German Sciences under Grant no. S134-10.021 (Dr Andrea Vodermaier). Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation after the patient gave written informed consent" "Random assignment was performed by means of numbered cards in envelopes", "stratified by age group" (p 2)
Allocation concealment (selection bias)	Low risk	"[N]umbered cards in envelopes" (p 2)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded - unclear if this would introduce bias to outcome assessed.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not blinded but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, p 5; baseline characteristics not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Volk 1999

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	80 + 80 men considering PSA testing in the USA

Volk 1999 *(Continued)*

Interventions	DA: Health Dialog videotape and brochure on options' outcomes, clinical problem, outcome probability, others' opinion. The DA was available from Informed Medical Decisions Foundation during the study but is no longer available. Comparator: usual care
Outcomes	Primary outcomes: knowledge, preferred/uptake of option
Notes	Source of funding: This project was supported by grants from the American Academy of Family Physicians Foundation and the American Academy of Family Physicians, Kansas City, Mo, and grant D32-PE10158-01 from the Bureau of Health Professions, Health Resources and Services Administration, Rockville, Md. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Volk 1999 (primary study), p 3: "[r]andomization by permuted blocks", "Each block included the numbers 1 through 4" Volk 2003 , p 2, Methods: Randomization by permuted blocks was used to balance the number of subjects in each arm of the study.
Allocation concealment (selection bias)	Unclear risk	Volk 1999 (primary study): no information provided Volk 2003, p 2: "[d]etails of the study procedures, subjects, and 2-week follow-up results can be found elsewhere"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were not blinded to the treatment assignment, but the physicians were; therefore, outcomes were unlikely to be biased.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers were not blinded, but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Volk 1999 (primary study), p 2, Procedures: baseline values included Volk 2003, p 4 Fig 1 - flow diagram; baseline data not included
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Volk 1999 (primary study): appears to be free of other potential biases. Volk 2003: appears to be free of other sources of bias.

Volk 2020

Study characteristics

Methods	Randomized to decision aid vs standard education

Volk 2020 *(Continued)*

Participants	259 + 257 tobacco quit line clients (ages 55 to 77 years) who reported a 30-plus pack-year smoking history in the USA
Interventions	DA: video decision aid used in preparation for consultation that includes clinical information, outcome probabilities, and implicit values clarification. The DA is available at https://www.youtube.com/watch?v=wir3w1eUAJk&ab_channel=MDAndersonCancerCenter . Comparator: standard education
Outcomes	Primary outcomes: preparation for decision-making, decisional conflict Secondary outcomes: knowledge, intentions to be screened, screening behaviors, if participants had a visit with a clinician to discuss screening, underwent low-dose computed tomography, DA acceptability
Notes	Source of funding: This study was supported by award CER-1306-03385 from the Patient-Centered Outcomes Research Institute; award P30CA016672 from the National Institutes of Health, National Cancer Institute (Drs Volk, Cantor, and Lin) that used the Biostatistics Resource Group, Clinical Protocol and Data Management, and Shared Decision Making Core, and a grant from The University of Texas MD Anderson Cancer Center Duncan Family Institute for Cancer Prevention and Risk Assessment (Drs Volk and Cantor) that supported the Shared Decision Making Collaborative and Center for Community-Engaged Translational Research. Conflicts of interest: Dr Volk reported receiving research support from the Patient-Centered Outcomes Research Institute (PCORI) and receiving grants from the National Institutes of Health and The University of Texas MD Anderson Cancer Center during the conduct of the study. Dr Lowenstein reported receiving grants from PCORI, The University of Texas MD Anderson Cancer Center Duncan Family Institute, and the National Institutes of Health during the conduct of the study. Ms Leal reported receiving grants from PCORI, the National Cancer Institute, and The University of Texas MD Anderson Cancer Center Duncan Family Institute during the conduct of the study. Dr Munden reported receiving stock options from Optellum Ltd and preferred stock from TheraBionic outside the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Clients within each state quit line were randomized to receive the PDA or standard educational material (EDU) using S-plus, version 8.04 (TIBCO Software Inc) statistical software to generate a randomization schedule with various block sizes.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded to intervention allocation. It is unclear how lack of blinding may have influenced outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study interviewers were blinded to participant allocation at the 3- and 6-month assessments, but not the 1-week follow-up, because questions about the PDA were asked of participants in this group. However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram. Low attrition for outcomes of interest (knowledge, decisional conflict, preparation for DM) collected at 1-week follow-up (completers: 235/259 (91%) DA and 233/257 control (91%)).

Volk 2020 *(Continued)*

Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02286713) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Vuorma 2003

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	184 + 179 women considering treatment for menorrhagia in Finland
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: usual care
Outcomes	Primary outcomes: uptake of option Secondary outcomes: knowledge, proportion remaining undecided, anxiety, satisfaction, health outcomes, use and cost of healthcare services
Notes	Source of funding: This study was supported by STAKES, the National Research and Development Centre for Welfare and Health, and Doctoral Programmes of Public Health of Helsinki and Tampere Universities. Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Vuorma 2003 (primary study), p 2, Randomization: computer-generated; done by a researcher who did not participate in the planning or concealment procedures "[D]one in STAKES, by researcher separately for each hospital in computer-generated varying clusters"(p 2) Vuorma 2004: no information provided
Allocation concealment (selection bias)	Low risk	Vuorma 2003 (primary study), p 2 "sequentially numbered, opaque and sealed envelopes" Vuorma 2004, p 2 "sequentially numbered, opaque, sealed envelopes"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding, unclear if measurements could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Study staff were not blinded, but outcomes were objectively measured and not subjective to interpretation.

Vuorma 2003 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Vuorma 2003 (primary study): flow chart balanced. Reasons for non-eligibility. "One women on HRT was randomized by mistake and included in analyses." Baseline characteristics included and balanced across groups (p 4-5) Vuorma 2004, flow diagram (p 3)
Selective reporting (reporting bias)	Unclear risk	Vuorma 2003 (primary study): no mention of study protocol Vuorma 2004: no information provided
Other bias	Low risk	Vuorma 2003 (primary study), p 7: "increase in knowledge in both study groups, carry-over effect; change in decision-making process of intervention group may have altered physician's negotiation with patients" appears to be free of other potential biases. Vuorma 2004, p 5: "comparison of the baseline characteristics presented elsewhere". In the pre-trial group compared with the control group, there was a greater increase in the dimensions of physical role functioning and emotional role functioning of the RAND-36.

Wallace 2021

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	15 + 6 patients aged 18 and older eligible for consideration of a primary prevention implantable cardioverter-defibrillator in the USA
Interventions	DA: Toolkit containing 4 decision aids used in preparation for consultation comprised of (1) a one-page Option Grid conversation aid, (2) a more in-depth paper pamphlet, (3) a video, and (4) an interactive website that included clinical information, outcome probabilities, explicit values clarification, patient narratives, frequently asked questions, guidance in decision-making (step-by-step process), and guidance in communication. The DA is publicly available at https://patientdecisionaid.org/ Comparator: usual care (pamphlets or communication normally given by the treatment facility)
Outcomes	Acceptability of the decision aid, feasibility, knowledge, decision quality (values concordance choice), choice, decision conflict, decision regret, participation
Notes	Source of funding: Financial support for this study was provided entirely by the Patient Centered Outcomes Research Institute (IP2 PI000116) and the National Institutes of Health (K23AG040696). Bryan Wallace is supported National Institutes of Health: National Heart, Lung, and Blood Institute (R01HL136403). Dr. Knoepke is supported National Institutes of Health: National Heart, Lung, and Blood Institute (1K23HL153892) and the American Heart Association (18CDA34110026). Conflicts of interest: Dr. Allen receives grant funding from American Heart Association, National Institutes of Health, and the Patient Centered Outcomes Research group; and consulting fees from ACI Clinical, Amgen/ Cytokinetics, Boston Scientific, and Novartis. Glyn Elwyn has edited and published books that provide royalties: Shared Decision Making (Oxford University Press) and Groups (Radcliffe Press). Glyn Elwyn's academic interests are focused on shared decision making and coproduction. He owns copyright in measures of shared decision making (collaboRATE) and care integration (integRATE), a measure of experience of care in serious illness (consideRATE), a measure of goal setting coopeRATE, a measure of clinician willingness to do shared decision making (incorpoRATE), an observer measures of shared decision making (Observer OPTION-5 and Observer OPTION-12). He is the Founder and Director of &think LLC which owns the registered trademark for Option Grids™ patient decision aids; Founder,

Wallace 2021 *(Continued)*

	Director of SHARPNETWORK LLC, a provider of online training for shared decision making, consultant to EBSCO Health, Bind On-Demand Health Insurance, and Chief Clinical Research Scientist to abridge AI Inc. The authors declare no conflict of interest. The PCORI and NIH had no role in the design or development of the tools, the methods by which they were created, the analyses conducted, or the decision to publish findings.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly assigned 2:1 to an intervention or control group with the goal of recruiting 60 patients
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram and text of the manuscript are inconsistent. Text of manuscript describes 21 participants with 15 randomized to intervention and flow diagram shows 9 randomized to intervention and 6 to control.
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT02026102) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	Small sample size (15 intervention + 6 control). Goal was to recruit 60 participants.

Wang 2021

Study characteristics

Methods	Randomized to decision aid vs usual care (standard education)
Participants	98 + 98 pregnant women who came for routine checkups 1 month before delivery in Taiwan
Interventions	DA: paper-based decision aid used in consultation with the nurse that includes clinical information, explicit values clarification, guidance in decision making, and guidance in communication. The DA is available as a supplementary appendix in the article. Comparator: usual care (standard education)
Outcomes	Primary outcome: decisional conflict Secondary outcome: decisional regret
Notes	Source of funding: none

Wang 2021 *(Continued)*

	Conflicts of interest: The authors reported no conflict of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Pregnant women were randomly divided into classic or SDM groups through computer-generated assignment by an outpatient clinic nurse.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-masking (participant, outcomes assessor) according to trial registry
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Before the mothers were discharged after delivery, the influence of SDM was investigated by a nurse who was blinded to the participants' group allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% included in analysis but missing data are balanced across groups (23% loss to follow-up in both arms), justification provided for loss to follow-up
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03528655) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Watson 2006

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	475 + 522 men considering prostate cancer screening in the UK
Interventions	DA: leaflet on options' outcomes, clinical problem, outcome probability. The DA is presented in Appendix A within the article. Comparator: usual care
Outcomes	Primary outcomes: knowledge, screening intention, attitudes Secondary outcomes: preferred role in decision-making
Notes	Source of funding: not reported Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Watson 2006 *(Continued)*

Random sequence generation (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
Allocation concealment (selection bias)	Low risk	"[R]andom numbers generated centrally by Stata v8.2" (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information provided
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 2); reason for exclusion from analysis mentioned. Sample characteristics of risk included.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Unclear risk	"Adjustment for multiple testing was not accounted for and hence a degree of caution with interpretation is required, particularly in relation to findings with a P-value close to 0.05" (p 3)

Watts 2015

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	63 + 65 male and female veterans diagnosed with post-traumatic stress disorder and seeking referral for treatment in the USA
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, and implicit values clarification. The DA is not publicly available; a copy was provided by the author (Bradley V. Watts; bradley.v.watts@dartmouth.edu) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict, and ability to indicate a treatment preference Secondary outcomes: satisfaction with care, symptom severity, participant functioning and quality of life
Notes	Source of funding: This work was supported by U.S. Department of Veterans Affairs (VA) Health Services Research and Development grant 07-266-1. The views expressed in this article do not necessarily represent the views of the VA or of the United States government. Conflicts of interest: The authors report no financial relationships with commercial interests.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Watts 2015 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Randomization was accomplished through selection of an identical sealed envelope, which contained information about the random assignment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported for patients. Double-masking (investigator, outcomes assessor) according to trial registry. Clinic providers were blinded regarding the participants' involvement in the study. Unclear how lack of blinding of participants influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	After the standard mental health evaluation, participants in both arms were seen by a research assistant who administered several assessments... The research assistant was blinded to the participants' treatment assignment.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram (supplementary material), > 90% of participants included in analysis, high rate of attrition but loss to follow-up similar across groups (DA group 16/66 (24%) and in control 13/66 (20%) (P = 0.528267))
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT00908440) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Weymiller 2007

Study characteristics	
Methods	Cluster-randomized to decision aid vs usual care
Participants	51 + 46 patients with type 2 diabetes in the USA
Interventions	DA (in consultation): 1-page decision aid options' outcomes, clinical problem, tailored outcome probability, guidance/coaching. An example DA is presented in Figure 1 of the article. Comparator: booklet on cholesterol management
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: consultation length, acceptability of the intervention, adherence, estimated personal risk, trust, patient participation (OPTION), choice
Notes	Source of funding: This study was supported by the Mayo Clinic Section of Patient Education and the American Diabetes Association. Conflicts of interest: none reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence (p 2) Nannenga 2009: no information provided

Weymiller 2007 *(Continued)*

Allocation concealment (selection bias)	Low risk	Computer-generated allocation sequence, unavailable to personnel enrolling patients. "[W]ith concealed allocation" (Abstract); "maintained allocation concealment" (p 5); randomized by concealed central allocation (Nannenga 2009, p 2)
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and clinicians blinded to the study objectives, providers and patients were naive to this study objective.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data analysts and statisticians blinded to allocation; intervention and outcomes; adequate blinding wherever possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram (p 3); reasons for attrition mentioned (p 4); baseline characteristics included; flow diagram Nannenga 2009, p 3: reasons for attrition mentioned and study groups balanced; baseline characteristics included
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov identifier: NCT00217061
Other bias	Low risk	Enrollment of patients already receiving statin therapy and limited statin uptake decreased the precision of our results; results should best be interpreted as preliminary and requiring verification. Nannenga 2009: appears to be free of other potential biases. Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Whelan 2003

Study characteristics	
Methods	Randomized to decision aid vs usual care
Participants	82 + 93 women with node negative breast cancer considering adjuvant chemotherapy in Canada
Interventions	DA: decision board and booklet on options' outcomes, clinical problem, outcome probability, guidance/coaching. The DA is presented in Figure 1 of the article Comparator: booklet on clinical problem
Outcomes	Primary outcomes: knowledge, satisfaction of participant Secondary outcomes: preferred option, anxiety, accurate risk perceptions, participation in decision-making
Notes	Source of funding: Supported by a grant from the Canadian Breast Cancer Research Initiative. Conflicts of interest: not reported

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Whelan 2003 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	No information provided
Allocation concealment (selection bias)	Low risk	Randomization, which was performed at a central location (p 3)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"Unable to blind participants in our trial for practical reasons, measures were taken to minimize bias in the design of the study and the assessment of outcomes"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram not included. "[O]ne patient excluded from analysis, determined by physician not to be candidate for chemotherapy" (p 4). Baseline data/characteristics included.
Selective reporting (reporting bias)	Unclear risk	Unclear if lack of blinding contributed to a potential risk of bias.
Other bias	Low risk	Appears to be free of other potential biases.

Whelan 2004

Study characteristics	
Methods	Cluster-randomized to decision aid vs usual care
Participants	94 + 107 women with Stage 1 or 2 breast cancer considering surgery (cluster-RCT with 27 surgeons randomized) in Canada
Interventions	DA: decision board on options' outcomes, outcome probability, guidance/coaching. The DA is presented in Figure 1 of the development article (Whelan 1999). Comparator: usual care
Outcomes	Primary outcomes: preferred option, knowledge, decisional conflict, satisfaction Secondary outcomes: accurate risk perceptions, anxiety
Notes	Source of funding: Dr Whelan is a Canada Research Chair funded by Health Canada. The Canadian Breast Cancer Research Initiative and the Ontario Ministry of Health and Long-Term Care, Health System-Linked Research Programme provided funding support for the study. Conflicts of interest: not reported

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Does not specify how the sequence was generated; a paired cluster-randomization process was used (p 2, Study design and procedures).

Whelan 2004 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Randomly assigned in a concealed fashion, but the method of concealment was not stated (p 2, Study design and procedures).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"[C]hose cluster randomization method to avoid contamination that might have occurred if surgeons used decision board for some patients and not others" (p 6); unclear if this would introduce bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included; reasons given for loss of participants.
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Wilkens 2019

Study characteristics	
Methods	Randomized to decision aid plus usual care (information) vs information only
Participants	45 + 45 patients older than 18 years, seeking care for trapeziometacarpal arthritis in the USA
Interventions	DA: Interactive online decision aid that includes information on the clinical problem, outcome probabilities, explicit values clarification, guidance in decision-making (step-by-step process for making the decision), guidance in communication, and summary that can be taken to the consultation. The DA is publicly available at https://www.decisionaid.info/pp/thumboa/intro . Comparator: usual information provided during consultation plus informational brochure
Outcomes	Primary outcome: decisional conflict Secondary outcomes: disability, pain intensity, depression, treatment choice, satisfaction with the visit, consultation duration, perception of physician's empathy, decision regret, treatment satisfaction, change in treatment choice, change of surgeon
Notes	Source of funding: not reported Conflicts of interest: D.R. has received support from Wright Medical (Memphis, TN), Skeletal Dynamics (Miami, FL), Biomet (Warsaw, IN), AO North America (Paoli, PA), and AO International (Dubendorf, Switzerland). T.T. has received support from AO Trauma (Dubendorf, Switzerland), Stryker (Kalamzoo, MI), DePuy Synthes (West Chester, PA), PATIENTþ (Den Haag, The Netherlands), and VCC (Zaltbommel, The Netherlands). N.C.C. has received support from Miami Device Solutions (Miami, FL) and Depuy Synthes (Paoli, PA). The rest of the authors declare that they have no relevant conflicts of interest.
Risk of bias	
Bias	**Authors' judgement** **Support for judgement**

Wilkens 2019 *(Continued)*

Random sequence generation (selection bias)	Low risk	"The allocation was based on a computer-generated sequence of random numbers and only accessible by the independent research assistant (S.C.W.) who was present in the room when patients were going through the decision aid"
Allocation concealment (selection bias)	Low risk	"The allocation was based on a computer-generated sequence of random numbers and only accessible by the independent research assistant (S.C.W.) who was present in the room when patients were going through the decision aid"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	"We considered this study unblinded for all parties because blinding of the surgeon could not be guaranteed." Unclear how physicians may have influenced decisions.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	"We considered this study unblinded for all parties because blinding of the surgeon could not be guaranteed." However, outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram: follow-up rate of 89%. "We planned an intention-to-treat analysis, but everyone was managed as assigned. Multiple imputation was used to complete missing data (number of imputations set to 40) for the 7 patients (8%) with no 6-week or 6-month measures of pain intensity, satisfaction, and decision regret (Fig. 1). We assumed the missing data to be at random. Medical records were reviewed for change in treatment and surgeon; we assumed missing patients had not changed treatment/ surgeon when no follow-up was noted in the medical record."
Selective reporting (reporting bias)	Unclear risk	No protocol/registration identified
Other bias	Low risk	The study appears to be free of other sources of bias.

Williams 2013

Study characteristics	
Methods	Randomized to decision aid at home or in clinic versus usual care at home or in clinic
Participants	134 + 138 + 134 +137 men aged 40 to 70 years with no history of prostate cancer who had pre-registered for screening in the USA
Interventions	DA: content adapted from the Centers for Disease Control and Prevention's PCS educational tool. Includes clinical problem, treatment options, outcome probabilities, explicit values clarification, others' stories, summary worksheet. The DA is not publicly available; a copy was provided by the author (taylorkl@georgetown.edu). Comparator: information booklet. A 3-page fact sheet requiring 5 minutes to read. Information presented in a Q&A format on who is recommended for testing, how to interpret results, and the limitations of testing.
Outcomes	Knowledge, decisional conflict, screening outcomes, satisfaction with decision Outcomes assessed at baseline, 2 months, 13 months, except satisfaction with decision (2 months and 13 months)
Notes	No primary outcome reported; trial registration not provided

Williams 2013 *(Continued)*

Source of funding: This work was supported by grant R01 CA98967-01 from the National Cancer Institute, Bethesda, MD, USA.

Conflicts of interest: None of the authors have any conflicts of interest or financial disclosures to report.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information to judge random sequence generation
Allocation concealment (selection bias)	Unclear risk	Insufficient information to judge allocation concealment
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to judge blinding of participants and personnel
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge blinding of outcome assessment
Incomplete outcome data (attrition bias) All outcomes	Low risk	There does not appear to be any outcome data missing.
Selective reporting (reporting bias)	Unclear risk	No registered or published protocol
Other bias	Low risk	Appears to be free of other potential biases.

Wise 2019

Study characteristics

Methods	Randomized to decision aid + standard care vs standard care alone
Participants	148 + 149 women with one previous cesarean and singleton pregnancy < 25 weeks in New Zealand and the USA
Interventions	DA: paper-based decision aid used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, guidance in decision-making, guidance in communication, and summary (values clarification activity) to share with doctor/midwife. The DA is not publicly available; a copy was provided by the author (Dr Michelle R. Wise; m.wise@auckland.ac.nz). Comparator: usual care (education)
Outcomes	Primary outcome: attempted vaginal birth after cesarean, also called trial of labor after cesarean, measured at the time of onset of labor Secondary outcomes: adherence to birth preference, actual mode of birth, knowledge, decisional conflict, birth mode preference, satisfaction with birth experience
Notes	Source of funding: A+ Trust, Auckland District Health Board (A+4946)

Wise 2019 *(Continued)*

Conflicts of interest: The authors report no conflicts of interest.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	This was a randomized trial using 1:1 allocation. Randomly assigned following simple randomization procedures (computerized random numbers).
Allocation concealment (selection bias)	Low risk	Opaque, sealed envelopes containing the group allocation were sequentially used. The envelopes were prepared in advance and kept in a locked cabinet in the clinic. The allocation sequence was concealed from the researchers.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Clinicians were blinded to group allocation. The original intention and study protocol were to allocate either the DA or the educational pamphlet. However, PBAC clinicians argued that to provide usual care of the PBAC clinic they needed a brief encounter tool with which to guide the consultation. Moreover, they felt if women brought the DA booklet with them into the consultation rather than the pamphlet, then clinicians would not be blinded, and that it may bias the consultation. Therefore, the clinical team made the decision for all participants to receive the pamphlet. Clinicians did not report on whether women brought the DA with them to consultations. Researchers were blinded to group allocation until data analysis was complete. Not reported for participants. Unclear how lack of blinding of participants influenced the study results.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers were blinded to group allocation until data analysis was complete.
Incomplete outcome data (attrition bias) All outcomes	High risk	Flow diagram. Loss to follow-up at Q2 when outcomes of interest were measured is significantly higher for the control group (8/148 DA and 18/149 usual care (P = 0.041838)). Justification for non-inclusion and loss to follow-up provided.
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12611000878976) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Wolf 1996

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	103 + 102 men considering PSA testing in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probability, others' opinions. The DA script is presented in Table 1 of the article. Comparator: usual care (single sentence)
Outcomes	Preferred option
Notes	Source of funding: This study was supported in part by grant IRG-72256 from the American Cancer Society, Atlanta, Ga.

Wolf 1996 *(Continued)*

	Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "the methodology of the randomized trial has been reported previously"
Allocation concealment (selection bias)	Unclear risk	Wolf 1996 (primary study): no information provided Wolf 1998, p 2: "The methodology of the randomized trial has been reported previously"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Wolf 1996 (primary study), p 2: needed a minimum sample size of 150 participants, and was achieved with a total sample size of 205. Reasons for attrition mentioned; baseline characteristics included Wolf 1998: no information provided except that the methodology of the randomized trial and the content of the informational intervention reported previously (p 2). Baseline characteristics included; flow of participants not included.
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry.
Other bias	Low risk	Wolf 1996 (primary study): participant population had lower SES, therefore external validity of the findings is limited, but overall it appears to be free of other potential biases. Wolf 1998: appears to be free of other potential biases.

Wolf 2000

Study characteristics

Methods	Randomized to decision aid vs usual care
Participants	266 + 133 elderly (≥ 65 years) considering CRC screening in the USA
Interventions	DA: script of options' outcomes, clinical problem, outcome probabilities. The DA script is presented in the Appendix within the article. Comparator: usual care (5 sentences)
Outcomes	Primary outcome: preferred option

Wolf 2000 *(Continued)*

	Secondary outcomes: accurate risk perceptions
Notes	Source of funding: Dr. Wolf is the recipient of an American Cancer Society Cancer Control Career Development Award for Primary Care Physicians. Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"[P]atients were randomised" (p 2); does not indicate how
Allocation concealment (selection bias)	Unclear risk	No information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline data not included (p 2, Results)
Selective reporting (reporting bias)	Unclear risk	Protocol not mentioned
Other bias	Low risk	Appears to be free of other potential biases.

Wong 2006

Study characteristics	
Methods	Randomized to decision aid vs placebo control leaflet
Participants	162 + 164 women referred for pregnancy termination in the UK
Interventions	DA: decision aid leaflet on options' outcomes, clinical problem, outcome probability, explicit values clarification. The DA is not publicly available and we were unable to obtain a copy from the authors. Comparator: placebo leaflet on contraception use post pregnancy termination
Outcomes	Primary outcomes: uptake of option, knowledge, decisional conflict, anxiety
Notes	Source of funding: not reported Conflicts of interest: not reported
Risk of bias	

Wong 2006 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"1:1 ratio, balanced block of 10"; "envelope preparation by drawing slips of paper labelled either control or intervention"; "the slip determined leaflet placed into envelope" (p 2)
Allocation concealment (selection bias)	Low risk	Consecutively numbered, opaque trial envelopes (p 2, Methods)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Unclear blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured and not subjective to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Baseline characteristics not included (p 3); reasons for attrition and incompletion mentioned.
Selective reporting (reporting bias)	Unclear risk	No information provided
Other bias	Low risk	Appears to be free of other potential biases.

Wyld 2021

Study characteristics	
Methods	Cluster-randomized to decision support intervention vs usual care
Participants	670 + 669 women aged 70 years or above at diagnosis with primary operable invasive breast cancer from 27 + 67 breast units in England and Wales
Interventions	DA: online algorithm used by healthcare professional during consult to generate personalized survival outcomes followed by access to booklet decision aids (print, PDF) that include clinical information, outcome probabilities, explicit values clarification, guidance in decision-making (step-by-step process), and guidance in communication. The DA is publicly available at https://agegap.shef.ac.uk/ . Comparator: usual care
Outcomes	Primary outcome: quality of life Secondary outcomes: breast cancer-specific quality of life, treatment choices, knowledge, shared decision-making, decision regret, anxiety, illness perception, coping strategies, breast cancer-specific survival
Notes	Source of funding: This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (grant reference number RP-PG-1209-10071). The views expressed are those of the authors and not necessarily those of the National Health Service, the NIHR or the Department of Health. Conflicts of interest: The authors declare no conflict of interest.

Wyld 2021 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Centers (breast units) were subjected to 1: 1 block randomization, stratified by high or low current primary endocrine therapy and chemotherapy rates. Centers were randomized either to have access to the decision support interventions and training in their use, or to continue with usual care (use of computer implied)
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported, but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, < 90% of participants included in analysis (excluded 311/670 (46%) DA and 288/669 (43%) usual care), however missing data are balanced across groups (P = 0.215147), justification for exclusion provided
Selective reporting (reporting bias)	Low risk	The study protocol is available (ISRCTN46099296) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Unclear risk	The low response rate to some of the questionnaires relating to decision quality metrics may also be a source of bias, with women potentially selectively agreeing to complete these if they had either a particularly positive or negative experience. Free of other potential biases: adjustment for clustering performed/no evidence of selective recruitment of cluster participants.

Ye 2021

Study characteristics	
Methods	Randomized to decision aid vs information
Participants	386 + 387 adults aged 50 to 80 with definite diagnosis of age-related cataract in China
Interventions	DA: paper-based DA used in preparation for consultation that includes clinical information, outcome probabilities, explicit values clarification, and guidance in decision-making and communication. The DA is not publicly available; a copy was provided by the authors (Yingfeng Zheng; zhyfeng@mail.sysu.edu.cn). Comparator: usual booklet developed by the National Eye Institute, available at https://www.nei.nih.gov/sites/default/files/health-pdfs/WYSK_Cataract_English_Sept2015_PRINT.pdf .
Outcomes	Primary outcome: informed choice (knowledge and attitude congruent with expressed intention)

Ye 2021 *(Continued)*

	Secondary outcomes: decisional conflict, confidence in decision-making, anxiety, worry, time perspective, anticipated regret, importance and personal chances of surgical outcomes, acceptance and usefulness of DA
Notes	Source of funding: This study was funded by the Construction Project of High-Level Hospitals in Guangdong Province (303020107; 303010303058); National Natural Science Foundation of China (81530028; 81721003); Clinical Innovation Research Program of Guangzhou Regenerative Medicine and Health Guangdong Laboratory (2018GZR0201001); Local Innovative and Research Teams Project of Guangdong Pearl River Talents Program; the State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University. Prof. Congdon is supported by the Ulverscroft Foundation (UK). Conflicts of interest: Prof. Liu reported receiving grants from the National Natural Science Foundation of China. Prof. Zheng has served on digital advisory board for Novartis. Prof. Congdon is Director of Research for Orbis International, a non-governmental organization which carries out children's eye health work in China. No other disclosures were reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomization sequence was generated by a statistician using an online random number generator (randomization.com).
Allocation concealment (selection bias)	Low risk	The randomization sequence was generated by a statistician using an online random number generator (randomization.com). The statistician had no contact with participants before enrolment. An independent coworker not involved in this study randomly assigned participants to one of two study groups in a 1:1 ratio with permuted block sizes of four and eight. The coworker put each booklet into a sequentially numbered, opaque, sealed folder using an allocation sequence provided by the statistician. Interviewers' performance was regularly monitored throughout the survey by study investigators during on-site visits, ensuring they read questions in a structured script.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Masking of participants was accomplished by printing both booklets with identical cover designs and titles. Study investigators responsible for recruitment and the interviewers were unaware of study allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Masking of participants was accomplished by printing both booklets with identical cover designs and titles. Study investigators responsible for recruitment and the interviewers were unaware of study allocation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flow diagram, ITT, < 90% included in ITT analysis but balanced across groups (50% in both arms), justifications for attrition provided
Selective reporting (reporting bias)	Low risk	The study protocol is available (NCT03992807) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

Zadro 2022

Study characteristics

Zadro 2022 *(Continued)*

Methods	Randomized to decision aid (side-by-side display) vs DA (top-and-bottom display) vs education material
Participants	211 + 214 people with shoulder pain considering surgery to treat their shoulder pain in Australia
Interventions	DA: online printable PDF used in preparation for consultation that includes outcome probabilities, implicit values clarification, and guidance in communication. The DA is available as a supplementary appendix in the article. Comparator: education (including clinical information and options)
Outcomes	Primary outcome: treatment intention Secondary outcomes: knowledge, attitude towards surgery, informed choice, decisional conflict
Notes	Source of funding: This study was funded from JZs National Health and Medical Research Council (NHMRC) Investigator Grant (APP1194105). Conflicts of interest: KM, RT, and TH are members of the International Patient Decision Aids Standard (IPDAS) Collaboration Steering Committee. RT receives personal royalties from the sale of a book on shared decision-making. All other authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomized through the online survey platform Qualtrics (1:1 ratio; concealed to investigators).
Allocation concealment (selection bias)	Low risk	Participants were randomized through the online survey platform Qualtrics (1:1 ratio; concealed to investigators).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Not reported but outcomes were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Flow diagram, > 90% of participants included in analysis and justification provided for attrition
Selective reporting (reporting bias)	Low risk	The study protocol is available (ACTRN12621000992808) and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
Other bias	Low risk	The study appears to be free of other sources of bias.

CHD : coronary heart disease; **CRC** : colorectal cancer; **DA** : decision aid; **DM** : decision-making; **FAQ** : frequently asked questions; **GP** : general practitioner; **HPV** : human papillomavirus; **HRT** : hormone replacement therapy; **ICD** : implantable cardioverter-defibrillator; **ITT** : intention-to-treat; **MMR** : measles, mumps and rubella; **NSW** : New South Wales; **OA** : osteoarthritis; **PDA** : patient decision aid; **PSA** : prostate-specific antigen; **PTSD** : post-traumatic stress disorder; **RCT** : randomized controlled trial; **SES** : socioeconomic status; **SDM** : shared decision-making; **SURE** : Sure of myself; Understand information; Risk-benefit ratio; Encouragement

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abadie 2009	Study did not evaluate the decision aid (evaluated clinician use of the decision aid in one arm of a study only)
Abhyankar 2011	Hypothetical choice
Adab 2003	Hypothetical choice, not at a point of decision-making
Adam 2018	Two decision aids compared
Adekpedjou 2020	Not a decision aid; not a treatment or screening decision
Akbari 2020	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Al Saffar 2008	Study not focused on making a choice; adhering to medications only
Alegría 2014	Not a patient decision aid
Ali 2020	Not a patient decision aid
Allen 2016	Two decision aids compared
Allen 2022	Not a randomized controlled trial
Almario 2022	Not a patient decision aid (no description of benefits of options)
AlSagheir 2020	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Altiner 2007	Not a patient decision aid
Anderson 2011	Not a randomized controlled trial
Arimori 2006	Not a patient decision aid (not including benefits and harms)
Armstrong 2005	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Arterburn 2013	Not evaluating a patient decision aid
Au 2011	Not a randomized controlled trial
Bakken 2014	Not a patient decision aid; related to lifestyle choices
Becker 2009	Hypothetical choice; not at the point of decision-making
Belkora 2012	Not a patient decision aid
Bellmunt 2010	Not a patient decision aid
Bennett 2011	Compares 3 versions of the same patient decision aid

Study	Reason for exclusion
Betz 2020	Not a treatment or screening decision
Betz 2021	Not a treatment or screening decision
Bhattacharya 2021	Two decision aids compared; about clinical trial entry
Bieber 2006	Study did not evaluate the patient decision aid (evaluated shared decision-making process); not a patient decision aid
Bombard 2020	Hypothetical choice
Boulware 2013	Not a patient decision aid (information about one choice only, no values clarification)
Boulware 2018	Study does not report outcomes of interest to this review
Branda 2013	Two patient decision aids with findings aggregated
Brenner 2014	Not a patient decision aid
Breslin 2008	Not a randomized controlled trial
Brown 2004	Not focused on making a choice (no specific decision to be made)
Brundage 2001	Not a randomized controlled trial
Brunette 2020	Not a decision aid; not a treatment or screening decision
Buhse 2015	Not a patient decision aid
Buhse 2018	Not a patient decision aid
Burton 2007	Not a patient decision aid (general patient education only)
Buzhardt 2011	Not evaluating patient decision-making
Campbell 2014	Not evaluating a patient decision aid
Carling 2008	Hypothetical choice, not at point of decision-making
Carlson 2021	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Carter-Harris 2020	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Causarano 2015	Not a patient decision aid
Chadwick 1991	Not a randomized controlled trial
Chan 2011	Not a patient decision aid
Chewning 1999	Not a randomized controlled trial
Chiew 2008	Not a randomized controlled trial

Study	Reason for exclusion
Chong 2020	Not a patient decision aid (no specific decision)
Christy 2022	Not a treatment or screening decision; about clinical trial entry
Clark 2022	Two decision aids compared
Clouston 2014	Not a patient decision aid
Col 2007	Unable to ascertain characteristics of the patient decision aid. Additional information requested from author but not provided (e.g. values clarification).
Colella 2004	Not a patient decision aid (describes model of care)
Coronado-Vazquez 2019	Not a patient decision aid
Costanza 2011	Not a randomized controlled trial
Coulter 2003	Not a randomized controlled trial (editorial)
Cox 2012	Not a randomized controlled trial
Crang-Svalenius 1996	Not a randomized controlled trial
Davies 2021	Not a patient decision aid
Davis 2014	Two decision aids compared
Davison 1999	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid
Davison 2007	Not a patient decision aid
De Boer 2012	Not a randomized controlled trial
De Haan 2013	Not a randomized controlled trial of a patient decision aid
Deen 2012	Not a patient decision aid
Dehlendorf 2019	Not a patient decision aid (no discussion of options, benefits, harms)
Deinzer 2009	Not a patient decision aid
Den Ouden 2017	Study does not report outcomes of interest to this review
Denig 2014	Not a patient decision aid
Deschamps 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Deyo 2000	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Diefenbach 2012	Not a patient decision aid
Diefenbach 2018	Two decision aids compared
Dobke 2008	Not focused on making a choice

Study	Reason for exclusion
Dodin 2001	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Doll 2019	Two decision aids compared
Donovan 2012	Does not report results of the randomized controlled trial; descriptive article offering techniques of provision of information
Driscoll 2008	Not a patient decision aid
Dunn 1998	Quasi-RCT: randomization was by days of the week
Eaton 2011	Not a decision aid (no decision support)
Eden 2009	Hypothetical choice, not at point of decision-making
Eden 2014	The educational brochure (control group) provided information about the options, benefits, and harms, making it a simple patient decision aid
Eden 2015	Not a treatment or screening decision
Edwards 2012	Hypothetical choice, not a randomized controlled trial
El Miedany 2019	Pediatric population
El-Jawahri 2010	End of life decision
Ellison 2008	Not a randomized controlled trial (quasi-experimental design); unclear whether at point of decision-making
Elwyn 2004	No difference in intervention between arms; risk communication did not have values clarification
Elwyn 2016	Not a randomized controlled trial
Emery 2007	Not a patient decision aid
Emmett 2007	Not a randomized controlled trial
Eneanya 2020	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Fadda 2017	Not a patient decision aid
Fagerlin 2021	Two decision aids compared
Fang 2021	Two decision aids compared
Feldman-Stewart 2006	Hypothetical choice, not at point of decision-making
Feldman-Stewart 2012	Same patient decision aid with vs without values clarification
Fiks 2013a	Not patient decision-making (uptake of vaccine)
Fiks 2015	Not a patient decision aid
Fleisher 2015	Study does not report outcomes of interest to this review

Study	Reason for exclusion
Flood 1996	Non-randomized allocation; wait list control
Francis 2009	Not a patient decision aid
Fraval 2015	Not a patient decision aid; general education material to obtain informed consent for surgery
Frosch 2001	Not a randomized controlled trial
Frosch 2003	Same decision aid delivered on the Internet versus on DVD plus booklet
Frosch 2008b	Not a randomized controlled trial
Frosch 2011	Not a patient decision aid
Frost 2009	Qualitative study for an included RCT
Fujiwara 2015	Not a patient decision aid and aims to increase screening rates
Garvelink 2013	Hypothetical decision
Garvelink 2017	Two decision aids compared
Genz 2012	Not a patient decision aid
Genz 2014	Not a patient decision aid
George 2021	Not a patient decision aid
Giordano 2014	Not a patient decision aid
Goel 2001	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Gong 2017	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Gorawara-Bhat 2017	Study does not report outcomes of interest to this review
Graham 2000	Not a patient decision aid (general information)
Gray 2009	Hypothetical choice, not at the point of decision-making
Green 2001b	Not a patient decision aid (educational intervention)
Green 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Green 2020	Advanced care planning
Greenfield 1985	Not focused on making a choice (intervention to increase patient involvement in care)
Griffith 2008a	Hypothetical choice, not at the point of decision-making
Griffith 2008b	Not a randomized controlled trial
Gruppen 1994	Not a patient decision aid

Study	Reason for exclusion
Guillen 2019	Not a patient decision aid (no description of options, benefits, or values clarification)
Gulliford 2014	Not a patient decision aid
Gummersbach 2015	Not a patient decision aid and a hypothetical decision
Hacking 2013	Not a patient decision aid
Hall 2007	Not about evaluating a patient decision aid
Hall 2011	Not a patient decision aid
Hamann 2014	Not a patient decision aid
Harmsen 2014	Not a patient decision aid
Harwood 2011	Not a randomized controlled trial
Hawley 2016	Not a randomized controlled trial
Healton 1999	Not a patient decision aid (education to promote compliance)
Heisler 2014	Not a patient decision aid
Henderson 2013	Not a treatment or screening decision
Henselmans 2020	Not a patient decision aid
Herrera 1983	Quasi-RCT: assigned to 1 of 2 alternating groups
Hersch 2021	Two decision aids compared
Hess 2015	Conjoint analysis for values clarification without information on options, pros and cons
Hewison 2001	Not a patient decision aid; no values clarification
Heyland 2020	Advanced care planning
Heyn 2013	Not a randomized controlled trial
Hickish 1995	Not a randomized controlled trial (letter)
Hinsberg 2018	Two decision aids compared
Hochlehnert 2006	Not a patient decision aid (general information; no values clarification)
Hofbauer 2008	Not a randomized controlled trial
Hoffman 2009	Not a patient decision aid
Hoffmann 2022	Study does not report outcomes of interest to this review (only clinician outcomes)
Holbrook 2007	Hypothetical choice, not at the point of decision-making
Hollen 2013	Not a treatment or screening decision

Study	Reason for exclusion
Holloway 2003	Not focused on making a choice (promotes complying with a recommended option)
Holmes-Rovner 2011	Not a randomized controlled trial
Holt 2009	Study does not evaluate a decision aid; evaluation of spiritual versus non-spiritual framework
Holt 2020	Not a patient decision aid
Holzhüter 2020	Not a patient decision aid
Hope 2010	Same content
Hopkin 2019	Hypothetical choice
Howard 2022	Advanced care planning
Huang 2017	Hypothetical choice
Huijbregts 2013	Not a patient decision aid
Hulbaek 2021	Study does not report outcomes of interest to this review (focused on feasibility of conducting the trial)
Hunt 2005	Not focused on making a choice (promotes complying with a recommended option)
Hunter 1999	Not focused on making a choice (no specific decision)
Hunter 2005	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Hutyra 2019	Two decision aids compared
Huyghe 2009	Hypothetical choice, not at point of decision-making for all participants
Ilic 2008	No difference in content of interventions - testing mode of delivery
Isebaert 2007	Not a randomized controlled trial (English paper published in 2008 *Urologia Internationalis*)
Jackson 2011	Not a patient decision aid
Jayakumar 2021	Two decision aids compared
Jerant 2007	Not focused on making a choice - adherence to screening
Jessop 2020	Not a patient decision aid
Jibaja-Weiss 2006	No comparison outcome data provided (only presents data for intervention group)
Jimbo 2019	Two decision aids compared
Jimenez 2017	Study does not report outcomes of interest to this review
Joosten 2009	Not a patient decision aid
Joosten 2011	Not a patient decision aid

Study	Reason for exclusion
Jorm 2003	Hypothetical choice, not at point of decision-making - community sample asked to evaluate information booklet on depression
Juraskova 2014	About clinical trial entry
Kahn 2022	Quasi-RCT: randomization was by odd/even days of the month
Kakkilaya 2011	Hypothetical choice, not at point of decision-making
Kang 2020	Advanced care planning
Kaplan 2014a	Not a patient decision aid
Kaplan 2014b	Not randomized controlled trial results; cross-sectional analysis of baseline data
Kask-Flight 2021	Not a treatment or screening decision
Kassan 2012	Web arm only, not a randomized controlled trial
Kawasaki 2015	Not a patient decision aid
Kayler 2020	Two decision aids compared
Kellar 2008	Hypothetical choice, not at point of decision-making
Kiatpongsan 2014	No specific decision to be made and not a true randomized controlled trial
Klifto 2021	Two decision aids compared
Kobelka 2009	Not a randomized controlled trial; not a patient decision aid
Kobewka 2021	Advanced care planning
Koelewijn-van Loon 2009	Lifestyle only
Korger 2021	Hypothetical choice; not a patient decision aid
Krawczyk 2012	Uptake of a recommended option
Kripalani 2007	Not a patient decision aid
Krones 2008	Not a patient decision aid - no benefits and harms
Kukafka 2018	Not a randomized controlled trial
Kuppermann 2009	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Kurian 2009	Not a randomized controlled trial; not a patient decision aid
Kushner 2022	Not a patient decision aid
Köpke 2009	Not a patient decision aid
Köpke 2014	Not a patient decision aid

Study	Reason for exclusion
Labrecque 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
LaCroix 1999	Inadequate comparison outcome data provided, secondary report of pilot study
Lai 2021	Not a randomized controlled trial
Lairson 2011	Not a patient decision aid (to increase uptake of screening)
Lalonde 2006	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Lancaster 2009	Not a patient decision aid
Landrey 2013	Not a patient decision aid
Langford 2020	Two decision aids compared
Lazcano Ponce 2000	Not a patient decision aid (no values clarification)
Legare 2003	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Leung 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Levin 2011	Not a patient decision aid
Lewis 2003	Hypothetical choice, not at the point of decision-making
Lewis 2012	Uptake of a recommended option
Lewis 2015	Study is not focused on evaluation of the decision aid (focused on dissemination methods)
Lipnick 2020	Advanced care planning
Lipstein 2021	Not a treatment or screening decision; pediatric population
Logan 2022	Not a patient decision aid
Lopez-Jornet 2012	Not a patient decision aid/not at point of decision-making
Lord 2017	Not a patient decision aid (no description of benefits and harms of options)
Lukens 2013	Not a patient decision aid; results in response to clinical vignettes (hypothetical scenarios)
Lurie 2011	Not a randomized controlled trial (all patients received decision aid)
Maisels 1983	Not a patient decision aid (no values clarification)
Makimoto 2020	Not a patient decision aid
Mancini 2006	Not about evaluating a patient decision aid
Mangla 2019	Two decision aids compared
Manne 2009	Not focused on making a choice (about adherence not decision-making)
Manne 2016	Two decision aids compared

Study	Reason for exclusion
Manns 2005	Not focused on making a choice (promotes complying with a recommended option)
Markham 2003	Not a patient decision aid (review of patient information pamphlets on pre-operative fasting)
Markun 2015	Not a patient decision aid
Martin 2012	Hypothetical choice, not at the point of decision-making
Maslin 1998	Insufficient outcome data provided in publication; requested from author but not provided
Matlock 2014	End of life
Matlock 2020	Study did not evaluate the decision aid (evaluated implementation)
Matloff 2006	Not a patient decision aid - genetic counseling only
Mazur 1994	Hypothetical choice, not at the point of decision-making
McBride 2016	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but they no longer have access
McCaffery 2007	Not a patient decision aid
McGinley 2002	Not a patient decision aid (no values clarification)
McGowan 2008	Not a patient decision aid
McInerney-Leo 2004	Not a patient decision aid (no risk/benefit information; no values clarification)
Mclaren 2012	Not a patient decision aid; hypothetical choice, not at point of decision-making
Meropol 2013	Not a patient decision aid
Mertz 2020	Not a patient decision aid
Michael 2022	Advanced care planning
Michie 1997	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid; additional information requested, but author was unable to provide the intervention.
Miller 2014a	No specific decision; related to increasing visits to healthcare provider
Miller 2014b	Aims to increase visits to healthcare providers; intervention targeted to partners
Minneci 2019	Control group received a decision support intervention with the key elements of the patient decision aid
Mishel 2009	Not a patient decision aid (information only)
Mohammad 2012	Not a patient decision aid; presents only benefits, not harms
Molenaar 2001	Not a randomized controlled trial
Mulley 2006	Not a randomized controlled trial (editorial)

Study	Reason for exclusion
Myers 2005a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Myers 2005b	Not a randomized controlled trial (editorial)
Myers 2007	Not a patient decision aid
Myers 2011	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Myers 2013	Uptake of screening
Myers 2019	Not a patient decision aid
Neubeck 2008	Study protocol, does not appear to be patient decision aid
Newton 2001	Not a randomized controlled trial
O'Cathain 2002	Suite of 8 decision aids (not an efficacy trial)
O'Connor 1999a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
O'Connor 1996	No patient decision aid - framing effects
O'Connor 1998a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
O'Connor 2009a	Not a patient decision aid
O'Connor 2011	Not a patient decision aid
Owens 2014A	Not an RCT; doctoral dissertation
Pablos 2020	Not a randomized controlled trial
Paquin 2021	Hypothetical choice
Parker 2017	Pediatric population
Patanwala 2011	Not a patient decision aid
Patel 2014	Not an RCT
Pearson 2005	Not a patient decision aid (focus on provision of information)
Peele 2005	Not a patient decision aid (decision aid only supplies mortality risk information; no risk info; no values clarification)
Petty 2014	Not a randomized controlled trial and not a patient decision aid
Philip 2010	Not a randomized controlled trial, not a patient decision aid (promotes complying with a recommended option)
Phillips 1995	Quasi-RCT: alternating order based on patients' initial appointment sequence
Pignone 2013	Not a patient decision aid; compared the effect of 3 different values clarification methods
Pinto 2008	About clinical trial entry

Study	Reason for exclusion
Politi 2020b	Not a treatment or screening decision
Powers 2011	Not a patient decision aid
Probst 2020	Not a patient decision aid
Proctor 2006	Not a patient decision aid (general patient education resource)
Prunty 2008	About a lifestyle choice - whether or not to have a child or have another child if I have multiple sclerosis
Qureshey 2022	Not a patient decision aid (promotes complying with a recommended option)
Ramallo-Farina 2020	Not a patient decision aid
Ranta 2015	Not a patient decision aid; intended to increase guideline adherence for transient ischemic attack/stroke
Rapley 2006	Not a randomized controlled trial
Raynes-Greenow 2009	No difference in intervention content; comparison of presentation formats; audio-guided decision aid versus booklet only
Raynes-Greenow 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Reder 2017	Two decision aids compared
Reder 2019	Two decision aids compared
Rimer 2001	Not focused on making a choice (promotes complying with a recommended option)
Rimer 2002	Not focused on making a choice (promotes complying with a recommended option)
Rising 2018	Not a patient decision aid
Robinson 2013	Not a patient decision aid
Rogojanski 2022	Not a randomized controlled trial
Ronda 2014	Benefits or harms of self-testing are not provided as information on the website; values clarification exercise asks users to qualify value statements as benefits or harms
Rosen 2022	Hypothetical choice
Rostom 2002	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Roter 2012	Not a patient decision aid
Rothert 1997	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Rothwell 2019	Two decision aids compared
Rovner 2004	Not a randomized controlled trial
Rubinstein 2011	Not a patient decision aid

Study	Reason for exclusion
Ruddy 2009	Not a patient decision aid
Ruehlman 2012	Not a patient decision aid
Ruland 2013	No specific decision to be made
Rutten 2022	Not a patient decision aid
Ryser 2004	Not focused on making a choice (promotes complying with a recommended option)
Sassen 2014	Not a patient decision aid evaluation study; healthcare professionals were recruited, not patients
Saver 2007	Not a patient decision aid - general information; not a specific decision
Sawka 2011	Not a randomized controlled trial
Sawka 2015a	Not a patient decision aid (information about one choice only, no values clarification reported)
Sawka 2015b	Not a patient decision aid (information about one choice only, no values clarification reported)
Scaffidi 2014	Not an RCT
Schaffer 2018	Not a patient decision aid
Schapira 2000	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Schapira 2007	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Scherr 2022	Two decision aids compared
Schnipper 2010	Not a patient decision aid
Scholl 2021	Not a patient decision aid (no specific decision)
Schroy 2016	Two decision aids compared
Schwartz 2009b	Hypothetical choice, not at the point of decision-making
Sears 2007	About do not resuscitate versus initiating cardiopulmonary resuscitation decision
Seitz 2018	Not a patient decision aid (no description of options, benefits, risks)
Sepucha 2022	Two decision aids compared
Sequist 2011	Not a patient decision aid (promotes complying with a recommended option)
Serovich 2020	Not a treatment or screening decision
Sferra 2021	Two decision aids compared
Shah 2012	Not a patient decision aid, lifestyle choices
Shegog 2020	Not a patient decision aid; not a treatment or screening decision
Sheppard 2012	Not a randomized controlled trial

Study	Reason for exclusion
Sheridan 2004	Not a randomized controlled trial
Sheridan 2010	Hypothetical choice, not at point of decision-making
Sheridan 2012	Not a patient decision aid - no benefits and harms
Sherman 2014	Not a randomized controlled trial
Sherman 2016	Two decision aids compared
Sherman 2017	Two decision aids compared
Shirai 2012	Not a patient decision aid
Silver 2012	Hypothetical choice, not at point of decision-making
Siminoff 2006	Not a patient decision aid (no discussion of harms)
Simon 2012a	Not a patient decision aid
Simon 2012b	Not a patient decision aid
Smith 2011a	No decision regarding treatment or screening to be made (decision regarding full disclosure)
Smith 2011b	Not a patient decision aid, not an RCT
Smith 2020	Not a patient decision aid
Solberg 2010	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Sorenson 2004	Not a randomized controlled trial
Sparano 2006	Not a patient decision aid
Stalmeier 2009	Not a randomized controlled trial (about instrument development)
Stankowski-Drengler 2019	Two decision aids compared
Starosta 2015	Not a patient decision aid - benefits and harms of screening are missing.
Stein 2013	End of life
Steiner 2003	Not a patient decision aid (only effectiveness not cons of options; not at point of decision-making)
Stephens 2008	Not a randomized controlled trial
Stiggelbout 2008	Not a patient decision aid
Stirling 2012	Not a treatment or screening decision
Stratton 2019	Not a treatment or screening decision
Street 1995	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Street 1998	Not focused on making a choice (promotes complying with a recommended option)

Study	Reason for exclusion
Suen 2021	Not a patient decision aid
Sundaresan 2011	Hypothetical choice, not at the point of decision-making, not a randomized controlled trial
Tabak 1995	Not a randomized controlled trial
Taksler 2021	Not a patient decision aid
Tanser 2021	Not a patient decision aid
Tappen 2020	Advanced care planning
Taylor 2013	Not a patient decision aid - benefits and harms of screening not included
Tebb 2019	Not a patient decision aid
Ten 2008	Not a patient decision aid; about stopping medication use
Ter Stege 2021	Study does not report outcomes of interest to this review
Thiede 2021	Advanced care planning
Thomas 2013	Not a patient decision aid
Thomson 2006	Not a randomized controlled trial; not at point of decision-making
Thornton 1995	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Tiedje 2021	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Tiller 2006	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Tinsel 2013	Not a patient decision aid
Tomko 2015	Not a patient decision aid - benefits and harms of screening are missing
Tran 2015	Not a patient decision aid (promotes complying with a recommended option)
Tsai 2022	Not a patient decision aid
Tucholka 2018	Two decision aids compared
Ufere 2022	Advanced care planning
Ukoli 2013	Not an RCT
Valdez 2001	Not a randomized controlled trial; not focused on making a choice (complying with a recommended option)
Van der Krieke 2013	Not a patient decision aid, no benefits/harms
Van Roosmalen 2004	Simple versus detailed patient decision aid (excluded in update after 2014 publication)

Study	Reason for exclusion
Van Steenkiste 2008	Not a randomized controlled trial
Van Til 2009	Hypothetical choice, not at the point of decision-making
Van Tol-Geerdink 2013	Not a randomized controlled trial; insufficient information to judge random sequence generation, allocation concealment, and blinding
VanScoy 2017	Advanced care planning
Veroff 2012	Not a patient decision aid
Volandes 2009	Advanced care planning options
Volandes 2011	Hypothetical choice, end of life decision
Volandes 2013	Advanced care planning
Volk 2008	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Von Wagner 2011	Not a randomized controlled trial (commentary)
Wagner 1995	Not a randomized controlled trial
Wakefield 2008a	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Wakefield 2008b	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Wakefield 2008c	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
Wallston 1991	Not a patient decision aid - patient preference study
Wang 2004	Not a patient decision aid - intent of intervention to facilitate genetic counseling process, no focused decision
Wang TJ 2021	Two decision aids compared
Warner 2015	Not a treatment or screening decision
Waterman 2018	Not a patient decision aid
Waterman 2019	Not a patient decision aid
Waterman 2021	Not a patient decision aid
Watts 2014	Simple versus detailed patient decision aid
Wehkamp 2021	Hypothetical choice
Welschen 2012	Not a patient decision aid
Weng 2017	Not a patient decision aid (information about one choice only, no values clarification)
Wennberg 2010	Same decision aid in both groups
Werk 2019	Not a patient decision aid

Study	Reason for exclusion
Westermann 2013	Not a patient decision aid
Weymann 2015	Patients not at the point of decision-making
Wilhelm 2009	Not a patient decision aid
Wilkes 2013	Unable to ascertain characteristics of the patient decision aid. Additional information requested from author but not provided (e.g. values clarification).
Wilkie 2013	Not treatment or screening decision
Wilkins 2006	Not a randomized controlled trial
Willemsen 2006	Lifestyle change
Williams-Piehota 2008	Not a randomized controlled trial
Williamson 2014	Lifestyle decision - not treatment or screening
Wilson 2019	Study does not report outcomes of interest to this review
Wolff 2020	Not a patient decision aid
Woltmann 2011	Not a patient decision aid
Wroe 2005	Not focused on making a choice - promotes complying with a recommended option
Yao 2017	Not a randomized controlled trial
Yee 2014	Not a patient decision aid
Yu 2020	Not a patient decision aid (no specific decision)
Yu 2021	Study does not report outcomes of interest to this review (focused on feasibility of conducting the trial)
Yun 2011	End of life decision
Zajac 2012	Hypothetical
Zapka 2004	Not focused on making a choice - promotes complying with a recommendation
Zhong 2021	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid; additional information requested from author but not provided
Zikmund-Fisher 2008	No difference in intervention content - comparison of presentation of probabilities
Zoffman 2012	Not a randomized controlled trial, not a patient decision aid

RCT: randomized controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12616001665426

Study name	Navigate: Randomised controlled trial of an online treatment decision aid for men with localised prostate cancer and their partners
Methods	RCT
Participants	304 adults diagnosed with localized prostate cancer in the last 3 months
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decisional regret, decisional satisfaction, preparedness for decision-making, quality of life, quality of patients' and partners' illness communication
Starting date	May 2017
Contact information	Ms Natalie Richards, navigate@petermac.org
Notes	Trial# ACTRN12616001665426

ACTRN12617001246370

Study name	Use of an internet-based decision aid (myAID) for ulcerative colitis patients to improve quality of life, empowerment, decision making and disease control
Methods	RCT
Participants	426 adults with a diagnosis of ulcerative colitis
Interventions	Patient decision aid vs usual care
Outcomes	Health-related quality of life, acceptability of the decision aid, anxiety, empowerment, health literacy, adherence, quality of decision-making
Starting date	October 2016
Contact information	Dr Andrew Kim, andrew.h.kim@student.unsw.edu.au
Notes	Trial# ACTRN12617001246370

ACTRN12618001219279

Study name	The Optimise Study - randomised trial of the use of a decision aid to improve informed choice regarding the benefits of low-dose aspirin to prevent cardiovascular disease and colorectal cancer
Methods	RCT
Participants	1780 adults aged 50 to 70 years who have not been diagnosed with a serious illness
Interventions	Patient decision aid vs usual care
Outcomes	Measure of informed choice (MMIC) incorporating assessments of knowledge, adherence to aspirin
Starting date	August 2018

ACTRN12618001219279 *(Continued)*

Contact information	Lyndal Trevena, lyndal.trevena@sydney.edu.au
Notes	Trial# ACTRN12618001219279

ACTRN12620001003965

Study name	Should I Take Aspirin? The SITA Trial, a randomised controlled trial of a decision aid to support informed choices about taking aspirin to prevent bowel cancer for Australians aged 50 to 70 years
Methods	RCT
Participants	258 adults aged 50 to 70
Interventions	Patient decision aid vs information
Outcomes	Adherence, ability to make an informed choice, decisional conflict
Starting date	October 2020
Contact information	Ms Shakira MIlton, shakira.milton@unimelb.edu.au
Notes	Trial# ACTRN12620001003965

ACTRN12620001032943

Study name	Comparing different information resources on the process and quality of decision making in women considering elective egg freezing
Methods	RCT
Participants	286 females aged 18 years or over considering egg freezing
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, length of time to make a decision, knowledge, distress, informed choice, level of involvement in decision-making, decisional regret
Starting date	September 2020
Contact information	Dr Michelle Peate, mpeate@unimelb.edu.au
Notes	Trial# ACTRN12620001032943

ACTRN12621000515897

Study name	Evaluating fertility decision aids for younger women with breast cancer
Methods	RCT

ACTRN12621000515897 *(Continued)*

Participants	236 women aged between 18 to 40 years (inclusive) who are pre-menopausal and have a histologically confirmed diagnosis of early-stage breast cancer
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decision regret, informed choices, knowledge, psychological outcomes
Starting date	July 2021
Contact information	Dr Michelle Peate, mpeate@unimelb.edu.au
Notes	Trial# ACTRN12621000515897

Al-Itejawi 2015

Study name	(Cost-)effectiveness and implementation of a decision aid for patients with prostate cancer
Methods	Stepped wedge cluster-RCT
Participants	Newly diagnosed adult participants with localized prostate cancer
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, quality of life, treatment preferences, participation in decision-making, knowledge, patient-provider communication
Starting date	May 2015
Contact information	Hoda Al-Itejawi, Afdeling Urologie, Amsterdam, the Netherlands
Notes	Trial #: NTR5177

Aslani 2014a

Study name	Computerized decision aid on mode of delivery
Methods	Cluster-RCT
Participants	Pregnant Iranian women
Interventions	Computerized decision aid
Outcomes	Decisional conflict, knowledge
Starting date	Not reported
Contact information	Azam Aslani, Mashhad University, Iran
Notes	Registration number IRCT2015093010777N4

Aslani 2014b

Study name	Impact of computer-based pregnancy-induced hypertension and diabetes decision aids on empowering pregnant women
Methods	RCT
Participants	420 healthy pregnant women
Interventions	Patient decision aid vs usual care
Outcomes	Self-efficacy, knowledge, type and frequency of doctor and/or medical center visits, anxiety
Starting date	November 2013
Contact information	Saeid Eslami, Mashhad University of Medical Science, eslams@mums.ac.ir
Notes	Trial# IRCT2013103010777N2

Bansback 2019

Study name	An individualized patient-reported outcome measure (PROM) based patient decision aid and surgeon report for patients considering total knee arthroplasty: protocol for a pragmatic randomized controlled trial
Methods	RCT
Participants	163 adults (age ≥ 30) patients with knee osteoarthritis (OA) who have an appointment with a surgeon for consultation about total knee arthroplasty
Interventions	Patient decision aid vs usual care
Outcomes	Decision quality, quality of life, depression, knowledge, values, decisional conflict, treatment preference, preference for involvement in decision-making, willingness to have surgery, patient-reported shared decision-making, decisional regret, satisfaction with knee replacement surgery, expectations, surgical consult, surgery, concordance
Starting date	June 2017
Contact information	Nick Bansback, nick.bansback@ubc.ca
Notes	Trial# NCT03240913

Baptista 2020

Study name	Comparison of explicit values clarification method (VCM), implicit VCM and no VCM decision aids for men considering prostate cancer screening: protocol of a randomized trial
Methods	RCT
Participants	276 adult men (50 to 69 years) with average risk for prostate cancer
Interventions	Patient decision aid with implicit values clarification vs patient decision aid with explicit values clarification vs control (information only)

Baptista 2020 *(Continued)*

Outcomes	Perceived clarity of personal values (3-item subscale of the Decisional Conflict Scale), decisional conflict, screening preference, actual choice
Starting date	September 2019
Contact information	Sofia Baptista, baptistas@med.up.pt
Notes	Trial# NCT03988673

Beach 2016

Study name	Protocol of a randomized controlled trial of an erythropoietin stimulating agent decision aid for anemia treatment in kidney disease
Methods	RCT
Participants	100 adults aged 18 to 80 with a diagnosis of chronic kidney disease (CKD) or end-stage renal disease (ESRD), and currently recieving erythropoietin-stimulating agent (ESA) therapy
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, satisfaction with provider communications, decisional conflict, perceived efficacy in patient-physician interactions
Starting date	November 2013
Contact information	Kerri Cavanaugh, kerri.cavanaugh@vanderbilt.edu
Notes	Trial# NCT01992926

Benoit 2020

Study name	Does a web-based decision aid improve informed choice for fertility preservation in women with breast cancer (DECISIF)? Study protocol for a randomised controlled trial
Methods	RCT
Participants	186 women 18 to 40 years old with breast cancer
Interventions	Patient decision aid vs usual care
Outcomes	Multidimensional Measure of Informed Choice (MMIC), decisional conflict, anxiety
Starting date	September 2018
Contact information	Alexandra Benoit, alexandra.benoit@aphp.fr
Notes	Trial# NCT03591848

Carhuapoma 2021

Study name	Employing a mobile health decision aid to improve decision-making for patients with advanced prostate cancer and their decision partners/proxies: the CHAMPION randomized controlled trial study design
Methods	RCT
Participants	316 adults with stages III/IV prostate cancer
Interventions	Patient decision aid vs usual care
Outcomes	Decision conflict, decision regret, health-related quality of life, decision-making participation preference
Starting date	July 2017
Contact information	Randy A Jones, raj9c@virginia.edu
Notes	Trial# NCT03327103

Chambers 2008

Study name	ProsCan for Men: randomized controlled trial of a decision support intervention for men with localised prostate cancer
Methods	RCT
Participants	700 men newly diagnosed with localized prostate cancer
Interventions	A tele-based nurse delivered 5-session decision support/psychosocial intervention vs usual care
Outcomes	Cancer threat appraisal; decision-related distress and bother from treatment side effects; involvement in decision-making; satisfaction with health care; healthcare utilization; use of healthcare resources; and a return to previous activities
Starting date	Not yet assessed
Contact information	Suzanne K Chambers, Griffith University
Notes	Trials #: ACTRN012607000233426

Columbo 2019

Study name	Design of the PReferences for Open Versus Endovascular Repair of Abdominal Aortic Aneurysm (PROVE-AAA) trial
Methods	Cluster-RCT
Participants	240 veterans with abdominal aortic aneurysm who are candidates for either endovascular or open repair
Interventions	Patient decision aid vs control (no intervention)

Columbo 2019 *(Continued)*

Outcomes	Preferred choice, congruence between preferred and actual choice, decision regret
Starting date	June 2017
Contact information	Philip Goodney, White River Junction VA Medical Center, White River Junction, VT
Notes	Trial# NCT03115346

CTRI/2019/06/019610

Study name	Effectiveness of Nursing Intervention Module on knowledge, adherence, complications and quality of life among persons receiving oral anticoagulation therapy
Methods	RCT
Participants	320 adults aged 21 and above on oral anticoagulation therapy
Interventions	Patient decision aid vs usual care
Outcomes	Adherence, knowledge, complication rates, quality of life
Starting date	June 2019
Contact information	Janet Prameela Dsouza, janet.p@manipal.edu
Notes	Trial# CTRI/2019/06/019610

de Molina-Férnandez 2019

Study name	The effectiveness of a digital shared decision-making tool in hormonal contraception during clinical assessment: study protocol of a randomized controlled trial in Spain
Methods	Cluster-RCT
Participants	1708 women who attend clinical contraceptive counseling units
Interventions	Decision-making tool vs usual care
Outcomes	Adherence to the chosen treatment, attitude towards compliance, actual choice, decisional conflict, satisfaction with the counselor or clinician with the use of the decision aid, knowledge
Starting date	January 2019
Contact information	Dr Maria Inmaculada de Molina-Fernandez, inmaculada.demolina@urv.cat
Notes	Trial# ISRCTN5827994

DRKS00014627

Study name	Evaluation of a patient-oriented decision aid and the German healthcare situation in non-metastatic prostate cancer
Methods	RCT
Participants	1115 male patients in the age group 18 to 80 with histologically confirmed adenocarcinoma of the prostate and no clinical evidence of metastases
Interventions	Patient decision aid vs information
Outcomes	Treatment decision, knowledge, acceptability of intervention/control, decisional conflict, doctor-patient communication, fear and depressiveness, decision regret, quality of life
Starting date	July 2018
Contact information	Johannes Huber, johannes.huber@gmail.com
Notes	Trial# DRKS00014627

DRKS00015823

Study name	Development and piloting of a decision support tool to support decision making in the context of risk-adapted prevention for patients with pathogenic BRCA1/2 mutations
Methods	RCT
Participants	78 females aged 18 to 70 with unilateral breast cancer (first disease without metastasis)
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Decisional conflict, stage of decision-making, knowledge, psychological stress consequences, anxiety and depression
Starting date	November 2018
Contact information	Sibylle Kautz-Freimuth, sibylle.kautz-freimuth@uk-koeln.de
Notes	Trial# DRKS00015823. Trial registered retrospectively.

Geiger 2011

Study name	Investigating a training supporting Shared Decision Making (IT'S SDM 2011): study protocol for a randomized controlled trial
Methods	RCT
Participants	40 physicians that contribute a sequence of 4 medical consultations including a diagnostic or treatment decision
Interventions	A training curriculum for doctors, intended to stimulate efforts to involve their patients in the decision-making process

Geiger 2011 *(Continued)*

Outcomes	Physician-patient communication, effect of SDM on perceived quality of the decision process and on the elaboration of the decision, decisional conflict
Starting date	Not yet assessed
Contact information	Friedemann Geiger, University Medical Center Schleswig - Holstein
Notes	Trials #: ISRCTN78716079

IRCT20191229045933N1

Study name	Effect of a patient decision aid to select for myopia correction surgery method
Methods	RCT
Participants	30 participants aged 15 years old to 40 years who are nearsighted and candidates for all 33 surgical procedures: Smile, Femto-LASIK and PRK
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Knowledge, Choice
Starting date	April 2021
Contact information	Fatemeh Zarei, f.zarei@modares.ac.ir
Notes	Trial# IRCT20191229045933N1

ISRCTN17611852

Study name	The impact of a decision aid on depressed patients' involvement in shared decision-making
Methods	RCT
Participants	44 patients aged 18 to 60 diagnosed with major depressive disorder
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Patient involvement in the decision-making scale
Starting date	March 2014
Contact information	Khalaf Aljumah, PO Box 33626 11458 Riyadh, Saudi Arabia
Notes	Trial# ISRCTN17611852

Isselhard 2020

Study name	Implementation and evaluation of a nurse-led decision-coaching program for healthy breast cancer susceptibility gene (BRCA1/2) mutation carriers: a study protocol for the randomized controlled EDCP-BRCA study
Methods	RCT
Participants	399 women aged 25 to 60 years with diagnosed, clearly pathogenic BRCA1/2 mutations who have not been diagnosed with breast or ovarian cancer
Interventions	Patient decision aid + decision coaching + optimized standard care vs optimized standard care only
Outcomes	Congruence between preferred and actual role in the decision-making process, satisfaction with the actual role, decisional conflict, knowledge and attitude towards preventions strategies, stage of decision-making, anxiety and depression, coping self-efficacy
Starting date	November 2019
Contact information	Anna Isselhard, Institute of Health Economics and Clinical Epidemiology, University Hospital of Cologne, Cologne, Germany, anna.isselhard@uk-koeln.de
Notes	Trial# DRKS00015527

JPRN-UMIN000024811

Study name	An interventional study to examine the effect of shared decision making in a family on intention of HPV vaccination in order to protect Japanese girls from HPV due to the low coverage of the vaccination and excess of mothers' responsibility to make a decision
Methods	RCT
Participants	900 mothers with daughters aged 12 to 18 years old
Interventions	Patient decision aid vs information
Outcomes	Intention to vaccinate
Starting date	November 2016
Contact information	Tadashi Kimura, tadashi@gyne.med.osaka-u.ac.jp
Notes	Trial# JPRN-UMIN000024811

JPRN-UMIN000032623

Study name	A randomized controlled trial on decision aid to support the stroke with older people in decision making about location of care at recovery rehabilitation ward: efficacy of decision conflict and participation
Methods	RCT
Participants	122 stroke survivors aged > 65 years who are admitted to the rehabilitation ward during their recovery period and facing discharge location decision-making

JPRN-UMIN000032623 *(Continued)*

Interventions	Patient decision aid vs information
Outcomes	Decision Conflict Scale, Control Preference Scale
Starting date	October 2018
Contact information	Yoriko Aoki, yoriko18@med.u-toyama.ac.jp
Notes	Trial# JPRN-UMIN000032623

KCT0006945

Study name	Development of health information communication strategy in response to COVID-19 crisis
Methods	RCT
Participants	Participants aged 18 to 80 years old who have been diagnosed with one or more of the following diseases: diabetes mellitus, heart failure, myocardial infarction, hypertension, renal insufficiency, pulmonary disease, chronic obstructive, asthma, liver
Interventions	Patient decision aid vs information
Outcomes	COVID-19 vaccination intention, decisional conflict, stress, knowledge
Starting date	December 2021
Contact information	Young-il Jung, extra012@knou.ac.kr
Notes	Trial #KCT0006945

Kim 2020

Study name	A web-based decision aid (myAID) to enhance quality of life, empowerment, decision making, and disease control for patients with ulcerative colitis: protocol for a cluster randomized controlled trial
Methods	Cluster-RCT
Participants	426 adults with a diagnosis of ulcerative colitis
Interventions	Patient decision aid vs usual care
Outcomes	Quality of life, empowerment, health literacy, decisional conflict, trust in physician, anxiety, intervention acceptability
Starting date	October 2016
Contact information	Dr Andrew Kim, Ingham Institute Liverpool Hospital, andrew.h.kim@student.unsw.edu.au
Notes	Trial# ACTRN12617001246370

Lange 2021

Study name	An individualized decision aid for physicians and patients for total knee replacement in osteoarthritis (Value-based TKR study): study protocol for a multi-center, stepped wedge, cluster randomized controlled trial
Methods	Cluster-RCT
Participants	1080 patients with knee osteoarthritis referred for total knee replacement
Interventions	Patient decision aid vs usual care
Outcomes	Decision quality, fulfillment of patient expectations
Starting date	June 2021
Contact information	Franziska Beyer, Franziska.Beyer@uniklinikum-dresden.de
Notes	Trial# NCT04837053

Layton 2011

Study name	Effects of a web-based decision aid on African American men's prostate screening knowledge and behavior
Methods	—
Participants	128 African American men
Interventions	—
Outcomes	—
Starting date	—
Contact information	Beverly Layton, Walden University
Notes	Unpublished thesis

Lin E 2022

Study name	Incorporating patient-reported outcomes into shared decision-making in the management of patients with osteoarthritis of the knee: a hybrid effectiveness-implementation study protocol
Methods	RCT
Participants	200 adults aged 45 to 89 with a presumptive diagnosis of knee OA
Interventions	Patient decision aid + education vs education only
Outcomes	Patient perception of decision process and quality, concordance between patient preferences and actual outcomes, patient perception of the level of shared decision-making, patient/provider satis-

Lin E 2022 *(Continued)*

	faction with discussion, total consultation time, patient-reported overall health, choice, decisional conflict, decision regret
Starting date	February 2021
Contact information	Lauren Uhler, lauren.uhler@austin.utexas.edu
Notes	Trial# NCT04805554

Mann 2012

Study name	Increasing efficacy of primary care-based counselling for diabetes prevention: rationale and design of the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) trial
Methods	RCT
Participants	Primary care providers
Interventions	Using the ADAPT (Avoiding Diabetes Thru Action Plan Targeting) system to enhance providers' effectiveness to counsel about lifestyle behavior changes
Outcomes	Outcome measurements are designed to detect changes in patient behaviors that are most likely to result from the use of ADAPT tool: difference between intervention and control patients in the change in mean steps per day at baseline and after 6 months, and 6-month difference of differences in hemoglobin A1C and self-reported diet between the 2 groups
Starting date	Not yet assessed
Contact information	Devin Mann, Boston University School of Medicine
Notes	Trial #: NCT01473654

NCT00813033

Study name	Use of a patient decision aid for gastrologic endoscopy in a paediatric setting
Methods	Interventional efficacy study
Participants	80 parents considering gastro-endoscopy for child
Interventions	Not yet assessed
Outcomes	Knowledge, expectations of outcomes, clarity of values, decision, decision conflict
Starting date	December 2008
Contact information	Nancy Neilan, Children's Mercy Hospital, Kansas City
Notes	Trials #: NCT00813033; completed March 2011

NCT01152307

Study name	Measuring quality of decisions about treatment of depression
Methods	RCT
Participants	Patients that talked to a healthcare provider about starting or stopping a treatment (prescription medicine for depression or counseling)
Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010
Contact information	Karen R Sepucha, Massachusetts General Hospital
Notes	NCT01152307; completed, study results on clinicaltrials.gov

NCT01976325

Study name	Incorporation of the 'Ottawa Malaria Decision Aid' into the pre-travel consultation process
Methods	RCT
Participants	100 adults attending a travel clinic before traveling to an area with known chloroquine-resistant malaria
Interventions	Decision aid vs usual care
Outcomes	Knowledge, decisional conflict, preparation for decision-making, medication adherence
Starting date	January 2014
Contact information	amccarthy@toh.on.ca, Anne E McCarthy, Ottawa Hospital Research Institute
Notes	Trial # NCT01976325

NCT02027545

Study name	Promoting veteran-centered colorectal cancer screening (PROM-IS)
Methods	Cluster-RCT
Participants	436 older individuals (ages 70 to 75) who are "due" for colorectal screening
Interventions	Patient decision aid + education vs education only
Outcomes	Whether screening was ordered, appropriateness of screening orders, conceptual understanding of screening, elements of informed decision-making addressed in the screening discussion, and screening utilization
Starting date	November 2015

NCT02027545 *(Continued)*

Contact information	Sameer D. Saini, VA Ann Arbor Healthcare System, Ann Arbor, MI
Notes	Trial# NCT02027545

NCT02084290

Study name	Evaluating a prediction tool and decision aid for patients with Crohn's disease
Methods	RCT
Participants	300 adults with Crohn's disease
Interventions	Patient decision aid and SDM program vs usual care
Outcomes	Preferred choice, actual choice, adherence, cost of care, remission, patient on steroids, surgeries, Crohn's disease-related hospitalizations
Starting date	March 2014
Contact information	Corey A Siegel, Dartmouth-Hitchcock Medical Center, corey.a.siegel@hitchcock.org
Notes	Trial #: NCT02084290

NCT02107794

Study name	Shared decision making in Graves disease - Graves disease (GD) choice
Methods	RCT
Participants	93 adults aged 18 years or older with a diagnosis of Graves disease
Interventions	Patient decision aid vs usual care
Outcomes	Decisional quality (knowledge, decisional conflict, satisfaction)
Starting date	December 2012
Contact information	Victor M Montori, Mayo Clinic
Notes	Trial# NCT02107794

NCT02145481

Study name	Decisional quality for patients with stable coronary artery disease
Methods	RCT
Participants	846 adults with stable coronary artery disease
Interventions	Patient decision aid vs standard education

NCT02145481 *(Continued)*

Outcomes	Quality of the decision-making process, knowledge, communication, involvement, treatment preferences
Starting date	May 2014
Contact information	R. Adams Dudley, University of California, San Francisco
Notes	Trial # NCT02145481

NCT02259699

Study name	Ovarian cancer patient-centered decision aid
Methods	RCT
Participants	221 women with stage III optimally debulked advanced ovarian cancer
Interventions	Patient decision aid vs usual care
Outcomes	Satisfaction with decision, evidence of shared decision-making, quality of life, satisfaction with care and satisfaction with cancer treatment
Starting date	December 2014
Contact information	Lari Wenzel, University of California, Irvine, USA, lwenzel@uci.edu
Notes	Trial #: NCT02259699

NCT02364128

Study name	Improving patient decisions about bariatric surgery
Methods	RCT
Participants	1000 adults aged 18 and older considering undergoing bariatric surgery
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Decision outcome, knowledge, preferences, weight, quality of life, comorbidity resolution, patient satisfaction
Starting date	January 2014
Contact information	Nancy Birkmeyer, University of Michigan
Notes	Trial# NCT02364128

NCT02488603

Study name	Utilization of decision aids for tamoxifen treatment in breast cancer patients

NCT02488603 *(Continued)*

Methods	RCT
Participants	360 breast cancer patients referred for tamoxifen treatment
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict scale, satisfaction with decision, quality of life
Starting date	August 2015
Contact information	Eun Sook Lee, National Cancer Center, Korea
Notes	Trial # NCT02488603

NCT02503553

Study name	Decision aids in cerebral aneurysm treatment
Methods	RCT
Participants	60 patients undergoing treatment for cerebral aneurysm
Interventions	Patient decision aid vs usual care
Outcomes	Participation in the shared-decision making process; stress levels, patient satisfaction level
Starting date	August 2015
Contact information	Kimon Bekelis, Dartmouth-Hitchcock Medical Center; New Hampshire, USA
Notes	This study was withdrawn on 2 February 2016.

NCT02540044

Study name	Supporting patient care with electronic resource (SuPER): efficacy of an online decision aid for patients considering biologic therapy for rheumatoid arthritis
Methods	RCT
Participants	144 adults with rheumatoid arthritis whose rheumatologists have recommended initiating a biologic/subsequent entry biologic or switching to another biologic agent
Interventions	Online patient decision aid vs online standard information
Outcomes	Decisional conflict, knowledge, self-efficacy, self-management behaviors, health resource utilization, choice, evidence of shared decision-making
Starting date	January 2016
Contact information	Linda Li, University of British Columbia, Vancouver, Canada
Notes	Trial #: NCT02540044

NCT02611050

Study name	Treatment decisions for multi-vessel CAD
Methods	RCT
Participants	160 adults with stable multi-vessel CAD at relative equipoise for at least 2 potential treatment options
Interventions	Option grid decision aid vs usual care
Outcomes	Decisional conflict, CollaboRATE score, knowledge, patient experience, treatment received
Starting date	December 2015
Contact information	Elizabeth L Nichols, the Dartmouth Institute
Notes	This study was terminated on 25 June 2018. Enrollment was not feasible.

NCT02759939

Study name	Right for me: birth control decisions made easier
Methods	RCT
Participants	5038 females aged 15 to 49 years
Interventions	Patient decision aids + training vs decision aids + training + video + prompt card vs video + prompt card vs no intervention
Outcomes	Shared decision-making, conversation about contraception, satisfaction with conversation, intended contraceptive method, values concordance, decision regret, contraceptive method(s) used, adherence
Starting date	July 2016
Contact information	Rachel L. Thompson, Dartmouth-Hitchcock Medical Center
Notes	Trial# NCT02759939

NCT02823262

Study name	A breast cancer treatment decision aid for women aged 70 and older
Methods	RCT
Participants	80 women 70 years or older newly diagnosed with estrogen receptor positive, clinically lymph node negative, HER2 negative, breast cancers that are 3 centimeters or less
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Decisional conflict, knowledge, change in stage of decision-making, self-efficacy, values, treatment preferences, desired role in decision-making, anxiety, quality of life, preparation for decision-mak-

NCT02823262 *(Continued)*

	ing, actual role in decision-making, decision regret, satisfaction with treatment decision, satisfaction with the decision process, treatment received, acceptability of the intervention
Starting date	July 2016
Contact information	Mara Schonberg, Dana-Farber Cancer Institute
Notes	Trial# NCT02823262

NCT02914197

Study name	Giving information on the risks and limitations of mammography screening (GIRLS)
Methods	RCT
Participants	608 females aged 47 to 69 due for a mammogram (have not had a mammogram ≥ 18 months) according to Canadian screening interval recommendations for routine screening
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Self-efficacy, informed choice (knowledge), informed choice (attitude), informed choice (intention), decisional conflict, anxiety, trust in medical system, perception of health provider recommendation, information relevant to the decision-making process, decision regret, screening participation, acceptance of a decision aid, knowledge of the benefits and risks of mammography
Starting date	November 2017
Contact information	McMaster University
Notes	Trial# NCT02914197

NCT02963584

Study name	Decision aid in chronic total occlusion (CTO) patients
Methods	RCT
Participants	160 adults aged 18 and older with coronary occlusion
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, quality of the decision-making process, acceptability with the decision aid, rate of percutaneous coronary intervention (PCI) or medication
Starting date	November 2016
Contact information	Rongchong Huang, The First Affiliated Hospital of Dalian Medical University
Notes	Trial# NCT02963584

NCT03088397

Study name	Effectiveness of a patient decision aid in immediate postpartum contraceptive counseling
Methods	RCT
Participants	126 females aged 14 to 50 postpartum day 1 or postoperative day 1 or 2 who delivered during current admission to hospital
Interventions	Patient decision aid vs information vs usual care
Outcomes	Preparation for decision-making, choice
Starting date	January 2017
Contact information	Erika Levi, Montefiore Medical Center
Notes	Trial# NCT03088397

NCT03099746

Study name	Decision support among surrogate decision makers of the chronically critically ill (INVOLVE)
Methods	RCT
Participants	281 surrogate decision-makers for chronically critically ill patients in the intensive care unit requiring mechanical ventilation
Interventions	Patient decision aid vs information vs usual care
Outcomes	Preparation for decision-making, decision-making self-efficacy, decisional role stress, decisional conflict, control preferences, decision regret, anxiety and depression
Starting date	September 2015
Contact information	Ronald Hickman, Case Western Reserve University
Notes	Trial# NCT03099746

NCT03141437

Study name	Decision aid website in helping to make decisions about fertility in participants with cancer
Methods	RCT
Participants	160 females aged 18 to 45 with newly diagnosed breast tumor, female genital system tumor, colorectal tumor, and/or lymphoma/myeloma and at risk for cancer-related infertility
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decision-making process (e.g. preparation for decision-making, decision self-efficacy, satisfaction) and decision quality (e.g. fertility preservation knowledge, clarity of patients' values, and congruence of preferences with the decision and/or treatment received)

NCT03141437 *(Continued)*

Starting date	April 2017
Contact information	Terri L Woodard MD, Anderson Cancer Center
Notes	Trial# NCT03141437

NCT03244202

Study name	Evaluation of a decision aid for incidental genomic findings
Methods	RCT
Participants	133 adults with a family history of cancer who received a negative single gene test for a cancer gene mutation (e.g. BRCA1/2, MLH, MSH, PMS, etc.) or received a negative panel test
Interventions	Patient decision aid + counseling vs counseling only
Outcomes	Decisional conflict, knowledge, preparation for decision-making, satisfaction with decision, anxiety
Starting date	September 2016
Contact information	Yvonne Bombard, St. Michael's Hospital and University of Toronto
Notes	Trial# NCT03244202

NCT03282097

Study name	Decisions about cancer screening in Alzheimer's disease
Methods	RCT
Participants	426 females aged 75 years or older who have had least one mammogram in the past 5 years and have a diagnosis of Alzheimer's disease or related dementia
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decision-making self-efficacy, role in decision-making, record of mammogram
Starting date	November 2017
Contact information	Nicole R. Fowler PhD, Indiana University
Notes	Trial# NCT03282097

NCT03374891

Study name	A multicenter trial of a shared decision support intervention for patients offered implantable cardioverter-defibrillators
Methods	RCT

NCT03374891 *(Continued)*

Participants	790 patients aged 18 and older that have been offered a primary prevention implantable cardioverter-defibrillator for initial implant, reimplantation, or cardiac resynchronization therapy defibrillator
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Knowledge
Starting date	May 2018
Contact information	Daniel D Matlock, University of Colorado, Denver
Notes	Trial# NCT03374891

NCT03454022

Study name	Decision-aid for renal therapy pilot trial
Methods	RCT
Participants	31 adults aged 70 or older with chronic kidney disease stages 4 or 5, not currently on dialysis
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, congruence in patient-caregiver goals of care, patient satisfaction, caregiver satisfaction, completion of an advance directive
Starting date	March 2017
Contact information	Keren Ladin, Tufts University
Notes	Trial# NCT03454022

NCT03477591

Study name	Evaluating the impact of evidence-based information about PSA testing on prostate cancer screening decisions
Methods	RCT
Participants	308 English-speaking men aged 50 and older
Interventions	Patient decision aid + evidence-based information vs evidence only vs control (sham information)
Outcomes	Decisional conflict, decision quality, preparation for decision-making, congruency between self-reported screening status and stated decision
Starting date	October 2018
Contact information	Maureen Dobbins, McMaster University
Notes	Trial# NCT03477591

NCT03500952

Study name	Family planning ahead
Methods	RCT
Participants	41 pregnant women aged 15 and older that are between 28 and 38 weeks' gestation at the time of enrollment
Interventions	Patient decision aid vs information
Outcomes	Perceived support in decision-making, feeling informed, values clarity, decisional uncertainty, decision self-efficacy, intended contraceptive method(s), values concordance of intended contraceptive method(s), trust in health professional(s), shared decision-making, concordance between preferred and actual decision-making involvement, time pressure in decision-making, pressure to use a certain contraceptive method, values concordance of contraceptive method(s) used, effective decision, contraceptive method(s) prescribed, contraceptive method(s) used, timing of decision about contraceptive method(s), perceived utility of the intervention
Starting date	March 2018
Contact information	Rachel L. Thompson, Dartmouth-Hitchcock Medical Center
Notes	Trial# NCT03500952

NCT03522740

Study name	Decision aid for renal therapy (DART)
Methods	RCT
Participants	400 adults aged 70 and older with chronic kidney disease stages 4 or 5 (non-dialysis) without an established dialysis start or transplant date within 3 months of expected randomization
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, Canadian Health Care Evaluation Project (CANHELP) questionnaire score, completion of an advance directive
Starting date	May 2018
Contact information	Keren Ladin, Tufts University
Notes	Trial# NCT03522740

NCT03578211

Study name	Impact of decision aids on bariatric surgery choice: a randomized controlled trial
Methods	RCT

NCT03578211 *(Continued)*

Participants	140 adults aged 20 to 70 with a body mass index ≥ 32 kg/m ^{2} with obesity-related comorbidity or body mass index ≥ 37 kg/m ^{2}
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decision regret
Starting date	May 2018
Contact information	Yen-Hao Su, Metabolic and Weight Management Center, Shuang-Ho Hospital
Notes	Trial# NCT03578211

NCT03631758

Study name	Evaluating the impact of evidence-based information about mammography on breast cancer screening decisions
Methods	RCT
Participants	209 English speaking women, 40 to 49 years old
Interventions	Patient decision aid + evidence-based information vs evidence only vs control
Outcomes	Decisional conflict, decision quality, preparation for decision-making, congruency between self-reported screening status and stated decision
Starting date	January 2019
Contact information	Maureen Dobbins, McMaster University
Notes	Trial# NCT03631758

NCT03766009

Study name	Increasing patients' engagement in breast cancer surgery decision-making
Methods	RCT
Participants	598 females aged 18 and older newly diagnosed with stage 0-III breast cancer planning breast surgery as a component of their definitive treatment
Interventions	Patient decision aid vs usual care
Outcomes	Self-efficacy, active patient participation, knowledge, concordance between personal values and surgery received
Starting date	March 2019
Contact information	Heather B. Neuman, University of Wisconsin, Madison
Notes	Trial# NCT03766009

NCT03791138

Study name	The impact of a web-based patient decision aid for women considering breast reconstruction
Methods	RCT
Participants	250 females aged 18 and older diagnosed with breast cancer or carcinoma in situ and will be treated with mastectomy and eligible for immediate breast reconstruction
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, decision regret, knowledge, preparation for decision-making, satisfaction with information, patient's perception of shared decision-making, actual choice, anxiety
Starting date	August 2017
Contact information	Eveline MA Bleiker, The Netherlands Cancer Institute
Notes	Trial# NCT03791138

NCT03834532

Study name	Living well after breast surgery
Methods	RCT
Participants	17 female aged 18 and older with new diagnosis of incident or recurrent stage I-III ductal or lobular carcinoma, or ductal carcinoma in situ
Interventions	Patient decision aid vs information
Outcomes	Knowledge, concordance of patient values and decisions, decision regret, satisfaction with decision
Starting date	February 2019
Contact information	Michael P Pignone, University of Texas at Austin
Notes	Trial# NCT03834532

NCT03884387

Study name	The use of a patient decision aid in the choice of surgery for herniated disc
Methods	RCT
Participants	142 adults aged 18 and older with lumbar disc herniation
Interventions	Patient decision aid vs usual care
Outcomes	Decision quality, decisional conflict, decisional regret, quality of life

NCT03884387 *(Continued)*

Starting date	May 2017
Contact information	Stina B Andersen, Sygehus Lillebaelt
Notes	Trial# NCT03884387

NCT03905369

Study name	Focus on values to stimulate shared decisions
Methods	RCT
Participants	128 adults aged 18 and older with thyroid cancer
Interventions	Patient decision aid + SDM booster + deliberation training vs training alone
Outcomes	Patient doctor communication, problem-solving decision-making scale, knowledge, decision evaluation (satisfaction, uncertainty, informed choice, and decision control), trust in oncologist, shared decision-making process
Starting date	March 2020
Contact information	Rosalie Koot, rosalie.koot@radboudumc.nl; Peep Stalmeier, peep.stalmeier@radboudumc.nl
Notes	Trial# NCT03905369

NCT03921437

Study name	Decision support for the renal replacement therapy with end-stage renal disease
Methods	RCT
Participants	76 adults over 20 years old with fifth stage of chronic renal failure
Interventions	Patient decision aid vs usual care
Outcomes	Control preferences, knowledge, decision self-efficacy, decisional conflict, satisfaction with decision, decisional regret
Starting date	April 2019
Contact information	Tasw Jyy Wang, National Taipei University of Nursing and Health Sciences
Notes	Trial# NCT03921437

NCT03995381

Study name	Using decision aids to reducing decision conflict in angiography patients for choosing hemostasis: a randomized controlled trial

NCT03995381 *(Continued)*

Methods	RCT
Participants	150 adults aged 18 to 75 years who need an angiographic examination or treatment
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, knowledge, communication
Starting date	October 2019
Contact information	Taipei Medical University Shuang Ho Hospital
Notes	Trial# NCT03995381

NCT04076332

Study name	How "shared decision making decision-aid" help patients with obstructive sleep apnea to choose treatment plan
Methods	RCT
Participants	90 adults aged 20 to 80 with obstructive sleep apnea
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, health literacy
Starting date	December 2019
Contact information	Dean Wu, Taipei Medical University Shuang Ho Hospital
Notes	Trial# NCT04076332

NCT04097717

Study name	"My Decision" tubal sterilization decision support tool
Methods	RCT
Participants	350 pregnant woman aged 21 to 45 considering tubal sterilization
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict, choice, satisfaction with decision making
Starting date	February 2020
Contact information	Sonya Borrero, borrsp@UPMC.edu; Kelsey Schorr, kls234@pitt.edu
Notes	Trial# NCT04097717

NCT04101409

Study name	Impact of shared decision-making with decision aids on acoustic neuroma treatment choice: a randomized controlled trial
Methods	RCT
Participants	78 adults aged 20 and older with acoustic neuroma
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, knowledge, decision regret, depression
Starting date	October 2019
Contact information	tsaiyichieh, Taipei Medical University Shuang Ho Hospital
Notes	Trial# NCT04101409

NCT04103931

Study name	Impact of a patient decision aid for treatment of aortic stenosis
Methods	RCT
Participants	67 adults aged 18 to 85 years with severe aortic stenosis
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, shared decision-making process, treatment preference, treatment received
Starting date	September 2019
Contact information	Karen R Sepucha, Massachusetts General Hospital
Notes	Trial# NCT04103931

NCT04122989

Study name	Validation of a shared decision-making tool for multiple sclerosis
Methods	RCT
Participants	501 adults aged 18 and older with multiple sclerosis
Interventions	Patient decision aid vs usual care
Outcomes	Proportion who start or switch therapy, patient-provider communication, adherence, decision quality, quality of life, quality of care, decisional conflict
Starting date	November 2019
Contact information	Nananda Col, Shared Decision Making Resources

NCT04122989 *(Continued)*

Notes	Trial# NCT04122989

NCT04175366

Study name	Shared decision making in psychiatric inpatient care
Methods	RCT
Participants	160 adults aged 18 to 100 admitted to psychiatric inpatient care
Interventions	Patient decision aid vs usual care
Outcomes	Patient perceived participation, percentage of carried out planned outpatient visits, number of re-hospitalisations, days of compulsory care, number of inpatient days, number of emergency visits, percentage of decisions on social support carried out, quality of life
Starting date	December 2019
Contact information	Mikael Sandlund, mikael.sandlund@umu.se; Tove Janarv, tove.janarv@umu.se
Notes	Trial# NCT04175366

NCT04177628

Study name	Shared decision making with breast cancer patients
Methods	RCT
Participants	664 females aged 18 and older with breast cancer or ductal carcinoma in situ breast cancer
Interventions	Patient decision aid vs usual care
Outcomes	Participant engagement in the decision-making process, effectiveness in decision-making, decision regret, quality of life
Starting date	March 2020
Contact information	Stine R Sondergaard, stine.rauff.sondergaard@rsyd.dk
Notes	Trial# NCT04177628

NCT04240717

Study name	Shared decision making on immunotherapy in oncology
Methods	RCT
Participants	90 adults aged 18 and older with a diagnosis of metastatic melanoma, stage 3 and 4
Interventions	Patient decision aid vs usual care

NCT04240717 *(Continued)*

Outcomes	Knowledge, decision satisfaction, patient involvement in the decision-making process, choice of treatment option, quality of physician-patient interaction
Starting date	February 2020
Contact information	Christiane Bieber, Heidelberg University
Notes	Trial# NCT04240717

NCT04241978

Study name	Development and evaluation of a web based decision aid for patients with hip osteoarthritis
Methods	RCT
Participants	154 adults aged 18 and older with a diagnosis of hip osteoarthritis
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, knowledge, values about characteristics of treatments, treatment preference, intention to undergo the preferred treatment, concordance between values and intention to undergo treatments, decision quality, satisfaction with the decision-making process
Starting date	February 2020
Contact information	Pedro Serrano Aguilar, pseragu@gobiernodecanarias.org; Lilisbeth Perestelo Perez, lilisbeth.perestelo perez@sescs.es
Notes	Trial# NCT04241978

NCT04260737

Study name	Interactive decision aid for men diagnosed with prostate cancer
Methods	RCT
Participants	200 adults aged 18 and older newly diagnosed with localized prostate cancer
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, decisional regret, satisfaction with decision, anxiety, depression, stress
Starting date	February 2020
Contact information	Valgerdur K Eiriksdottir, valgerdure@ru.is
Notes	Trial# NCT04260737

NCT04270630

Study name	A pilot proof of concept, randomized controlled, single-center study of a decision aid tool for older patients considering LHC as treatment for NSTEMI
Methods	RCT
Participants	50 adults aged 75 and older with non-ST elevation myocardial infarction eligible for non-urgent revascularization
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, anxiety, depression, decision self-efficacy, knowledge
Starting date	July 2020
Contact information	John Dodson, NYU Langone Health
Notes	Trial# NCT04270630

NCT04272177

Study name	Influence of shared-decision making in reducing decision conflict on the choice of awakening agent after general anesthesia
Methods	RCT
Participants	3309 adults aged 20 and older who will receive general anesthesia
Interventions	Patient decision aid vs usual care
Outcomes	Decision conflict, knowledge, percentage of choices of reversal drugs
Starting date	March 2020
Contact information	Ka-Wai Tam, Taipei Medical University Shuang Ho Hospital
Notes	Trial# NCT04272177

NCT04291040

Study name	Use of an educational multimedia tool versus routine care for the uptake of postpartum LARC in high-risk pregnancies (SUSTAIN)
Methods	RCT
Participants	380 females aged 13 to 50 who have high risk pregnancy due to either maternal medical conditions or obstetric/neonatal complications
Interventions	Decision aid vs usual care
Outcomes	Rate of initial LARC utilization, number of patients who keep the LARC after placement
Starting date	July 2020

NCT04291040 *(Continued)*

Contact information	Emma Jean Qureshey, The University of Texas Health Science Center, Houston
Notes	Trial #NCT04291040

NCT04357288

Study name	Randomized evaluation of decision support interventions for atrial fibrillation
Methods	RCT
Participants	1200 adults aged 18 and older diagnosed with atrial fibrillation with additional risk of thromboembolic events
Interventions	Patient decision aid vs encounter decision aid vs patient and encounter decision aids vs usual care
Outcomes	Decisional conflict, knowledge, shared decision-making, decision regret, preparation for decision-making, quality of communication, control preference scale, patient satisfaction with the decision aid, concordance between the participant and the clinician, adherence, treatment choice, encounter length
Starting date	December 2020
Contact information	Maddie McCarty, maddie.mccarty@hsc.utah.edu; Elissa Ozanne, elissa.ozanne@hsc.utah.edu
Notes	Trial# NCT04357288

NCT04364958

Study name	Decision aid for patients with generalized anxiety disorder: protocol for a randomized controlled trial
Methods	RCT
Participants	156 adults aged 18 and older with a diagnosis of generalized anxiety disorder
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, knowledge, treatment preference, actual treatment choice, concordance between preference and choice, decision quality
Starting date	May 2021
Contact information	Lilisbeth Perestelo Pérez, lilisbeth.peresteloperez@sescs.es; Pedro Serrano Aguilar, pseragu@gobiernodecanarias.org
Notes	Trial# NCT04364958

NCT04373590

Study name	Decision-making and decision support among emerging adults with first episode psychosis

NCT04373590 *(Continued)*

Methods	RCT
Participants	18 adults aged 18 to 25 experiencing early psychosis
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decision-making self-efficacy, decision-making attitudes, decisional conflict, shared decision-making, adherence, service use, service engagement
Starting date	February 2019
Contact information	Yaara Zisman Ilani, Temple University
Notes	Trial# NCT04373590

NCT04378816

Study name	A patient-centered continuous and interdisciplinary shared decision making approach for breast cancer rehabilitation
Methods	RCT
Participants	264 patients aged 20 and older with a diagnosis of breast cancer
Interventions	Patient decision aid vs no intervention
Outcomes	Control Preference Scale, Patient-Physician Interactions Questionnaire, Decision Self Efficacy Scale, Patients' Perceived Involvement in Care Scale, Health Care Climate Questionnaire, SURE Test, State-Trait Anxiety Inventory, shared decision-making (collaboRATE)
Starting date	May 2020
Contact information	Wen-Hsuan Hou, Taipei Medical University
Notes	Trial #NCT04378816

NCT04397016

Study name	Cost talk: discussing cancer care costs
Methods	Stepped wedge RCT
Participants	117 adults aged 18 and older with slow growing prostate cancer visiting a participating urologist/urologic surgeon to discuss treatment options
Interventions	Patient decision aid vs usual care
Outcomes	Frequency of cost conversations, initiator (surgeon, patient, or caregiver) of cost conversations, whether or not a referral is made to address costs, decisional conflict, shared decision-making, decision regret
Starting date	June 2020

NCT04397016 *(Continued)*

Contact information	Mary Politi, Washington University School of Medicine; Glyn Elwyn, Dartmouth College
Notes	Trial# NCT04397016

NCT04410029

Study name	Evaluation of a decision aid for early pregnancy loss
Methods	RCT
Participants	60 adults aged 18 and older with a definitive diagnosis of early intrauterine pregnancy loss
Interventions	Patient decision aid vs information
Outcomes	Decision conflict, knowledge, decision regret, shared decision-making
Starting date	July 2020
Contact information	University of Pennsylvania
Notes	Trial# NCT04410029

NCT04437069

Study name	Improving patient and family health using family-centered outcomes and shared decision-making
Methods	RCT
Participants	215 parents aged 18 and older whose fetus/neonate was diagnosed with a life-threatening congenital heart disease
Interventions	Patient decision aid + values clarification exercise vs decision aid only vs usual care
Outcomes	Distress, decision quality - values, decision quality - knowledge, effectiveness of risk communication, preference for shared decision-making, preparation for decision-making, decision self-efficacy, decisional conflict, decisional regret, treatment choice and treatment received, control preferences, acceptability of the decision aid, consultation quality
Starting date	October 2020
Contact information	Angela Fagerlin, University of Utah
Notes	Trial# NCT04437069

NCT04496739

Study name	Making informed choices on incorporating chemoprevention into care (MiCHOICE)
Methods	RCT

NCT04496739 *(Continued)*

Participants	415 women aged 35 to 74 with atypical hyperplasia or lobular carcinoma in situ
Interventions	Patient decision aid vs information
Outcomes	Informed choice, perceived risk, actual risk score, accuracy of risk perception, worry, decision conflict, decision regret, chemoprevention usage, adherence, shared decision-making
Starting date	September 2020
Contact information	Katherine D Crew, Southwest Oncology Group
Notes	Trial# NCT04496739

NCT04504084

Study name	Influence of patient decision-making aids for patients with unilateral ureteral stone: a randomized-controlled trial
Methods	RCT
Participants	100 adults aged 18 to 75 with ureteral stone
Interventions	Patient decision aid vs information
Outcomes	Decision conflict
Starting date	September 2020
Contact information	Yi-Te Chiang, Taipei Medical University Shuang Ho Hospital
Notes	Trial# NCT04504084

NCT04548531

Study name	Engaging patients in colon cancer screening decisions during COVID-19
Methods	RCT
Participants	Adults aged 45 to 75 who had screening or surveillance colonoscopy delayed or canceled from March to June 2020
Interventions	Decision aid vs usual care
Outcomes	Shared decision-making, decisional conflict, preferred approach to screening, number reporting "very likely" to follow through with screening, colon cancer screening rate
Starting date	September 2020
Contact information	Karen Sepucha, Massachusetts General Hospital
Notes	Trial #NCT04548531

NCT04549571	
Study name	Improving patient-centered communication in breast cancer through patient and provider interventions
Methods	RCT
Participants	Women newly diagnosed with stage 0-III breast cancer
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, patient self-efficacy, patient cancer worry
Starting date	January 2021
Contact information	Sarah T. Hawley, sarahawl@umich.edu
Notes	Trial #NCT04549571

NCT04584294	
Study name	Patient-centered reproductive decision support tool for women veterans
Methods	RCT
Participants	456 females aged 18 to 44 interested in receiving information or talking with their provider about pregnancy and/or birth control
Interventions	Patient decision aid vs usual care
Outcomes	Shared decision-making, perceived self-efficacy in communicating with providers, knowledge, decisional conflict, confidence, choice of treatment, use of treatment, adherence, satisfaction with treatment
Starting date	March 2021
Contact information	Lisa S Callegari, lisa.callegari@va.gov; Samantha K Benson, Samantha.Benson@va.gov
Notes	Trial# NCT04584294

NCT04621760	
Study name	The OPENS trial: offering women PrEP (Aim 1)
Methods	RCT
Participants	384 women aged 18 to 45 years old not known to be living with HIV
Interventions	Patient decision aid vs usual care

NCT04621760 *(Continued)*

Outcomes	Number of prescriptions, treatment use, perceived risk, knowledge, decisional conflict, intention for treatment, satisfaction with information received, perceived quality of information received, treatment adherence
Starting date	May 2021
Contact information	Whitney Wilson, whitney.wilson@ucsf.edu; Dominika Seidman, dominika.seidman@ucsf.edu
Notes	Trial# NCT04621760

NCT04692987

Study name	Effectiveness of decision-aid video on colorectal cancer screening
Methods	RCT
Participants	400 Malaysian adults aged 50 to 74 with no previous history or family history of colorectal cancer who have never participated in screening
Interventions	Patient decision aid vs usual care
Outcomes	Number who underwent screening, time from intervention to screening uptake, barriers to screening uptake
Starting date	March 2021
Contact information	Azmawati Mohammed Nawi, azmawati@ppukm.ukm.edu.my
Notes	Trial# NCT04692987

NCT04725565

Study name	Genetics adviser: evaluating a digital decision support tool for genetic results
Methods	RCT
Participants	130 cancer patients aged 18 and older who have had genomic sequencing for their cancer (but did not receive incidental findings) or adult patients who have had a negative genetic panel test
Interventions	Patient decision aid + counseling vs counseling only
Outcomes	Decisional conflict, knowledge, satisfaction with decision, preparation for decision-making, anxiety, depression, acceptability, time with genetic counselor
Starting date	June 2021
Contact information	Marc Clausen, Marc.Clausen@unityhealth.to
Notes	Trial# NCT04725565

NCT04741503

Study name	Project Insight: feasibility of a breast cancer screening decision support tool
Methods	RCT
Participants	1277 Latina, Black, or non-Latina White women aged 40 to 49
Interventions	Patient decision aid vs information
Outcomes	Knowledge, decisional conflict subscales (uncertainty, informed, values clarity, and support), decision self-efficacy, preparation for decision making
Starting date	April 2021
Contact information	Ashley J Housten, Washington University School of Medicine
Notes	Trial# NCT04741503

NCT04748380

Study name	Shared decision-making and colorectal cancer screening
Methods	RCT
Participants	60 participants aged 75 to 85 with low health literacy
Interventions	Patient decision aid vs attention control
Outcomes	Screening intentions, knowledge, perceptions of shared decision-making role
Starting date	January 2023
Contact information	Tamara Cadet, cadet@upenn.edu
Notes	Trial #NCT04748380

NCT04805554

Study name	Incorporating patient-reported outcomes into shared decision making with patients with osteoarthritis of the hip or knee
Methods	RCT
Participants	200 patients aged 45 to 89 with knee OA
Interventions	Patient decision aid vs education
Outcomes	Patient perception of decision process, decision quality, concordance between patient preferences and actual outcomes, patient perception of the level of shared decision-making, patient/provider satisfaction with discussion, total consultation time (minutes), patient-reported overall health, treatment selected, decisional conflict, decision regret
Starting date	February 2021

NCT04805554 *(Continued)*

Contact information	Lauren Uhler, lauren.uhler@austin.utexas.edu
Notes	Trial #NCT04805554

NCT04837053

Study name	Implementation of indication criteria for total knee replacement in osteoarthritis (Value-based TKR)
Methods	Cluster-RCT
Participants	1080 patients aged 18 and older with knee osteoarthritis who are candidates for knee replacement
Interventions	Patient decision aid vs usual care
Outcomes	Decision quality, fulfillment of patient expectations, Oxford Knee Score
Starting date	June 2021
Contact information	Franziska Beyer, Franziska.Beyer@uniklinikum-dresden.de
Notes	Trial #NCT04837053

NCT04858282

Study name	Application-enabled shared decision-making
Methods	RCT
Participants	31 women aged 20 and older and newly diagnosed early breast cancer (stages 0-II)
Interventions	Patient decision aid vs information
Outcomes	Knowledge, decisional conflict, decision regret
Starting date	August 2019
Contact information	Chia-Wen, Chuang, Chang Gung Memorial Hospital
Notes	Trial# NCT04858282

NCT04869917

Study name	Behavioral nudges for diabetes prevention (BEGIN) trial in primary care (BEGIN)
Methods	RCT
Participants	Adults aged 18 to 80 with prediabetes
Interventions	Decision aid vs usual care

NCT04869917 *(Continued)*

Outcomes	Weight, participant initiation of treatment to intensive lifestyle or metformin
Starting date	March 2022
Contact information	Matthew J O'Brien, Northwestern University
Notes	Trial #NCT04869917

NCT04879745

Study name	MyVoice:Rheum decision aid for women with rheumatic diseases
Methods	RCT
Participants	50 females aged 18 to 44 with at least one of 4 rheumatic diseases diagnosed by a rheumatologist: rheumatoid arthritis, systemic sclerosis, myositis, and systemic lupus erythematosus
Interventions	Patient decision aid vs information vs provider experience
Outcomes	Acceptability/usability of intervention, knowledge, shared decision-making, perceived efficacy in patient-physician interactions, change in pregnancy intention, receipt of care, satisfaction with family planning conversation, decisional conflict, interpersonal quality of care
Starting date	July 2021
Contact information	Olivia M Stransky, olivia.stransky@pitt.edu; Alison Decker, apd22@pitt.edu
Notes	Trial# NCT04879745

NCT04919941

Study name	A pilot study of a guide to conservative care
Methods	RCT
Participants	92 adults aged 75 or older with advanced chronic kidney disease who do not wish to pursue maintenance dialysis
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Patient-provider discussions of conservative care, attrition, treatment preference, treatment goals, acceptability of the intervention
Starting date	August 2020
Contact information	Susan P Wong, University of Washington
Notes	Trial# NCT04919941

NCT04940936

Study name	Shared decision making on radiation dose for lung malignancies
Methods	RCT
Participants	40 patients aged 18 and older with non-small cell lung cancer, or metastasis from other cancer, located ≤ 1 cm from the thoracic wall
Interventions	Decision aid vs usual care
Outcomes	Shared decision-making, decisional conflict, decision regret
Starting date	November 2021
Contact information	Thomas L Fink, thomas.leth.fink@rsyd.dk
Notes	Trial #NCT04940936

NCT04946279

Study name	Decision aid for the improvement of decision-making in patients with non-small cell lung cancer
Methods	RCT
Participants	100 patients with non-small cell lung cancer
Interventions	Patient decision aid vs usual care
Outcomes	Feasibilty/acceptablity of the intervention, anxiety, decisional conflict, decisional regret, perceived involvement in care, shared decision-making quality, decision-making involvement, self-efficacy, values-treatment concordance
Starting date	August 2020
Contact information	Donald Sullivan, OHSU Knight Cancer Institute
Notes	Trial# NCT04946279

NCT04948983

Study name	The effect of a patient decision aids for breast cancer screening
Methods	RCT
Participants	3269 women aged 50 to 69 attending primary care centers
Interventions	Patient decision aid vs information
Outcomes	Informed choice, decisional conflict, depression, anxiety and stress, satisfaction with the decision, uptake of screening
Starting date	July 2021

NCT04948983 *(Continued)*

Contact information	Paulina Bravo, pbbravo@uc.cl; Alejandra Martinez, alejandra.martinez@uc.cl
Notes	Trial# NCT04948983

NCT04956978

Study name	Shared decision making to address racial disparities in oral anticoagulation in NVAF
Methods	RCT
Participants	40 adults aged 18 and older with with non-valvular atrial fibrillation
Interventions	Patient decision aid + counseling vs counseling only
Outcomes	Study feasibility outcomes, decision quality, decision to initiate treatment
Starting date	July 2023
Contact information	Larry Jackson, larry.jackson@duke.edu
Notes	Trial# NCT04956978

NCT05033067

Study name	The personal patient profile decision support for patients with bladder cancer
Methods	RCT
Participants	45 adults aged 18 and older with bladder cancer undergoing radical cystectomy (bladder removal)
Interventions	Patient decision aid vs usual care
Outcomes	Acceptability, shared decision-making, decisional conflict, control preferences scale, communication with providers, knowledge
Starting date	June 2021
Contact information	Nihal Mohamed, nihal.mohamed@mountsinai.org; Holden Kata, holden.kata@mountsinai.org
Notes	Trial# NCT05033067

NCT05091944

Study name	An interactive web-based birth decision aid for shared decision making
Methods	RCT
Participants	86 pregnant women who have had one previous cesarean with at least a half year interval between current pregnancy and the previous birth

NCT05091944 *(Continued)*

Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, knowledge, preference, acceptability of the decision aid, satisfaction with the decision
Starting date	September 2021
Contact information	Shu Wen Chen, shuwen@ntunhs.edu.tw; Chang-Ching Yeh, ccyeh39@gmail.com
Notes	Trial# NCT05091944

NCT05130580

Study name	Patient-specific decision aid system for shared decision making about breast reconstruction
Methods	RCT
Participants	40 adults aged 21 and older planning to undergo mastectomy and considering immediate breast reconstruction
Interventions	Patient decision aid + enhanced consult + education vs education + standard care
Outcomes	Length of consultation visit, decisional conflict
Starting date	October 2020
Contact information	Gregory Reece, greece@mdanderson.org
Notes	Trial# NCT05130580

NCT05135156

Study name	Lung transplant READY pilot study
Methods	RCT
Participants	50 adults aged 18 and older with cystic fibrosis
Interventions	Patient decision aid vs information
Outcomes	Preparedness for shared decision-making, knowledge, decisional conflict, preparedness to discuss lung transplant, anxiety
Starting date	December 2021
Contact information	Lauren Bartlett, lrejman@uw.edu
Notes	Trial# NCT05135156

NCT05177783

Study name	Contraception decision aid use and patient outcomes
Methods	RCT
Participants	500 females 18 to 34 years of age
Interventions	Patient decision aid vs control (no intervention)
Outcomes	Decisional conflict, self-efficacy, knowledge, intention to use treatment, patient satisfaction
Starting date	January 2022
Contact information	Sarah E Hill, s.e.hill@tcu.edu; Summer Mengelkoch, s.mengelkoch@tcu.edu
Notes	Trial# NCT05177783

NCT05182008

Study name	A patient decision aid for method of early abortion: a randomized control trial
Methods	RCT
Participants	440 females of reproductive age seeking termination of pregnancy
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, satisfaction with decision, decision concordance, knowledge
Starting date	May 2022
Contact information	Melissa Brooks, melissa.brooks@iwk.nshealth.ca
Notes	Trial# NCT05182008

NCT05219786

Study name	Online field test of an appendicitis decision support tool
Methods	RCT
Participants	194 adults aged 18 and older who have not previously had appendicitis
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, acceptability, trust and accuracy of information
Starting date	October 2021
Contact information	David R Flum, University of Washington
Notes	Trial# NCT05219786

NL7939

Study name	Decision aid for breast reconstruction after mastectomy: a randomized controlled trial
Methods	RCT
Participants	120 females aged 18 and older who have undergone mastectomy
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, satisfaction (with visit, with information), shared decision-making, treatment choice, consultation time, number of consultations, patient-rated physician empathy, anxiety, depression, decision regret, changes in treatment choice
Starting date	June 2020
Contact information	Claudia Bargon, c.bargon@antoniusziekenhuis.nl
Notes	Trial# NL7939

NL9666

Study name	RCT for evaluation of a personalized online decision aid for colorectal cancer screening participation
Methods	RCT
Participants	324 men and women aged 45 to 55 years
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, clarity of values, deliberation, anxiety, risk perception, intention to participate, usability and acceptability
Starting date	July 2021
Contact information	Linda Pluymen, l.p.m.pluymen@amsterdamumc.nl
Notes	Trial# NL9666

NTR4435

Study name	Improving patient involvement in the decision for joint replacement surgery, using decision aids
Methods	RCT
Participants	256 adults aged > 18 and older with moderate or severe osteoarthritis in either knee or hip
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, satisfaction, physical function, anxiety, health consumption

NTR4435 *(Continued)*

Starting date	March 2014
Contact information	M. Hageman, michiel.hageman@amc.uva.nl
Notes	Trial# NTR4435

NTR5467

Study name	Decision-support for couples with hereditary cancer and child wish: weighing pros and cons of reproductive options regarding transmission of gene mutations
Methods	RCT
Participants	256 woman in reproductive age (18 to 40 years) with hereditary cancer and active child wish
Interventions	Patient decision aid vs information
Outcomes	Decisional conflict, knowledge, accuracy of perceived risks, satisfaction with the decision and the decision-making process, decision self-efficacy, informed choice
Starting date	February 2017
Contact information	Kelly Reumkens, kelly.reumkens@mumc.nl
Notes	Trial# NTR5467

NTR5785

Study name	Effect of a decision aid about postoperative epidural analgesia on patients' knowledge: a randomized controlled trial
Methods	RCT
Participants	300 adults aged 18 and older undergoing major thoracic or abdominal surgery with indication for epidural postoperative analgesia
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, preferred and perceived participation, satisfaction/uncertainty, informed choice, decision control
Starting date	June 2016
Contact information	Amy van den Berg, Amy.vandenBerg@Radboudumc.nl
Notes	Trial# NTR5785

NTR6070

Study name	Study on shared decision making in choosing a treatment for pelvic organ prolapse

NTR6070 *(Continued)*

Methods	RCT
Participants	415 women with symptomatic pelvic organ prolapse for whom a (new) treatment must be chosen
Interventions	Patient decision aid vs information
Outcomes	Satisfaction with treatment decision (making), and satisfaction with information, satisfaction with care and treatment, decisional conflict, decisional regret, quality of life
Starting date	December 2016
Contact information	M.C. Vos, c.vos@elisabeth.nl
Notes	Trial# NTR6070

NTR6379

Study name	Shared decision making in patients with castration-resistant prostate cancer
Methods	RCT
Participants	168 men that are newly diagnosed with castration-resistant prostate cancer
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, informed choice, correlation between G8 score and treatment decision, correlation between TUG-test and treatment decision, quality of life, anxiety, value clarification, satisfaction with decision-making, information and treatment, preparation for decision-making, partner involvement in SDM, treatment outcome
Starting date	September 2016
Contact information	Isabel de Angst, i.deangst@etz.nl
Notes	Trial# NTR6379

O'Connor 2019

Study name	Evaluating a patient decision aid for people with degenerative knee disease considering arthroscopic surgery: protocol for a randomised controlled trial
Methods	RCT
Participants	592 adults aged 45 and older with doctor-diagnosed degenerative knee disease considering knee arthroscopy
Interventions	Patient decision aid vs usual care
Outcomes	Referral to an orthopedic surgeon, attendance at an orthopedic surgeon consultation, attitudes towards knee arthroscopy, informed choice (composite measure of knowledge, attitudes and treatment intentions), treatment intentions, actual choice, knowledge, decisional conflict, satisfaction with preparation for making a decision

O'Connor 2019 *(Continued)*

Starting date	February 2022
Contact information	Denise O'Connor, Monash University and Cabrini Health, denise.oconnor@monash.edu
Notes	Trial# ACTRN12622000204741

Patzer 2019

Study name	A culturally sensitive web-based intervention to improve living donor kidney transplant among African Americans
Methods	RCT
Participants	850 African American or Black adults aged 18 to 65 years referred and scheduled for a transplant medical evaluation
Interventions	Patient decision aid + education vs education alone
Outcomes	Knowledge, confidence
Starting date	February 2019
Contact information	Rachel Patzer, rpatzer@emory.edu
Notes	Trial# NCT03819686

Rahn 2021

Study name	Evaluation of an interactive web-based programme on relapse management for people with multiple sclerosis (POWER@MS2): study protocol for a process evaluation accompanying a randomised controlled trial
Methods	RCT
Participants	160 adults aged 18 to 65 years clinically isolated syndrome, suspected or diagnosed relapsing remitting multiple sclerosis
Interventions	Patient decision aid vs information
Outcomes	Change in treatment, knowledge, control preferences, patient activation measure, quality of life, depression and anxiety, health economic evaluation
Starting date	February 2020
Contact information	Sascha Köpke, Institute of Nursing Science, University of Cologne; Anne C Rahn, Institute of Social Medicine and Epidemiology, Nursing Research Unit, University of Lübeck
Notes	Trial# NCT04233970

Rieckert 2019

Study name	Reduction of the long-term use of proton pump inhibitors by a patient-oriented electronic decision support tool (arriba-PPI): study protocol for a randomized controlled trial
Methods	Cluster-RCT
Participants	3060 patients with a regular prescription of proton pump inhibitors of ≥ 6 months
Interventions	Patient decision aid vs usual care
Outcomes	Medication use
Starting date	December 2018
Contact information	Anja Rieckert, ed.hw-inu@trekc
Notes	Trial# DRKS00016364

Samalin 2018

Study name	Efficacy of shared decision-making on treatment adherence of patients with bipolar disorder: a cluster randomized trial (ShareD-BD)
Methods	Cluster-RCT
Participants	300 adults with bipolar disorder
Interventions	Patient decision aid vs usual care
Outcomes	Treatment adherence, decisional conflict, satisfaction with care and involvement in decision-making, beliefs about treatment, therapeutic relationship, knowledge, clinical outcomes (depression, mania, functioning, and quality of life) and feasibility of SDM processes in clinical practice
Starting date	April 2018
Contact information	Ludovic Samalin, lsamalin@chu-clermontferrand.fr
Notes	Trial# NCT03245593

Schoenfeld 2021

Study name	Feasibility and efficacy of a decision aid for emergency department patients with suspected ureterolithiasis: protocol for an adaptive randomized controlled trial
Methods	RCT
Participants	250 adults age 18 to 55 presenting to the emergency department with a chief complaint of flank pain who are being considered by the treating clinician for a CT scan for the diagnosis of ureterolithiasis
Interventions	Patient decision aid vs usual care

Schoenfeld 2021 *(Continued)*

Outcomes	Knowledge, CT scan rate, patient satisfaction, patient engagement, occurrence of shared decision-making, trust in physician, emergency department revisits, emergency department length of stay
Starting date	December 2019
Contact information	Kye Poronsky, Kye.Poronsky@baystatehealth.org
Notes	Trial# NCT04234035

CA-125 : cancer antigen 125; **CAD** : coronary artery disease; **CT** : computerized tomography; **LARC** : long-acting reversible contraceptive; **NIH** : National Institutes of Health; **NSW** : New South Wales; **OA** : osteoarthritis; **PSA** : prostate specific antigen; **RCT** : randomized controlled trial; **SDM** : shared decision-making.

DATA AND ANALYSES

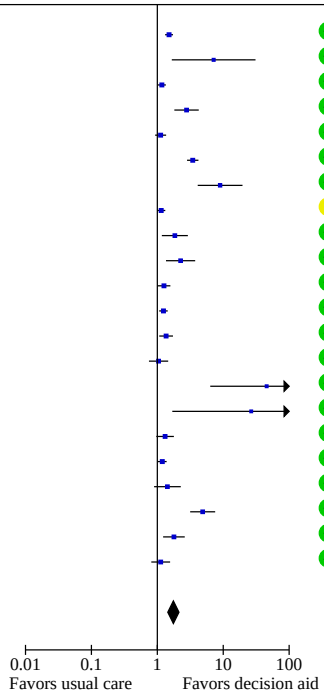
Comparison 1. Informed values-choice congruence

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Informed values-choice congruence - all studies	21	9377	Risk Ratio (M-H, Random, 95% CI)	1.75 [1.44, 2.13]
1.2 Informed values-choice congruence - without studies of high risk of bias	18	7182	Risk Ratio (M-H, Random, 95% CI)	1.96 [1.54, 2.50]
1.3 Informed values-choice congruence - old vs new studies	21	9377	Risk Ratio (M-H, Random, 95% CI)	1.75 [1.44, 2.13]
1.3.1 Older studies (2014 and earlier)	10	4626	Risk Ratio (M-H, Random, 95% CI)	2.06 [1.46, 2.91]
1.3.2 Newer studies (2015-2022)	11	4751	Risk Ratio (M-H, Random, 95% CI)	1.52 [1.22, 1.89]
1.4 Informed values-chose congruence - using MMIC	13	6030	Risk Ratio (M-H, Random, 95% CI)	1.75 [1.37, 2.23]
1.5 Informed values-chose congruence - using non-MMIC measures	8	3327	Risk Ratio (M-H, Random, 95% CI)	1.82 [1.29, 2.55]

Analysis 1.1. Comparison 1: Informed values-choice congruence, Outcome 1: Informed values-choice congruence - all studies

Study or Subgroup	Decision aid Events	Total	Comparison Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
Mathieu 2007	227	309	136	279	5.8%	1.51 [1.31 , 1.73]	+ + ? + + + +
Trevena 2008	14	134	2	137	1.4%	7.16 [1.66 , 30.89]	+ + ? + ? + +
Nagle 2008	127	167	111	171	5.8%	1.17 [1.02 , 1.35]	+ + ? + + + +
Smith 2010	121	357	21	172	4.7%	2.78 [1.81 , 4.25]	+ + + + + + +
Mathieu 2010	65	91	70	110	5.7%	1.12 [0.93 , 1.36]	+ ? ? + + ? +
Steckelberg 2011	345	785	101	792	5.6%	3.45 [2.83 , 4.20]	+ + + + + + ?
Fagerlin 2011	202	383	6	102	3.1%	8.97 [4.10 , 19.60]	+ + ? + ? ? +
Bjorklund 2012	128	179	123	197	5.8%	1.15 [0.99 , 1.32]	? + ? + ? ? +
Schwalm 2012	36	76	19	74	4.5%	1.84 [1.17 , 2.91]	+ + ? + + + +
Stacey 2014a	31	55	14	56	4.3%	2.25 [1.35 , 3.75]	+ + + + + + +
Stacey 2016	87	155	69	155	5.6%	1.26 [1.01 , 1.58]	+ + + + + + +
Beulen 2016	102	124	83	125	5.8%	1.24 [1.07 , 1.44]	+ ? ? ? + ? +
Ickenroth 2016 (1)	96	224	76	241	5.5%	1.36 [1.07 , 1.73]	+ ? + + − + ?
Ickenroth 2016 (2)	51	217	54	240	5.1%	1.04 [0.75 , 1.46]	+ ? + + − + ?
Perez-Lacasta 2019	47	203	1	197	0.8%	45.61 [6.35 , 327.38]	+ + ? + ? + ?
Berger-Hoger 2019	18	31	0	22	0.5%	26.59 [1.69 , 419.10]	+ + ? + + + +
Singh 2019	62	151	46	147	5.2%	1.31 [0.97 , 1.78]	+ ? ? + + + +
Roberto 2020	207	472	195	529	5.8%	1.19 [1.02 , 1.38]	+ ? ? + − + ?
Fisher 2020 (3)	22	40	17	44	4.5%	1.42 [0.89 , 2.27]	+ ? ? + ? + +
Ye 2021	107	386	22	387	4.6%	4.88 [3.15 , 7.55]	+ + + + ? + +
Crew 2022	48	117	31	135	4.9%	1.79 [1.22 , 2.61]	+ ? ? + − ? +
Zadro 2022	56	204	50	205	5.1%	1.13 [0.81 , 1.56]	+ + ? + + + +
Total (95% CI)		**4860**		**4517**	**100.0%**	**1.75 [1.44 , 2.13]**	
Total events:	2199		1247				

Heterogeneity: Tau² = 0.17; Chi² = 248.91, df = 21 (P < 0.00001); I² = 92%
Test for overall effect: Z = 5.63 (P < 0.00001)
Test for subgroup differences: Not applicable



Footnotes

(1) Ickenroth 2016 measured informed choice for 2 different screening options: cholesterol and diabetes. This data row pertains to screening for diabetes.
(2) Ickenroth 2016 measured informed choice for 2 different screening options: cholesterol and diabetes. This data row pertains to screening for cholesterol.
(3) Fisher 2020 measured informed choice for 2 different treatment options: medication and psychological treatment and some participants were included in both analyses. To avoid

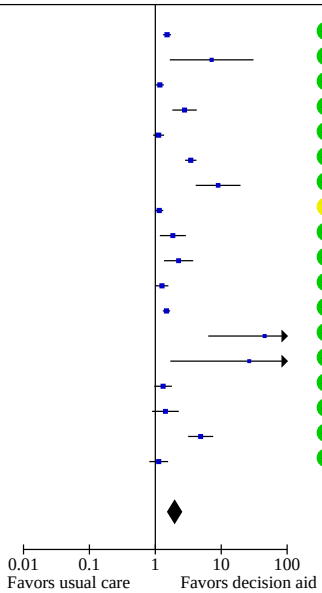
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.2. Comparison 1: Informed values-choice congruence, Outcome 2: Informed values-choice congruence - without studies of high risk of bias

Study or Subgroup	Decision aid Events	Total	Comparison Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A	B	C	D	E	F	G
Mathieu 2007	227	309	136	279	7.2%	1.51 [1.31 , 1.73]	+	+	?	+	+	+	+
Trevena 2008	14	134	2	137	2.0%	7.16 [1.66 , 30.89]	+	+	?	+	?	+	+
Nagle 2008	127	167	111	171	7.2%	1.17 [1.02 , 1.35]	+	+	?	+	+	+	+
Smith 2010	121	357	21	172	6.0%	2.78 [1.81 , 4.25]	+	+	+	+	+	+	+
Mathieu 2010	65	91	70	110	7.0%	1.12 [0.93 , 1.36]	+	?	?	+	+	?	+
Steckelberg 2011	345	785	101	792	7.0%	3.45 [2.83 , 4.20]	+	+	+	+	+	+	?
Fagerlin 2011	202	383	6	102	4.2%	8.97 [4.10 , 19.60]	+	+	?	+	?	?	+
Bjorklund 2012	128	179	123	197	7.2%	1.15 [0.99 , 1.32]	?	+	?	+	?	?	+
Schwalm 2012	36	76	19	74	5.8%	1.84 [1.17 , 2.91]	+	+	?	+	+	+	+
Stacey 2014a	31	55	14	56	5.6%	2.25 [1.35 , 3.75]	+	+	+	+	+	+	+
Stacey 2016	87	155	69	155	6.9%	1.26 [1.01 , 1.58]	+	+	+	+	+	+	+
Beulen 2016	102	104	83	125	7.2%	1.48 [1.30 , 1.68]	+	?	?	?	+	?	+
Perez-Lacasta 2019	47	203	1	197	1.3%	45.61 [6.35 , 327.38]	+	+	?	+	?	+	?
Berger-Hoger 2019	18	31	0	22	0.7%	26.59 [1.69 , 419.10]	+	+	?	+	+	+	+
Singh 2019	62	151	46	147	6.6%	1.31 [0.97 , 1.78]	+	?	?	+	+	+	+
Fisher 2020	22	40	17	44	5.8%	1.42 [0.89 , 2.27]	+	?	?	+	?	+	+
Ye 2021	107	386	22	387	5.9%	4.88 [3.15 , 7.55]	+	+	+	+	?	+	+
Zadro 2022	56	204	50	205	6.5%	1.13 [0.81 , 1.56]	+	+	?	+	+	+	+
Total (95% CI)		**3810**		**3372**	**100.0%**	**1.96 [1.54 , 2.50]**							
Total events:	1797		891										

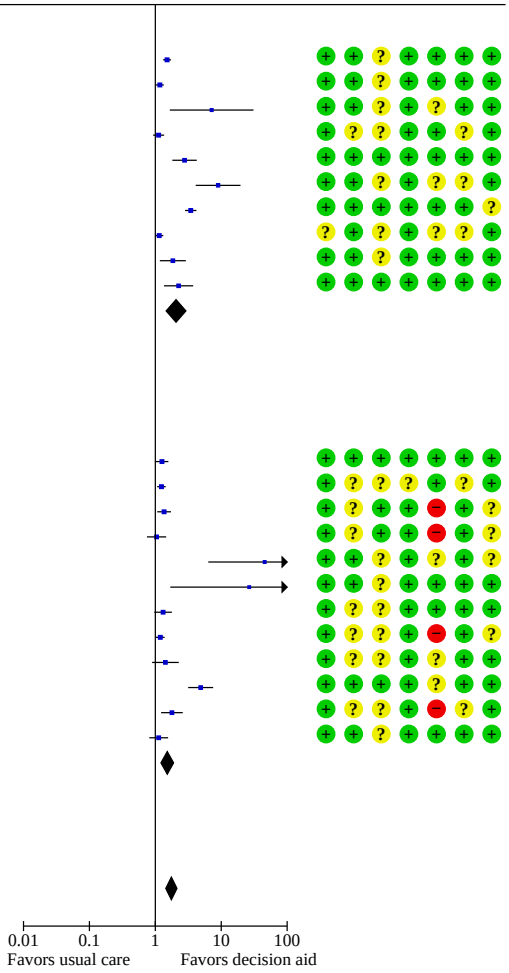
Heterogeneity: Tau² = 0.21; Chi² = 253.16, df = 17 (P < 0.00001); I² = 93%
Test for overall effect: Z = 5.43 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.3. Comparison 1: Informed values-choice congruence, Outcome 3: Informed values-choice congruence - old vs new studies

Study or Subgroup	Decision aid Events	Total	Comparison Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.3.1 Older studies (2014 and earlier)						
Mathieu 2007	227	309	136	279	5.8%	1.51 [1.31 , 1.73]
Nagle 2008	127	167	111	171	5.8%	1.17 [1.02 , 1.35]
Trevena 2008	14	134	2	137	1.4%	7.16 [1.66 , 30.89]
Mathieu 2010	65	91	70	110	5.7%	1.12 [0.93 , 1.36]
Smith 2010	121	357	21	172	4.7%	2.78 [1.81 , 4.25]
Fagerlin 2011	202	383	6	102	3.1%	8.97 [4.10 , 19.60]
Steckelberg 2011	345	785	101	792	5.6%	3.45 [2.83 , 4.20]
Bjorklund 2012	128	179	123	197	5.8%	1.15 [0.99 , 1.32]
Schwalm 2012	36	76	19	74	4.5%	1.84 [1.17 , 2.91]
Stacey 2014a	31	55	14	56	4.3%	2.25 [1.35 , 3.75]
Subtotal (95% CI)		**2536**		**2090**	**46.6%**	**2.06 [1.46 , 2.91]**
Total events:	1296		603			
Heterogeneity: Tau² = 0.26; Chi² = 186.48, df = 9 (P < 0.00001); I² = 95%						
Test for overall effect: Z = 4.11 (P < 0.0001)						
1.3.2 Newer studies (2015-2022)						
Stacey 2016	87	155	69	155	5.6%	1.26 [1.01 , 1.58]
Beulen 2016	102	124	83	125	5.8%	1.24 [1.07 , 1.44]
Ickenroth 2016	96	224	76	241	5.5%	1.36 [1.07 , 1.73]
Ickenroth 2016	51	217	54	240	5.1%	1.04 [0.75 , 1.46]
Perez-Lacasta 2019	47	203	1	197	0.8%	45.61 [6.35 , 327.38]
Berger-Hoger 2019	18	31	0	22	0.5%	26.59 [1.69 , 419.10]
Singh 2019	62	151	46	147	5.2%	1.31 [0.97 , 1.78]
Roberto 2020	207	472	195	529	5.8%	1.19 [1.02 , 1.38]
Fisher 2020	22	40	17	44	4.5%	1.42 [0.89 , 2.27]
Ye 2021	107	386	22	387	4.6%	4.88 [3.15 , 7.55]
Crew 2022	48	117	31	135	4.9%	1.79 [1.22 , 2.61]
Zadro 2022	56	204	50	205	5.1%	1.13 [0.81 , 1.56]
Subtotal (95% CI)		**2324**		**2427**	**53.4%**	**1.52 [1.22 , 1.89]**
Total events:	903		644			
Heterogeneity: Tau² = 0.10; Chi² = 68.25, df = 11 (P < 0.00001); I² = 84%						
Test for overall effect: Z = 3.71 (P = 0.0002)						
Total (95% CI)		**4860**		**4517**	**100.0%**	**1.75 [1.44 , 2.13]**
Total events:	2199		1247			
Heterogeneity: Tau² = 0.17; Chi² = 248.91, df = 21 (P < 0.00001); I² = 92%						
Test for overall effect: Z = 5.63 (P < 0.00001)						
Test for subgroup differences: Chi² = 2.14, df = 1 (P = 0.14), I² = 53.4%						



Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.4. Comparison 1: Informed values-choice congruence, Outcome 4: Informed values-chose congruence - using MMIC

Study or Subgroup	Decision aid Events	Total	Comparison Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Mathieu 2007	227	309	136	279	9.8%	1.51 [1.31 , 1.73]
Nagle 2008	127	167	111	171	9.8%	1.17 [1.02 , 1.35]
Trevena 2008	14	134	2	137	2.2%	7.16 [1.66 , 30.89]
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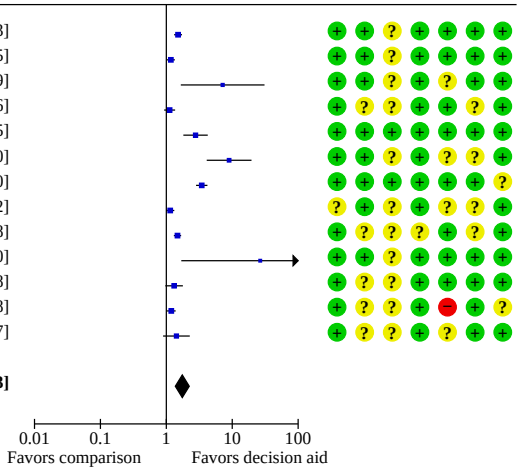
Steckelberg 2011	345	785	101	792	9.5%	3.45 [2.83 , 4.20]
Bjorklund 2012	128	179	123	197	9.8%	1.15 [0.99 , 1.32]
Beulen 2016	102	104	83	125	9.9%	1.48 [1.30 , 1.68]
Berger-Hoger 2019	18	31	0	22	0.7%	26.59 [1.69 , 419.10]
Singh 2019	62	151	46	147	8.8%	1.31 [0.97 , 1.78]
Roberto 2020	207	472	195	529	9.8%	1.19 [1.02 , 1.38]
Fisher 2020	22	40	17	44	7.4%	1.42 [0.89 , 2.27]
Total (95% CI)		**3203**		**2827**	**100.0%**	**1.75 [1.37 , 2.23]**
Total events:	1640		911			

Heterogeneity: Tau² = 0.15; Chi² = 180.07, df = 12 (P < 0.00001); I² = 93%
Test for overall effect: Z = 4.50 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
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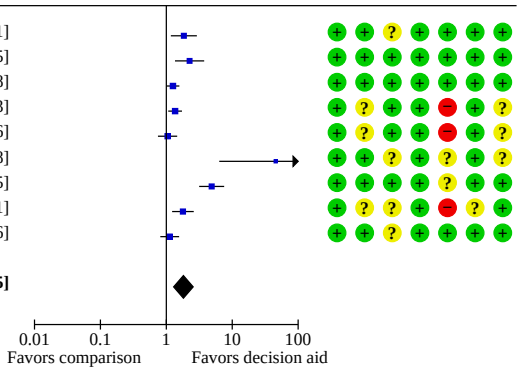
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 1.5. Comparison 1: Informed values-choice congruence, Outcome 5: Informed values-chose congruence - using non-MMIC measures

Study or Subgroup	Decision aid Events	Total	Comparison Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Schwalm 2012	36	76	19	74	11.4%	1.84 [1.17 , 2.91]
Stacey 2014a	31	55	14	56	10.8%	2.25 [1.35 , 3.75]
Stacey 2016	87	155	69	155	13.4%	1.26 [1.01 , 1.58]
Ickenroth 2016	96	224	76	241	13.3%	1.36 [1.07 , 1.73]
Ickenroth 2016	51	217	54	240	12.5%	1.04 [0.75 , 1.46]
Perez-Lacasta 2019	47	203	1	197	2.5%	45.61 [6.35 , 327.38]
Ye 2021	107	386	22	387	11.5%	4.88 [3.15 , 7.55]
Crew 2022	48	117	31	135	12.1%	1.79 [1.22 , 2.61]
Zadro 2022	56	204	50	205	12.6%	1.13 [0.81 , 1.56]
Total (95% CI)		**1637**		**1690**	**100.0%**	**1.82 [1.29 , 2.55]**
Total events:	559		336			

Heterogeneity: Tau² = 0.21; Chi² = 60.16, df = 8 (P < 0.00001); I² = 87%
Test for overall effect: Z = 3.43 (P = 0.0006)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 2. Knowledge

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Knowledge - all studies	107	25492	Mean Difference (IV, Random, 95% CI)	11.90 [10.60, 13.19]
2.2 Knowledge - studies without high risk of bias	95	23083	Mean Difference (IV, Random, 95% CI)	12.13 [10.74, 13.52]
2.3 Knowledge - old vs new studies	107	25492	Mean Difference (IV, Random, 95% CI)	11.90 [10.60, 13.19]
2.3.1 Older studies (2014 and earlier)	51	13194	Mean Difference (IV, Random, 95% CI)	13.02 [11.08, 14.96]
2.3.2 Newer studies (2015-2022)	56	12298	Mean Difference (IV, Random, 95% CI)	11.01 [8.75, 13.27]

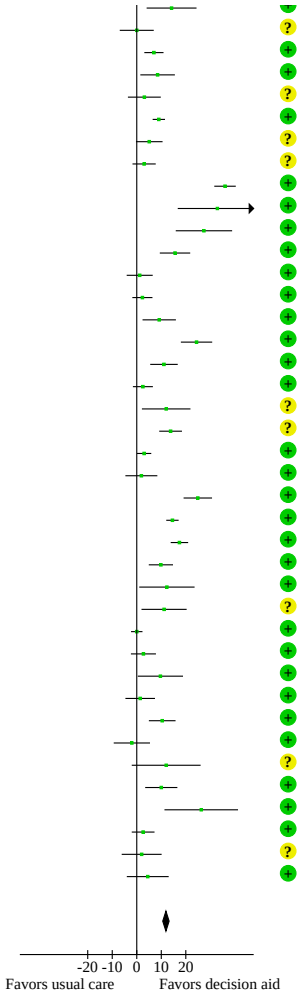
Analysis 2.1. Comparison 2: Knowledge, Outcome 1: Knowledge - all studies

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Lerman 1997	68.9	19	122	49	21.7	164	1.0%	19.90 [15.17 , 24.63]	? ? ? + ? ? +
Barry 1997	75	45	104	54	45	123	0.6%	21.00 [9.25 , 32.75]	+ + + + + ? +
Bernstein 1998	83	16	61	58	16	48	1.0%	25.00 [18.95 , 31.05]	+ + ? + + ? +
Man-Son-Hing 1999	75.91	15.72	137	66.46	16.07	136	1.1%	9.45 [5.68 , 13.22]	+ + − + ? ? +
Volk 1999	48	21.6	78	31	18.8	80	0.9%	17.00 [10.68 , 23.32]	+ ? + + + ? +
Morgan 2000	75	32.04	86	62	32.04	94	0.7%	13.00 [3.63 , 22.37]	+ + ? + + ? ?
Green 2001	95	7	29	65	21	14	0.6%	30.00 [18.71 , 41.29]	+ ? ? + ? ? +
Schwartz 2001	65.71	14.29	191	57.14	15.71	190	1.1%	8.57 [5.55 , 11.59]	+ ? ? + + ? +
Montgomery 2003	75	17	50	60	18	58	0.9%	15.00 [8.39 , 21.61]	+ + ? + + ? +
Whelan 2003	80.2	14.4	82	71.7	13.3	93	1.1%	8.50 [4.37 , 12.63]	? + ? + ? ? +
Gattellari 2003	50	18.4	106	45	15.9	108	1.0%	5.00 [0.39 , 9.61]	? + ? + ? ? +
Bekker 2004	74	14.5	50	71.5	16	56	1.0%	2.50 [-3.31 , 8.31]	? + + + ? ? ?
Gattellari 2005	57.2	21.3	131	42.2	16.7	136	1.0%	15.00 [10.40 , 19.60]	+ + + + + ? +
Shorten 2005	75.33	15	99	60.53	17.07	92	1.0%	14.80 [10.23 , 19.37]	+ + ? + ? + +
Johnson 2006	92.6	11	32	85.2	15.6	35	0.9%	7.40 [0.98 , 13.82]	+ ? ? + + ? ?
Laupacis 2006	83	19.5	53	67.4	17	53	0.9%	15.60 [8.64 , 22.56]	+ + ? + + ? +
Wong 2006	85	26.7	154	60	21.7	159	1.0%	25.00 [19.60 , 30.40]	+ + ? + ? ? +
Taylor 2006	77.3	15.5	80	62.7	11.8	74	1.1%	14.60 [10.27 , 18.93]	? ? ? ? + ? ?
Krist 2007	69	33.21	196	54	33.21	75	0.8%	15.00 [6.16 , 23.84]	+ + − + + ? ?
Montgomery 2007	69.7	18	196	57.5	18.5	202	1.1%	12.20 [8.61 , 15.79]	+ + ? + + + +
Protheroe 2007	59.7	18.4	54	48.8	19.6	54	0.9%	10.90 [3.73 , 18.07]	+ ? ? + + + +
Nassar 2007	88	19	98	79	18	90	1.0%	9.00 [3.71 , 14.29]	+ + ? + + + +
Thomson 2007	62.91	14.26	53	62.35	14.1	56	1.0%	0.56 [-4.77 , 5.89]	+ + ? + + + +
Frosch 2008a	81.4	18.7	155	72.4	19.7	151	1.1%	9.00 [4.69 , 13.31]	+ + ? + + ? +
Mullan 2009	63.5	24.4	48	53	18.2	37	0.8%	10.50 [1.44 , 19.56]	+ + ? + ? + +
Vandemheen 2009	74	27.07	70	49	23.33	79	0.8%	25.00 [16.83 , 33.17]	+ + ? + + + +
Mann E 2010	64.14	21.86	273	41.29	21	134	1.1%	22.85 [18.45 , 27.25]	? + + + + ? ?
Smith 2010	54.17	27.83	357	34.17	14.25	173	1.1%	20.00 [16.42 , 23.58]	+ + + + + + +
Van Peperstraten 2010	62	28.3	123	43	20.5	132	0.9%	19.00 [12.90 , 25.10]	+ + + + ? + +
Allen 2010	66	35.48	291	60	29.24	334	1.0%	6.00 [0.86 , 11.14]	+ ? ? + + ? +
Lewis 2010	45.1	34.01	93	46.7	34.01	107	0.7%	-1.60 [-11.05 , 7.85]	+ ? ? + + ? −
Mathieu 2010	73.5	27.6	113	62.7	27.6	189	0.9%	10.80 [4.37 , 17.23]	+ ? ? + + ? +
McCaffery 2010	81	23.51	77	72	23.51	71	0.9%	9.00 [1.42 , 16.58]	+ + ? + + + +
Schroy 2011	89.17	15	223	71.67	22.5	231	1.1%	17.50 [13.99 , 21.01]	? ? ? + + ? +
Steckelberg 2011	53.75	28.75	785	31.25	15	792	1.2%	22.50 [20.23 , 24.77]	+ + + + + + ?
Arterburn 2011	72	12	75	65	17	77	1.0%	7.00 [2.33 , 11.67]	+ ? ? + ? ? +
Jibaja-Weiss 2011	61.22	20.38	44	43.59	26.61	39	0.7%	17.63 [7.33 , 27.93]	+ ? ? + ? ? +
Hanson 2011	88.4	21.64	127	79.5	21.64	129	1.0%	8.90 [3.60 , 14.20]	+ ? ? + ? + +
Leighl 2011	72.5	26.86	100	60	26.86	100	0.9%	12.50 [5.05 , 19.95]	+ + ? + ? ? +
Montori 2011	63.3	29.61	49	43.3	29.61	46	0.6%	20.00 [8.09 , 31.91]	+ + ? + + + ?
Bjorklund 2012	77	17	182	71	20	204	1.1%	6.00 [2.31 , 9.69]	? + ? + ? ? +
Hess 2012	51.43	18.2	101	42.86	18.3	103	1.0%	8.57 [3.56 , 13.58]	+ + + + ? + +
Schwalm 2012	60	30	76	40	26	74	0.8%	20.00 [11.02 , 28.98]	+ + ? + + + +
Sawka 2012	97	6	37	78	13	37	1.0%	19.00 [14.39 , 23.61]	+ + + ? + ? +
Lepore 2012	61.6	0.13	215	54.7	0.13	216	1.2%	6.90 [6.88 , 6.92]	+ ? ? + + + +
Williams 2013	64.4	18.5	196	61.7	17.8	185	1.1%	2.70 [-0.95 , 6.35]	? ? ? ? + ? +
Lam 2013	61	21	113	59	21	112	1.0%	2.00 [-3.49 , 7.49]	+ + + ? + + +
Kupke 2013	60	23.3	50	27	16.7	31	0.8%	33.00 [24.27 , 41.73]	+ − + ? + ? −
Kuppermann 2014	62.7	21.3	357	57.3	21.3	353	1.1%	5.40 [2.27 , 8.53]	+ + + + + + +
Stacey 2014a	71.2	23.7	66	46.6	21.4	66	0.8%	24.60 [16.90 , 32.30]	+ + + + + + +
Knops 2014	76.92	16.92	80	72.3	16.15	84	1.0%	4.62 [-0.45 , 9.69]	+ + + + + ? −
Watts 2015	70.83	21.67	63	55.42	20.42	65	0.9%	15.41 [8.11 , 22.71]	? + ? + ? + +
Meade 2015	81.85	11.95	78	66.9	13.69	66	1.1%	14.95 [10.71 , 19.19]	+ ? ? + ? + ?
LeBlanc 2015b	63.5	23.4	137	56.3	18.4	116	1.0%	7.20 [2.05 , 12.35]	? + ? − ? + +
Chabrera 2015	75.7	19	61	49.9	16	61	0.9%	25.80 [19.57 , 32.03]	+ ? ? ? + ? ?
Perestelo-Perez 2016	47.63	22.88	78	29.38	24.5	74	0.9%	18.25 [10.70 , 25.80]	+ ? ? + ? + −
Stacey 2016	68.9	15.5	156	61.1	18.1	157	1.1%	7.80 [4.07 , 11.53]	+ + + + + + +
Love 2016	81.43	20	13	56.43	15.71	16	0.5%	25.00 [11.68 , 38.32]	+ − ? + ? ? ?
Coylewright 2016	65.1	24.47	65	42.7	25.87	59	0.8%	22.40 [13.51 , 31.29]	+ + ? + + + +
Karagiannis 2016	68.4	75.13	99	70.7	89.84	103	0.3%	-2.30 [-25.10 , 20.50]	+ + ? + ? + ?
Hess 2016	46.7	16.7	451	40	16.7	447	1.2%	6.70 [4.52 , 8.88]	+ + ? + + + ?
Beulen 2016	78.42	12.63	131	67.37	16.32	130	1.1%	11.05 [7.51 , 14.59]	+ ? ? ? + ? +
Oostendorp 2017	68	26	68	70	26	40	0.7%	-2.00 [-12.15 , 8.15]	+ + ? + ? + +
Perestelo-Perez 2017	86.13	15.63	68	57.88	18.5	79	1.0%	28.25 [22.73 , 33.77]	+ + ? + + ? +
Metcalfe 2017	89.9	9.4	76	89.9	9.8	74	1.1%	0.00 [-3.07 , 3.07]	+ + ? + + ? +
McGrath 2017	71.8	15.33	30	51.73	15.13	37	0.9%	20.07 [12.73 , 27.41]	+ + ? + ? + +
Gordon 2017	66.74	21.21	133	44.97	16.87	155	1.1%	21.77 [17.29 , 26.25]	+ + ? + + ? ?
Hoffman 2017	77.3	16	58	64	16.7	28	0.9%	13.30 [5.87 , 20.73]	+ ? + + + ? +
Carroll 2017	66.6	23.8	41	52.4	23.2	41	0.7%	14.20 [4.03 , 24.37]	+ + ? + + + +
Stamm 2017	64.29	24.04	98	64.29	24.39	90	0.9%	0.00 [-6.93 , 6.93]	? ? ? + ? ? ?
Patzer 2018	67.89	21.22	226	60.89	20.78	217	1.1%	7.00 [3.09 , 10.91]	+ ? ? + + ? +

Analysis 2.1. (Continued)

Carroll 2017	66.6	25.6	41	52.4	25.2	41	0.7%	14.20 [4.03 , 24.37]
Stamm 2017	64.29	24.04	98	64.29	24.39	90	0.9%	0.00 [-6.93 , 6.93]
Patzer 2018	67.89	21.22	226	60.89	20.78	217	1.1%	7.00 [3.09 , 10.91]
Kostick 2018	67.8	15.6	29	59.3	12.4	34	0.9%	8.50 [1.46 , 15.54]
McIlvennan 2018	76.4	22.26	68	73.3	22.12	111	0.9%	3.10 [-3.60 , 9.80]
Hess 2018	62	20	493	53	20	478	1.1%	9.00 [6.48 , 11.52]
Allen 2018	70	21.42	104	64.9	20.68	132	1.0%	5.10 [-0.32 , 10.52]
Cuypers 2018	75	21	235	72	20	101	1.0%	3.00 [-1.74 , 7.74]
Lewis 2018	82	22	212	46	24	212	1.1%	36.00 [31.62 , 40.38]
Brown 2019	60.39	25.67	16	27.51	23.73	21	0.4%	32.88 [16.72 , 49.04]
Perestelo-Perez 2019	87.5	11.3	10	60.1	17.4	14	0.6%	27.40 [15.91 , 38.89]
Perestelo-Perez 2019	75	14.4	43	59.4	14.4	40	0.9%	15.60 [9.40 , 21.80]
Cox 2019	67.5	20.1	110	66.3	20.4	114	1.0%	1.20 [-4.10 , 6.50]
Vigod 2019	67.9	8.28	39	65.6	10.6	43	1.1%	2.30 [-1.80 , 6.40]
Montoya 2019	88.33	6.67	15	79.17	11.67	15	0.9%	9.16 [2.36 , 15.96]
Berger-Hoger 2019	69.66	18.75	36	45.28	4.91	28	0.9%	24.38 [17.99 , 30.77]
Case 2019	80.5	12.9	43	69.4	14.4	48	1.0%	11.10 [5.49 , 16.71]
Carlson 2019	90.83	13.33	92	88.33	15.83	105	1.1%	2.50 [-1.57 , 6.57]
Schapira 2019	76	26.24	54	64	27.43	59	0.7%	12.00 [2.10 , 21.90]
Subramanian 2019	90.3	11.9	63	76.5	15.3	70	1.0%	13.80 [9.17 , 18.43]
Singh 2019	76.9	12.29	151	73.9	13.34	147	1.1%	3.00 [0.09 , 5.91]
Khalifeh 2019	78.13	10.63	23	76.25	11.88	23	0.9%	1.88 [-4.63 , 8.39]
Politi 2020a	84.6	14.2	60	59.7	18	60	1.0%	24.90 [19.10 , 30.70]
Schonberg 2020	71.82	15.29	283	57.27	14.74	263	1.1%	14.55 [12.03 , 17.07]
Volk 2020	57.5	21.9	235	40.1	17.1	233	1.1%	17.40 [13.84 , 20.96]
Fisher 2020	73.13	14.68	68	63.29	14.03	62	1.0%	9.84 [4.90 , 14.78]
Varelas 2020	83.1	13.8	13	70.8	15.5	13	0.6%	12.30 [1.02 , 23.58]
Manne 2020	62.47	23.06	46	51.33	22.21	47	0.7%	11.14 [1.94 , 20.34]
Kuppermann 2020	62.5	22.5	676	62.5	21.25	681	1.2%	0.00 [-2.33 , 2.33]
Gabel 2020a	74.43	24.45	173	71.71	23.48	166	1.0%	2.72 [-2.38 , 7.82]
McLean 2020	82.33	11.93	16	72.69	14.09	15	0.7%	9.64 [0.42 , 18.86]
Durand 2021	56.3	22.5	66	54.9	21.4	257	1.0%	1.40 [-4.63 , 7.43]
Rivero-Santana 2021	61.27	19.67	97	50.89	18.89	96	1.0%	10.38 [4.94 , 15.82]
Omaki 2021	64	22	65	66	20	59	0.9%	-2.00 [-9.39 , 5.39]
Wallace 2021	70	13	15	58	15.5	6	0.5%	12.00 [-2.04 , 26.04]
van Dijk 2021	92.5	15	66	82.5	22.5	65	0.9%	10.00 [3.44 , 16.56]
Lewis 2021	77.4	16.8	14	51.1	24	15	0.5%	26.30 [11.30 , 41.30]
Zadro 2022	37.7	24.3	204	35.1	23.6	205	1.0%	2.60 [-2.04 , 7.24]
Tilburt 2022	58	16.7	43	56	23.2	50	0.8%	2.00 [-6.14 , 10.14]
Jalil 2022	48.96	15	27	44.48	15.3	22	0.8%	4.48 [-4.06 , 13.02]
Total (95% CI)			**12851**			**12641**	**100.0%**	**11.90 [10.60 , 13.19]**

Heterogeneity: Tau² = 36.39; Chi² = 1351.85, df = 107 (P < 0.00001); I² = 92%
Test for overall effect: Z = 17.99 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

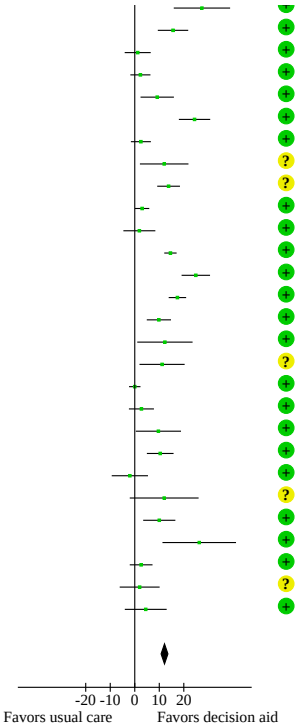
Analysis 2.2. Comparison 2: Knowledge, Outcome 2: Knowledge - studies without high risk of bias

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Mean Difference IV, Random, 95% CI	Risk of Bias A	B	C	D	E	F	G
Lerman 1997	68.9	19	122	49	21.7	164	1.2%	19.90 [15.17 , 24.63]		?	?	?	+	?	?	+
Barry 1997	75	45	104	54	45	123	0.7%	21.00 [9.25 , 32.75]		+	+	+	+	+	?	+
Bernstein 1998	83	16	61	58	16	48	1.1%	25.00 [18.95 , 31.05]		+	+	?	+	+	?	+
Volk 1999	48	21.6	78	31	18.8	80	1.0%	17.00 [10.68 , 23.32]		+	?	+	+	+	?	+
Morgan 2000	75	32.04	86	62	32.04	94	0.8%	13.00 [3.63 , 22.37]		+	+	?	+	+	?	?
Green 2001	95	7	29	65	21	14	0.7%	30.00 [18.71 , 41.29]		+	?	?	+	?	?	+
Schwartz 2001	65.71	14.29	191	57.14	15.71	190	1.3%	8.57 [5.55 , 11.59]		+	?	?	+	+	?	+
Montgomery 2003	75	17	50	60	18	58	1.0%	15.00 [8.39 , 21.61]		+	+	?	+	+	?	+
Whelan 2003	80.2	14.4	82	71.7	13.3	93	1.2%	8.50 [4.37 , 12.63]		?	+	?	+	?	?	+
Gattellari 2003	50	18.4	106	45	15.9	108	1.2%	5.00 [0.39 , 9.61]		?	+	?	+	?	?	+
Bekker 2004	74	14.5	50	71.5	16	56	1.1%	2.50 [-3.31 , 8.31]		?	+	+	+	?	?	?
Gattellari 2005	57.2	21.3	131	42.2	16.7	136	1.2%	15.00 [10.40 , 19.60]		+	+	+	+	+	?	+
Shorten 2005	75.33	15	99	60.53	17.07	92	1.2%	14.80 [10.23 , 19.37]		+	+	?	+	?	+	+
Johnson 2006	92.6	11	32	85.2	15.6	35	1.0%	7.40 [0.98 , 13.82]		+	?	?	+	+	?	?
Laupacis 2006	83	19.5	53	67.4	17	53	1.0%	15.60 [8.64 , 22.56]		+	+	?	+	+	?	+
Wong 2006	85	26.7	154	60	21.7	159	1.1%	25.00 [19.60 , 30.40]		+	+	?	+	?	?	+
Taylor 2006	77.3	15.5	80	62.7	11.8	74	1.2%	14.60 [10.27 , 18.93]		?	?	?	?	+	?	?
Montgomery 2007	69.7	18	196	57.5	18.5	202	1.2%	12.20 [8.61 , 15.79]		+	+	?	+	+	+	+
Protheroe 2007	59.7	18.4	54	48.8	19.6	54	1.0%	10.90 [3.73 , 18.07]		+	?	?	+	+	+	+
Nassar 2007	88	19	98	79	18	90	1.1%	9.00 [3.71 , 14.29]		+	+	?	+	+	+	+
Thomson 2007	62.91	14.26	53	62.35	14.1	56	1.1%	0.56 [-4.77 , 5.89]		+	+	?	+	+	+	+
Frosch 2008a	81.4	18.7	155	72.4	19.7	151	1.2%	9.00 [4.69 , 13.31]		+	+	?	+	+	?	+
Mullan 2009	63.5	24.4	48	53	18.2	37	0.9%	10.50 [1.44 , 19.56]		+	+	?	+	?	+	+
Vandemheen 2009	74	27.07	70	49	23.33	79	0.9%	25.00 [16.83 , 33.17]		+	+	?	+	+	+	+
Mann E 2010	64.14	21.86	273	41.29	21	134	1.2%	22.85 [18.45 , 27.25]		?	+	+	+	+	?	?
Smith 2010	54.17	27.83	357	34.17	14.25	173	1.2%	20.00 [16.42 , 23.58]		+	+	+	+	+	+	+
Van Peperstraten 2010	62	28.3	123	43	20.5	132	1.1%	19.00 [12.90 , 25.10]		+	+	+	+	?	+	+
Allen 2010	66	35.48	291	60	29.24	334	1.1%	6.00 [0.86 , 11.14]		+	?	?	+	+	?	+
Mathieu 2010	73.5	27.6	113	62.7	27.6	189	1.0%	10.80 [4.37 , 17.23]		+	?	?	+	+	?	+
McCaffery 2010	81	23.51	77	72	23.51	71	1.0%	9.00 [1.42 , 16.58]		+	+	?	+	+	+	+
Schroy 2011	89.17	15	223	71.67	22.5	231	1.2%	17.50 [13.99 , 21.01]		?	?	?	+	+	?	+
Steckelberg 2011	53.75	28.75	785	31.25	15	792	1.3%	22.50 [20.23 , 24.77]		+	+	+	+	+	+	?
Arterburn 2011	72	12	75	65	17	77	1.2%	7.00 [2.33 , 11.67]		+	?	?	+	?	?	+
Jibaja-Weiss 2011	61.22	20.38	44	43.59	26.61	39	0.8%	17.63 [7.33 , 27.93]		+	?	?	+	?	?	+
Hanson 2011	88.4	21.64	127	79.5	21.64	129	1.1%	8.90 [3.60 , 14.20]		+	?	?	+	?	+	+
Leighl 2011	72.5	26.86	100	60	26.86	100	1.0%	12.50 [5.05 , 19.95]		+	+	?	+	?	?	+
Montori 2011	63.3	29.61	49	43.3	29.61	46	0.7%	20.00 [8.09 , 31.91]		+	+	?	+	+	+	?
Bjorklund 2012	77	17	182	71	20	204	1.2%	6.00 [2.31 , 9.69]		?	+	?	+	?	?	+
Hess 2012	51.43	18.2	101	42.86	18.3	103	1.1%	8.57 [3.56 , 13.58]		+	+	+	+	?	+	+
Schwalm 2012	60	30	76	40	26	74	0.9%	20.00 [11.02 , 28.98]		+	+	?	+	+	+	+
Sawka 2012	97	6	37	78	13	37	1.2%	19.00 [14.39 , 23.61]		+	+	+	?	+	?	+
Lepore 2012	61.6	0.13	215	54.7	0.13	216	1.3%	6.90 [6.88 , 6.92]		+	?	?	+	+	+	+
Williams 2013	64.4	18.5	196	61.7	17.8	185	1.2%	2.70 [-0.95 , 6.35]		?	?	?	?	+	?	+
Lam 2013	61	21	113	59	21	112	1.1%	2.00 [-3.49 , 7.49]		+	+	+	?	+	+	+
Kuppermann 2014	62.7	21.3	357	57.3	21.3	353	1.3%	5.40 [2.27 , 8.53]		+	+	+	+	+	+	+
Stacey 2014a	71.2	23.7	66	46.6	21.4	66	0.9%	24.60 [16.90 , 32.30]		+	+	+	+	+	+	+
Watts 2015	70.83	21.67	63	55.42	20.42	65	1.0%	15.41 [8.11 , 22.71]		?	+	?	+	?	+	+
Meade 2015	81.85	11.95	78	66.9	13.69	66	1.2%	14.95 [10.71 , 19.19]		+	?	?	+	?	+	?
Chabrera 2015	75.7	19	61	49.9	16	61	1.1%	25.80 [19.57 , 32.03]		+	?	?	?	+	?	?
Stacey 2016	68.9	15.5	156	61.1	18.1	157	1.2%	7.80 [4.07 , 11.53]		+	+	+	+	+	+	+
Coylewright 2016	65.1	24.47	65	42.7	25.87	59	0.9%	22.40 [13.51 , 31.29]		+	+	?	+	+	+	+
Karagiannis 2016	68.4	75.13	99	70.7	89.84	103	0.3%	-2.30 [-25.10 , 20.50]		+	+	?	+	?	+	?
Hess 2016	46.7	16.7	451	40	16.7	447	1.3%	6.70 [4.52 , 8.88]		+	+	?	+	+	+	?
Beulen 2016	78.42	12.63	131	67.37	16.32	130	1.2%	11.05 [7.51 , 14.59]		+	?	?	?	+	?	+
Oostendorp 2017	68	26	68	70	26	40	0.8%	-2.00 [-12.15 , 8.15]		+	+	?	+	?	+	+
Perestelo-Perez 2017	86.13	15.63	68	57.88	18.5	79	1.1%	28.25 [22.73 , 33.77]		+	+	?	+	+	?	+
Metcalfe 2017	89.9	9.4	76	89.9	9.8	74	1.3%	0.00 [-3.07 , 3.07]		+	+	?	+	+	?	+
McGrath 2017	71.8	15.33	30	51.73	15.13	37	1.0%	20.07 [12.73 , 27.41]		+	+	?	+	?	+	+
Gordon 2017	66.74	21.21	133	44.97	16.87	155	1.2%	21.77 [17.29 , 26.25]		+	+	?	+	+	?	?
Hoffman 2017	77.3	16	58	64	16.7	28	1.0%	13.30 [5.87 , 20.73]		+	?	+	+	+	?	+
Carroll 2017	66.6	23.8	41	52.4	23.2	41	0.8%	14.20 [4.03 , 24.37]		+	+	?	+	+	+	+
Stamm 2017	64.29	24.04	98	64.29	24.39	90	1.0%	0.00 [-6.93 , 6.93]		?	?	?	+	?	?	?
Patzer 2018	67.89	21.22	226	60.89	20.78	217	1.2%	7.00 [3.09 , 10.91]		+	?	?	+	+	?	+
Kostick 2018	67.8	15.6	29	59.3	12.4	34	1.0%	8.50 [1.46 , 15.54]		+	+	?	+	?	+	+
McIlvennan 2018	76.4	22.26	68	73.3	22.12	111	1.0%	3.10 [-3.60 , 9.80]		?	?	?	+	?	+	?
Hess 2018	62	20	493	53	20	478	1.3%	9.00 [6.48 , 11.52]		+	+	?	+	+	+	+
Lewis 2018	82	22	212	46	24	212	1.2%	36.00 [31.62 , 40.38]		+	?	?	+	+	+	+
Brown 2019	60.39	25.67	16	27.51	23.73	21	0.5%	32.88 [16.72 , 49.04]		+	?	?	+	+	+	+
Perestelo-Perez 2019	87.5	11.3	10	60.1	17.4	14	0.7%	27.40 [15.91 , 38.89]		+	+	?	+	+	?	?
Perestelo-Perez 2019	75	14.4	43	59.4	14.4	40	1.1%	15.60 [9.40 , 21.80]		+	+	?	+	+	?	?
Cox 2019	67.5	20.1	110	66.3	20.4	114	1.1%	1.20 [-4.10 , 6.50]		+	+	?	+	+	+	?

Analysis 2.2. (Continued)

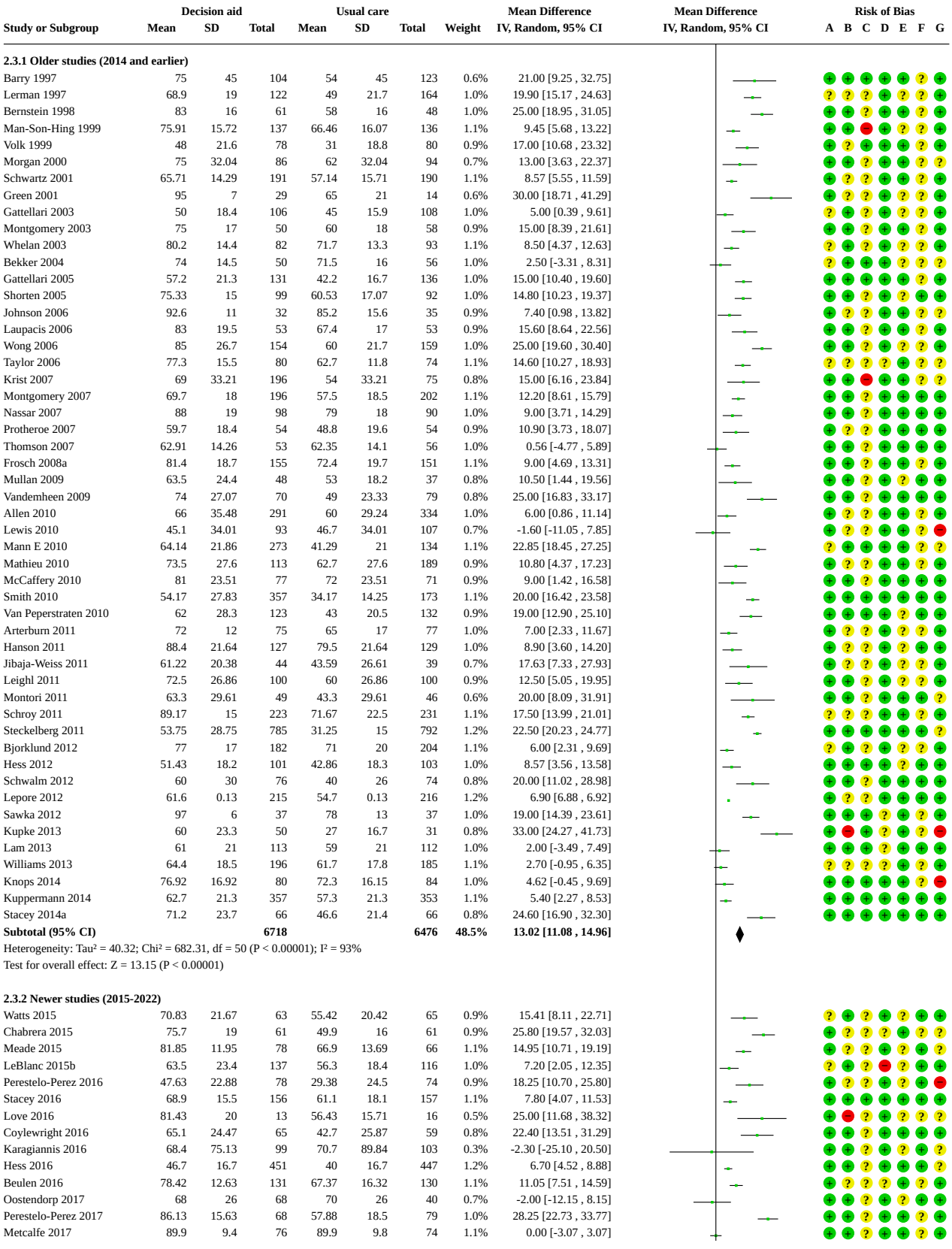
Perestelo-Perez 2019	75	14.4	43	59.4	14.4	40	1.1%	15.60 [9.40 , 21.80]
Cox 2019	67.5	20.1	110	66.3	20.4	114	1.1%	1.20 [-4.10 , 6.50]
Vigod 2019	67.9	8.28	39	65.6	10.6	43	1.2%	2.30 [-1.80 , 6.40]
Montoya 2019	88.33	6.67	15	79.17	11.67	15	1.0%	9.16 [2.36 , 15.96]
Berger-Hoger 2019	69.66	18.75	36	45.28	4.91	28	1.0%	24.38 [17.99 , 30.77]
Carlson 2019	90.83	13.33	92	88.33	15.83	105	1.2%	2.50 [-1.57 , 6.57]
Schapira 2019	76	26.24	54	64	27.43	59	0.8%	12.00 [2.10 , 21.90]
Subramanian 2019	90.3	11.9	63	76.5	15.3	70	1.2%	13.80 [9.17 , 18.43]
Singh 2019	76.9	12.29	151	73.9	13.34	147	1.3%	3.00 [0.09 , 5.91]
Khalifeh 2019	78.13	10.63	23	76.25	11.88	23	1.0%	1.88 [-4.63 , 8.39]
Schonberg 2020	71.82	15.29	283	57.27	14.74	263	1.3%	14.55 [12.03 , 17.07]
Politi 2020a	84.6	14.2	60	59.7	18	60	1.1%	24.90 [19.10 , 30.70]
Volk 2020	57.5	21.9	235	40.1	17.1	233	1.2%	17.40 [13.84 , 20.96]
Fisher 2020	73.13	14.68	68	63.29	14.03	62	1.1%	9.84 [4.90 , 14.78]
Varelas 2020	83.1	13.8	13	70.8	15.5	13	0.7%	12.30 [1.02 , 23.58]
Manne 2020	62.47	23.06	46	51.33	22.21	47	0.8%	11.14 [1.94 , 20.34]
Kuppermann 2020	62.5	22.5	676	62.5	21.25	681	1.3%	0.00 [-2.33 , 2.33]
Gabel 2020a	74.43	24.45	173	71.71	23.48	166	1.1%	2.72 [-2.38 , 7.82]
McLean 2020	82.33	11.93	16	72.69	14.09	15	0.8%	9.64 [0.42 , 18.86]
Rivero-Santana 2021	61.27	19.67	97	50.89	18.89	96	1.1%	10.38 [4.94 , 15.82]
Omaki 2021	64	22	65	66	20	59	1.0%	-2.00 [-9.39 , 5.39]
Wallace 2021	70	13	15	58	15.5	6	0.6%	12.00 [-2.04 , 26.04]
van Dijk 2021	92.5	15	66	82.5	22.5	65	1.0%	10.00 [3.44 , 16.56]
Lewis 2021	77.4	16.8	14	51.1	24	15	0.5%	26.30 [11.30 , 41.30]
Zadro 2022	37.7	24.3	204	35.1	23.6	205	1.2%	2.60 [-2.04 , 7.24]
Tilburt 2022	58	16.7	43	56	23.2	50	0.9%	2.00 [-6.14 , 10.14]
Jalil 2022	48.96	15	27	44.48	15.3	22	0.9%	4.48 [-4.06 , 13.02]
Total (95% CI)			**11619**			**11464**	**100.0%**	**12.13 [10.74 , 13.52]**

Heterogeneity: Tau² = 37.69; Chi² = 1284.53, df = 95 (P < 0.00001); I² = 93%
Test for overall effect: Z = 17.09 (P < 0.00001)
Test for subgroup differences: Not applicable



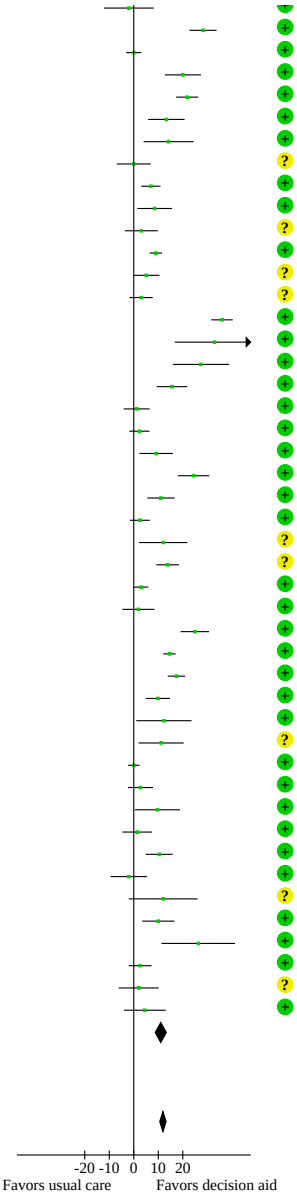
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 2.3. Comparison 2: Knowledge, Outcome 3: Knowledge - old vs new studies



Analysis 2.3. (Continued)

Perestelo-Perez 2017	86.13	15.63	68	57.88	18.5	79	1.0%	28.25 [22.73 , 33.77]
Metcalfe 2017	89.9	9.4	76	89.9	9.8	74	1.1%	0.00 [-3.07 , 3.07]
McGrath 2017	71.8	15.33	30	51.73	15.13	37	0.9%	20.07 [12.73 , 27.41]
Gordon 2017	66.74	21.21	133	44.97	16.87	155	1.1%	21.77 [17.29 , 26.25]
Hoffman 2017	77.3	16	58	64	16.7	28	0.9%	13.30 [5.87 , 20.73]
Carroll 2017	66.6	23.8	41	52.4	23.2	41	0.7%	14.20 [4.03 , 24.37]
Stamm 2017	64.29	24.04	98	64.29	24.39	90	0.9%	0.00 [-6.93 , 6.93]
Patzer 2018	67.89	21.22	226	60.89	20.78	217	1.1%	7.00 [3.09 , 10.91]
Kostick 2018	67.8	15.6	29	59.3	12.4	34	0.9%	8.50 [1.46 , 15.54]
McIlvennan 2018	76.4	22.26	68	73.3	22.12	111	0.9%	3.10 [-3.60 , 9.80]
Hess 2018	62	20	493	53	20	478	1.1%	9.00 [6.48 , 11.52]
Allen 2018	70	21.42	104	64.9	20.68	132	1.0%	5.10 [-0.32 , 10.52]
Cuypers 2018	75	21	235	72	20	101	1.0%	3.00 [-1.74 , 7.74]
Lewis 2018	82	22	212	46	24	212	1.1%	36.00 [31.62 , 40.38]
Brown 2019	60.39	25.67	16	27.51	23.73	21	0.4%	32.88 [16.72 , 49.04]
Perestelo-Perez 2019	87.5	11.3	10	60.1	17.4	14	0.6%	27.40 [15.91 , 38.89]
Perestelo-Perez 2019	75	14.4	43	59.4	14.4	40	0.9%	15.60 [9.40 , 21.80]
Cox 2019	67.5	20.1	110	66.3	20.4	114	1.0%	1.20 [-4.10 , 6.50]
Vigod 2019	67.9	8.28	39	65.6	10.6	43	1.1%	2.30 [-1.80 , 6.40]
Montoya 2019	88.33	6.67	15	79.17	11.67	15	0.9%	9.16 [2.36 , 15.96]
Berger-Hoger 2019	69.66	18.75	36	45.28	4.91	28	0.9%	24.38 [17.99 , 30.77]
Case 2019	80.5	12.9	43	69.4	14.4	48	1.0%	11.10 [5.49 , 16.71]
Carlson 2019	90.83	13.33	92	88.33	15.83	105	1.1%	2.50 [-1.57 , 6.57]
Schapira 2019	76	26.24	54	64	27.43	59	0.7%	12.00 [2.10 , 21.90]
Subramanian 2019	90.3	11.9	63	76.5	15.3	70	1.0%	13.80 [9.17 , 18.43]
Singh 2019	76.9	12.29	151	73.9	13.34	147	1.1%	3.00 [0.09 , 5.91]
Khalifeh 2019	78.13	10.63	23	76.25	11.88	23	0.9%	1.88 [-4.63 , 8.39]
Politi 2020a	84.6	14.2	60	59.7	18	60	1.0%	24.90 [19.10 , 30.70]
Schonberg 2020	71.82	15.29	283	57.27	14.74	263	1.1%	14.55 [12.03 , 17.07]
Volk 2020	57.5	21.9	235	40.1	17.1	233	1.1%	17.40 [13.84 , 20.96]
Fisher 2020	73.13	14.68	68	63.29	14.03	62	1.0%	9.84 [4.90 , 14.78]
Varelas 2020	83.1	13.8	13	70.8	15.5	13	0.6%	12.30 [1.02 , 23.58]
Manne 2020	62.47	23.06	46	51.33	22.21	47	0.7%	11.14 [1.94 , 20.34]
Kuppermann 2020	62.5	22.5	676	62.5	21.25	681	1.2%	0.00 [-2.33 , 2.33]
Gabel 2020a	74.43	24.45	173	71.71	23.48	166	1.0%	2.72 [-2.38 , 7.82]
McLean 2020	82.33	11.93	16	72.69	14.09	15	0.7%	9.64 [0.42 , 18.86]
Durand 2021	56.3	22.5	66	54.9	21.4	257	1.0%	1.40 [-4.63 , 7.43]
Rivero-Santana 2021	61.27	19.67	97	50.89	18.89	96	1.0%	10.38 [4.94 , 15.82]
Omaki 2021	64	22	65	66	20	59	0.9%	-2.00 [-9.39 , 5.39]
Wallace 2021	70	13	15	58	15.5	6	0.5%	12.00 [-2.04 , 26.04]
van Dijk 2021	92.5	15	66	82.5	22.5	65	0.9%	10.00 [3.44 , 16.56]
Lewis 2021	77.4	16.8	14	51.1	24	15	0.5%	26.30 [11.30 , 41.30]
Zadro 2022	37.7	24.3	204	35.1	23.6	205	1.0%	2.60 [-2.04 , 7.24]
Tilburt 2022	58	16.7	43	56	23.2	50	0.8%	2.00 [-6.14 , 10.14]
Jalil 2022	48.96	15	27	44.48	15.3	22	0.8%	4.48 [-4.06 , 13.02]
Subtotal (95% CI)			**6133**			**6165**	**51.5%**	**11.01 [8.75 , 13.27]**
Heterogeneity: Tau² = 63.05; Chi² = 619.57, df = 56 (P < 0.00001); I² = 91%								
Test for overall effect: Z = 9.54 (P < 0.00001)								
Total (95% CI)			**12851**			**12641**	**100.0%**	**11.90 [10.60 , 13.19]**
Heterogeneity: Tau² = 36.39; Chi² = 1351.85, df = 107 (P < 0.00001); I² = 92%								
Test for overall effect: Z = 17.99 (P < 0.00001)								
Test for subgroup differences: Chi² = 1.74, df = 1 (P = 0.19), I² = 42.5%								



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 3. Accurate risk perceptions

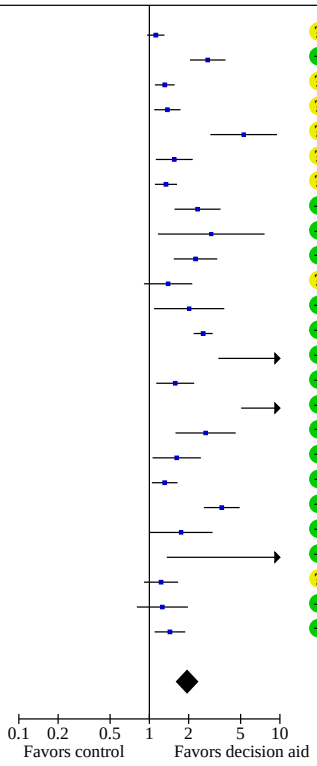
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Accurate risk perceptions - all studies	25	7796	Risk Ratio (M-H, Random, 95% CI)	1.94 [1.61, 2.34]

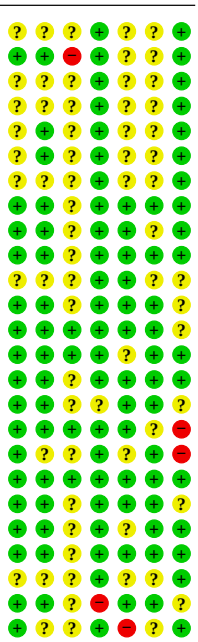
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.2 Accurate risk perceptions - studies without high risk of bias	20	6152	Risk Ratio (M-H, Random, 95% CI)	1.99 [1.60, 2.48]
3.3 Accurate risk perceptions - old vs new studies	25	7796	Risk Ratio (M-H, Random, 95% CI)	1.94 [1.61, 2.34]
3.3.1 Older Studies (2014 and earlier)	16	5019	Risk Ratio (M-H, Random, 95% CI)	2.07 [1.62, 2.64]
3.3.2 Newer studies (2015-2022)	9	2777	Risk Ratio (M-H, Random, 95% CI)	1.76 [1.30, 2.39]

Analysis 3.1. Comparison 3: Accurate risk perceptions, Outcome 1: Accurate risk perceptions - all studies

Study or Subgroup	Decision aid Events	Decision aid Total	Control Events	Control Total	Weight	Risk Ratio M-H, Random, 95% CI
Lerman 1997	90	122	108	164	5.2%	1.12 [0.96 , 1.31]
Man-Son-Hing 1999	92	139	35	148	4.7%	2.80 [2.05 , 3.83]
Wolf 2000	189	266	72	133	5.2%	1.31 [1.10 , 1.56]
McBride 2002	109	265	82	274	5.0%	1.37 [1.09 , 1.73]
Gattellari 2003	57	106	11	108	3.5%	5.28 [2.93 , 9.50]
Whelan 2003	47	82	34	92	4.6%	1.55 [1.12 , 2.15]
Whelan 2004	73	94	62	107	5.1%	1.34 [1.10 , 1.63]
McAlister 2005	66	175	25	155	4.3%	2.34 [1.56 , 3.51]
Laupacis 2006	14	47	5	50	2.3%	2.98 [1.16 , 7.63]
Vandemheen 2009	46	70	23	79	4.4%	2.26 [1.54 , 3.31]
Mann D 2010	35	80	22	70	4.2%	1.39 [0.91 , 2.13]
Montori 2011	23	49	10	43	3.4%	2.02 [1.09 , 3.75]
Steckelberg 2011	361	785	141	792	5.2%	2.58 [2.18 , 3.05]
Hess 2012	24	101	1	103	0.8%	24.48 [3.37 , 177.53]
Schwalm 2012	47	76	29	74	4.6%	1.58 [1.13 , 2.20]
Mathers 2012	67	95	4	75	2.2%	13.22 [5.05 , 34.62]
LeBlanc 2015	23	32	12	45	3.8%	2.70 [1.59 , 4.58]
Perestelo-Perez 2016	37	81	22	78	4.2%	1.62 [1.06 , 2.48]
Stacey 2016	88	156	68	158	5.0%	1.31 [1.05 , 1.64]
Hess 2016	152	451	42	447	4.7%	3.59 [2.62 , 4.92]
Kostick 2018	15	20	9	21	3.7%	1.75 [1.00 , 3.05]
Berger-Hoger 2019	15	32	0	22	0.4%	21.61 [1.36 , 343.21]
Schapira 2019	36	54	32	59	4.7%	1.23 [0.91 , 1.66]
Kunneman 2020	40	445	31	434	4.1%	1.26 [0.80 , 1.97]
Crew 2022	64	114	50	128	4.8%	1.44 [1.10 , 1.88]
Total (95% CI)		**3937**		**3859**	**100.0%**	**1.94 [1.61 , 2.34]**
Total events:	1810		930			

Heterogeneity: Tau² = 0.17; Chi² = 190.86, df = 24 (P < 0.00001); I² = 87%
Test for overall effect: Z = 7.00 (P < 0.00001)
Test for subgroup differences: Not applicable



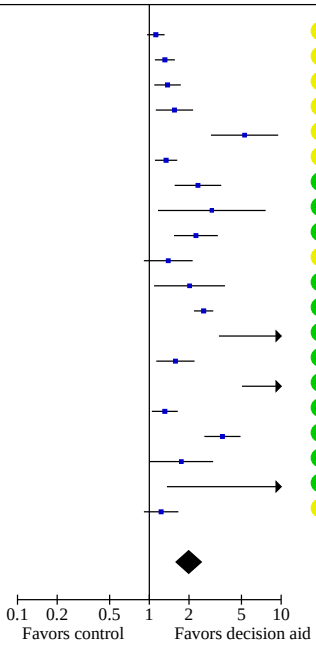


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 3.2. Comparison 3: Accurate risk perceptions, Outcome 2: Accurate risk perceptions - studies without high risk of bias

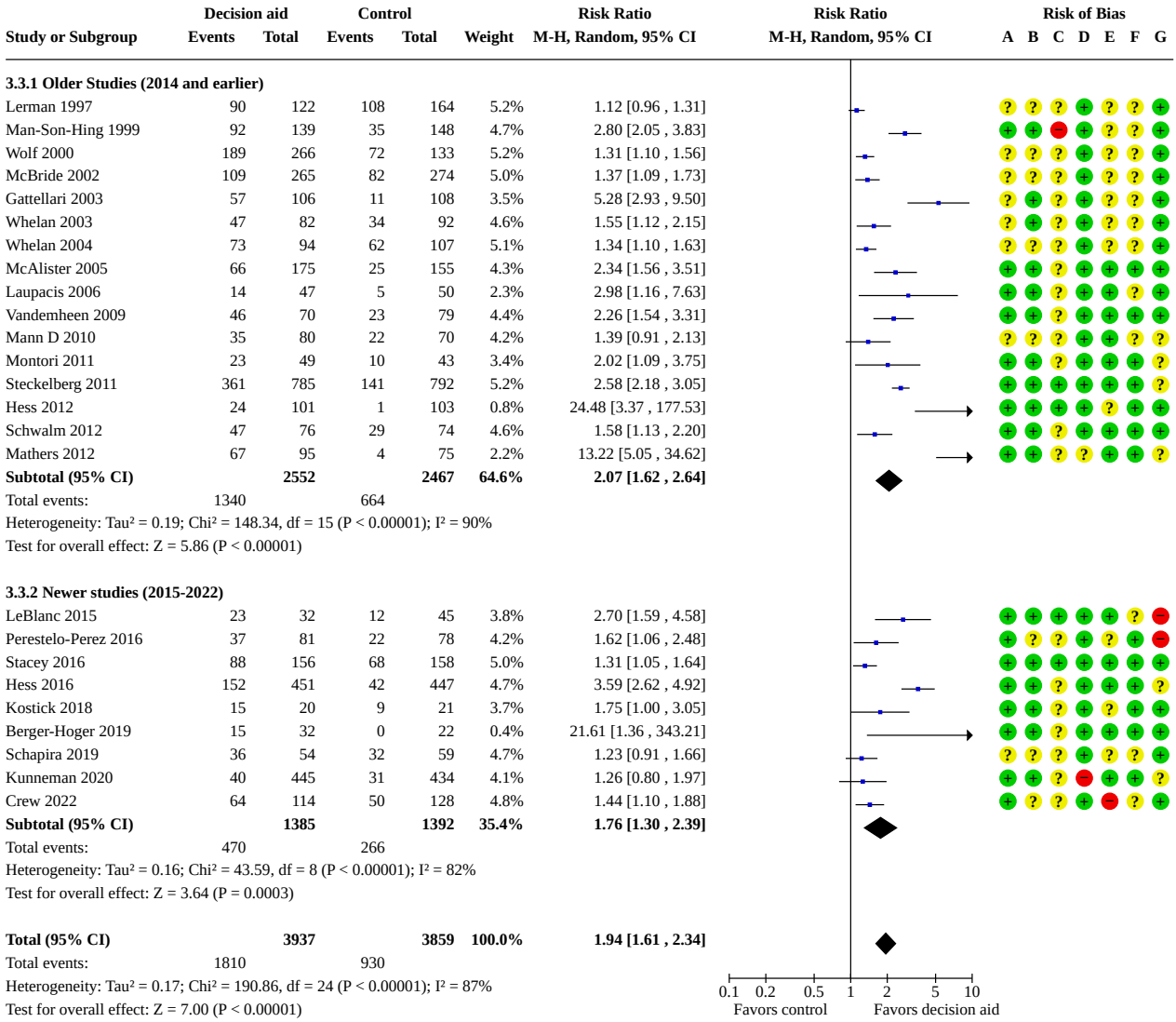
Study or Subgroup	Decision aid Events	Total	Control Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A	B	C	D	E	F	G
Lerman 1997	90	122	108	164	6.5%	1.12 [0.96 , 1.31]	?	?	?	+	?	?	+
Wolf 2000	189	266	72	133	6.5%	1.31 [1.10 , 1.56]	?	?	?	+	?	?	+
McBride 2002	109	265	82	274	6.3%	1.37 [1.09 , 1.73]	?	?	?	+	?	?	+
Whelan 2003	47	82	34	92	5.9%	1.55 [1.12 , 2.15]	?	+	?	+	?	?	+
Gattellari 2003	57	106	11	108	4.6%	5.28 [2.93 , 9.50]	?	+	?	+	?	?	+
Whelan 2004	73	94	62	107	6.4%	1.34 [1.10 , 1.63]	?	?	?	+	?	?	+
McAlister 2005	66	175	25	155	5.5%	2.34 [1.56 , 3.51]	+	+	?	+	+	+	+
Laupacis 2006	14	47	5	50	3.0%	2.98 [1.16 , 7.63]	+	+	?	+	+	?	+
Vandemheen 2009	46	70	23	79	5.6%	2.26 [1.54 , 3.31]	+	+	?	+	+	+	+
Mann D 2010	35	80	22	70	5.4%	1.39 [0.91 , 2.13]	?	?	?	+	+	?	?
Montori 2011	23	49	10	43	4.4%	2.02 [1.09 , 3.75]	+	+	?	+	+	+	?
Steckelberg 2011	361	785	141	792	6.5%	2.58 [2.18 , 3.05]	+	+	+	+	+	+	?
Hess 2012	24	101	1	103	1.0%	24.48 [3.37 , 177.53]	+	+	+	+	?	+	+
Schwalm 2012	47	76	29	74	5.8%	1.58 [1.13 , 2.20]	+	+	?	+	+	+	+
Mathers 2012	67	95	4	75	3.0%	13.22 [5.05 , 34.62]	+	+	?	?	+	+	?
Stacey 2016	88	156	68	158	6.3%	1.31 [1.05 , 1.64]	+	+	+	+	+	+	+
Hess 2016	152	451	42	447	5.9%	3.59 [2.62 , 4.92]	+	+	?	+	+	+	?
Kostick 2018	15	20	9	21	4.7%	1.75 [1.00 , 3.05]	+	+	?	+	?	+	+
Berger-Hoger 2019	15	32	0	22	0.6%	21.61 [1.36 , 343.21]	+	+	?	+	+	+	+
Schapira 2019	36	54	32	59	6.0%	1.23 [0.91 , 1.66]	?	?	?	+	?	?	+
Total (95% CI)		**3126**		**3026**	**100.0%**	**1.99 [1.60 , 2.48]**							
Total events:	1554		780										

Heterogeneity: Tau² = 0.19; Chi² = 177.84, df = 19 (P < 0.00001); I² = 89%
Test for overall effect: Z = 6.11 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 3.3. Comparison 3: Accurate risk perceptions, Outcome 3: Accurate risk perceptions - old vs new studies



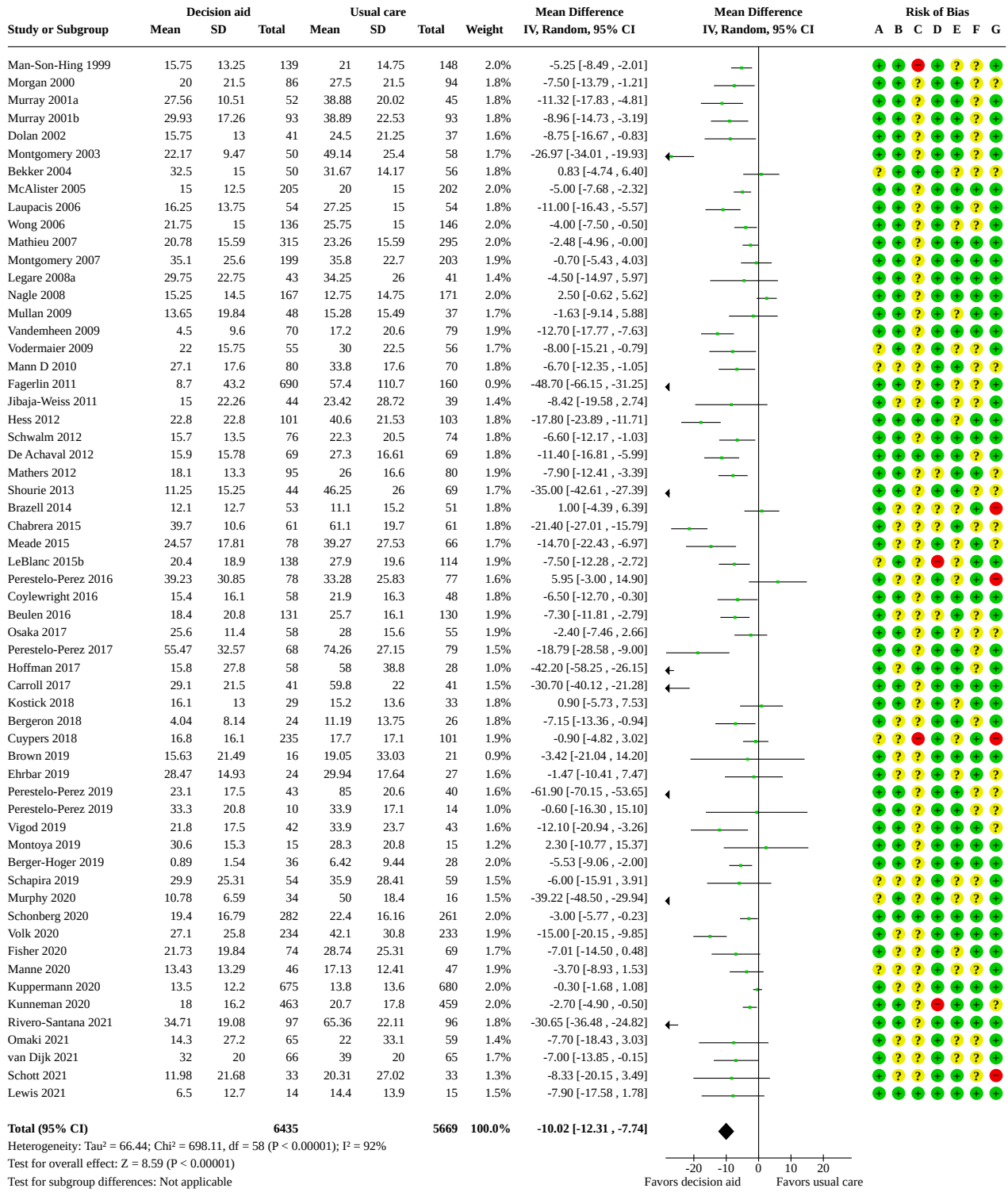
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 4. Decisional conflict

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Decisional conflict - uninformed - all studies	58	12104	Mean Difference (IV, Random, 95% CI)	-10.02 [-12.31, -7.74]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.2 Decisional conflict - uninformed - without studies having high risk of bias	51	9982	Mean Difference (IV, Random, 95% CI)	-11.18 [-13.82, -8.54]
4.3 Decisional conflict - uninformed - old vs new studies	58	12104	Mean Difference (IV, Random, 95% CI)	-10.02 [-12.31, -7.74]
4.3.1 Older studies (2014 and earlier)	26	5585	Mean Difference (IV, Random, 95% CI)	-8.73 [-11.57, -5.90]
4.3.2 Newer studies (2015-2022)	32	6519	Mean Difference (IV, Random, 95% CI)	-11.03 [-14.58, -7.47]
4.4 Decisional conflict - unclear values - all studies	55	11880	Mean Difference (IV, Random, 95% CI)	-7.86 [-9.69, -6.02]
4.5 Decisional conflict - unclear values - without studies having high risk of bias	48	9758	Mean Difference (IV, Random, 95% CI)	-8.60 [-10.73, -6.47]
4.6 Unclear values - old vs new studies	55	11880	Mean Difference (IV, Random, 95% CI)	-7.86 [-9.69, -6.02]
4.6.1 Older studies (2014 and earlier)	22	4946	Mean Difference (IV, Random, 95% CI)	-7.74 [-10.51, -4.96]
4.6.2 Newer studies (2015-2022)	33	6934	Mean Difference (IV, Random, 95% CI)	-8.03 [-10.69, -5.38]

Analysis 4.1. Comparison 4: Decisional conflict, Outcome 1: Decisional conflict - uninformed - all studies



Heterogeneity: Tau² = 66.44; Chi² = 698.11, df = 58 (P < 0.00001); I² = 92%
Test for overall effect: Z = 8.59 (P < 0.00001)
Test for subgroup differences: Not applicable

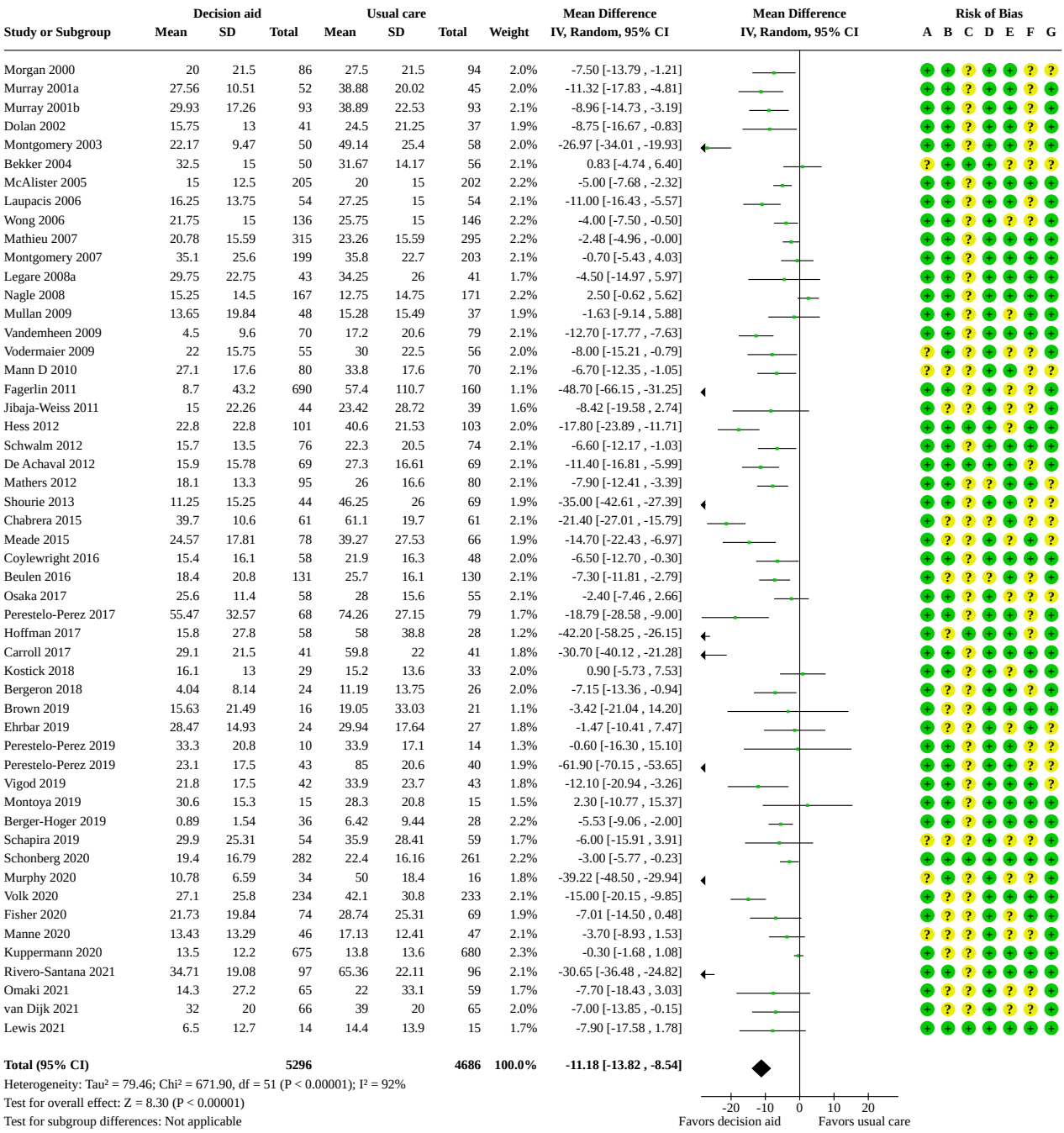
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)

Analysis 4.1. (Continued)

(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 4.2. Comparison 4: Decisional conflict, Outcome 2: Decisional conflict - uninformed - without studies having high risk of bias

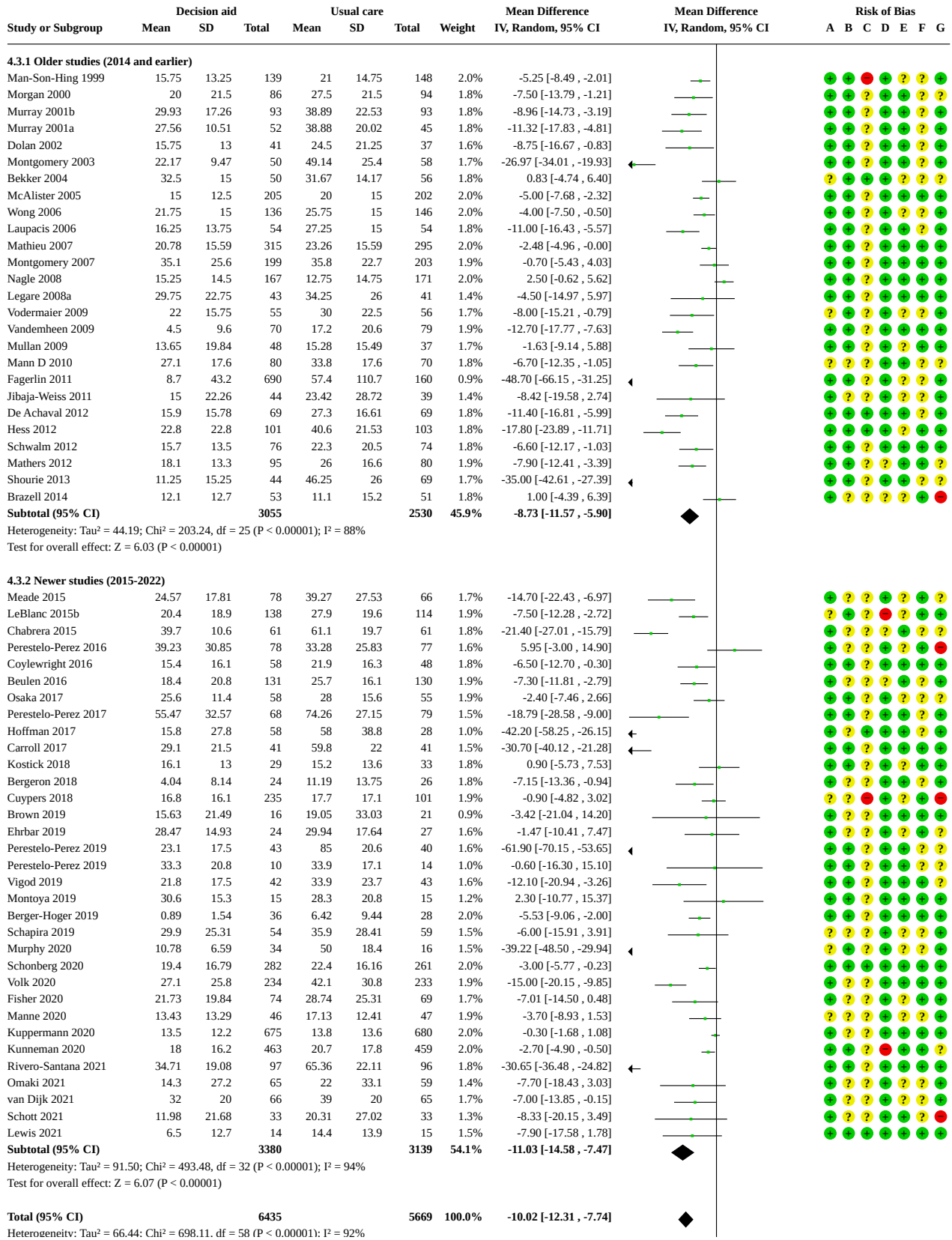


Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Morgan 2000	20	21.5	86	27.5	21.5	94	2.0%	-7.50 [-13.79 , -1.21]	+ + ? + + ? ?
Murray 2001a	27.56	10.51	52	38.88	20.02	45	2.0%	-11.32 [-17.83 , -4.81]	+ + ? + + ? +
Murray 2001b	29.93	17.26	93	38.89	22.53	93	2.1%	-8.96 [-14.73 , -3.19]	+ + ? + + ? +
Dolan 2002	15.75	13	41	24.5	21.25	37	1.9%	-8.75 [-16.67 , -0.83]	+ + ? + + ? +
Montgomery 2003	22.17	9.47	50	49.14	25.4	58	2.0%	-26.97 [-34.01 , -19.93]	+ + ? + + ? +
Bekker 2004	32.5	15	50	31.67	14.17	56	2.1%	0.83 [-4.74 , 6.40]	? + + + ? ? ?
McAlister 2005	15	12.5	205	20	15	202	2.2%	-5.00 [-7.68 , -2.32]	+ + ? + + + +
Laupacis 2006	16.25	13.75	54	27.25	15	54	2.1%	-11.00 [-16.43 , -5.57]	+ + ? + + ? +
Wong 2006	21.75	15	136	25.75	15	146	2.2%	-4.00 [-7.50 , -0.50]	+ + ? + ? ? +
Mathieu 2007	20.78	15.59	315	23.26	15.59	295	2.2%	-2.48 [-4.96 , -0.00]	+ + ? + + + +
Montgomery 2007	35.1	25.6	199	35.8	22.7	203	2.1%	-0.70 [-5.43 , 4.03]	+ + ? + + + +
Legare 2008a	29.75	22.75	43	34.25	26	41	1.7%	-4.50 [-14.97 , 5.97]	+ + ? + + + +
Nagle 2008	15.25	14.5	167	12.75	14.75	171	2.2%	2.50 [-0.62 , 5.62]	+ + ? + + + +
Mullan 2009	13.65	19.84	48	15.28	15.49	37	1.9%	-1.63 [-9.14 , 5.88]	+ + ? + ? + +
Vandemheen 2009	4.5	9.6	70	17.2	20.6	79	2.1%	-12.70 [-17.77 , -7.63]	+ + ? + + + +
Vodermaier 2009	22	15.75	55	30	22.5	56	2.0%	-8.00 [-15.21 , -0.79]	? + ? + ? ? +
Mann D 2010	27.1	17.6	80	33.8	17.6	70	2.1%	-6.70 [-12.35 , -1.05]	? ? ? + + ? ?
Fagerlin 2011	8.7	43.2	690	57.4	110.7	160	1.1%	-48.70 [-66.15 , -31.25]	+ + ? + ? ? +
Jibaja-Weiss 2011	15	22.26	44	23.42	28.72	39	1.6%	-8.42 [-19.58 , 2.74]	+ ? ? + ? ? +
Hess 2012	22.8	22.8	101	40.6	21.53	103	2.0%	-17.80 [-23.89 , -11.71]	+ + + + ? + +
Schwalm 2012	15.7	13.5	76	22.3	20.5	74	2.1%	-6.60 [-12.17 , -1.03]	+ + ? + + + +
De Achaval 2012	15.9	15.78	69	27.3	16.61	69	2.1%	-11.40 [-16.81 , -5.99]	+ + + + + ? +
Mathers 2012	18.1	13.3	95	26	16.6	80	2.1%	-7.90 [-12.41 , -3.39]	+ + ? ? + + ?
Shourie 2013	11.25	15.25	44	46.25	26	69	1.9%	-35.00 [-42.61 , -27.39]	+ + ? + + ? ?
Chabrera 2015	39.7	10.6	61	61.1	19.7	61	2.1%	-21.40 [-27.01 , -15.79]	+ ? ? ? + ? ?
Meade 2015	24.57	17.81	78	39.27	27.53	66	1.9%	-14.70 [-22.43 , -6.97]	+ ? ? + ? + ?
Coylewright 2016	15.4	16.1	58	21.9	16.3	48	2.0%	-6.50 [-12.70 , -0.30]	+ + ? + + + +
Beulen 2016	18.4	20.8	131	25.7	16.1	130	2.1%	-7.30 [-11.81 , -2.79]	+ ? ? ? + ? +
Osaka 2017	25.6	11.4	58	28	15.6	55	2.1%	-2.40 [-7.46 , 2.66]	+ + ? + ? ? ?
Perestelo-Perez 2017	55.47	32.57	68	74.26	27.15	79	1.7%	-18.79 [-28.58 , -9.00]	+ + ? + + ? +
Hoffman 2017	15.8	27.8	58	58	38.8	28	1.2%	-42.20 [-58.25 , -26.15]	+ ? + + + ? +
Carroll 2017	29.1	21.5	41	59.8	22	41	1.8%	-30.70 [-40.12 , -21.28]	+ + ? + + + +
Kostick 2018	16.1	13	29	15.2	13.6	33	2.0%	0.90 [-5.73 , 7.53]	+ + ? + ? + +
Bergeron 2018	4.04	8.14	24	11.19	13.75	26	2.0%	-7.15 [-13.36 , -0.94]	+ ? ? + + ? +
Brown 2019	15.63	21.49	16	19.05	33.03	21	1.1%	-3.42 [-21.04 , 14.20]	+ ? ? + + + +
Ehrbar 2019	28.47	14.93	24	29.94	17.64	27	1.8%	-1.47 [-10.41 , 7.47]	+ ? ? + ? + ?
Perestelo-Perez 2019	33.3	20.8	10	33.9	17.1	14	1.3%	-0.60 [-16.30 , 15.10]	+ + ? + + ? ?
Perestelo-Perez 2019	23.1	17.5	43	85	20.6	40	1.9%	-61.90 [-70.15 , -53.65]	+ + ? + + ? ?
Vigod 2019	21.8	17.5	42	33.9	23.7	43	1.8%	-12.10 [-20.94 , -3.26]	+ + ? + + + ?
Montoya 2019	30.6	15.3	15	28.3	20.8	15	1.5%	2.30 [-10.77 , 15.37]	+ + ? + + + +
Berger-Hoger 2019	0.89	1.54	36	6.42	9.44	28	2.2%	-5.53 [-9.06 , -2.00]	+ + ? + + + +
Schapira 2019	29.9	25.31	54	35.9	28.41	59	1.7%	-6.00 [-15.91 , 3.91]	? ? ? + ? ? +
Schonberg 2020	19.4	16.79	282	22.4	16.16	261	2.2%	-3.00 [-5.77 , -0.23]	+ + + + + + +
Murphy 2020	10.78	6.59	34	50	18.4	16	1.8%	-39.22 [-48.50 , -29.94]	? + ? + ? ? +
Volk 2020	27.1	25.8	234	42.1	30.8	233	2.1%	-15.00 [-20.15 , -9.85]	+ ? ? + + + +
Fisher 2020	21.73	19.84	74	28.74	25.31	69	1.9%	-7.01 [-14.50 , 0.48]	+ ? ? + ? + +
Manne 2020	13.43	13.29	46	17.13	12.41	47	2.1%	-3.70 [-8.93 , 1.53]	? ? ? + ? ? +
Kuppermann 2020	13.5	12.2	675	13.8	13.6	680	2.3%	-0.30 [-1.68 , 1.08]	+ ? ? + + + +
Rivero-Santana 2021	34.71	19.08	97	65.36	22.11	96	2.1%	-30.65 [-36.48 , -24.82]	+ + ? + + + +
Omaki 2021	14.3	27.2	65	22	33.1	59	1.7%	-7.70 [-18.43 , 3.03]	+ ? ? + ? ? +
van Dijk 2021	32	20	66	39	20	65	2.0%	-7.00 [-13.85 , -0.15]	+ ? ? + ? ? +
Lewis 2021	6.5	12.7	14	14.4	13.9	15	1.7%	-7.90 [-17.58 , 1.78]	+ + + + + + +
Total (95% CI)			**5296**			**4686**	**100.0%**	**-11.18 [-13.82 , -8.54]**	

Heterogeneity: Tau² = 79.46; Chi² = 671.90, df = 51 (P < 0.00001); I² = 92%
Test for overall effect: Z = 8.30 (P < 0.00001)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

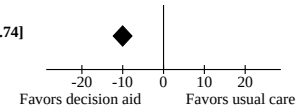
Analysis 4.3. Comparison 4: Decisional conflict, Outcome 3: Decisional conflict - uninformed - old vs new studies



Analysis 4.3. (Continued)

Total (95% CI)	**6435**	**5669**	**100.0%**	**-10.02 [-12.31 , -7.74]**

Heterogeneity: Tau² = 66.44; Chi² = 698.11, df = 58 (P < 0.00001); I² = 92%
Test for overall effect: Z = 8.59 (P < 0.00001)
Test for subgroup differences: Chi² = 0.97, df = 1 (P = 0.32), I² = 0%

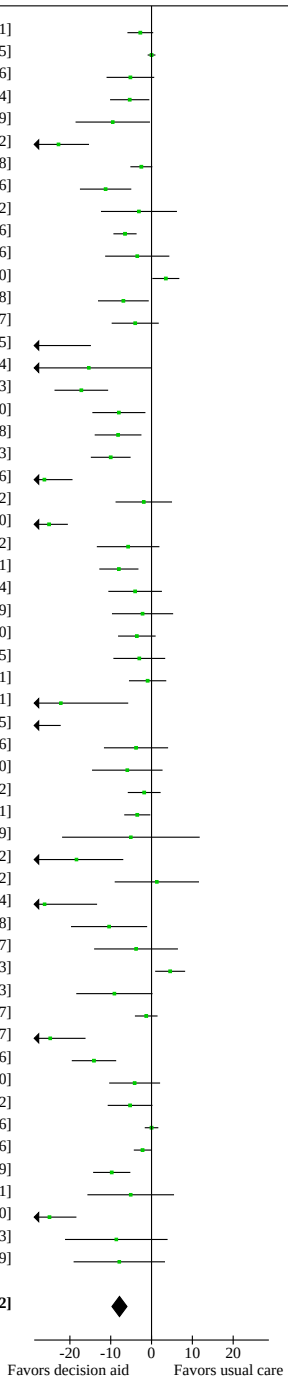


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 4.4. Comparison 4: Decisional conflict, Outcome 4: Decisional conflict - unclear values - all studies

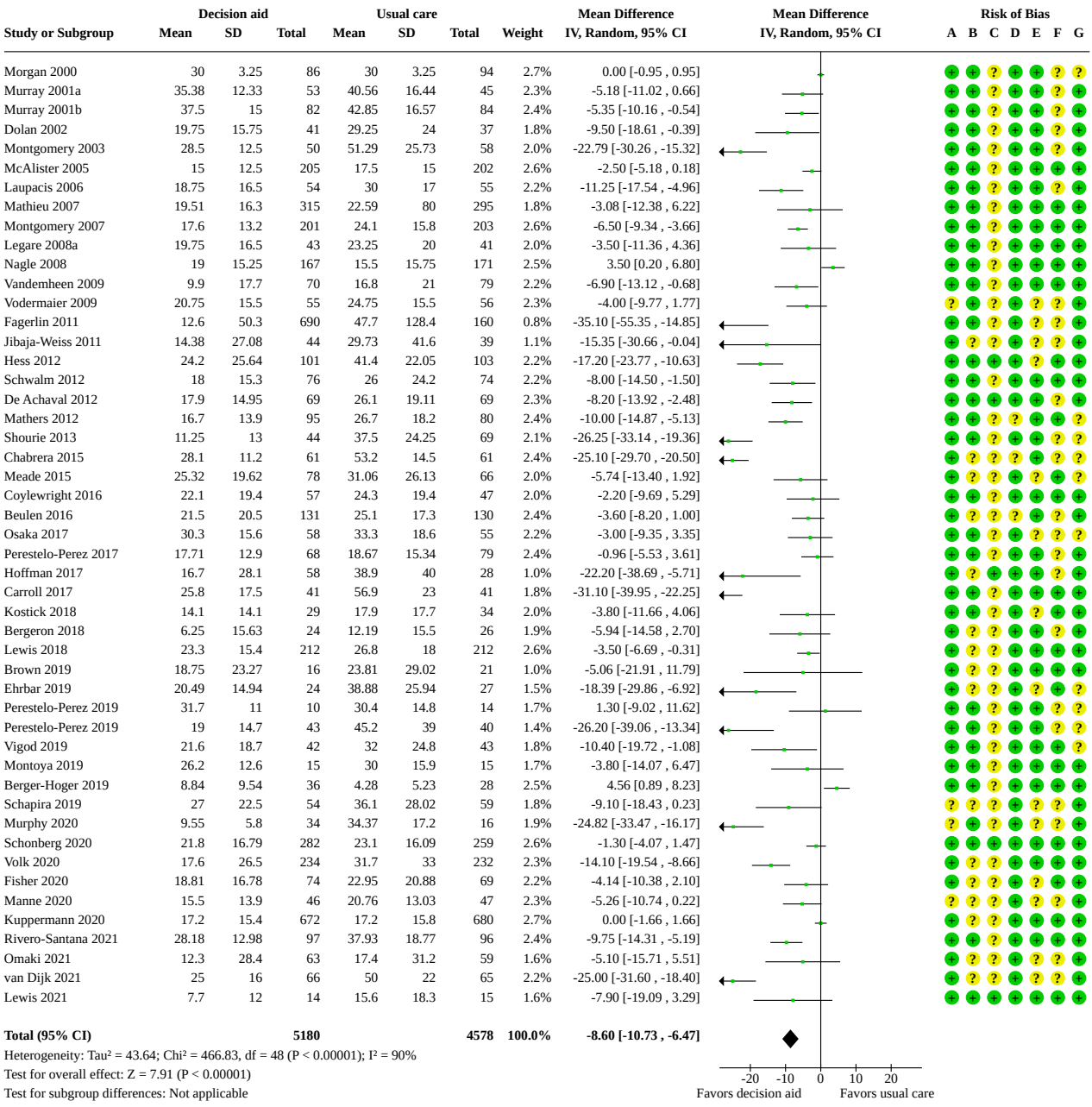
Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Man-Son-Hing 1999	16.25	12.5	139	19	14.75	148	2.3%	-2.75 [-5.91 , 0.41]
Morgan 2000	30	3.25	86	30	3.25	94	2.4%	0.00 [-0.95 , 0.95]
Murray 2001a	35.38	12.33	53	40.56	16.44	45	2.0%	-5.18 [-11.02 , 0.66]
Murray 2001b	37.5	15	82	42.85	16.57	84	2.1%	-5.35 [-10.16 , -0.54]
Dolan 2002	19.75	15.75	41	29.25	24	37	1.5%	-9.50 [-18.61 , -0.39]
Montgomery 2003	28.5	12.5	50	51.29	25.73	58	1.7%	-22.79 [-30.26 , -15.32]
McAlister 2005	15	12.5	205	17.5	15	202	2.3%	-2.50 [-5.18 , 0.18]
Laupacis 2006	18.75	16.5	54	30	17	55	1.9%	-11.25 [-17.54 , -4.96]
Mathieu 2007	19.51	16.3	315	22.59	80	295	1.5%	-3.08 [-12.38 , 6.22]
Montgomery 2007	17.6	13.2	201	24.1	15.8	203	2.3%	-6.50 [-9.34 , -3.66]
Legare 2008a	19.75	16.5	43	23.25	20	41	1.7%	-3.50 [-11.36 , 4.36]
Nagle 2008	19	15.25	167	15.5	15.75	171	2.3%	3.50 [0.20 , 6.80]
Vandemheen 2009	9.9	17.7	70	16.8	21	79	1.9%	-6.90 [-13.12 , -0.68]
Vodermaier 2009	20.75	15.5	55	24.75	15.5	56	2.0%	-4.00 [-9.77 , 1.77]
Fagerlin 2011	12.6	50.3	690	47.7	128.4	160	0.6%	-35.10 [-55.35 , -14.85]
Jibaja-Weiss 2011	14.38	27.08	44	29.73	41.6	39	0.9%	-15.35 [-30.66 , -0.04]
Hess 2012	24.2	25.64	101	41.4	22.05	103	1.9%	-17.20 [-23.77 , -10.63]
Schwalm 2012	18	15.3	76	26	24.2	74	1.9%	-8.00 [-14.50 , -1.50]
De Achaval 2012	17.9	14.95	69	26.1	19.11	69	2.0%	-8.20 [-13.92 , -2.48]
Mathers 2012	16.7	13.9	95	26.7	18.2	80	2.1%	-10.00 [-14.87 , -5.13]
Shourie 2013	11.25	13	44	37.5	24.25	69	1.8%	-26.25 [-33.14 , -19.36]
Brazell 2014	15.3	15.5	53	17.2	20.1	51	1.8%	-1.90 [-8.82 , 5.02]
Chabrera 2015	28.1	11.2	61	53.2	14.5	61	2.1%	-25.10 [-29.70 , -20.50]
Meade 2015	25.32	19.62	78	31.06	26.13	66	1.7%	-5.74 [-13.40 , 1.92]
LeBlanc 2015b	18.7	18.6	138	26.7	19.9	114	2.1%	-8.00 [-12.79 , -3.21]
Perestelo-Perez 2016	21.69	21.21	78	25.71	20.46	77	1.9%	-4.02 [-10.58 , 2.54]
Coylewright 2016	22.1	19.4	57	24.3	19.4	47	1.7%	-2.20 [-9.69 , 5.29]
Beulen 2016	21.5	20.5	131	25.1	17.3	130	2.1%	-3.60 [-8.20 , 1.00]
Osaka 2017	30.3	15.6	58	33.3	18.6	55	1.9%	-3.00 [-9.35 , 3.35]
Perestelo-Perez 2017	17.71	12.9	68	18.67	15.34	79	2.1%	-0.96 [-5.53 , 3.61]
Hoffman 2017	16.7	28.1	58	38.9	40	28	0.8%	-22.20 [-38.69 , -5.71]
Carroll 2017	25.8	17.5	41	56.9	23	41	1.6%	-31.10 [-39.95 , -22.25]
Kostick 2018	14.1	14.1	29	17.9	17.7	34	1.7%	-3.80 [-11.66 , 4.06]
Bergeron 2018	6.25	15.63	24	12.19	15.5	26	1.6%	-5.94 [-14.58 , 2.70]
Cuypers 2018	30	17.8	235	31.8	17	101	2.2%	-1.80 [-5.82 , 2.22]
Lewis 2018	23.3	15.4	212	26.8	18	212	2.3%	-3.50 [-6.69 , -0.31]
Brown 2019	18.75	23.27	16	23.81	29.02	21	0.8%	-5.06 [-21.91 , 11.79]
Ehrbar 2019	20.49	14.94	24	38.88	25.94	27	1.3%	-18.39 [-29.86 , -6.92]
Perestelo-Perez 2019	31.7	11	10	30.4	14.8	14	1.4%	1.30 [-9.02 , 11.62]
Perestelo-Perez 2019	19	14.7	43	45.2	39	40	1.1%	-26.20 [-39.06 , -13.34]
Vigod 2019	21.6	18.7	42	32	24.8	43	1.5%	-10.40 [-19.72 , -1.08]
Montoya 2019	26.2	12.6	15	30	15.9	15	1.4%	-3.80 [-14.07 , 6.47]
Berger-Hoger 2019	8.84	9.54	36	4.28	5.23	28	2.2%	4.56 [0.89 , 8.23]
Schapira 2019	27	22.5	54	36.1	28.02	59	1.5%	-9.10 [-18.43 , 0.23]
Schonberg 2020	21.8	16.79	282	23.1	16.09	259	2.3%	-1.30 [-4.07 , 1.47]
Murphy 2020	9.55	5.8	34	34.37	17.2	16	1.6%	-24.82 [-33.47 , -16.17]
Volk 2020	17.6	26.5	234	31.7	33	232	2.0%	-14.10 [-19.54 , -8.66]
Fisher 2020	18.81	16.78	74	22.95	20.88	69	1.9%	-4.14 [-10.38 , 2.10]
Manne 2020	15.5	13.9	46	20.76	13.03	47	2.0%	-5.26 [-10.74 , 0.22]
Kuppermann 2020	17.2	15.4	672	17.2	15.8	680	2.4%	0.00 [-1.66 , 1.66]
Kunneman 2020	16.6	16.1	463	18.8	17.1	459	2.4%	-2.20 [-4.34 , -0.06]
Rivero-Santana 2021	28.18	12.98	97	37.93	18.77	96	2.1%	-9.75 [-14.31 , -5.19]
Omaki 2021	12.3	28.4	63	17.4	31.2	59	1.3%	-5.10 [-15.71 , 5.51]
van Dijk 2021	25	16	66	50	22	65	1.9%	-25.00 [-31.60 , -18.40]
Schott 2021	8.87	17.73	33	17.5	32.26	33	1.1%	-8.63 [-21.19 , 3.93]
Lewis 2021	7.7	12	14	15.6	18.3	15	1.3%	-7.90 [-19.09 , 3.29]
Total (95% CI)			**6319**			**5561**	**100.0%**	**-7.86 [-9.69 , -6.02]**

Heterogeneity: Tau² = 36.03; Chi² = 472.97, df = 55 (P < 0.00001); I² = 88%
Test for overall effect: Z = 8.38 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 4.5. Comparison 4: Decisional conflict, Outcome 5: Decisional conflict - unclear values - without studies having high risk of bias

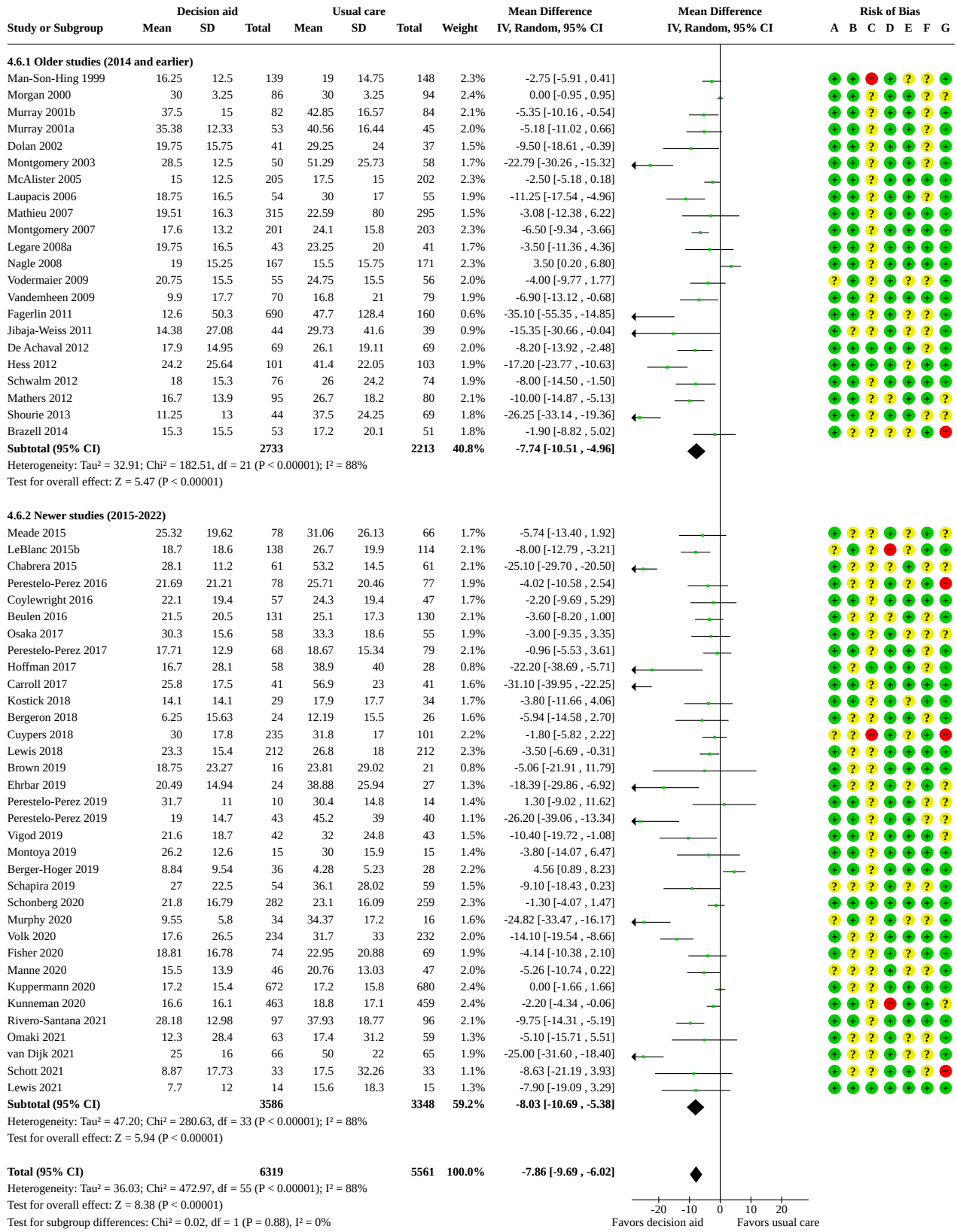


Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Morgan 2000	30	3.25	86	30	3.25	94	2.7%	0.00 [-0.95 , 0.95]	+ + ? + + ? ?
Murray 2001a	35.38	12.33	53	40.56	16.44	45	2.3%	-5.18 [-11.02 , 0.66]	+ + ? + + ? +
Murray 2001b	37.5	15	82	42.85	16.57	84	2.4%	-5.35 [-10.16 , -0.54]	+ + ? + + ? +
Dolan 2002	19.75	15.75	41	29.25	24	37	1.8%	-9.50 [-18.61 , -0.39]	+ + ? + + ? +
Montgomery 2003	28.5	12.5	50	51.29	25.73	58	2.0%	-22.79 [-30.26 , -15.32]	+ + ? + + ? +
McAlister 2005	15	12.5	205	17.5	15	202	2.6%	-2.50 [-5.18 , 0.18]	+ + ? + + + +
Laupacis 2006	18.75	16.5	54	30	17	55	2.2%	-11.25 [-17.54 , -4.96]	+ + ? + + ? +
Mathieu 2007	19.51	16.3	315	22.59	80	295	1.8%	-3.08 [-12.38 , 6.22]	+ + ? + + + +
Montgomery 2007	17.6	13.2	201	24.1	15.8	203	2.6%	-6.50 [-9.34 , -3.66]	+ + ? + + + +
Legare 2008a	19.75	16.5	43	23.25	20	41	2.0%	-3.50 [-11.36 , 4.36]	+ + ? + + + +
Nagle 2008	19	15.25	167	15.5	15.75	171	2.5%	3.50 [0.20 , 6.80]	+ + ? + + + +
Vandemheen 2009	9.9	17.7	70	16.8	21	79	2.2%	-6.90 [-13.12 , -0.68]	+ + ? + + + +
Vodermaier 2009	20.75	15.5	55	24.75	15.5	56	2.3%	-4.00 [-9.77 , 1.77]	? + ? + ? ? +
Fagerlin 2011	12.6	50.3	690	47.7	128.4	160	0.8%	-35.10 [-55.35 , -14.85]	+ + ? + ? ? +
Jibaja-Weiss 2011	14.38	27.08	44	29.73	41.6	39	1.1%	-15.35 [-30.66 , -0.04]	+ ? ? + ? ? +
Hess 2012	24.2	25.64	101	41.4	22.05	103	2.2%	-17.20 [-23.77 , -10.63]	+ + + + ? + +
Schwalm 2012	18	15.3	76	26	24.2	74	2.2%	-8.00 [-14.50 , -1.50]	+ + ? + + + +
De Achaval 2012	17.9	14.95	69	26.1	19.11	69	2.3%	-8.20 [-13.92 , -2.48]	+ + + + + ? +
Mathers 2012	16.7	13.9	95	26.7	18.2	80	2.4%	-10.00 [-14.87 , -5.13]	+ + ? ? + + ?
Shourie 2013	11.25	13	44	37.5	24.25	69	2.1%	-26.25 [-33.14 , -19.36]	+ + ? + + ? ?
Chabrera 2015	28.1	11.2	61	53.2	14.5	61	2.4%	-25.10 [-29.70 , -20.50]	+ ? ? ? + ? ?
Meade 2015	25.32	19.62	78	31.06	26.13	66	2.0%	-5.74 [-13.40 , 1.92]	+ ? ? + ? + ?
Coylewright 2016	22.1	19.4	57	24.3	19.4	47	2.0%	-2.20 [-9.69 , 5.29]	+ + ? + + + +
Beulen 2016	21.5	20.5	131	25.1	17.3	130	2.4%	-3.60 [-8.20 , 1.00]	+ ? ? ? + ? +
Osaka 2017	30.3	15.6	58	33.3	18.6	55	2.2%	-3.00 [-9.35 , 3.35]	+ + ? + ? ? ?
Perestelo-Perez 2017	17.71	12.9	68	18.67	15.34	79	2.4%	-0.96 [-5.53 , 3.61]	+ + ? + + ? +
Hoffman 2017	16.7	28.1	58	38.9	40	28	1.0%	-22.20 [-38.69 , -5.71]	+ ? + + + ? +
Carroll 2017	25.8	17.5	41	56.9	23	41	1.8%	-31.10 [-39.95 , -22.25]	+ + ? + + + +
Kostick 2018	14.1	14.1	29	17.9	17.7	34	2.0%	-3.80 [-11.66 , 4.06]	+ + ? + ? + +
Bergeron 2018	6.25	15.63	24	12.19	15.5	26	1.9%	-5.94 [-14.58 , 2.70]	+ ? ? + + ? +
Lewis 2018	23.3	15.4	212	26.8	18	212	2.6%	-3.50 [-6.69 , -0.31]	+ ? ? + + + +
Brown 2019	18.75	23.27	16	23.81	29.02	21	1.0%	-5.06 [-21.91 , 11.79]	+ ? ? + + + +
Ehrbar 2019	20.49	14.94	24	38.88	25.94	27	1.5%	-18.39 [-29.86 , -6.92]	+ ? ? + ? + ?
Perestelo-Perez 2019	31.7	11	10	30.4	14.8	14	1.7%	1.30 [-9.02 , 11.62]	+ + ? + + ? ?
Perestelo-Perez 2019	19	14.7	43	45.2	39	40	1.4%	-26.20 [-39.06 , -13.34]	+ + ? + + ? ?
Vigod 2019	21.6	18.7	42	32	24.8	43	1.8%	-10.40 [-19.72 , -1.08]	+ + ? + + + ?
Montoya 2019	26.2	12.6	15	30	15.9	15	1.7%	-3.80 [-14.07 , 6.47]	+ + ? + + + +
Berger-Hoger 2019	8.84	9.54	36	4.28	5.23	28	2.5%	4.56 [0.89 , 8.23]	+ + ? + + + +
Schapira 2019	27	22.5	54	36.1	28.02	59	1.8%	-9.10 [-18.43 , 0.23]	? ? ? + ? ? +
Murphy 2020	9.55	5.8	34	34.37	17.2	16	1.9%	-24.82 [-33.47 , -16.17]	? + ? + ? ? +
Schonberg 2020	21.8	16.79	282	23.1	16.09	259	2.6%	-1.30 [-4.07 , 1.47]	+ + + + + + +
Volk 2020	17.6	26.5	234	31.7	33	232	2.3%	-14.10 [-19.54 , -8.66]	+ ? ? + + + +
Fisher 2020	18.81	16.78	74	22.95	20.88	69	2.2%	-4.14 [-10.38 , 2.10]	+ ? ? + ? + +
Manne 2020	15.5	13.9	46	20.76	13.03	47	2.3%	-5.26 [-10.74 , 0.22]	? ? ? + ? ? +
Kuppermann 2020	17.2	15.4	672	17.2	15.8	680	2.7%	0.00 [-1.66 , 1.66]	+ ? ? + + + +
Rivero-Santana 2021	28.18	12.98	97	37.93	18.77	96	2.4%	-9.75 [-14.31 , -5.19]	+ + ? + + + +
Omaki 2021	12.3	28.4	63	17.4	31.2	59	1.6%	-5.10 [-15.71 , 5.51]	+ ? ? + ? ? +
van Dijk 2021	25	16	66	50	22	65	2.2%	-25.00 [-31.60 , -18.40]	+ ? ? + ? ? +
Lewis 2021	7.7	12	14	15.6	18.3	15	1.6%	-7.90 [-19.09 , 3.29]	+ + + + + + +
Total (95% CI)			**5180**			**4578**	**100.0%**	**-8.60 [-10.73 , -6.47]**	

Heterogeneity: Tau² = 43.64; Chi² = 466.83, df = 48 (P < 0.00001); I² = 90%
Test for overall effect: Z = 7.91 (P < 0.00001)
Test for subgroup differences: Not applicable

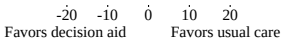
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 4.6. Comparison 4: Decisional conflict, Outcome 6: Unclear values - old vs new studies



Analysis 4.6. (Continued)

Test for overall effect: Z = 8.38 (P < 0.00001)
Test for subgroup differences: Chi² = 0.02, df = 1 (P = 0.88), I² = 0%



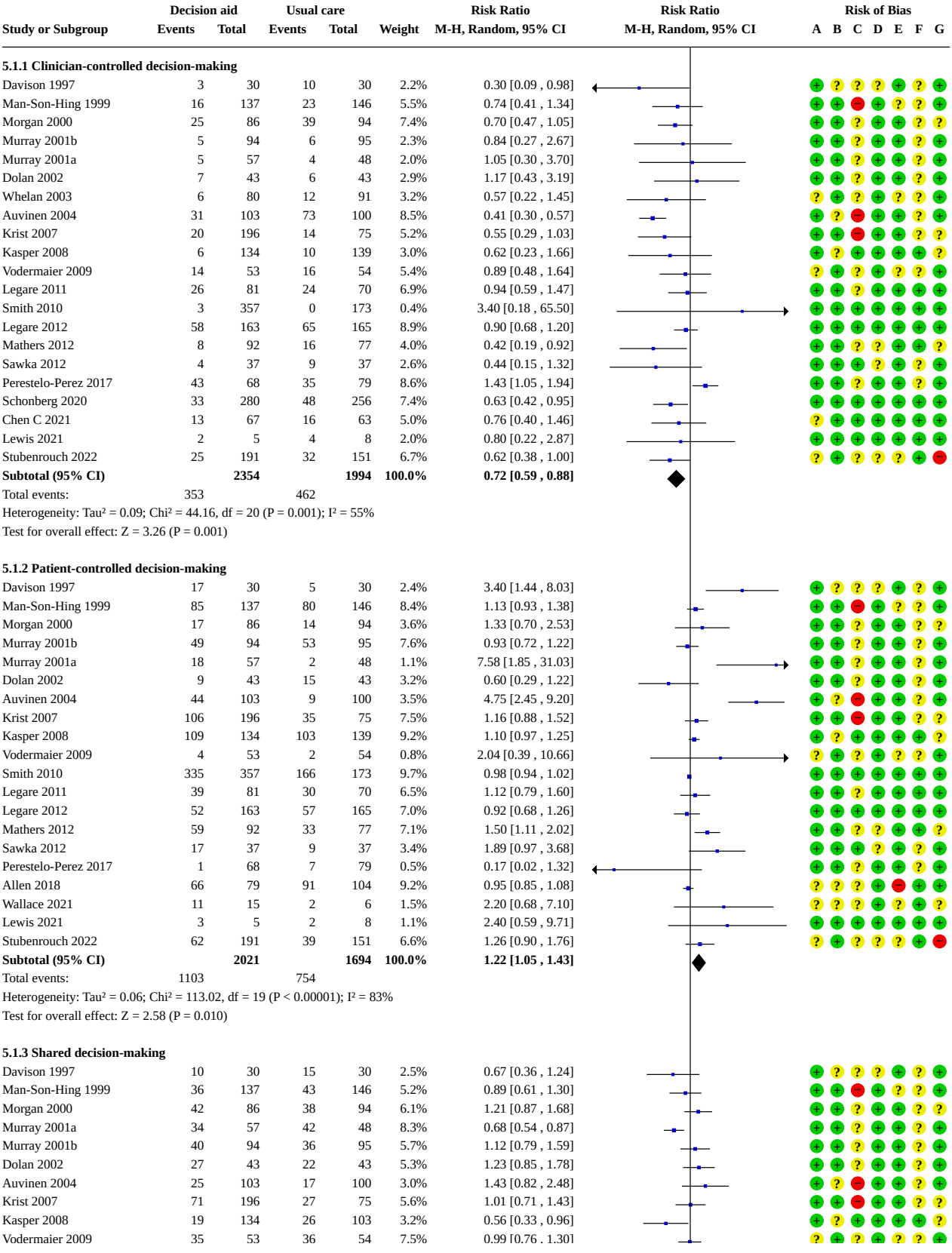
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 5. Participation in decision making

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Participation in decision-making - all studies	25		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1.1 Clinician-controlled decision-making	21	4348	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.59, 0.88]
5.1.2 Patient-controlled decision-making	20	3715	Risk Ratio (M-H, Random, 95% CI)	1.22 [1.05, 1.43]
5.1.3 Shared decision-making	20	3799	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.88, 1.09]
5.2 Participation in decision-making - studies without high risk of bias	20		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.2.1 Clinician-controlled decision-making	17	3249	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.66, 0.98]
5.2.2 Patient-controlled decision-making	15	2433	Risk Ratio (M-H, Random, 95% CI)	1.20 [0.99, 1.45]
5.2.3 Shared decision-making	16	2700	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.83, 1.10]
5.3 Participation in decision-making - clinician-controlled - old vs new studies	21	4348	Risk Ratio (M-H, Random, 95% CI)	0.72 [0.59, 0.88]
5.3.1 Older studies (2014 and earlier)	16	3180	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.55, 0.83]
5.3.2 Newer studies (2015-2022)	5	1168	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.53, 1.29]
5.4 Participation in decision-making - patient-controlled - old vs new studies	20	3715	Risk Ratio (M-H, Random, 95% CI)	1.22 [1.05, 1.43]
5.4.1 Older studies (2014 and earlier)	15	3009	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.05, 1.55]
5.4.2 Newer studies (2015-2022)	5	706	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.77, 1.68]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.5 Participation in decision-making - shared decision-making - old vs new studies	20	3799	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.88, 1.09]
5.5.1 Older studies (2014 and earlier)	16	3196	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.86, 1.11]
5.5.2 Newer studies (2015-2022)	4	603	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.84, 1.17]

Analysis 5.1. Comparison 5: Participation in decision making, Outcome 1: Participation in decision-making - all studies

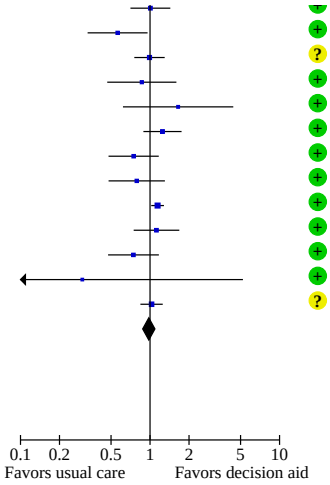


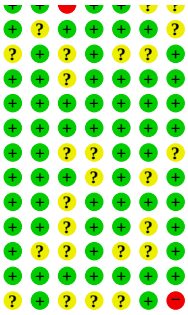
Analysis 5.1. (Continued)

Kasper 2008	19	134	26	103	3.2%	0.56 [0.33 , 0.96]
Vodermaier 2009	35	53	36	54	7.5%	0.99 [0.76 , 1.30]
Legare 2011	16	81	16	70	2.5%	0.86 [0.47 , 1.60]
Smith 2010	17	357	5	173	1.1%	1.65 [0.62 , 4.39]
Legare 2012	53	163	43	165	5.9%	1.25 [0.89 , 1.75]
Mathers 2012	25	92	28	77	4.1%	0.75 [0.48 , 1.17]
Sawka 2012	15	37	19	37	3.5%	0.79 [0.48 , 1.30]
van Tol-Geerdink 2013	145	153	58	70	12.0%	1.14 [1.02 , 1.28]
Perestelo-Perez 2017	28	68	29	79	4.7%	1.12 [0.75 , 1.68]
Omaki 2021	19	51	25	50	4.1%	0.75 [0.47 , 1.17]
Lewis 2021	0	5	2	8	0.1%	0.30 [0.02 , 5.21]
Stubenrouch 2022	104	191	80	151	9.4%	1.03 [0.84 , 1.25]
Subtotal (95% CI)		**2131**		**1668**	**100.0%**	**0.98 [0.88 , 1.09]**
Total events:	761		607			

Heterogeneity: Tau² = 0.02; Chi² = 34.49, df = 19 (P = 0.02); I² = 45%
Test for overall effect: Z = 0.39 (P = 0.69)

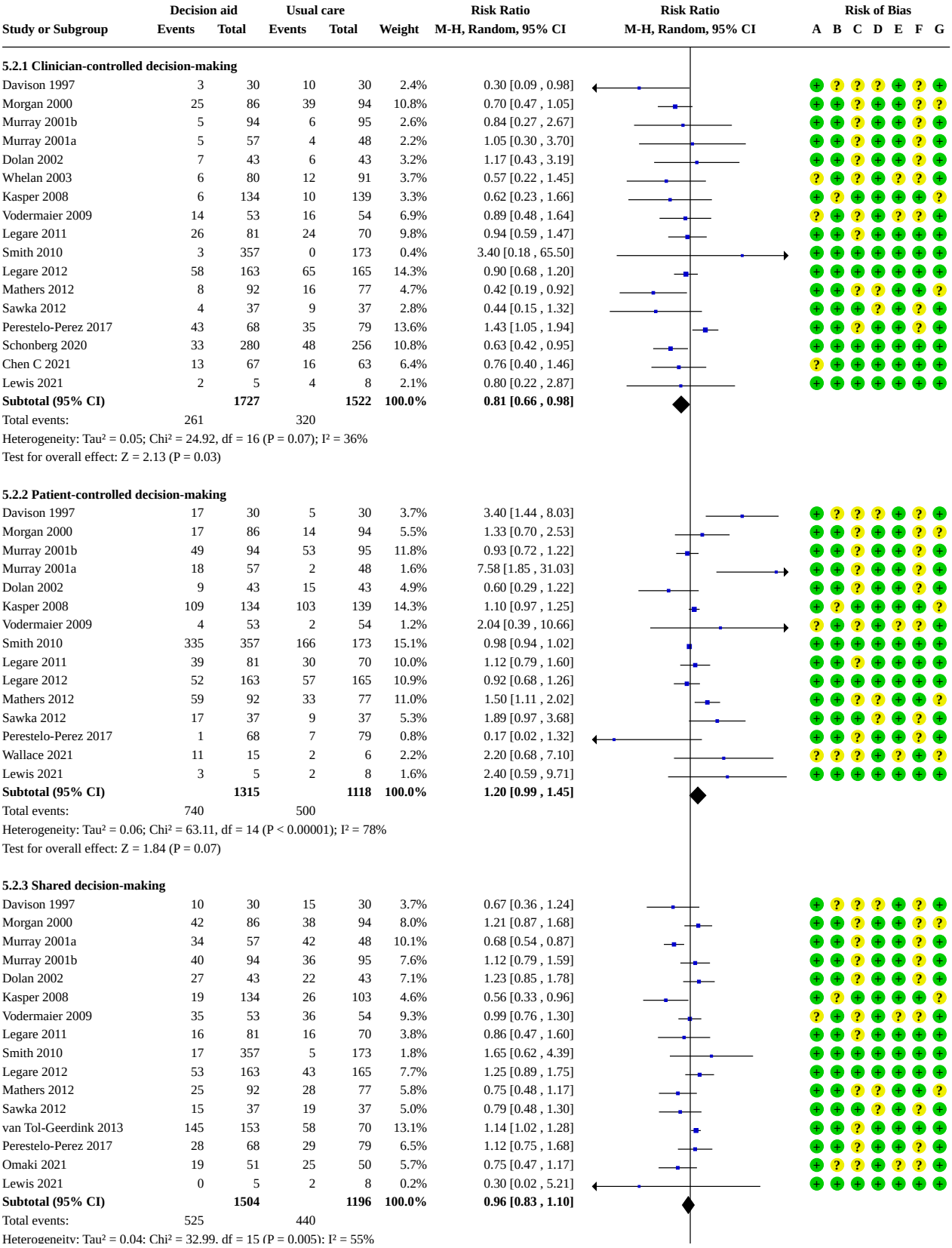
Test for subgroup differences: Chi² = 0.00, df = 2 (P < 0.00001), I² = 0%





Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.2. Comparison 5: Participation in decision making, Outcome 2: Participation in decision-making - studies without high risk of bias



Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
5.2.1 Clinician-controlled decision-making						
Davison 1997	3	30	10	30	2.4%	0.30 [0.09 , 0.98]
Morgan 2000	25	86	39	94	10.8%	0.70 [0.47 , 1.05]
Murray 2001b	5	94	6	95	2.6%	0.84 [0.27 , 2.67]
Murray 2001a	5	57	4	48	2.2%	1.05 [0.30 , 3.70]
Dolan 2002	7	43	6	43	3.2%	1.17 [0.43 , 3.19]
Whelan 2003	6	80	12	91	3.7%	0.57 [0.22 , 1.45]
Kasper 2008	6	134	10	139	3.3%	0.62 [0.23 , 1.66]
Vodermaier 2009	14	53	16	54	6.9%	0.89 [0.48 , 1.64]
Legare 2011	26	81	24	70	9.8%	0.94 [0.59 , 1.47]
Smith 2010	3	357	0	173	0.4%	3.40 [0.18 , 65.50]
Legare 2012	58	163	65	165	14.3%	0.90 [0.68 , 1.20]
Mathers 2012	8	92	16	77	4.7%	0.42 [0.19 , 0.92]
Sawka 2012	4	37	9	37	2.8%	0.44 [0.15 , 1.32]
Perestelo-Perez 2017	43	68	35	79	13.6%	1.43 [1.05 , 1.94]
Schonberg 2020	33	280	48	256	10.8%	0.63 [0.42 , 0.95]
Chen C 2021	13	67	16	63	6.4%	0.76 [0.40 , 1.46]
Lewis 2021	2	5	4	8	2.1%	0.80 [0.22 , 2.87]
Subtotal (95% CI)		**1727**		**1522**	**100.0%**	**0.81 [0.66 , 0.98]**
Total events:	261		320			
Heterogeneity: Tau² = 0.05; Chi² = 24.92, df = 16 (P = 0.07); I² = 36%						
Test for overall effect: Z = 2.13 (P = 0.03)						
5.2.2 Patient-controlled decision-making						
Davison 1997	17	30	5	30	3.7%	3.40 [1.44 , 8.03]
Morgan 2000	17	86	14	94	5.5%	1.33 [0.70 , 2.53]
Murray 2001b	49	94	53	95	11.8%	0.93 [0.72 , 1.22]
Murray 2001a	18	57	2	48	1.6%	7.58 [1.85 , 31.03]
Dolan 2002	9	43	15	43	4.9%	0.60 [0.29 , 1.22]
Kasper 2008	109	134	103	139	14.3%	1.10 [0.97 , 1.25]
Vodermaier 2009	4	53	2	54	1.2%	2.04 [0.39 , 10.66]
Smith 2010	335	357	166	173	15.1%	0.98 [0.94 , 1.02]
Legare 2011	39	81	30	70	10.0%	1.12 [0.79 , 1.60]
Legare 2012	52	163	57	165	10.9%	0.92 [0.68 , 1.26]
Mathers 2012	59	92	33	77	11.0%	1.50 [1.11 , 2.02]
Sawka 2012	17	37	9	37	5.3%	1.89 [0.97 , 3.68]
Perestelo-Perez 2017	1	68	7	79	0.8%	0.17 [0.02 , 1.32]
Wallace 2021	11	15	2	6	2.2%	2.20 [0.68 , 7.10]
Lewis 2021	3	5	2	8	1.6%	2.40 [0.59 , 9.71]
Subtotal (95% CI)		**1315**		**1118**	**100.0%**	**1.20 [0.99 , 1.45]**
Total events:	740		500			
Heterogeneity: Tau² = 0.06; Chi² = 63.11, df = 14 (P < 0.00001); I² = 78%						
Test for overall effect: Z = 1.84 (P = 0.07)						
5.2.3 Shared decision-making						
Davison 1997	10	30	15	30	3.7%	0.67 [0.36 , 1.24]
Morgan 2000	42	86	38	94	8.0%	1.21 [0.87 , 1.68]
Murray 2001a	34	57	42	48	10.1%	0.68 [0.54 , 0.87]
Murray 2001b	40	94	36	95	7.6%	1.12 [0.79 , 1.59]
Dolan 2002	27	43	22	43	7.1%	1.23 [0.85 , 1.78]
Kasper 2008	19	134	26	103	4.6%	0.56 [0.33 , 0.96]
Vodermaier 2009	35	53	36	54	9.3%	0.99 [0.76 , 1.30]
Legare 2011	16	81	16	70	3.8%	0.86 [0.47 , 1.60]
Smith 2010	17	357	5	173	1.8%	1.65 [0.62 , 4.39]
Legare 2012	53	163	43	165	7.7%	1.25 [0.89 , 1.75]
Mathers 2012	25	92	28	77	5.8%	0.75 [0.48 , 1.17]
Sawka 2012	15	37	19	37	5.0%	0.79 [0.48 , 1.30]
van Tol-Geerdink 2013	145	153	58	70	13.1%	1.14 [1.02 , 1.28]
Perestelo-Perez 2017	28	68	29	79	6.5%	1.12 [0.75 , 1.68]
Omaki 2021	19	51	25	50	5.7%	0.75 [0.47 , 1.17]
Lewis 2021	0	5	2	8	0.2%	0.30 [0.02 , 5.21]
Subtotal (95% CI)		**1504**		**1196**	**100.0%**	**0.96 [0.83 , 1.10]**
Total events:	525		440			
Heterogeneity: Tau² = 0.04; Chi² = 32.99, df = 15 (P = 0.005); I² = 55%						

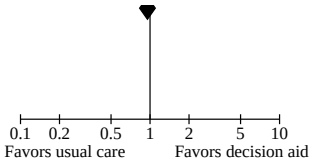
Analysis 5.2. (Continued)

Total events: 525 440

Heterogeneity: Tau² = 0.04; Chi² = 32.99, df = 15 (P = 0.005); I² = 55%

Test for overall effect: Z = 0.65 (P = 0.52)

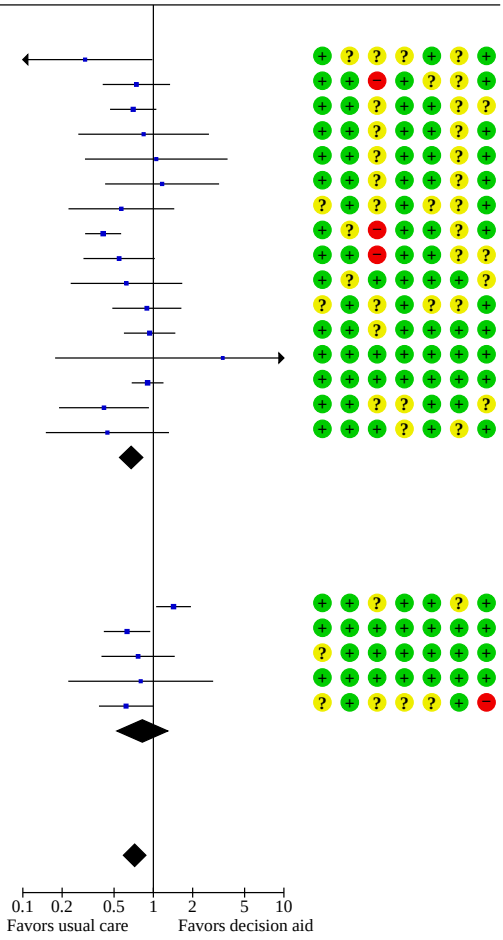
Test for subgroup differences: Chi² = 0.00, df = 2 (P < 0.00001), I² = 0%



Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.3. Comparison 5: Participation in decision making, Outcome 3: Participation in decision-making - clinician-controlled - old vs new studies



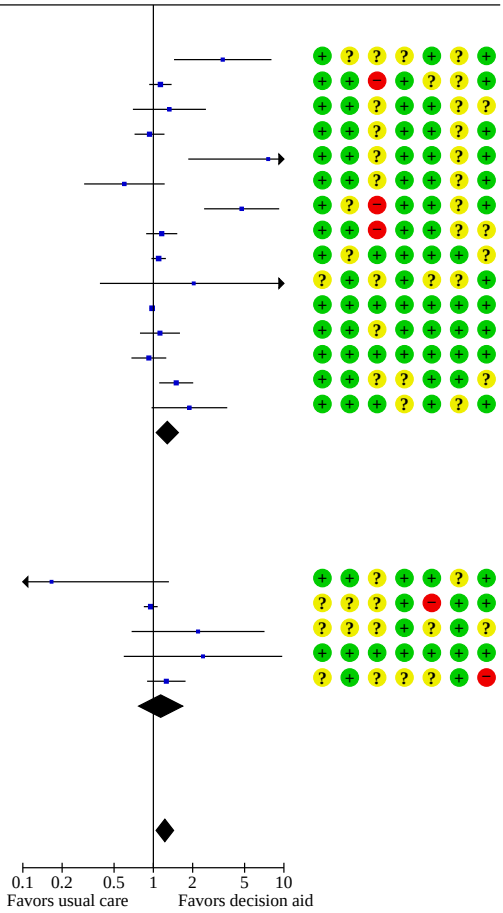
Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
5.3.1 Older studies (2014 and earlier)						
Davison 1997	3	30	10	30	2.2%	0.30 [0.09 , 0.98]
Man-Son-Hing 1999	16	137	23	146	5.5%	0.74 [0.41 , 1.34]
Morgan 2000	25	86	39	94	7.4%	0.70 [0.47 , 1.05]
Murray 2001b	5	94	6	95	2.3%	0.84 [0.27 , 2.67]
Murray 2001a	5	57	4	48	2.0%	1.05 [0.30 , 3.70]
Dolan 2002	7	43	6	43	2.9%	1.17 [0.43 , 3.19]
Whelan 2003	6	80	12	91	3.2%	0.57 [0.22 , 1.45]
Auvinen 2004	31	103	73	100	8.5%	0.41 [0.30 , 0.57]
Krist 2007	20	196	14	75	5.2%	0.55 [0.29 , 1.03]
Kasper 2008	6	134	10	139	3.0%	0.62 [0.23 , 1.66]
Vodermaier 2009	14	53	16	54	5.4%	0.89 [0.48 , 1.64]
Legare 2011	26	81	24	70	6.9%	0.94 [0.59 , 1.47]
Smith 2010	3	357	0	173	0.4%	3.40 [0.18 , 65.50]
Legare 2012	58	163	65	165	8.9%	0.90 [0.68 , 1.20]
Mathers 2012	8	92	16	77	4.0%	0.42 [0.19 , 0.92]
Sawka 2012	4	37	9	37	2.6%	0.44 [0.15 , 1.32]
Subtotal (95% CI)		**1743**		**1437**	**70.3%**	**0.68 [0.55 , 0.83]**
Total events:	237		327			
Heterogeneity: Tau² = 0.05; Chi² = 23.59, df = 15 (P = 0.07); I² = 36%						
Test for overall effect: Z = 3.74 (P = 0.0002)						
5.3.2 Newer studies (2015-2022)						
Perestelo-Perez 2017	43	68	35	79	8.6%	1.43 [1.05 , 1.94]
Schonberg 2020	33	280	48	256	7.4%	0.63 [0.42 , 0.95]
Chen C 2021	13	67	16	63	5.0%	0.76 [0.40 , 1.46]
Lewis 2021	2	5	4	8	2.0%	0.80 [0.22 , 2.87]
Stubenrouch 2022	25	191	32	151	6.7%	0.62 [0.38 , 1.00]
Subtotal (95% CI)		**611**		**557**	**29.7%**	**0.82 [0.53 , 1.29]**
Total events:	116		135			
Heterogeneity: Tau² = 0.17; Chi² = 15.24, df = 4 (P = 0.004); I² = 74%						
Test for overall effect: Z = 0.85 (P = 0.39)						
Total (95% CI)		**2354**		**1994**	**100.0%**	**0.72 [0.59 , 0.88]**
Total events:	353		462			
Heterogeneity: Tau² = 0.09; Chi² = 44.16, df = 20 (P = 0.001); I² = 55%						
Test for overall effect: Z = 3.26 (P = 0.001)						
Test for subgroup differences: Chi² = 0.61, df = 1 (P = 0.44), I² = 0%						

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.4. Comparison 5: Participation in decision making, Outcome 4: Participation in decision-making - patient-controlled - old vs new studies

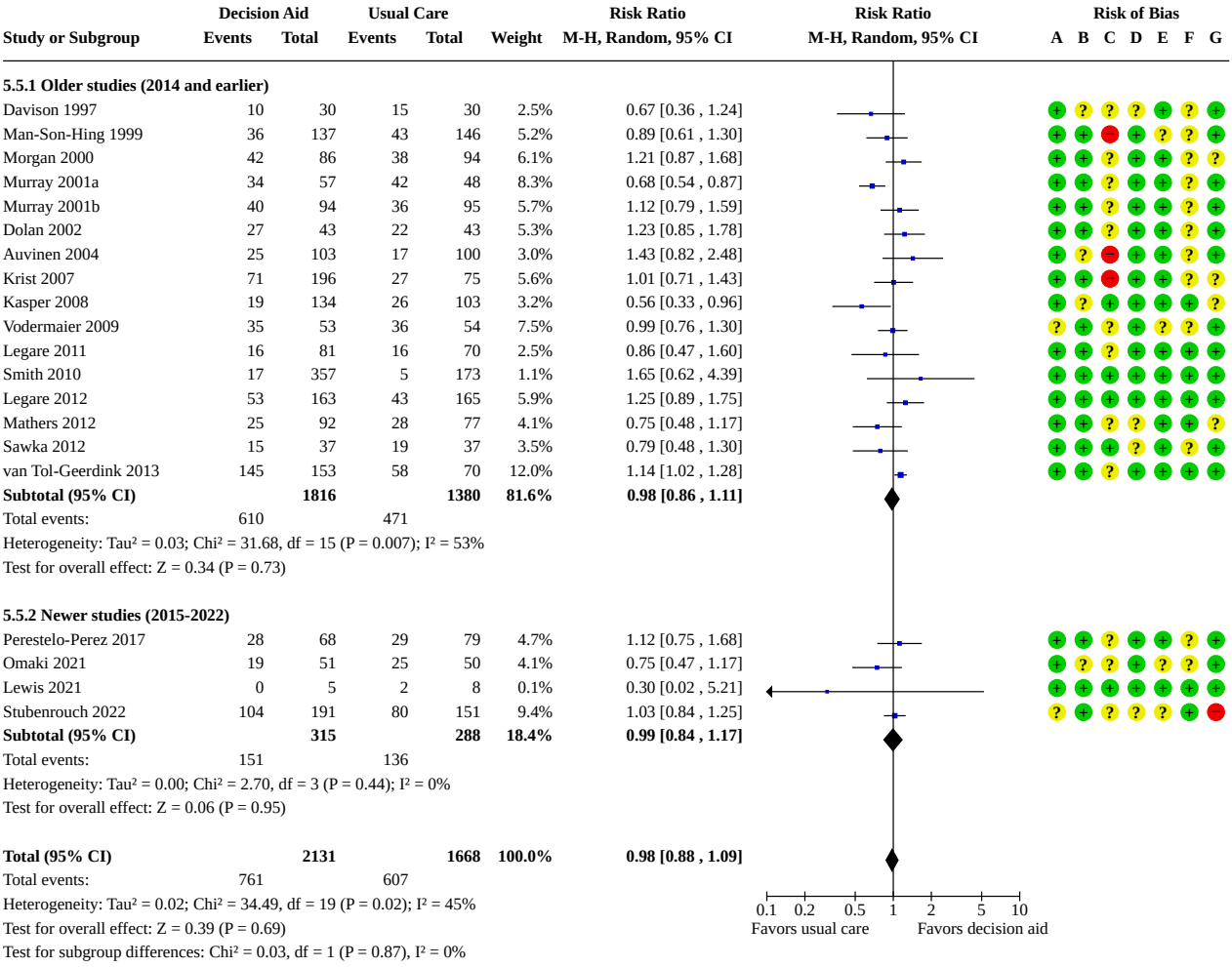
Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
5.4.1 Older studies (2014 and earlier)						
Davison 1997	17	30	5	30	2.4%	3.40 [1.44 , 8.03]
Man-Son-Hing 1999	85	137	80	146	8.4%	1.13 [0.93 , 1.38]
Morgan 2000	17	86	14	94	3.6%	1.33 [0.70 , 2.53]
Murray 2001b	49	94	53	95	7.6%	0.93 [0.72 , 1.22]
Murray 2001a	18	57	2	48	1.1%	7.58 [1.85 , 31.03]
Dolan 2002	9	43	15	43	3.2%	0.60 [0.29 , 1.22]
Auvinen 2004	44	103	9	100	3.5%	4.75 [2.45 , 9.20]
Krist 2007	106	196	35	75	7.5%	1.16 [0.88 , 1.52]
Kasper 2008	109	134	103	139	9.2%	1.10 [0.97 , 1.25]
Vodermaier 2009	4	53	2	54	0.8%	2.04 [0.39 , 10.66]
Smith 2010	335	357	166	173	9.7%	0.98 [0.94 , 1.02]
Legare 2011	39	81	30	70	6.5%	1.12 [0.79 , 1.60]
Legare 2012	52	163	57	165	7.0%	0.92 [0.68 , 1.26]
Mathers 2012	59	92	33	77	7.1%	1.50 [1.11 , 2.02]
Sawka 2012	17	37	9	37	3.4%	1.89 [0.97 , 3.68]
Subtotal (95% CI)		**1663**		**1346**	**81.1%**	**1.28 [1.05 , 1.55]**
Total events:	960		613			
Heterogeneity: Tau² = 0.09; Chi² = 109.06, df = 14 (P < 0.00001); I² = 87%						
Test for overall effect: Z = 2.47 (P = 0.01)						
5.4.2 Newer studies (2015-2022)						
Perestelo-Perez 2017	1	68	7	79	0.5%	0.17 [0.02 , 1.32]
Allen 2018	66	79	91	104	9.2%	0.95 [0.85 , 1.08]
Wallace 2021	11	15	2	6	1.5%	2.20 [0.68 , 7.10]
Lewis 2021	3	5	2	8	1.1%	2.40 [0.59 , 9.71]
Stubenrouch 2022	62	191	39	151	6.6%	1.26 [0.90 , 1.76]
Subtotal (95% CI)		**358**		**348**	**18.9%**	**1.14 [0.77 , 1.68]**
Total events:	143		141			
Heterogeneity: Tau² = 0.08; Chi² = 9.64, df = 4 (P = 0.05); I² = 58%						
Test for overall effect: Z = 0.65 (P = 0.51)						
Total (95% CI)		**2021**		**1694**	**100.0%**	**1.22 [1.05 , 1.43]**
Total events:	1103		754			
Heterogeneity: Tau² = 0.06; Chi² = 113.02, df = 19 (P < 0.00001); I² = 83%						
Test for overall effect: Z = 2.58 (P = 0.010)						
Test for subgroup differences: Chi² = 0.28, df = 1 (P = 0.60), I² = 0%						



Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.5. Comparison 5: Participation in decision making, Outcome 5: Participation in decision-making - shared decision-making - old vs new studies



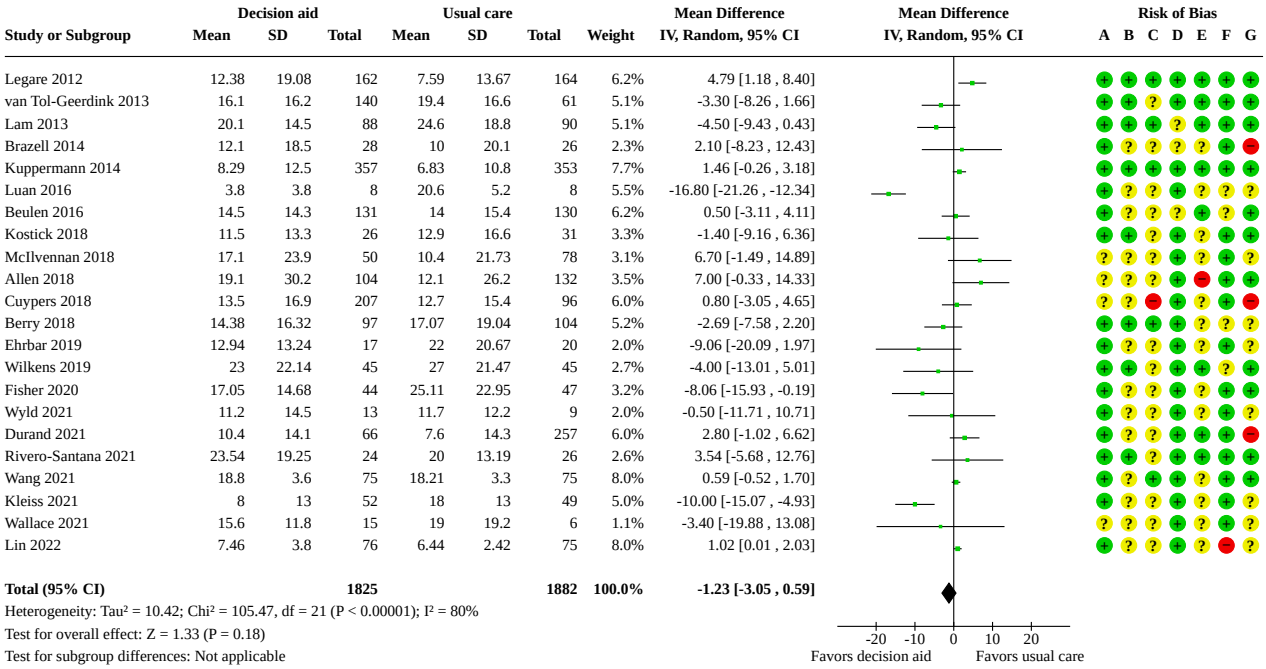
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 6. Decision regret

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Decision regret - all studies	22	3707	Mean Difference (IV, Random, 95% CI)	-1.23 [-3.05, 0.59]
6.2 Decision regret - studies without high risk of bias	17	2640	Mean Difference (IV, Random, 95% CI)	-2.58 [-5.16, -0.01]
6.3 Decision regret - old vs new studies	22	3707	Mean Difference (IV, Random, 95% CI)	-1.23 [-3.05, 0.59]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.3.1 Older studies (2014 and earlier)	5	1469	Mean Difference (IV, Random, 95% CI)	0.27 [-2.98, 3.52]
6.3.2 Newer studies (2015-2022)	17	2238	Mean Difference (IV, Random, 95% CI)	-1.79 [-4.06, 0.49]

Analysis 6.1. Comparison 6: Decision regret, Outcome 1: Decision regret - all studies



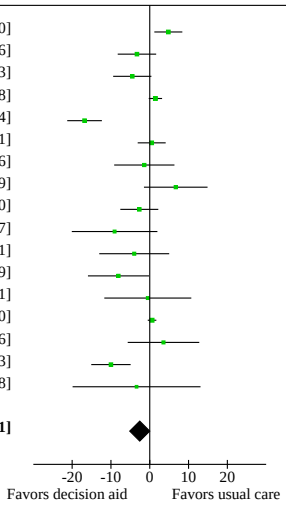
Heterogeneity: Tau² = 10.42; Chi² = 105.47, df = 21 (P < 0.00001); I² = 80%
Test for overall effect: Z = 1.33 (P = 0.18)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 6.2. Comparison 6: Decision regret, Outcome 2: Decision regret - studies without high risk of bias

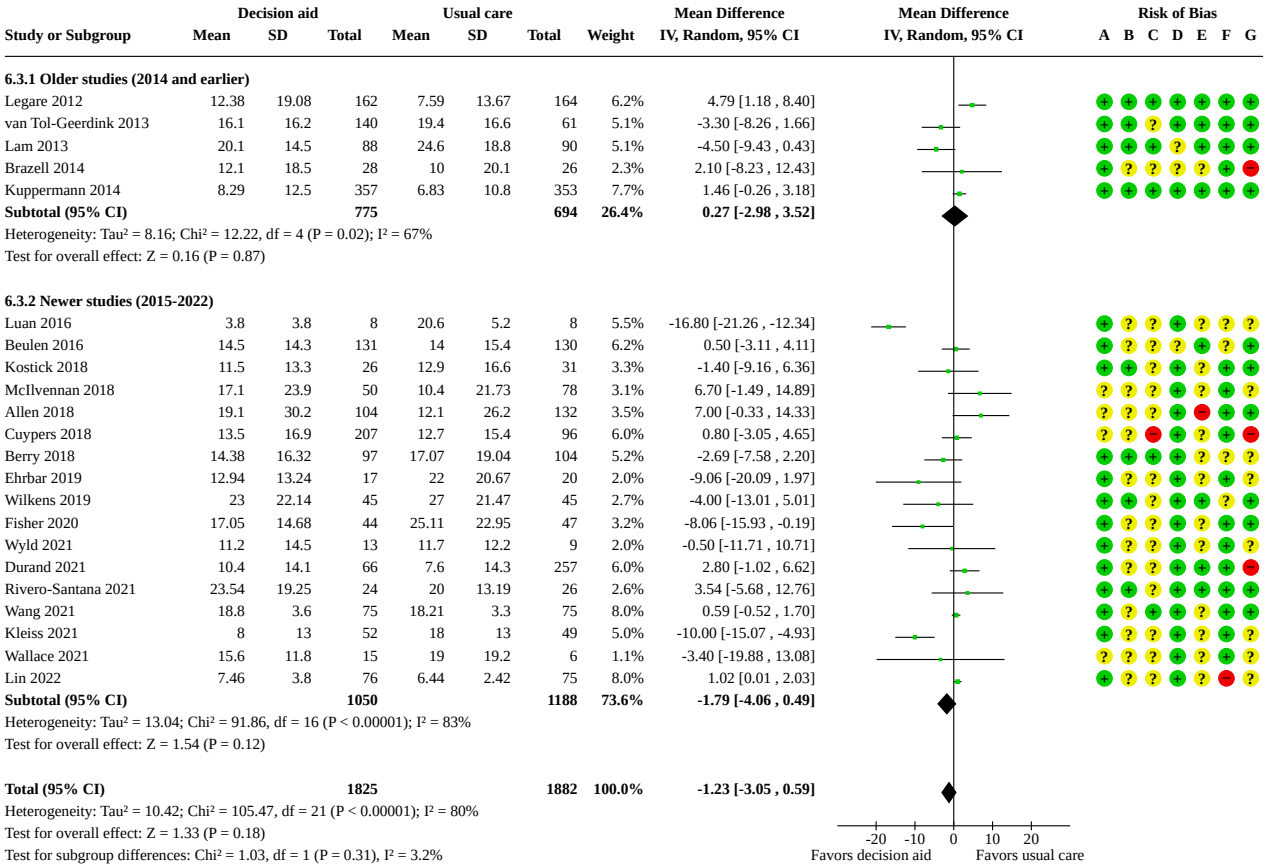
Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Legare 2012	12.38	19.08	162	7.59	13.67	164	7.8%	4.79 [1.18 , 8.40]
van Tol-Geerdink 2013	16.1	16.2	140	19.4	16.6	61	6.9%	-3.30 [-8.26 , 1.66]
Lam 2013	20.1	14.5	88	24.6	18.8	90	6.9%	-4.50 [-9.43 , 0.43]
Kuppermann 2014	8.29	12.5	357	6.83	10.8	353	8.8%	1.46 [-0.26 , 3.18]
Luan 2016	3.8	3.8	8	20.6	5.2	8	7.2%	-16.80 [-21.26 , -12.34]
Beulen 2016	14.5	14.3	131	14	15.4	130	7.8%	0.50 [-3.11 , 4.11]
Kostick 2018	11.5	13.3	26	12.9	16.6	31	5.0%	-1.40 [-9.16 , 6.36]
McIlvennan 2018	17.1	23.9	50	10.4	21.73	78	4.8%	6.70 [-1.49 , 14.89]
Berry 2018	14.38	16.32	97	17.07	19.04	104	6.9%	-2.69 [-7.58 , 2.20]
Ehrbar 2019	12.94	13.24	17	22	20.67	20	3.4%	-9.06 [-20.09 , 1.97]
Wilkens 2019	23	22.14	45	27	21.47	45	4.3%	-4.00 [-13.01 , 5.01]
Fisher 2020	17.05	14.68	44	25.11	22.95	47	4.9%	-8.06 [-15.93 , -0.19]
Wyld 2021	11.2	14.5	13	11.7	12.2	9	3.4%	-0.50 [-11.71 , 10.71]
Wang 2021	18.8	3.6	75	18.21	3.3	75	9.0%	0.59 [-0.52 , 1.70]
Rivero-Santana 2021	23.54	19.25	24	20	13.19	26	4.2%	3.54 [-5.68 , 12.76]
Kleiss 2021	8	13	52	18	13	49	6.8%	-10.00 [-15.07 , -4.93]
Wallace 2021	15.6	11.8	15	19	19.2	6	1.9%	-3.40 [-19.88 , 13.08]
Total (95% CI)			**1344**			**1296**	**100.0%**	**-2.58 [-5.16 , -0.01]**

Heterogeneity: Tau² = 18.78; Chi² = 96.52, df = 16 (P < 0.00001); I² = 83%
Test for overall effect: Z = 1.96 (P = 0.05)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 6.3. Comparison 6: Decision regret, Outcome 3: Decision regret - old vs new studies



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 7. Proportion undecided

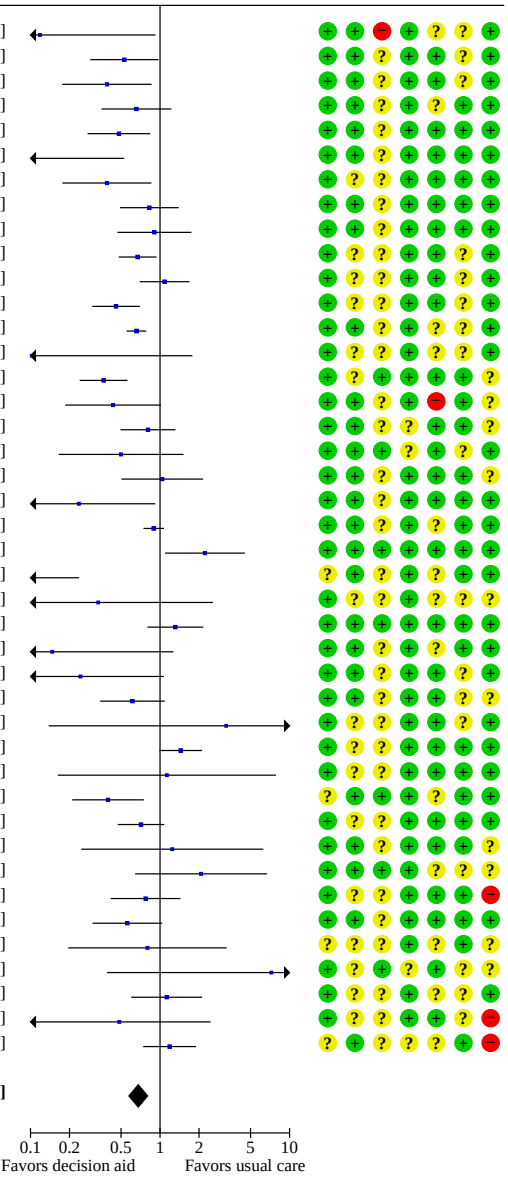
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Proportion undecided - all studies	42	8548	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.58, 0.80]
7.2 Proportion undecided - studies without high risk of bias	37	7471	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.57, 0.81]
7.3 Proportion undecided - old vs new studies	42	8548	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.58, 0.80]
7.3.1 Older studies (2014 and earlier)	22	5341	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.52, 0.77]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.3.2 Newer studies (2015-2022)	20	3207	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.55, 1.03]

Analysis 7.1. Comparison 7: Proportion undecided, Outcome 1: Proportion undecided - all studies

Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Man-Son-Hing 1999	1	139	9	148	0.6%	0.12 [0.02 , 0.92]
Murray 2001b	13	94	25	96	3.0%	0.53 [0.29 , 0.97]
Vuorma 2003	8	184	20	179	2.4%	0.39 [0.18 , 0.86]
Shorten 2005	14	99	20	93	3.0%	0.66 [0.35 , 1.22]
Mathieu 2007	17	349	36	356	3.2%	0.48 [0.28 , 0.84]
Nassar 2007	1	98	13	90	0.6%	0.07 [0.01 , 0.53]
Protheroe 2007	7	56	18	56	2.4%	0.39 [0.18 , 0.86]
Legare 2008a	16	44	18	41	3.4%	0.83 [0.49 , 1.40]
Vandemheen 2009	13	70	16	78	2.8%	0.91 [0.47 , 1.75]
Schwartz 2009a	33	100	56	114	4.2%	0.67 [0.48 , 0.94]
Allen 2010	34	291	36	334	3.8%	1.08 [0.70 , 1.69]
Mathieu 2010	21	117	82	209	3.8%	0.46 [0.30 , 0.70]
Fagerlin 2011	171	382	68	100	4.8%	0.66 [0.55 , 0.78]
Jibaja-Weiss 2011	0	44	4	39	0.3%	0.10 [0.01 , 1.78]
Miller 2011	22	132	60	132	3.8%	0.37 [0.24 , 0.56]
Chambers 2012	6	48	17	59	2.2%	0.43 [0.19 , 1.01]
Mathers 2012	23	95	24	80	3.5%	0.81 [0.50 , 1.32]
Sawka 2012	4	37	8	37	1.6%	0.50 [0.16 , 1.52]
Berry 2013	14	120	12	107	2.6%	1.04 [0.50 , 2.15]
van Tol-Geerdink 2013	3	163	6	77	1.2%	0.24 [0.06 , 0.92]
Bozic 2013	45	60	52	62	4.8%	0.89 [0.75 , 1.07]
Stacey 2014a	20	66	9	66	2.6%	2.22 [1.09 , 4.51]
Watts 2015	3	63	40	65	1.5%	0.08 [0.03 , 0.24]
Luan 2016	1	8	3	8	0.6%	0.33 [0.04 , 2.56]
Stacey 2016	30	156	23	157	3.5%	1.31 [0.80 , 2.16]
Oostendorp 2017	1	68	4	40	0.5%	0.15 [0.02 , 1.27]
Perestelo-Perez 2017	2	65	10	79	1.0%	0.24 [0.06 , 1.07]
Smallwood 2017	11	29	13	21	3.2%	0.61 [0.35 , 1.09]
Bergeron 2018	1	24	0	26	0.3%	3.24 [0.14 , 75.91]
Lewis 2018	52	212	36	212	4.0%	1.44 [0.99 , 2.11]
Carlson 2019	2	85	2	96	0.6%	1.13 [0.16 , 7.84]
Subramanian 2019	10	63	28	70	2.9%	0.40 [0.21 , 0.75]
Singh 2019	30	151	41	147	3.9%	0.71 [0.47 , 1.08]
Madden 2020	5	161	2	80	0.9%	1.24 [0.25 , 6.26]
McLean 2020	7	18	3	16	1.4%	2.07 [0.64 , 6.70]
Durand 2021	10	60	47	218	3.0%	0.77 [0.42 , 1.44]
Rivero-Santana 2021	13	97	23	96	3.0%	0.56 [0.30 , 1.04]
Wallace 2021	4	15	2	6	1.1%	0.80 [0.20 , 3.27]
Chen S 2021	3	29	0	30	0.3%	7.23 [0.39 , 134.16]
van Dijk 2021	16	66	14	65	2.9%	1.13 [0.60 , 2.11]
Schott 2021	2	32	4	31	0.9%	0.48 [0.10 , 2.46]
Stubenrouch 2022	36	191	24	151	3.6%	1.19 [0.74 , 1.90]
Total (95% CI)		**4381**		**4167**	**100.0%**	**0.68 [0.58 , 0.80]**
Total events:	725		928			

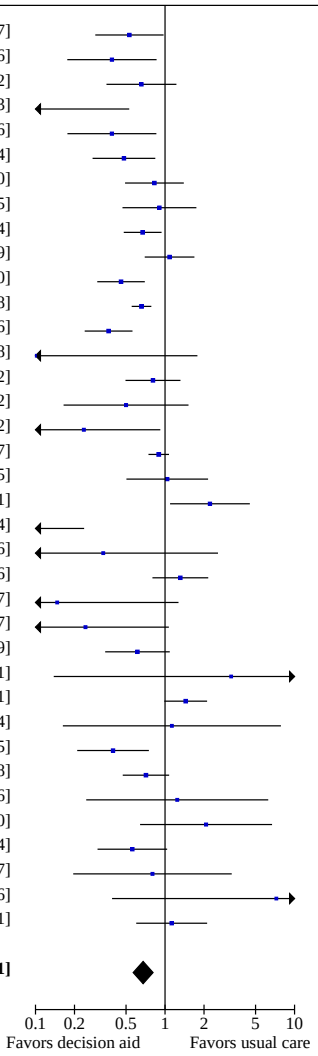
Heterogeneity: Tau² = 0.14; Chi² = 116.64, df = 41 (P < 0.00001); I² = 65%
Test for overall effect: Z = 4.57 (P < 0.00001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 7.2. Comparison 7: Proportion undecided, Outcome 2: Proportion undecided - studies without high risk of bias

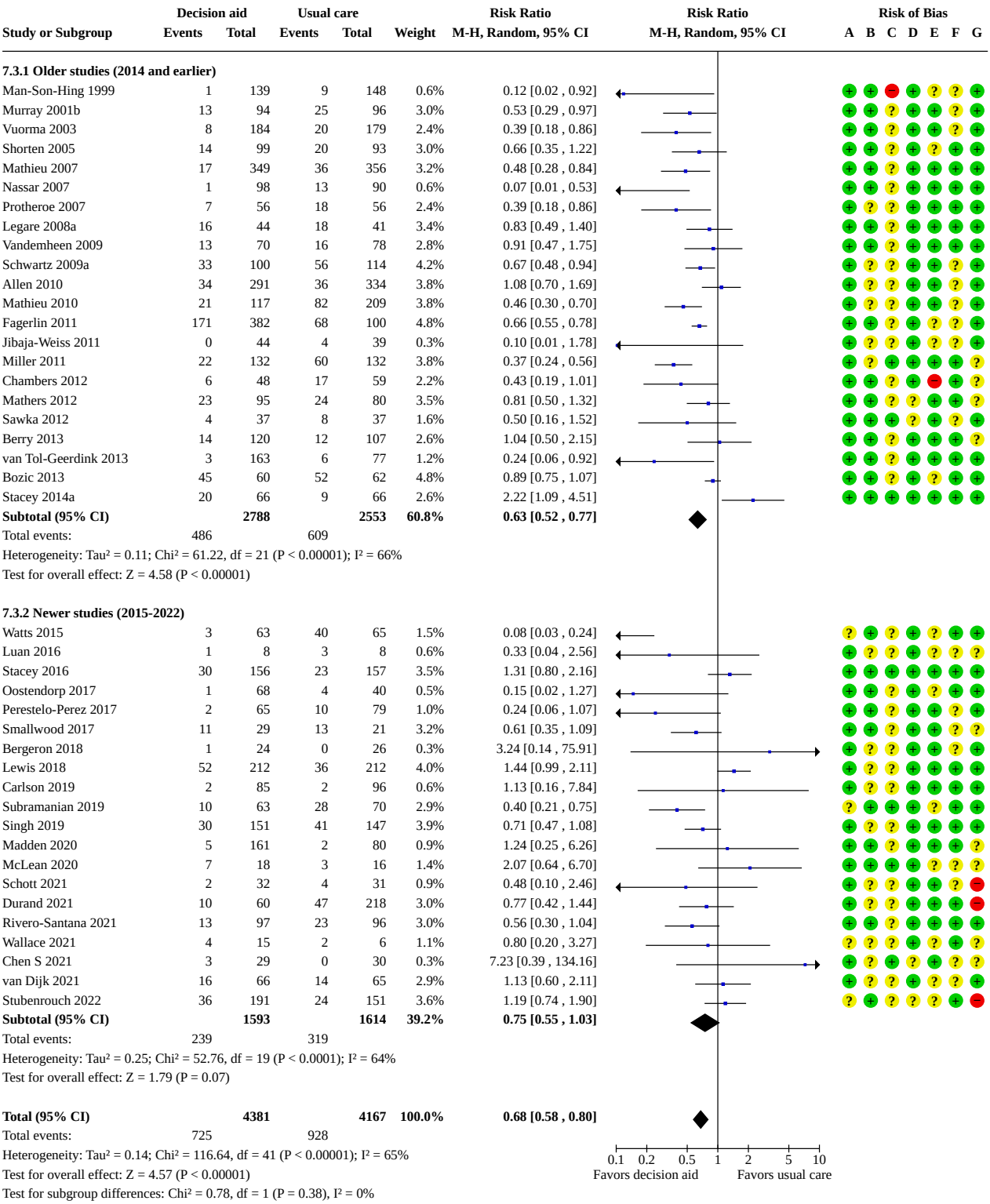
Study or Subgroup	Decision aid Events	Decision aid Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A	B	C	D	E	F	G
Murray 2001b	13	94	25	96	3.4%	0.53 [0.29 , 0.97]	+	+	?	+	+	?	+
Vuorma 2003	8	184	20	179	2.6%	0.39 [0.18 , 0.86]	+	+	?	+	+	?	+
Shorten 2005	14	99	20	93	3.3%	0.66 [0.35 , 1.22]	+	+	?	+	?	+	+
Nassar 2007	1	98	13	90	0.7%	0.07 [0.01 , 0.53]	+	+	?	+	+	+	+
Protheroe 2007	7	56	18	56	2.6%	0.39 [0.18 , 0.86]	+	?	?	+	+	+	+
Mathieu 2007	17	349	36	356	3.6%	0.48 [0.28 , 0.84]	+	+	?	+	+	+	+
Legare 2008a	16	44	18	41	3.8%	0.83 [0.49 , 1.40]	+	+	?	+	+	+	+
Vandemheen 2009	13	70	16	78	3.2%	0.91 [0.47 , 1.75]	+	+	?	+	+	+	+
Schwartz 2009a	33	100	56	114	4.7%	0.67 [0.48 , 0.94]	+	?	?	+	+	?	+
Allen 2010	34	291	36	334	4.2%	1.08 [0.70 , 1.69]	+	?	?	+	+	?	+
Mathieu 2010	21	117	82	209	4.3%	0.46 [0.30 , 0.70]	+	?	?	+	+	?	+
Fagerlin 2011	171	382	68	100	5.4%	0.66 [0.55 , 0.78]	+	+	?	+	?	?	+
Miller 2011	22	132	60	132	4.3%	0.37 [0.24 , 0.56]	+	?	+	+	+	+	?
Jibaja-Weiss 2011	0	44	4	39	0.3%	0.10 [0.01 , 1.78]	+	?	?	+	?	?	+
Mathers 2012	23	95	24	80	3.9%	0.81 [0.50 , 1.32]	+	+	?	?	+	+	?
Sawka 2012	4	37	8	37	1.7%	0.50 [0.16 , 1.52]	+	+	+	?	+	?	+
van Tol-Geerdink 2013	3	163	6	77	1.3%	0.24 [0.06 , 0.92]	+	+	?	+	+	+	+
Bozic 2013	45	60	52	62	5.3%	0.89 [0.75 , 1.07]	+	+	?	+	?	+	+
Berry 2013	14	120	12	107	2.9%	1.04 [0.50 , 2.15]	+	+	?	+	+	+	?
Stacey 2014a	20	66	9	66	3.0%	2.22 [1.09 , 4.51]	+	+	+	+	+	+	+
Watts 2015	3	63	40	65	1.7%	0.08 [0.03 , 0.24]	?	+	?	+	?	+	+
Luan 2016	1	8	3	8	0.7%	0.33 [0.04 , 2.56]	+	?	?	+	?	?	?
Stacey 2016	30	156	23	157	3.9%	1.31 [0.80 , 2.16]	+	+	+	+	+	+	+
Oostendorp 2017	1	68	4	40	0.6%	0.15 [0.02 , 1.27]	+	+	?	+	?	+	+
Perestelo-Perez 2017	2	65	10	79	1.1%	0.24 [0.06 , 1.07]	+	+	?	+	+	?	+
Smallwood 2017	11	29	13	21	3.5%	0.61 [0.35 , 1.09]	+	+	?	+	+	?	?
Bergeron 2018	1	24	0	26	0.3%	3.24 [0.14 , 75.91]	+	?	?	+	+	?	+
Lewis 2018	52	212	36	212	4.5%	1.44 [0.99 , 2.11]	+	?	?	+	+	+	+
Carlson 2019	2	85	2	96	0.7%	1.13 [0.16 , 7.84]	+	?	?	+	+	+	+
Subramanian 2019	10	63	28	70	3.3%	0.40 [0.21 , 0.75]	?	+	+	+	?	+	+
Singh 2019	30	151	41	147	4.3%	0.71 [0.47 , 1.08]	+	?	?	+	+	+	+
Madden 2020	5	161	2	80	1.0%	1.24 [0.25 , 6.26]	+	+	?	+	+	+	?
McLean 2020	7	18	3	16	1.6%	2.07 [0.64 , 6.70]	+	+	+	+	?	?	?
Rivero-Santana 2021	13	97	23	96	3.3%	0.56 [0.30 , 1.04]	+	+	?	+	+	+	+
Wallace 2021	4	15	2	6	1.2%	0.80 [0.20 , 3.27]	?	?	?	+	?	+	?
Chen S 2021	3	29	0	30	0.3%	7.23 [0.39 , 134.16]	+	?	+	?	+	?	?
van Dijk 2021	16	66	14	65	3.3%	1.13 [0.60 , 2.11]	+	?	?	+	?	?	+
Total (95% CI)		**3911**		**3560**	**100.0%**	**0.68 [0.57 , 0.81]**							
Total events:	670		827										



Heterogeneity: Tau² = 0.14; Chi² = 107.90, df = 36 (P < 0.00001); I² = 67%
Test for overall effect: Z = 4.33 (P < 0.0001)
Test for subgroup differences: Not applicable

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 7.3. Comparison 7: Proportion undecided, Outcome 3: Proportion undecided - old vs new studies



Risk of bias legend

(A) Random sequence generation (selection bias)

(B) Allocation concealment (selection bias)

(C) Blinding of participants and personnel (performance bias)

Analysis 7.3. (Continued)

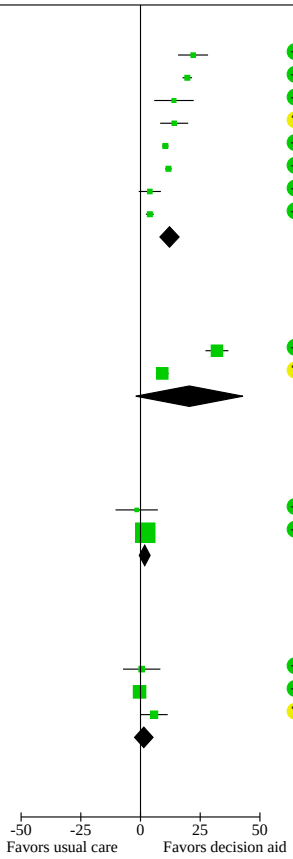
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 8. Patient-clinician communication

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Patient-clinician communication - continuous measures (OPTION, CollaboRATE, SDM-Q-9)	14		Mean Difference (IV, Random, 95% CI)	Subtotals only
8.1.1 OPTION-12	8	2391	Mean Difference (IV, Random, 95% CI)	12.14 [8.12, 16.16]
8.1.2 OPTION-5	2	665	Mean Difference (IV, Random, 95% CI)	20.46 [-1.98, 42.90]
8.1.3 Collaborate	2	112	Mean Difference (IV, Random, 95% CI)	1.76 [-0.50, 4.03]
8.1.4 SDM-Q-9	3	1525	Mean Difference (IV, Random, 95% CI)	1.38 [-2.50, 5.25]
8.2 Discussed topic with provider	11	3913	Risk Ratio (M-H, Random, 95% CI)	1.42 [1.19, 1.70]
8.3 Patient-clinician communication - continuous measures (OPTION, CollaboRATE, SDM-Q-9) - studies without high risk of bias	7		Mean Difference (IV, Random, 95% CI)	Subtotals only
8.3.1 OPTION-12	3	825	Mean Difference (IV, Random, 95% CI)	17.01 [9.40, 24.61]
8.3.2 OPTION-5	0	0	Mean Difference (IV, Random, 95% CI)	Not estimable
8.3.3 Collaborate	2	112	Mean Difference (IV, Random, 95% CI)	1.76 [-0.50, 4.03]
8.3.4 SDM-Q-9	3	1525	Mean Difference (IV, Random, 95% CI)	1.38 [-2.50, 5.25]
8.4 Discussed topic with provider - studies without high risk of bias	10	3157	Risk Ratio (M-H, Random, 95% CI)	1.47 [1.17, 1.84]

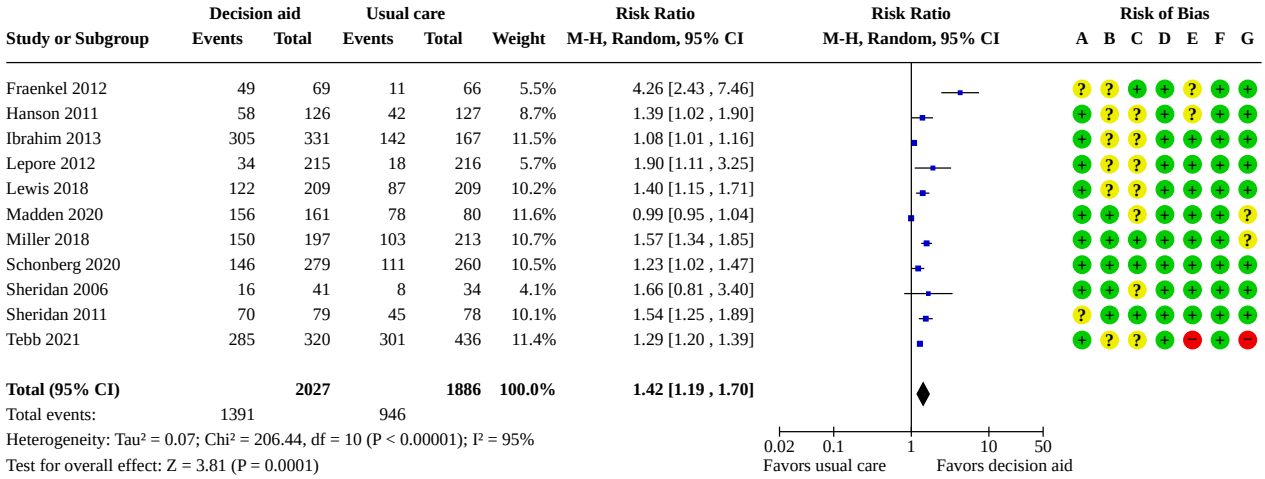
Analysis 8.1. Comparison 8: Patient-clinician communication, Outcome 1: Patient-clinician communication - continuous measures (OPTION, CollaboRATE, SDM-Q-9)

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
8.1.1 OPTION-12									
Mullan 2009	49.7	17.74	48	27.7	11.75	37	10.7%	22.00 [15.71 , 28.29]	+ + ? + ? + +
Hess 2012	26.6	8.5	101	7	5.7	103	14.1%	19.60 [17.61 , 21.59]	+ + + + ? + +
LeBlanc 2015	57	16.9	25	43	9.1	13	9.0%	14.00 [5.73 , 22.27]	+ + + + + ? −
LeBlanc 2015b	46.6	16.4	57	32.5	12.9	39	11.1%	14.10 [8.22 , 19.98]	? + ? − ? + +
Hess 2016	18.3	9.4	264	7.9	5.4	272	14.3%	10.40 [9.10 , 11.70]	+ + ? + + + ?
Hess 2018	25	8.5	267	13.3	6.5	249	14.3%	11.70 [10.40 , 13.00]	+ + ? + + + +
Meier 2019	28.8	10.9	48	24.9	10.9	38	12.2%	3.90 [-0.74 , 8.54]	+ + ? + ? ? +
Kunneman 2020	33	10.8	419	29.1	13.1	411	14.2%	3.90 [2.26 , 5.54]	+ + ? − + + ?
Subtotal (95% CI)			**1229**			**1162**	**100.0%**	**12.14 [8.12 , 16.16]**	
Heterogeneity: Tau² = 28.90; Chi² = 168.22, df = 7 (P < 0.00001); I² = 96%									
Test for overall effect: Z = 5.92 (P < 0.00001)									
8.1.2 OPTION-5									
Durand 2021	73	14.2	66	41	27.5	257	49.6%	32.00 [27.20 , 36.80]	+ ? ? + + + −
Stubenrouch 2022	37.8	12.4	191	28.7	12.4	151	50.4%	9.10 [6.45 , 11.75]	? + ? ? ? + −
Subtotal (95% CI)			**257**			**408**	**100.0%**	**20.46 [-1.98 , 42.90]**	
Heterogeneity: Tau² = 258.29; Chi² = 67.05, df = 1 (P < 0.00001); I² = 99%									
Test for overall effect: Z = 1.79 (P = 0.07)									
8.1.3 Collaborate									
Kostick 2018	88.4	19.3	28	90	15.6	34	6.5%	-1.60 [-10.47 , 7.27]	+ + ? + ? + +
Bergeron 2018	98.56	5.52	24	96.56	2.04	26	93.5%	2.00 [-0.34 , 4.34]	+ ? ? + + ? +
Subtotal (95% CI)			**52**			**60**	**100.0%**	**1.76 [-0.50 , 4.03]**	
Heterogeneity: Tau² = 0.00; Chi² = 0.59, df = 1 (P = 0.44); I² = 0%									
Test for overall effect: Z = 1.53 (P = 0.13)									
8.1.4 SDM-Q-9									
Kostick 2018	84.8	16.8	27	84.3	13.6	34	17.6%	0.50 [-7.31 , 8.31]	+ + ? + ? + +
Kuppermann 2020	74.4	14.9	664	74.8	15.9	672	55.8%	-0.40 [-2.05 , 1.25]	+ ? ? + + + +
Chen C 2021	87.5	12.3	66	81.8	19.5	62	26.6%	5.70 [0.01 , 11.39]	? + + + + + +
Subtotal (95% CI)			**757**			**768**	**100.0%**	**1.38 [-2.50 , 5.25]**	
Heterogeneity: Tau² = 6.29; Chi² = 4.08, df = 2 (P = 0.13); I² = 51%									
Test for overall effect: Z = 0.70 (P = 0.49)									
Test for subgroup differences: Chi² = 0.00, df = 3 (P < 0.00001), I² = 0%									



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 8.2. Comparison 8: Patient-clinician communication, Outcome 2: Discussed topic with provider



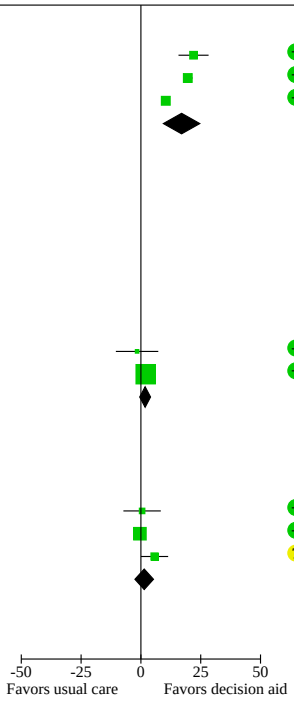
Heterogeneity: Tau² = 0.07; Chi² = 206.44, df = 10 (P < 0.00001); I² = 95%
Test for overall effect: Z = 3.81 (P = 0.0001)
Test for subgroup differences: Not applicable

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

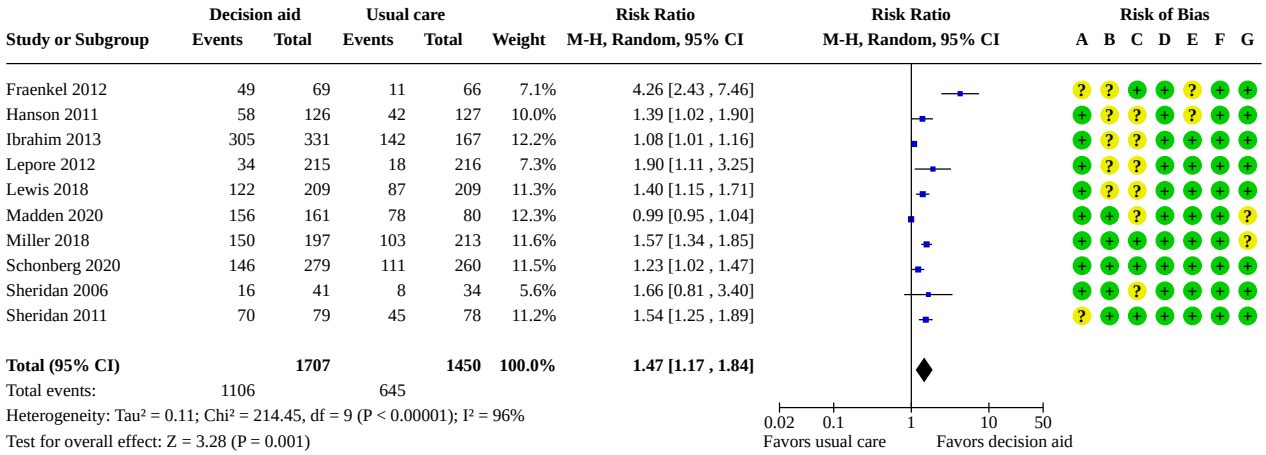
Analysis 8.3. Comparison 8: Patient-clinician communication, Outcome 3: Patient-clinician communication - continuous measures (OPTION, CollaboRATE, SDM-Q-9) - studies without high risk of bias

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
8.3.1 OPTION-12									
Mullan 2009	49.7	17.74	48	27.7	11.75	37	29.0%	22.00 [15.71 , 28.29]	+ + ? + ? + +
Hess 2012	26.6	8.5	101	7	5.7	103	35.3%	19.60 [17.61 , 21.59]	+ + + + ? + +
Hess 2016	18.3	9.4	264	7.9	5.4	272	35.8%	10.40 [9.10 , 11.70]	+ + ? + + + ?
Subtotal (95% CI)			**413**			**412**	**100.0%**	**17.01 [9.40 , 24.61]**	
Heterogeneity: Tau² = 41.70; Chi² = 64.85, df = 2 (P < 0.00001); I² = 97%									
Test for overall effect: Z = 4.38 (P < 0.0001)									
8.3.2 OPTION-5									
Subtotal (95% CI)			**0**			**0**		**Not estimable**	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
8.3.3 Collaborate									
Kostick 2018	88.4	19.3	28	90	15.6	34	6.5%	-1.60 [-10.47 , 7.27]	+ + ? + ? + +
Bergeron 2018	98.56	5.52	24	96.56	2.04	26	93.5%	2.00 [-0.34 , 4.34]	+ ? ? + + ? +
Subtotal (95% CI)			**52**			**60**	**100.0%**	**1.76 [-0.50 , 4.03]**	
Heterogeneity: Tau² = 0.00; Chi² = 0.59, df = 1 (P = 0.44); I² = 0%									
Test for overall effect: Z = 1.53 (P = 0.13)									
8.3.4 SDM-Q-9									
Kostick 2018	84.8	16.8	27	84.3	13.6	34	17.6%	0.50 [-7.31 , 8.31]	+ + ? + ? + +
Kuppermann 2020	74.4	14.9	664	74.8	15.9	672	55.8%	-0.40 [-2.05 , 1.25]	+ ? ? + + + +
Chen C 2021	87.5	12.3	66	81.8	19.5	62	26.6%	5.70 [0.01 , 11.39]	? + + + + + +
Subtotal (95% CI)			**757**			**768**	**100.0%**	**1.38 [-2.50 , 5.25]**	
Heterogeneity: Tau² = 6.29; Chi² = 4.08, df = 2 (P = 0.13); I² = 51%									
Test for overall effect: Z = 0.70 (P = 0.49)									
Test for subgroup differences: Chi² = 0.00, df = 2 (P < 0.00001), I² = 0%									



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 8.4. Comparison 8: Patient-clinician communication, Outcome 4: Discussed topic with provider - studies without high risk of bias



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

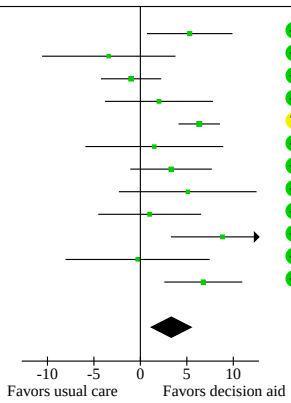
Comparison 9. Satisfaction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Satisfaction with the decision-making process - all studies	12	2066	Mean Difference (IV, Random, 95% CI)	3.33 [1.18, 5.48]
9.2 Satisfaction with the decision-making process - studies without high risk of bias	8	1394	Mean Difference (IV, Random, 95% CI)	3.90 [1.71, 6.09]
9.3 Satisfaction with the decision-making process - old vs new studies	12	2066	Mean Difference (IV, Random, 95% CI)	3.33 [1.18, 5.48]
9.3.1 Older studies (2014 and earlier)	9	1663	Mean Difference (IV, Random, 95% CI)	2.57 [0.12, 5.01]
9.3.2 Newer studies (2015-2022)	3	403	Mean Difference (IV, Random, 95% CI)	5.90 [1.52, 10.27]

Analysis 9.1. Comparison 9: Satisfaction, Outcome 1: Satisfaction with the decision-making process - all studies

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barry 1997	76.38	16.5	104	71.07	18.4	117	9.3%	5.31 [0.71 , 9.91]
Bernstein 1998	73.1	20.6	61	76.5	17.6	48	5.8%	-3.40 [-10.58 , 3.78]
Man-Son-Hing 1999	83.75	14.79	146	84.75	13.04	138	11.9%	-1.00 [-4.24 , 2.24]
Morgan 2000	72	19.88	86	70	19.88	94	7.4%	2.00 [-3.81 , 7.81]
Schroy 2011	84.17	10.33	214	77.83	13.17	217	13.9%	6.34 [4.11 , 8.57]
Jibaja-Weiss 2011	94	17	43	92.5	17	38	5.5%	1.50 [-5.92 , 8.92]
Bozic 2013	94.4	10	60	91.1	14.4	62	9.7%	3.30 [-1.09 , 7.69]
Kupke 2013	91.4	12.5	50	86.3	18.6	31	5.6%	5.10 [-2.31 , 12.51]
Knops 2014	74	16	74	73	19	80	7.8%	1.00 [-4.53 , 6.53]
Perestelo-Perez 2016	70.4	17.62	80	61.56	17.37	73	7.8%	8.84 [3.29 , 14.39]
Kostick 2018	82.5	13.8	26	82.8	16.1	31	5.2%	-0.30 [-8.06 , 7.46]
Rivero-Santana 2021	56.62	15.58	97	49.85	14.13	96	10.1%	6.77 [2.57 , 10.97]
Total (95% CI)			**1041**			**1025**	**100.0%**	**3.33 [1.18 , 5.48]**

Heterogeneity: Tau² = 7.38; Chi² = 25.72, df = 11 (P = 0.007); I² = 57%
Test for overall effect: Z = 3.03 (P = 0.002)
Test for subgroup differences: Not applicable

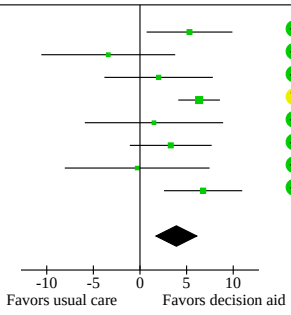


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 9.2. Comparison 9: Satisfaction, Outcome 2: Satisfaction with the decision-making process - studies without high risk of bias

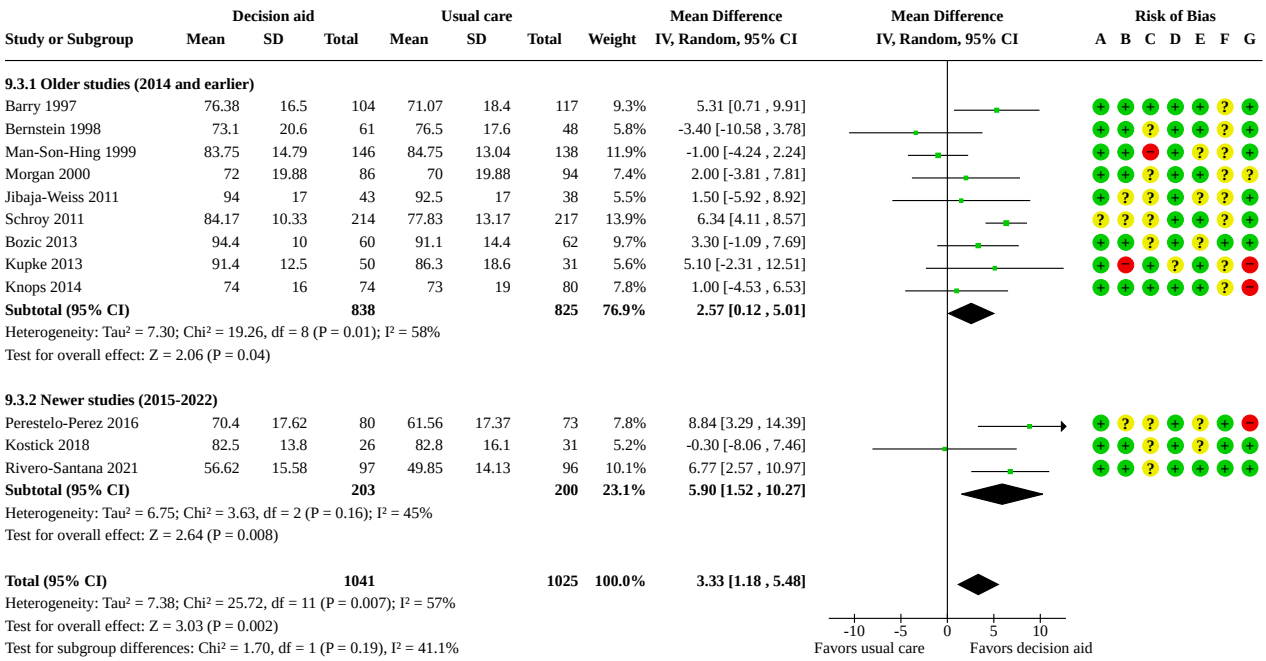
Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barry 1997	76.38	16.5	104	71.07	18.4	117	13.7%	5.31 [0.71 , 9.91]
Bernstein 1998	73.1	20.6	61	76.5	17.6	48	7.3%	-3.40 [-10.58 , 3.78]
Morgan 2000	72	19.88	86	70	19.88	94	10.1%	2.00 [-3.81 , 7.81]
Schroy 2011	84.17	10.33	214	77.83	13.17	217	25.6%	6.34 [4.11 , 8.57]
Jibaja-Weiss 2011	94	17	43	92.5	17	38	7.0%	1.50 [-5.92 , 8.92]
Bozic 2013	94.4	10	60	91.1	14.4	62	14.5%	3.30 [-1.09 , 7.69]
Kostick 2018	82.5	13.8	26	82.8	16.1	31	6.5%	-0.30 [-8.06 , 7.46]
Rivero-Santana 2021	56.62	15.58	97	49.85	14.13	96	15.3%	6.77 [2.57 , 10.97]
Total (95% CI)			**691**			**703**	**100.0%**	**3.90 [1.71 , 6.09]**

Heterogeneity: Tau² = 3.58; Chi² = 11.49, df = 7 (P = 0.12); I² = 39%
Test for overall effect: Z = 3.49 (P = 0.0005)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 9.3. Comparison 9: Satisfaction, Outcome 3: Satisfaction with the decision-making process - old vs new studies



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

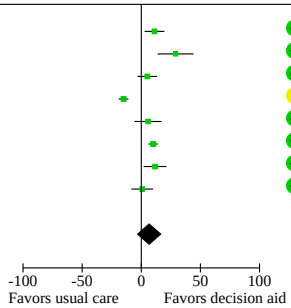
Comparison 10. Preparation for decision-making

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
10.1 Preparation for decision-making - all studies	8	1249	Mean Difference (IV, Random, 95% CI)	6.63 [-3.09, 16.35]
10.2 Preparation for decision-making studies without high risk of bias	7	913	Mean Difference (IV, Random, 95% CI)	9.24 [4.78, 13.71]
10.3 Preparation for decision-making - old vs new studies	8	1249	Mean Difference (IV, Random, 95% CI)	6.63 [-3.09, 16.35]
10.3.1 Older studies (2014 and earlier)	1	149	Mean Difference (IV, Random, 95% CI)	11.20 [2.85, 19.55]
10.3.2 Newer studies (2015-2022)	7	1100	Mean Difference (IV, Random, 95% CI)	6.02 [-4.77, 16.80]

Analysis 10.1. Comparison 10: Preparation for decision-making, Outcome 1: Preparation for decision-making - all studies

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Vandemheen 2009	65.1	24.9	70	53.9	27.1	79	12.7%	11.20 [2.85 , 19.55]	+ + ? + + + +
Smallwood 2017	68.1	23.4	29	39.1	29.4	21	10.5%	29.00 [13.81 , 44.19]	+ + ? + + ? ?
Kostick 2018	86.9	15.1	27	81.8	17.4	33	12.8%	5.10 [-3.13 , 13.33]	+ + ? + ? + +
Cuypers 2018	65	22.5	235	80	15	101	13.7%	-15.00 [-19.10 , -10.90]	? ? - + ? + -
Brown 2019	83.44	13.26	16	77.74	22.3	21	11.7%	5.70 [-5.84 , 17.24]	+ ? ? + + + +
Volk 2020	79.4	17.7	227	69.4	22.9	224	13.8%	10.00 [6.22 , 13.78]	+ ? ? + + + +
Fisher 2020	62.08	24.31	59	50.47	28.46	58	12.4%	11.61 [2.01 , 21.21]	+ ? ? + ? + +
Jalil 2022	76.02	22.21	27	75.23	9.16	22	12.5%	0.79 [-8.42 , 10.00]	+ + ? + ? + ?
Total (95% CI)			**690**			**559**	**100.0%**	**6.63 [-3.09 , 16.35]**	

Heterogeneity: Tau² = 175.07; Chi² = 104.78, df = 7 (P < 0.00001); I² = 93%
Test for overall effect: Z = 1.34 (P = 0.18)
Test for subgroup differences: Not applicable

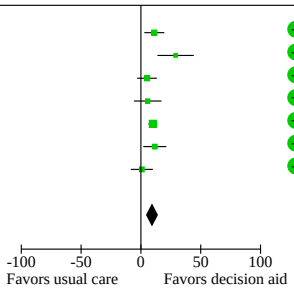


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 10.2. Comparison 10: Preparation for decision-making, Outcome 2: Preparation for decision-making studies without high risk of bias

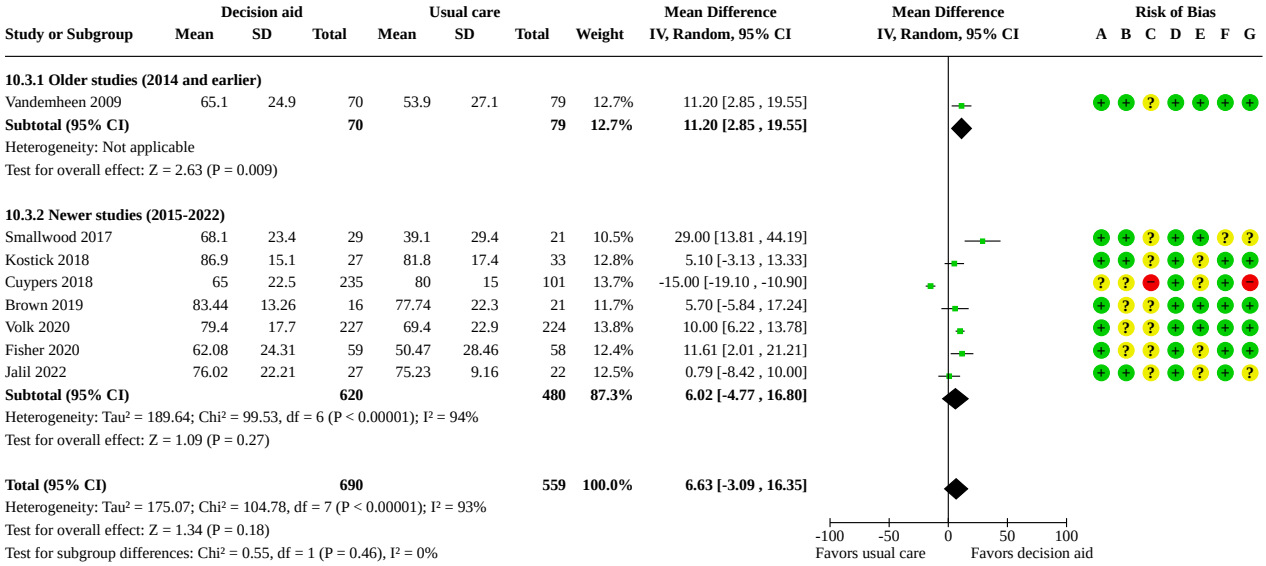
Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
Vandemheen 2009	65.1	24.9	70	53.9	27.1	79	15.1%	11.20 [2.85 , 19.55]	+ + ? + + + +
Smallwood 2017	68.1	23.4	29	39.1	29.4	21	6.8%	29.00 [13.81 , 44.19]	+ + ? + + ? ?
Kostick 2018	86.9	15.1	27	81.8	17.4	33	15.3%	5.10 [-3.13 , 13.33]	+ + ? + ? + +
Brown 2019	83.44	13.26	16	77.74	22.3	21	10.2%	5.70 [-5.84 , 17.24]	+ ? ? + + + +
Volk 2020	79.4	17.7	227	69.4	22.9	224	26.1%	10.00 [6.22 , 13.78]	+ ? ? + + + +
Fisher 2020	62.08	24.31	59	50.47	28.46	58	12.9%	11.61 [2.01 , 21.21]	+ ? ? + ? + +
Jalil 2022	76.02	22.21	27	75.23	9.16	22	13.6%	0.79 [-8.42 , 10.00]	+ + ? + ? + ?
Total (95% CI)			**455**			**458**	**100.0%**	**9.24 [4.78 , 13.71]**	

Heterogeneity: Tau² = 16.18; Chi² = 11.67, df = 6 (P = 0.07); I² = 49%
Test for overall effect: Z = 4.06 (P < 0.0001)
Test for subgroup differences: Not applicable



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 10.3. Comparison 10: Preparation for decision-making, Outcome 3: Preparation for decision-making - old vs new studies



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 11. Choice

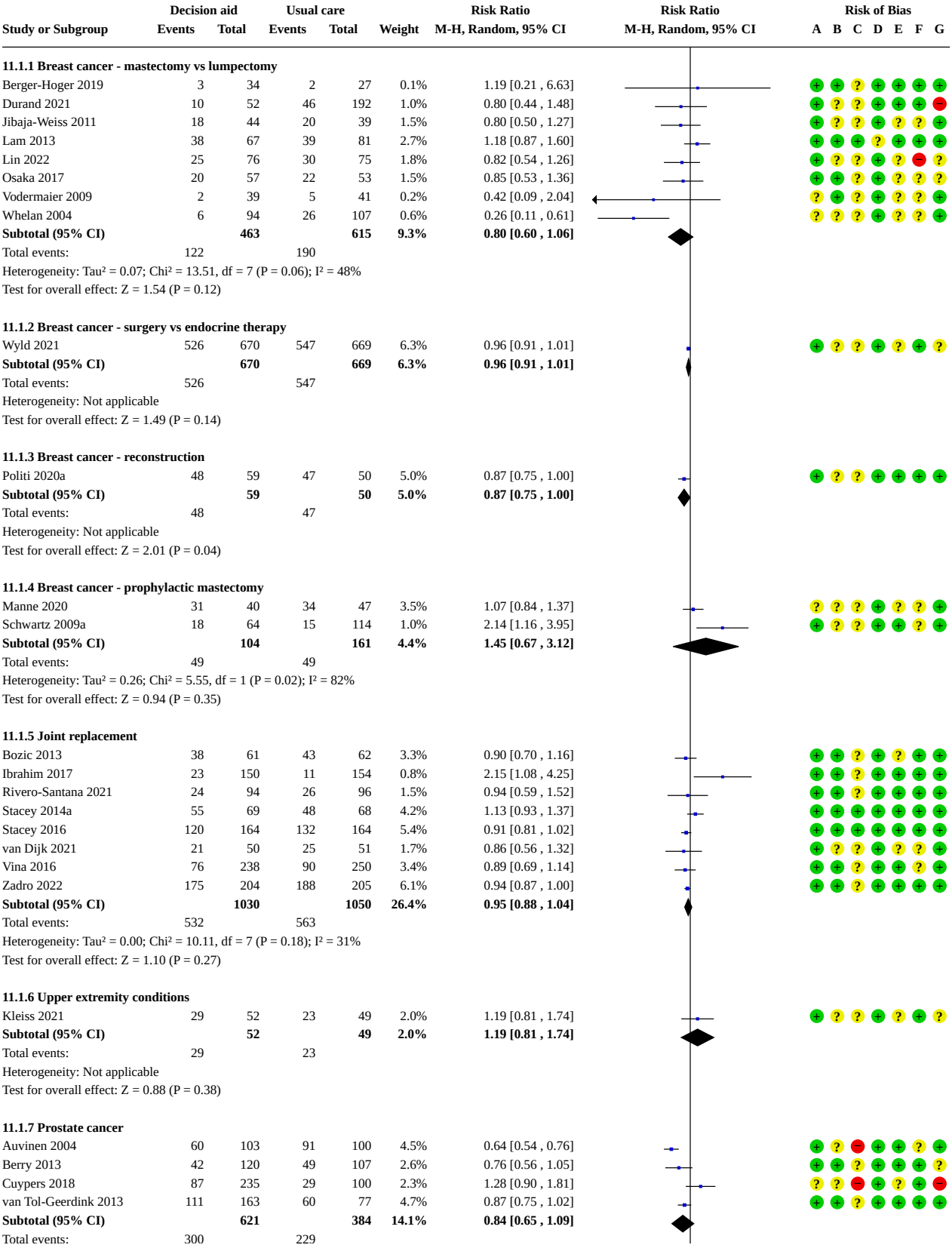
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1 Choice: surgery over conservative option (subgroup by condition)	38	8467	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.83, 0.95]
11.1.1 Breast cancer - mastectomy vs lumpectomy	8	1078	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.60, 1.06]
11.1.2 Breast cancer - surgery vs endocrine therapy	1	1339	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.91, 1.01]
11.1.3 Breast cancer - reconstruction	1	109	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.75, 1.00]
11.1.4 Breast cancer - prophylactic mastectomy	2	265	Risk Ratio (M-H, Random, 95% CI)	1.45 [0.67, 3.12]
11.1.5 Joint replacement	8	2080	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.88, 1.04]
11.1.6 Upper extremity conditions	1	101	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.81, 1.74]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.1.7 Prostate cancer	4	1005	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.65, 1.09]
11.1.8 Benign prostatic hyperplasia	2	321	Risk Ratio (M-H, Random, 95% CI)	1.41 [0.16, 12.84]
11.1.9 Left ventricular assist device (LVAD)	3	469	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.60, 0.93]
11.1.10 Coronary revascularization	2	290	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.62, 0.94]
11.1.11 Abdominal aortic aneurysm	1	178	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.73, 1.46]
11.1.12 Renal stone treatment	1	115	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.58, 1.09]
11.1.13 Bariatric surgery	1	145	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.51, 0.99]
11.1.14 Menorrhagia	3	972	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.70, 1.36]
11.2 Choice for screening	42	46638	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.98, 1.10]
11.2.1 PSA screening	11	4185	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.81, 0.99]
11.2.2 Colorectal cancer screening	17	17510	Risk Ratio (M-H, Random, 95% CI)	1.22 [1.07, 1.41]
11.2.3 Breast cancer genetic testing	4	925	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.77, 1.39]
11.2.4 Breast cancer screening (mammography)	7	22498	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.94, 0.99]
11.2.5 Prenatal diagnostic testing	4	1520	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.95, 1.10]
11.3 Choice: diabetes medication (uptake of new medication)	6	1960	Risk Ratio (M-H, Random, 95% CI)	2.43 [0.64, 9.17]
11.4 Choice: surgery over conservative option - studies without high risk of bias	32	7121	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.86, 0.97]
11.4.1 Breast cancer - mastectomy vs lumpectomy	6	683	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.49, 1.16]
11.4.2 Breast cancer - surgery vs endocrine therapy	1	1339	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.91, 1.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.4.3 Breast cancer - reconstruction	1	109	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.75, 1.00]
11.4.4 Breast cancer - prophylactic mastectomy	2	265	Risk Ratio (M-H, Random, 95% CI)	1.45 [0.67, 3.12]
11.4.5 Joint replacement	8	2080	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.88, 1.04]
11.4.6 Upper extremity conditions	1	101	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.81, 1.74]
11.4.7 Prostate cancer	2	467	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.74, 0.98]
11.4.8 Benign prostatic hyperplasia	2	321	Risk Ratio (M-H, Random, 95% CI)	1.41 [0.16, 12.84]
11.4.9 Left ventricular assist device (LVAD)	2	234	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.63, 1.07]
11.4.10 Coronary revascularization	2	290	Risk Ratio (M-H, Random, 95% CI)	0.76 [0.62, 0.94]
11.4.11 Abdominal aortic aneurysm	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
11.4.12 Renal stone treatment	1	115	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.58, 1.09]
11.4.13 Bariatric surgery	1	145	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.51, 0.99]
11.4.14 Menorrhagia	3	972	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.70, 1.36]
11.5 Choice for screening - studies without high risk of bias	37	28877	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.96, 1.10]
11.5.1 PSA screening	10	3914	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.77, 0.99]
11.5.2 Colorectal cancer screening	15	16812	Risk Ratio (M-H, Random, 95% CI)	1.17 [1.02, 1.35]
11.5.3 Breast cancer genetic testing	4	925	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.77, 1.39]
11.5.4 Breast cancer screening (mammography)	5	5706	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.89, 1.00]
11.5.5 Prenatal diagnostic testing	4	1520	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.95, 1.10]

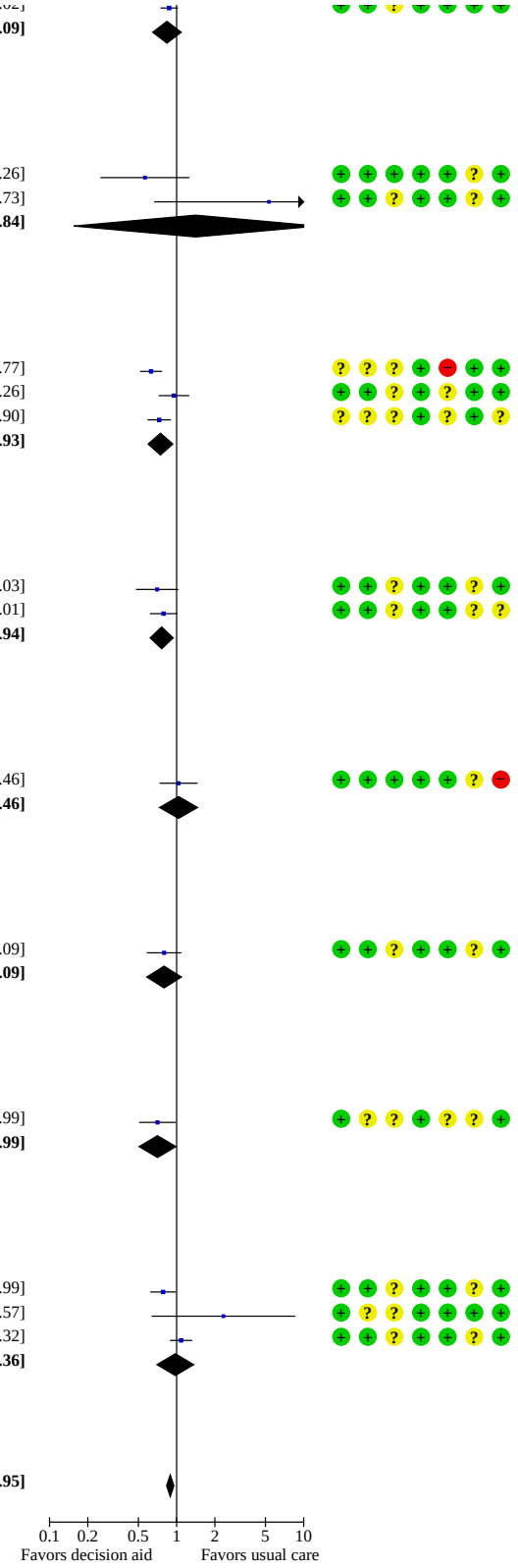
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
11.6 Choice: diabetes medication (uptake of new medication) - studies without high risk of bias	4	447	Risk Ratio (M-H, Random, 95% CI)	1.65 [1.06, 2.56]

Analysis 11.1. Comparison 11: Choice, Outcome 1: Choice: surgery over conservative option (subgroup by condition)



Analysis 11.1. (Continued)

Subtotal (95% CI)		**621**		**384**	**14.1%**	**0.84 [0.65 , 1.09]**
Total events:	300		229			
Heterogeneity: Tau² = 0.05; Chi² = 15.11, df = 3 (P = 0.002); I² = 80%						
Test for overall effect: Z = 1.33 (P = 0.18)						
11.1.8 Benign prostatic hyperplasia						
Barry 1997	8	103	16	116	0.6%	0.56 [0.25 , 1.26]
Murray 2001a	6	54	1	48	0.1%	5.33 [0.67 , 42.73]
Subtotal (95% CI)		**157**		**164**	**0.7%**	**1.41 [0.16 , 12.84]**
Total events:	14		17			
Heterogeneity: Tau² = 1.98; Chi² = 4.05, df = 1 (P = 0.04); I² = 75%						
Test for overall effect: Z = 0.31 (P = 0.76)						
11.1.9 Left ventricular assist device (LVAD)						
Allen 2018	54	103	110	132	4.1%	0.63 [0.52 , 0.77]
Kostick 2018	21	28	26	33	3.0%	0.95 [0.72 , 1.26]
McIlvennan 2018	39	64	91	109	3.9%	0.73 [0.59 , 0.90]
Subtotal (95% CI)		**195**		**274**	**11.0%**	**0.75 [0.60 , 0.93]**
Total events:	114		227			
Heterogeneity: Tau² = 0.03; Chi² = 5.83, df = 2 (P = 0.05); I² = 66%						
Test for overall effect: Z = 2.56 (P = 0.01)						
11.1.10 Coronary revascularization						
Bernstein 1998	25	61	28	48	2.0%	0.70 [0.48 , 1.03]
Morgan 2000	45	86	63	95	3.4%	0.79 [0.62 , 1.01]
Subtotal (95% CI)		**147**		**143**	**5.4%**	**0.76 [0.62 , 0.94]**
Total events:	70		91			
Heterogeneity: Tau² = 0.00; Chi² = 0.25, df = 1 (P = 0.62); I² = 0%						
Test for overall effect: Z = 2.55 (P = 0.01)						
11.1.11 Abdominal aortic aneurysm						
Knops 2014	39	91	36	87	2.3%	1.04 [0.73 , 1.46]
Subtotal (95% CI)		**91**		**87**	**2.3%**	**1.04 [0.73 , 1.46]**
Total events:	39		36			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.20 (P = 0.84)						
11.1.12 Renal stone treatment						
Gokce 2019	30	58	37	57	2.6%	0.80 [0.58 , 1.09]
Subtotal (95% CI)		**58**		**57**	**2.6%**	**0.80 [0.58 , 1.09]**
Total events:	30		37			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.42 (P = 0.16)						
11.1.13 Bariatric surgery						
Arterburn 2011	30	72	43	73	2.4%	0.71 [0.51 , 0.99]
Subtotal (95% CI)		**72**		**73**	**2.4%**	**0.71 [0.51 , 0.99]**
Total events:	30		43			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.03 (P = 0.04)						
11.1.14 Menorrhagia						
Kennedy 2002	82	253	101	244	3.6%	0.78 [0.62 , 0.99]
Protheroe 2007	7	56	3	56	0.2%	2.33 [0.64 , 8.57]
Vuorma 2003	98	184	88	179	4.1%	1.08 [0.89 , 1.32]
Subtotal (95% CI)		**493**		**479**	**7.9%**	**0.98 [0.70 , 1.36]**
Total events:	187		192			
Heterogeneity: Tau² = 0.05; Chi² = 6.15, df = 2 (P = 0.05); I² = 67%						
Test for overall effect: Z = 0.14 (P = 0.89)						
Total (95% CI)		**4212**		**4255**	**100.0%**	**0.89 [0.83 , 0.95]**
Total events:	2090		2291			
Heterogeneity: Tau² = 0.02; Chi² = 95.33, df = 37 (P < 0.00001); I² = 61%						
Test for overall effect: Z = 3.45 (P = 0.0006)						
Test for subgroup differences: Chi² = 18.53, df = 13 (P = 0.14), I² = 29.8%						



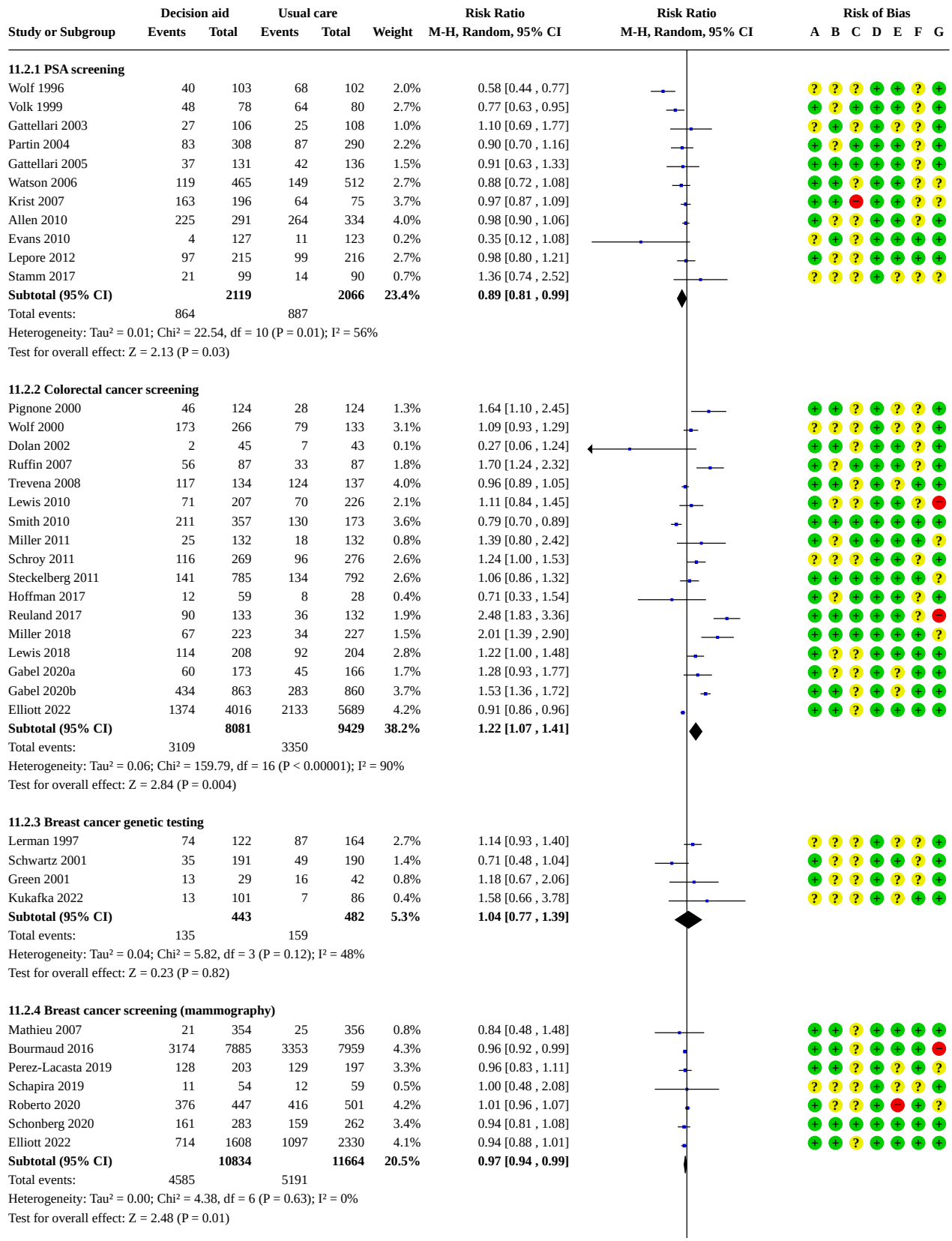
Risk of bias legend

Analysis 11.1. (Continued)

Test for subgroup differences: Chi² = 18.53, df = 13 (P = 0.14), I² = 29.8%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 11.2. Comparison 11: Choice, Outcome 2: Choice for screening



Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
11.2.1 PSA screening							
Wolf 1996	40	103	68	102	2.0%	0.58 [0.44 , 0.77]	? ? ? + + ? +
Volk 1999	48	78	64	80	2.7%	0.77 [0.63 , 0.95]	+ ? + + + ? +
Gattellari 2003	27	106	25	108	1.0%	1.10 [0.69 , 1.77]	? + ? + ? ? +
Partin 2004	83	308	87	290	2.2%	0.90 [0.70 , 1.16]	+ ? + + + ? +
Gattellari 2005	37	131	42	136	1.5%	0.91 [0.63 , 1.33]	+ + + + + ? +
Watson 2006	119	465	149	512	2.7%	0.88 [0.72 , 1.08]	+ + ? + + ? ?
Krist 2007	163	196	64	75	3.7%	0.97 [0.87 , 1.09]	+ + − + + ? ?
Allen 2010	225	291	264	334	4.0%	0.98 [0.90 , 1.06]	+ ? ? + + ? +
Evans 2010	4	127	11	123	0.2%	0.35 [0.12 , 1.08]	? + ? + + + +
Lepore 2012	97	215	99	216	2.7%	0.98 [0.80 , 1.21]	+ ? ? + + + +
Stamm 2017	21	99	14	90	0.7%	1.36 [0.74 , 2.52]	? ? ? + ? ? ?
Subtotal (95% CI)		**2119**		**2066**	**23.4%**	**0.89 [0.81 , 0.99]**	
Total events:	864		887				
Heterogeneity: Tau² = 0.01; Chi² = 22.54, df = 10 (P = 0.01); I² = 56%							
Test for overall effect: Z = 2.13 (P = 0.03)							
11.2.2 Colorectal cancer screening							
Pignone 2000	46	124	28	124	1.3%	1.64 [1.10 , 2.45]	+ + ? + ? ? +
Wolf 2000	173	266	79	133	3.1%	1.09 [0.93 , 1.29]	? ? ? + ? ? +
Dolan 2002	2	45	7	43	0.1%	0.27 [0.06 , 1.24]	+ + ? + + ? +
Ruffin 2007	56	87	33	87	1.8%	1.70 [1.24 , 2.32]	+ ? + + + ? +
Trevena 2008	117	134	124	137	4.0%	0.96 [0.89 , 1.05]	+ + ? + ? + +
Lewis 2010	71	207	70	226	2.1%	1.11 [0.84 , 1.45]	+ ? ? + + ? −
Smith 2010	211	357	130	173	3.6%	0.79 [0.70 , 0.89]	+ + + + + + +
Miller 2011	25	132	18	132	0.8%	1.39 [0.80 , 2.42]	+ ? + + + + ?
Schroy 2011	116	269	96	276	2.6%	1.24 [1.00 , 1.53]	? ? ? + + ? +
Steckelberg 2011	141	785	134	792	2.6%	1.06 [0.86 , 1.32]	+ + + + + + ?
Hoffman 2017	12	59	8	28	0.4%	0.71 [0.33 , 1.54]	+ ? + + + ? +
Reuland 2017	90	133	36	132	1.9%	2.48 [1.83 , 3.36]	+ + + + + ? −
Miller 2018	67	223	34	227	1.5%	2.01 [1.39 , 2.90]	+ + + + + + ?
Lewis 2018	114	208	92	204	2.8%	1.22 [1.00 , 1.48]	+ ? ? + + + +
Gabel 2020a	60	173	45	166	1.7%	1.28 [0.93 , 1.77]	+ ? ? + ? + +
Gabel 2020b	434	863	283	860	3.7%	1.53 [1.36 , 1.72]	+ + ? + ? + +
Elliott 2022	1374	4016	2133	5689	4.2%	0.91 [0.86 , 0.96]	+ + ? + + + +
Subtotal (95% CI)		**8081**		**9429**	**38.2%**	**1.22 [1.07 , 1.41]**	
Total events:	3109		3350				
Heterogeneity: Tau² = 0.06; Chi² = 159.79, df = 16 (P < 0.00001); I² = 90%							
Test for overall effect: Z = 2.84 (P = 0.004)							
11.2.3 Breast cancer genetic testing							
Lerman 1997	74	122	87	164	2.7%	1.14 [0.93 , 1.40]	? ? ? + ? ? +
Schwartz 2001	35	191	49	190	1.4%	0.71 [0.48 , 1.04]	+ ? ? + + ? +
Green 2001	13	29	16	42	0.8%	1.18 [0.67 , 2.06]	+ ? ? + ? ? +
Kukafka 2022	13	101	7	86	0.4%	1.58 [0.66 , 3.78]	? ? ? + ? + +
Subtotal (95% CI)		**443**		**482**	**5.3%**	**1.04 [0.77 , 1.39]**	
Total events:	135		159				
Heterogeneity: Tau² = 0.04; Chi² = 5.82, df = 3 (P = 0.12); I² = 48%							
Test for overall effect: Z = 0.23 (P = 0.82)							
11.2.4 Breast cancer screening (mammography)							
Mathieu 2007	21	354	25	356	0.8%	0.84 [0.48 , 1.48]	+ + ? + + + +
Bourmaud 2016	3174	7885	3353	7959	4.3%	0.96 [0.92 , 0.99]	+ + ? + + + −
Perez-Lacasta 2019	128	203	129	197	3.3%	0.96 [0.83 , 1.11]	+ + ? + + + ?
Schapira 2019	11	54	12	59	0.5%	1.00 [0.48 , 2.08]	? ? ? + ? ? +
Roberto 2020	376	447	416	501	4.2%	1.01 [0.96 , 1.07]	+ ? ? + − + ?
Schonberg 2020	161	283	159	262	3.4%	0.94 [0.81 , 1.08]	+ + + + + + +
Elliott 2022	714	1608	1097	2330	4.1%	0.94 [0.88 , 1.01]	+ + ? + + + +
Subtotal (95% CI)		**10834**		**11664**	**20.5%**	**0.97 [0.94 , 0.99]**	
Total events:	4585		5191				
Heterogeneity: Tau² = 0.00; Chi² = 4.38, df = 6 (P = 0.63); I² = 0%							
Test for overall effect: Z = 2.48 (P = 0.01)							

Analysis 11.2. (Continued)

Heterogeneity: Tau² = 0.00; Chi² = 4.38, df = 6 (P = 0.63); I² = 0%
Test for overall effect: Z = 2.48 (P = 0.01)

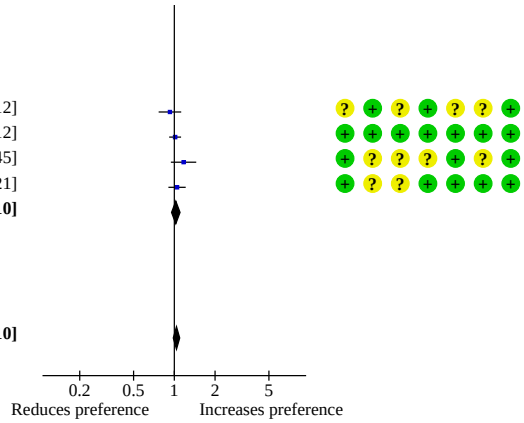
11.2.5 Prenatal diagnostic testing

Bjorklund 2012	92	184	111	206	2.8%	0.93 [0.77 , 1.12]
Kuppermann 2014	244	357	238	353	3.8%	1.01 [0.92 , 1.12]
Beulen 2016	79	130	67	129	2.6%	1.17 [0.94 , 1.45]
Carlson 2019	56	67	75	94	3.3%	1.05 [0.90 , 1.21]
Subtotal (95% CI)		**738**		**782**	**12.6%**	**1.03 [0.95 , 1.10]**
Total events:	471		491			

Heterogeneity: Tau² = 0.00; Chi² = 2.62, df = 3 (P = 0.45); I² = 0%
Test for overall effect: Z = 0.68 (P = 0.50)

Total (95% CI)		**22215**		**24423**	**100.0%**	**1.04 [0.98 , 1.10]**
Total events:	9164		10078			

Heterogeneity: Tau² = 0.02; Chi² = 204.90, df = 42 (P < 0.00001); I² = 80%
Test for overall effect: Z = 1.32 (P = 0.19)
Test for subgroup differences: Chi² = 15.42, df = 4 (P = 0.004), I² = 74.1%



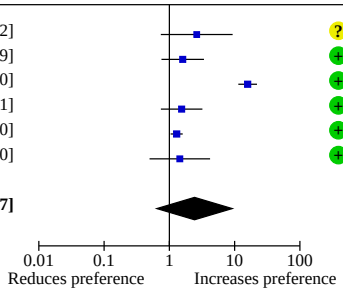
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 11.3. Comparison 11: Choice, Outcome 3: Choice: diabetes medication (uptake of new medication)

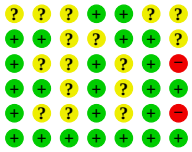
Study or Subgroup	Decision aid Events	Decision aid Total	Usual care Events	Usual care Total	Weight	Risk Ratio M-H, Random, 95% CI
Mann D 2010	9	80	3	70	15.3%	2.63 [0.74 , 9.32]
Mathers 2012	17	92	9	78	16.8%	1.60 [0.76 , 3.39]
Moin 2019	200	351	37	1028	17.5%	15.83 [11.39 , 22.00]
Mullan 2009	16	48	8	37	16.8%	1.54 [0.74 , 3.21]
Perestelo-Perez 2016	56	68	42	66	17.7%	1.29 [1.05 , 1.60]
Weymiller 2007	7	23	4	19	15.9%	1.45 [0.50 , 4.20]
Total (95% CI)		**662**		**1298**	**100.0%**	**2.43 [0.64 , 9.17]**
Total events:	305		103			

Heterogeneity: Tau² = 2.59; Chi² = 209.17, df = 5 (P < 0.00001); I² = 98%
Test for overall effect: Z = 1.31 (P = 0.19)
Test for subgroup differences: Not applicable

Risk Ratio M-H, Random, 95% CI



Risk of Bias: A B C D E F G



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 11.4. Comparison 11: Choice, Outcome 4: Choice: surgery over conservative option - studies without high risk of bias

Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI	Risk of Bias A B C D E F G
11.4.1 Breast cancer - mastectomy vs lumpectomy								
Berger-Hoger 2019	3	34	2	27	0.1%	1.19 [0.21 , 6.63]		+ + ? + + + +
Jibaja-Weiss 2011	18	44	20	39	1.5%	0.80 [0.50 , 1.27]		+ ? ? + ? ? +
Lam 2013	38	67	39	81	2.9%	1.18 [0.87 , 1.60]		+ + + ? + + +
Osaka 2017	20	57	22	53	1.4%	0.85 [0.53 , 1.36]		+ + ? + ? ? ?
Vodermaier 2009	2	39	5	41	0.1%	0.42 [0.09 , 2.04]		? + ? + ? ? +
Whelan 2004	6	94	26	107	0.5%	0.26 [0.11 , 0.61]		? ? ? + ? ? +
Subtotal (95% CI)		**335**		**348**	**6.5%**	**0.75 [0.49 , 1.16]**		
Total events:	87		114					
Heterogeneity: Tau² = 0.15; Chi² = 13.59, df = 5 (P = 0.02); I² = 63%								
Test for overall effect: Z = 1.28 (P = 0.20)								
11.4.2 Breast cancer - surgery vs endocrine therapy								
Wyld 2021	526	670	547	669	9.5%	0.96 [0.91 , 1.01]		+ ? ? + ? + ?
Subtotal (95% CI)		**670**		**669**	**9.5%**	**0.96 [0.91 , 1.01]**		
Total events:	526		547					
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.49 (P = 0.14)								
11.4.3 Breast cancer - reconstruction								
Politi 2020a	48	59	47	50	6.6%	0.87 [0.75 , 1.00]		+ ? ? + + + +
Subtotal (95% CI)		**59**		**50**	**6.6%**	**0.87 [0.75 , 1.00]**		
Total events:	48		47					
Heterogeneity: Not applicable								
Test for overall effect: Z = 2.01 (P = 0.04)								
11.4.4 Breast cancer - prophylactic mastectomy								
Manne 2020	31	40	34	47	3.9%	1.07 [0.84 , 1.37]		? ? ? + ? ? +
Schwartz 2009a	18	64	15	114	0.9%	2.14 [1.16 , 3.95]		+ ? ? + + ? +
Subtotal (95% CI)		**104**		**161**	**4.8%**	**1.45 [0.67 , 3.12]**		
Total events:	49		49					
Heterogeneity: Tau² = 0.26; Chi² = 5.55, df = 1 (P = 0.02); I² = 82%								
Test for overall effect: Z = 0.94 (P = 0.35)								
11.4.5 Joint replacement								
Bozic 2013	38	61	43	62	3.7%	0.90 [0.70 , 1.16]		+ + ? + ? + +
Ibrahim 2017	23	150	11	154	0.8%	2.15 [1.08 , 4.25]		+ + ? + + + +
Rivero-Santana 2021	24	94	26	96	1.4%	0.94 [0.59 , 1.52]		+ + ? + + + +
Stacey 2014a	55	69	48	68	5.0%	1.13 [0.93 , 1.37]		+ + + + + + +
Stacey 2016	120	164	132	164	7.3%	0.91 [0.81 , 1.02]		+ + + + + + +
van Dijk 2021	21	50	25	51	1.7%	0.86 [0.56 , 1.32]		+ ? ? + ? ? +
Vina 2016	76	238	90	250	3.8%	0.89 [0.69 , 1.14]		+ + ? + + ? +
Zadro 2022	175	204	188	205	9.0%	0.94 [0.87 , 1.00]		+ + ? + + + +
Subtotal (95% CI)		**1030**		**1050**	**32.8%**	**0.95 [0.88 , 1.04]**		
Total events:	532		563					
Heterogeneity: Tau² = 0.00; Chi² = 10.11, df = 7 (P = 0.18); I² = 31%								
Test for overall effect: Z = 1.10 (P = 0.27)								
11.4.6 Upper extremity conditions								
Kleiss 2021	29	52	23	49	2.0%	1.19 [0.81 , 1.74]		+ ? ? + ? + ?
Subtotal (95% CI)		**52**		**49**	**2.0%**	**1.19 [0.81 , 1.74]**		
Total events:	29		23					
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.88 (P = 0.38)								
11.4.7 Prostate cancer								
Berry 2013	42	120	49	107	2.7%	0.76 [0.56 , 1.05]		+ + ? + + + ?
van Tol-Geerdink 2013	111	163	60	77	6.1%	0.87 [0.75 , 1.02]		+ + ? + + + +
Subtotal (95% CI)		**283**		**184**	**8.8%**	**0.85 [0.74 , 0.98]**		
Total events:	153		109					
Heterogeneity: Tau² = 0.00; Chi² = 0.65, df = 1 (P = 0.42); I² = 0%								
Test for overall effect: Z = 2.23 (P = 0.03)								
11.4.8 Benign prostatic hyperplasia								

Analysis 11.4. (Continued)

Test for overall effect: Z = 2.23 (P = 0.03)

11.4.8 Benign prostatic hyperplasia

Barry 1997	8	103	16	116	0.5%	0.56 [0.25 , 1.26]
Murray 2001a	6	54	1	48	0.1%	5.33 [0.67 , 42.73]
Subtotal (95% CI)		**157**		**164**	**0.6%**	**1.41 [0.16 , 12.84]**
Total events:	14		17			

Heterogeneity: Tau² = 1.98; Chi² = 4.05, df = 1 (P = 0.04); I² = 75%
Test for overall effect: Z = 0.31 (P = 0.76)

11.4.9 Left ventricular assist device (LVAD)

Kostick 2018	21	28	26	33	3.3%	0.95 [0.72 , 1.26]
McIlvennan 2018	39	64	91	109	4.6%	0.73 [0.59 , 0.90]
Subtotal (95% CI)		**92**		**142**	**7.9%**	**0.82 [0.63 , 1.07]**
Total events:	60		117			

Heterogeneity: Tau² = 0.02; Chi² = 2.28, df = 1 (P = 0.13); I² = 56%
Test for overall effect: Z = 1.47 (P = 0.14)

11.4.10 Coronary revascularization

Bernstein 1998	25	61	28	48	2.0%	0.70 [0.48 , 1.03]
Morgan 2000	45	86	63	95	3.8%	0.79 [0.62 , 1.01]
Subtotal (95% CI)		**147**		**143**	**5.9%**	**0.76 [0.62 , 0.94]**
Total events:	70		91			

Heterogeneity: Tau² = 0.00; Chi² = 0.25, df = 1 (P = 0.62); I² = 0%
Test for overall effect: Z = 2.55 (P = 0.01)

11.4.11 Abdominal aortic aneurysm

Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

11.4.12 Renal stone treatment

Gokce 2019	30	58	37	57	2.8%	0.80 [0.58 , 1.09]
Subtotal (95% CI)		**58**		**57**	**2.8%**	**0.80 [0.58 , 1.09]**
Total events:	30		37			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.42 (P = 0.16)

11.4.13 Bariatric surgery

Arterburn 2011	30	72	43	73	2.5%	0.71 [0.51 , 0.99]
Subtotal (95% CI)		**72**		**73**	**2.5%**	**0.71 [0.51 , 0.99]**
Total events:	30		43			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.03 (P = 0.04)

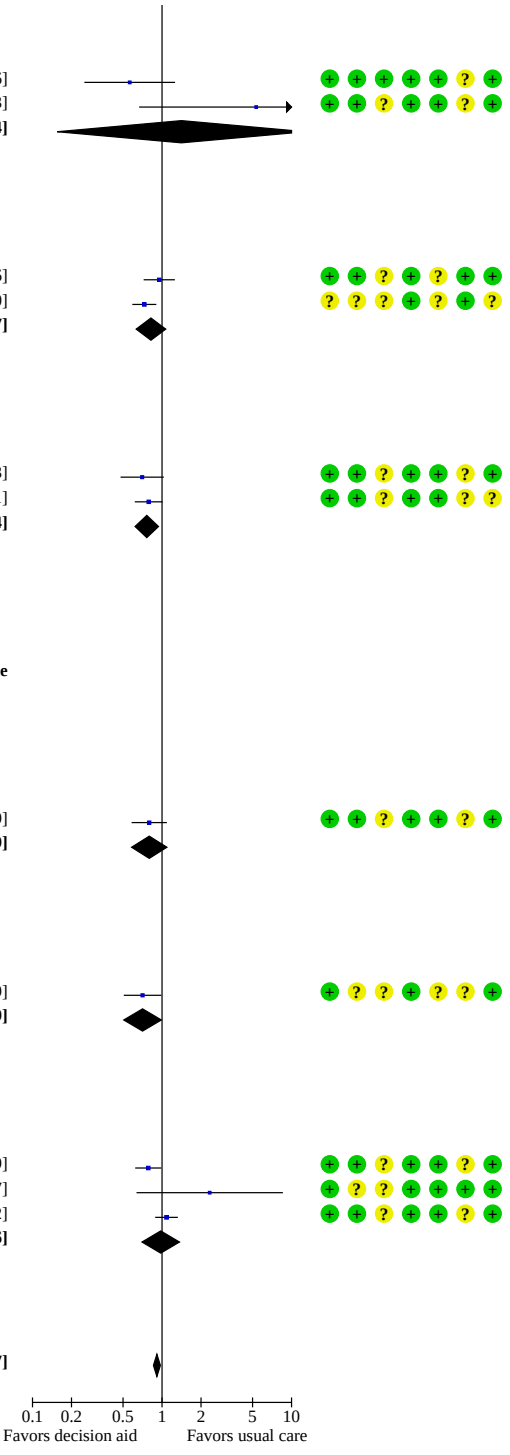
11.4.14 Menorrhagia

Kennedy 2002	82	253	101	244	4.1%	0.78 [0.62 , 0.99]
Protheroe 2007	7	56	3	56	0.2%	2.33 [0.64 , 8.57]
Vuorma 2003	98	184	88	179	4.9%	1.08 [0.89 , 1.32]
Subtotal (95% CI)		**493**		**479**	**9.2%**	**0.98 [0.70 , 1.36]**
Total events:	187		192			

Heterogeneity: Tau² = 0.05; Chi² = 6.15, df = 2 (P = 0.05); I² = 67%
Test for overall effect: Z = 0.14 (P = 0.89)

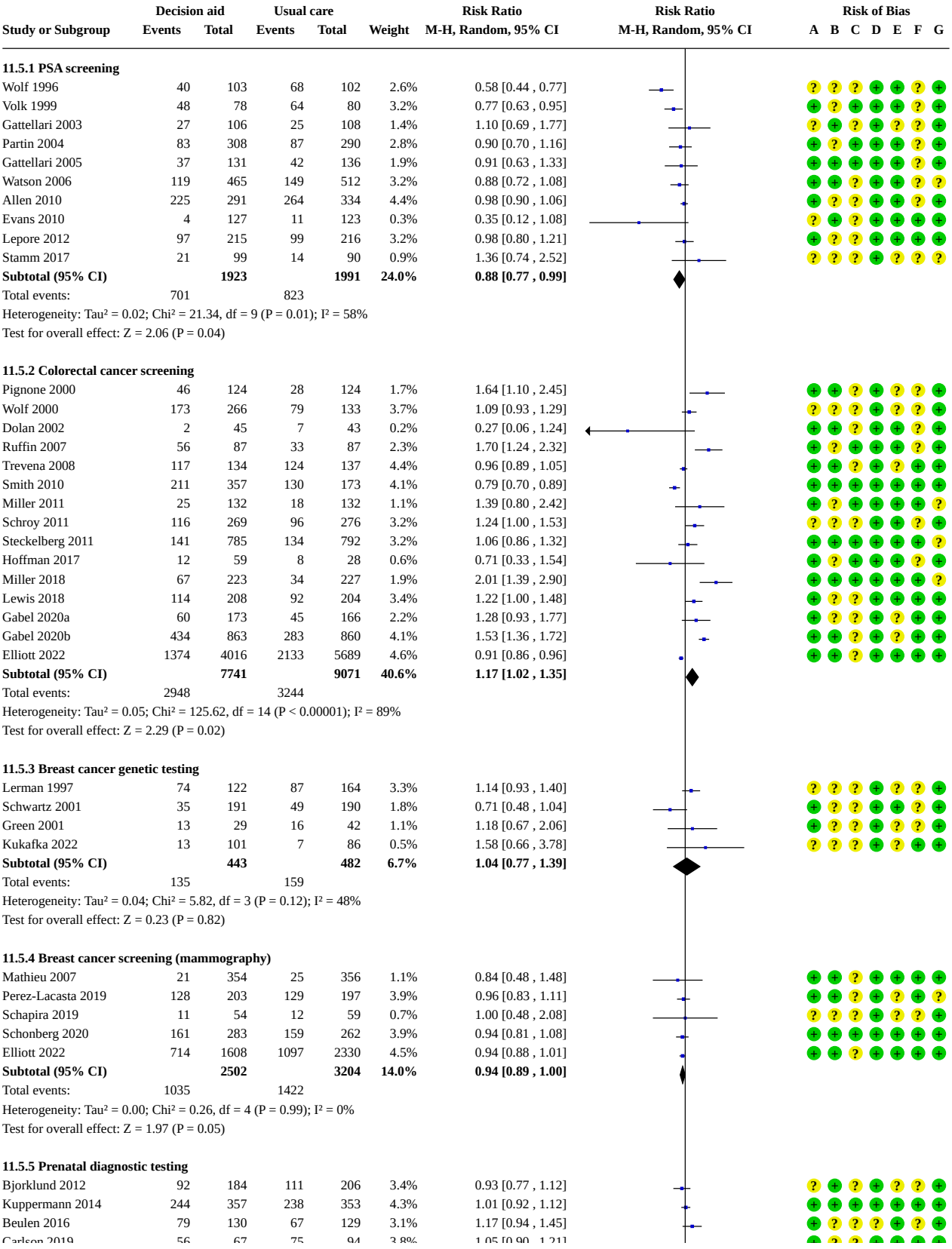
Total (95% CI)		**3552**		**3569**	**100.0%**	**0.91 [0.86 , 0.97]**
Total events:	1815		1949			

Heterogeneity: Tau² = 0.01; Chi² = 60.07, df = 31 (P = 0.001); I² = 48%
Test for overall effect: Z = 2.91 (P = 0.004)
Test for subgroup differences: Chi² = 16.03, df = 12 (P = 0.19), I² = 25.1%



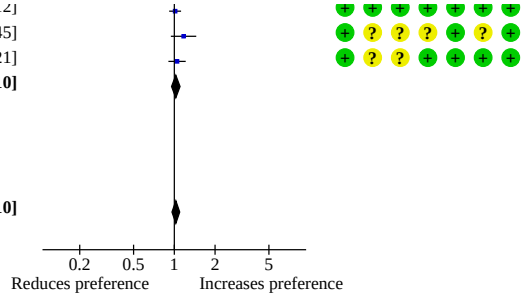
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 11.5. Comparison 11: Choice, Outcome 5: Choice for screening - studies without high risk of bias



Analysis 11.5. (Continued)

Kuppermann 2014	244	357	238	353	4.3%	1.01 [0.92 , 1.12]
Beulen 2016	79	130	67	129	3.1%	1.17 [0.94 , 1.45]
Carlson 2019	56	67	75	94	3.8%	1.05 [0.90 , 1.21]
Subtotal (95% CI)		**738**		**782**	**14.7%**	**1.03 [0.95 , 1.10]**
Total events:	471		491			
Heterogeneity: Tau² = 0.00; Chi² = 2.62, df = 3 (P = 0.45); I² = 0%						
Test for overall effect: Z = 0.68 (P = 0.50)						
Total (95% CI)		**13347**		**15530**	**100.0%**	**1.03 [0.96 , 1.10]**
Total events:	5290		6139			
Heterogeneity: Tau² = 0.02; Chi² = 165.08, df = 37 (P < 0.00001); I² = 78%						
Test for overall effect: Z = 0.77 (P = 0.44)						
Test for subgroup differences: Chi² = 12.93, df = 4 (P = 0.01), I² = 69.1%						



Risk of bias legend
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(B) Allocation concealment (selection bias)
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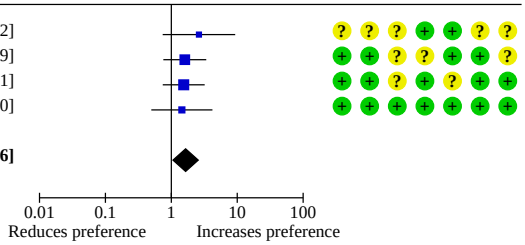
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 11.6. Comparison 11: Choice, Outcome 6: Choice: diabetes medication (uptake of new medication) - studies without high risk of bias

Study or Subgroup	Decision aid Events	Total	Usual care Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Mann D 2010	9	80	3	70	12.1%	2.63 [0.74 , 9.32]
Mathers 2012	17	92	9	78	34.6%	1.60 [0.76 , 3.39]
Mullan 2009	16	48	8	37	36.2%	1.54 [0.74 , 3.21]
Weymiller 2007	7	23	4	19	17.1%	1.45 [0.50 , 4.20]
Total (95% CI)		**243**		**204**	**100.0%**	**1.65 [1.06 , 2.56]**
Total events:	49		24			
Heterogeneity: Tau² = 0.00; Chi² = 0.62, df = 3 (P = 0.89); I² = 0%						
Test for overall effect: Z = 2.22 (P = 0.03)						
Test for subgroup differences: Not applicable						



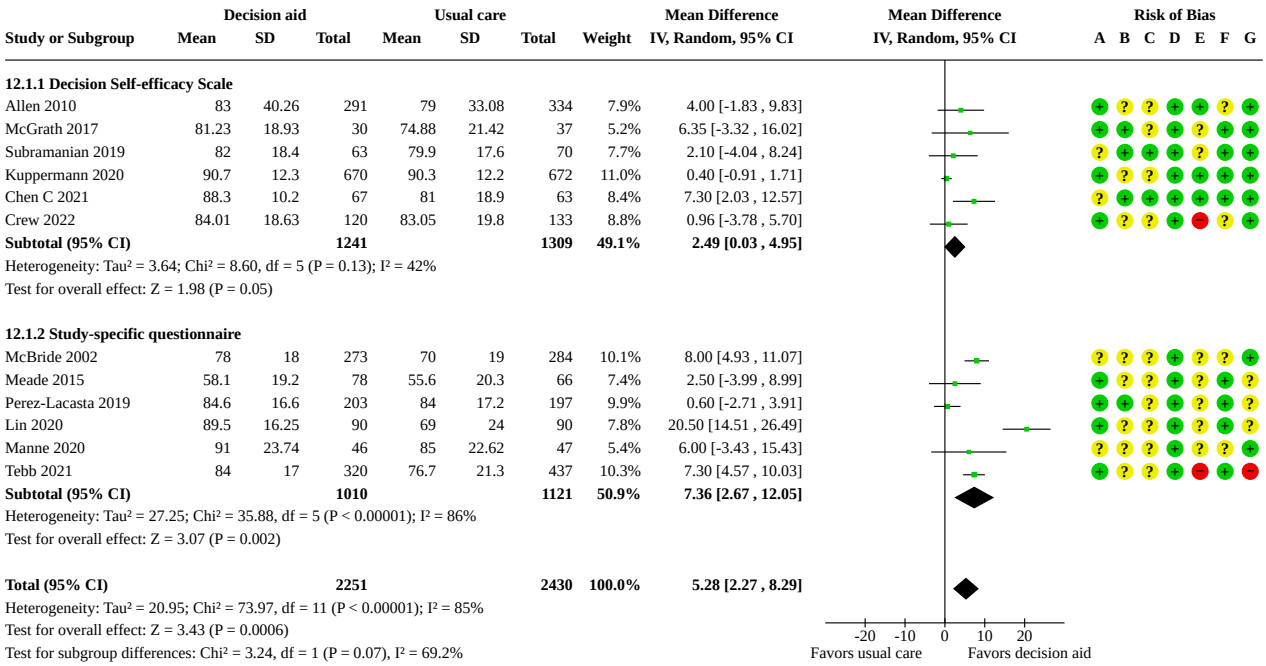
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Comparison 12. Confidence

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1 Confidence - all studies	12	4681	Mean Difference (IV, Random, 95% CI)	5.28 [2.27, 8.29]
12.1.1 Decision Self-efficacy Scale	6	2550	Mean Difference (IV, Random, 95% CI)	2.49 [0.03, 4.95]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
12.1.2 Study-specific questionnaire	6	2131	Mean Difference (IV, Random, 95% CI)	7.36 [2.67, 12.05]
12.2 Confidence - studies without high risk of bias	10	3671	Mean Difference (IV, Random, 95% CI)	5.53 [1.95, 9.11]
12.2.1 Decision Self-efficacy Scale	5	2297	Mean Difference (IV, Random, 95% CI)	3.15 [-0.04, 6.34]
12.2.2 Study-specific questionnaire	5	1374	Mean Difference (IV, Random, 95% CI)	7.44 [0.97, 13.91]
12.3 Confidence - old vs new studies	12	4681	Mean Difference (IV, Random, 95% CI)	5.28 [2.27, 8.29]
12.3.1 Decision Self-efficacy Scale - older studies (2014 and earlier)	1	625	Mean Difference (IV, Random, 95% CI)	4.00 [-1.83, 9.83]
12.3.2 Decision Self-efficacy Scale - newer studies (2015-2022)	5	1925	Mean Difference (IV, Random, 95% CI)	2.37 [-0.42, 5.17]
12.3.3 Study-specific questionnaire - older studies (2014 and earlier)	1	557	Mean Difference (IV, Random, 95% CI)	8.00 [4.93, 11.07]
12.3.4 Study-specific questionnaire - newer studies (2015-2022)	5	1574	Mean Difference (IV, Random, 95% CI)	7.27 [1.05, 13.49]

Analysis 12.1. Comparison 12: Confidence, Outcome 1: Confidence - all studies



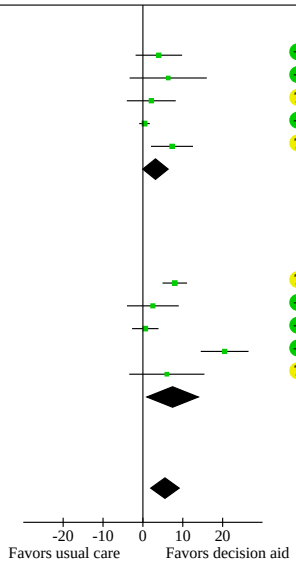
Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
12.1.1 Decision Self-efficacy Scale									
Allen 2010	83	40.26	291	79	33.08	334	7.9%	4.00 [-1.83 , 9.83]	+ ? ? + + ? +
McGrath 2017	81.23	18.93	30	74.88	21.42	37	5.2%	6.35 [-3.32 , 16.02]	+ + ? + ? + +
Subramanian 2019	82	18.4	63	79.9	17.6	70	7.7%	2.10 [-4.04 , 8.24]	? + + + ? + +
Kuppermann 2020	90.7	12.3	670	90.3	12.2	672	11.0%	0.40 [-0.91 , 1.71]	+ ? ? + + + +
Chen C 2021	88.3	10.2	67	81	18.9	63	8.4%	7.30 [2.03 , 12.57]	? + + + + + +
Crew 2022	84.01	18.63	120	83.05	19.8	133	8.8%	0.96 [-3.78 , 5.70]	+ ? ? + − ? +
Subtotal (95% CI)			**1241**			**1309**	**49.1%**	**2.49 [0.03 , 4.95]**	
Heterogeneity: Tau² = 3.64; Chi² = 8.60, df = 5 (P = 0.13); I² = 42%									
Test for overall effect: Z = 1.98 (P = 0.05)									
12.1.2 Study-specific questionnaire									
McBride 2002	78	18	273	70	19	284	10.1%	8.00 [4.93 , 11.07]	? ? ? + ? ? +
Meade 2015	58.1	19.2	78	55.6	20.3	66	7.4%	2.50 [-3.99 , 8.99]	+ ? ? + ? + ?
Perez-Lacasta 2019	84.6	16.6	203	84	17.2	197	9.9%	0.60 [-2.71 , 3.91]	+ + ? + ? + ?
Lin 2020	89.5	16.25	90	69	24	90	7.8%	20.50 [14.51 , 26.49]	+ ? ? + ? + ?
Manne 2020	91	23.74	46	85	22.62	47	5.4%	6.00 [-3.43 , 15.43]	? ? ? + ? ? +
Tebb 2021	84	17	320	76.7	21.3	437	10.3%	7.30 [4.57 , 10.03]	+ ? ? + − + −
Subtotal (95% CI)			**1010**			**1121**	**50.9%**	**7.36 [2.67 , 12.05]**	
Heterogeneity: Tau² = 27.25; Chi² = 35.88, df = 5 (P < 0.00001); I² = 86%									
Test for overall effect: Z = 3.07 (P = 0.002)									
Total (95% CI)			**2251**			**2430**	**100.0%**	**5.28 [2.27 , 8.29]**	
Heterogeneity: Tau² = 20.95; Chi² = 73.97, df = 11 (P < 0.00001); I² = 85%									
Test for overall effect: Z = 3.43 (P = 0.0006)									
Test for subgroup differences: Chi² = 3.24, df = 1 (P = 0.07), I² = 69.2%									

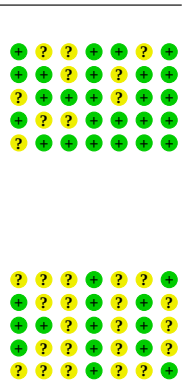
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 12.2. Comparison 12: Confidence, Outcome 2: Confidence - studies without high risk of bias

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
12.2.1 Decision Self-efficacy Scale								
Allen 2010	83	40.26	291	79	33.08	334	9.9%	4.00 [-1.83 , 9.83]
McGrath 2017	81.23	18.93	30	74.88	21.42	37	6.8%	6.35 [-3.32 , 16.02]
Subramanian 2019	82	18.4	63	79.9	17.6	70	9.6%	2.10 [-4.04 , 8.24]
Kuppermann 2020	90.7	12.3	670	90.3	12.2	672	13.2%	0.40 [-0.91 , 1.71]
Chen C 2021	88.3	10.2	67	81	18.9	63	10.4%	7.30 [2.03 , 12.57]
Subtotal (95% CI)			**1121**			**1176**	**49.8%**	**3.15 [-0.04 , 6.34]**
Heterogeneity: Tau² = 6.45; Chi² = 8.60, df = 4 (P = 0.07); I² = 53%								
Test for overall effect: Z = 1.93 (P = 0.05)								
12.2.2 Study-specific questionnaire								
McBride 2002	78	18	273	70	19	284	12.2%	8.00 [4.93 , 11.07]
Meade 2015	58.1	19.2	78	55.6	20.3	66	9.3%	2.50 [-3.99 , 8.99]
Perez-Lacasta 2019	84.6	16.6	203	84	17.2	197	12.0%	0.60 [-2.71 , 3.91]
Lin 2020	89.5	16.25	90	69	24	90	9.7%	20.50 [14.51 , 26.49]
Manne 2020	91	23.74	46	85	22.62	47	6.9%	6.00 [-3.43 , 15.43]
Subtotal (95% CI)			**690**			**684**	**50.2%**	**7.44 [0.97 , 13.91]**
Heterogeneity: Tau² = 45.70; Chi² = 35.44, df = 4 (P < 0.00001); I² = 89%								
Test for overall effect: Z = 2.25 (P = 0.02)								
Total (95% CI)			**1811**			**1860**	**100.0%**	**5.53 [1.95 , 9.11]**
Heterogeneity: Tau² = 24.95; Chi² = 62.74, df = 9 (P < 0.00001); I² = 86%								
Test for overall effect: Z = 3.03 (P = 0.002)								
Test for subgroup differences: Chi² = 1.36, df = 1 (P = 0.24), I² = 26.4%								

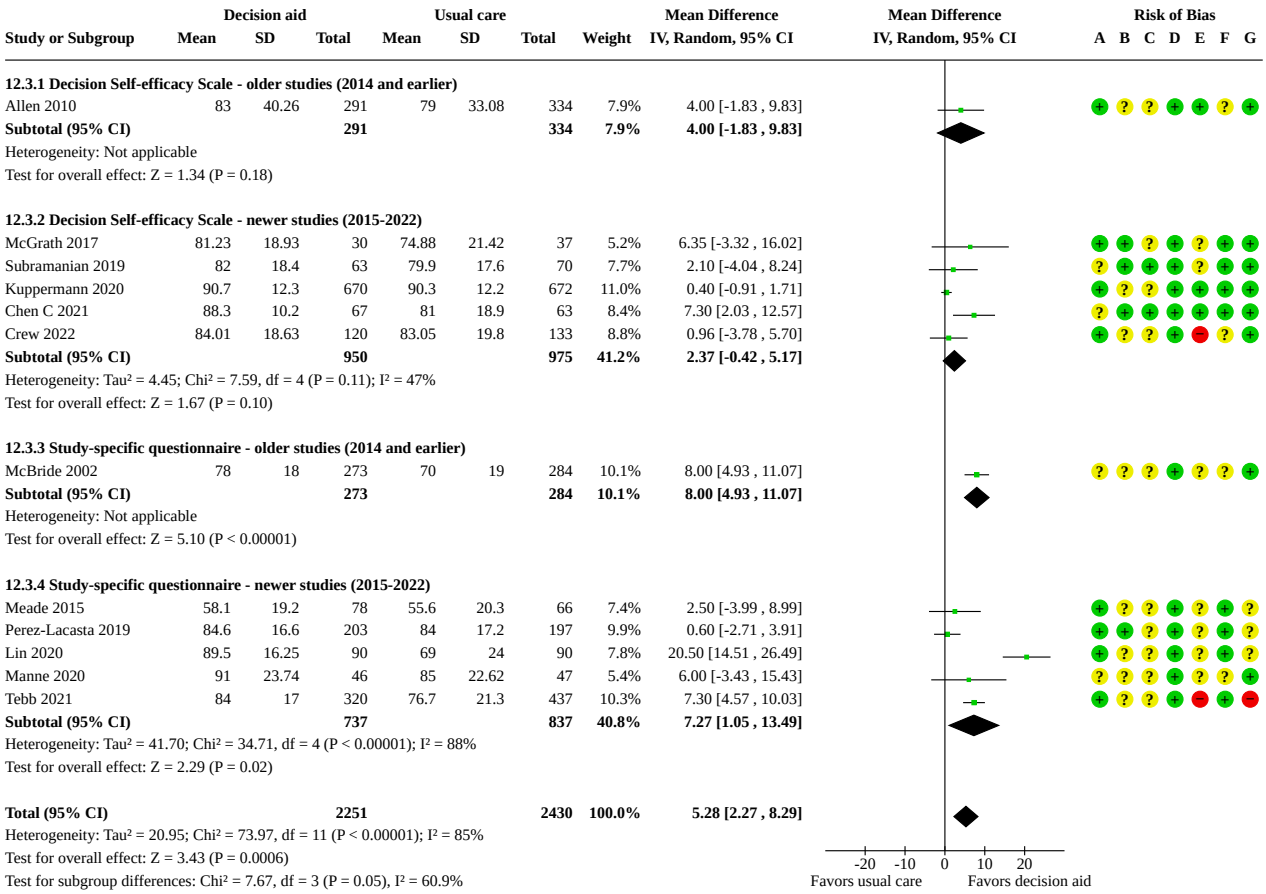




Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 12.3. Comparison 12: Confidence, Outcome 3: Confidence - old vs new studies



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
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(F) Selective reporting (reporting bias)
(G) Other bias

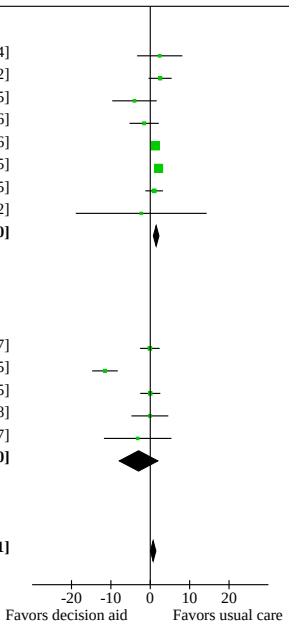
Comparison 13. Consultation length

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.1 Consultation length - subgroup by timing of intervention (in consultation versus in preparation for consultation)	13	3122	Mean Difference (IV, Random, 95% CI)	0.73 [0.05, 1.41]
13.1.1 In consultation	8	2702	Mean Difference (IV, Random, 95% CI)	1.50 [0.79, 2.20]
13.1.2 In preparation for consultation	5	420	Mean Difference (IV, Random, 95% CI)	-2.97 [-7.84, 1.90]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
13.2 Consultation length - subgroup by timing of intervention - studies without high risk of bias	10	1871	Mean Difference (IV, Random, 95% CI)	0.87 [0.15, 1.59]
13.2.1 In consultation	5	1451	Mean Difference (IV, Random, 95% CI)	1.75 [1.00, 2.50]
13.2.2 In preparation for consultation	5	420	Mean Difference (IV, Random, 95% CI)	-2.97 [-7.84, 1.90]
13.3 Consultation length - old vs new studies (in consultation)	8	2702	Mean Difference (IV, Random, 95% CI)	1.50 [0.79, 2.20]
13.3.1 Older studies	2	317	Mean Difference (IV, Random, 95% CI)	2.48 [-0.13, 5.09]
13.3.2 Newer studies	6	2385	Mean Difference (IV, Random, 95% CI)	1.43 [0.70, 2.16]
13.4 Consultation length - old vs new studies (in preparation for consultation)	5	420	Mean Difference (IV, Random, 95% CI)	-2.97 [-7.84, 1.90]
13.4.1 Older studies	1	123	Mean Difference (IV, Random, 95% CI)	-0.10 [-2.57, 2.37]
13.4.2 Newer studies	4	297	Mean Difference (IV, Random, 95% CI)	-3.78 [-10.41, 2.86]

Analysis 13.1. Comparison 13: Consultation length, Outcome 1: Consultation length - subgroup by timing of intervention (in consultation versus in preparation for consultation)

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
13.1.1 In consultation								
Ozanne 2007	24.3	7.5	15	21.9	8.51	15	1.3%	2.40 [-3.34 , 8.14]
Loh 2007	29.2	10.7	191	26.7	12.5	96	4.6%	2.50 [-0.42 , 5.42]
LeBlanc 2015b	44	22	158	48	27	139	1.4%	-4.00 [-9.65 , 1.65]
Perestelo-Perez 2016	18.1	8.07	61	19.65	12.61	63	3.0%	-1.55 [-5.26 , 2.16]
Hess 2016	4.4	0.4	264	3.1	0.29	272	32.0%	1.30 [1.24 , 1.36]
Hess 2018	7.6	0.4	267	5.5	0.2	249	32.0%	2.10 [2.05 , 2.15]
Kunneman 2020	32	16	419	31	17	411	7.1%	1.00 [-1.25 , 3.25]
Tilburt 2022	56.7	20.23	32	59	54.37	50	0.2%	-2.30 [-18.92 , 14.32]
Subtotal (95% CI)			**1407**			**1295**	**81.7%**	**1.50 [0.79 , 2.20]**
Heterogeneity: Tau² = 0.32; Chi² = 389.98, df = 7 (P < 0.00001); I² = 98%								
Test for overall effect: Z = 4.16 (P < 0.0001)								
13.1.2 In preparation for consultation								
Bozic 2013	20.9	6.8	61	21	7.2	62	6.1%	-0.10 [-2.57 , 2.37]
Berger-Hoger 2019	12.8	6.6	34	24.3	6.3	27	3.8%	-11.50 [-14.75 , -8.25]
Wilkens 2019	11	6.7	45	11	5.6	45	5.8%	0.00 [-2.55 , 2.55]
Politi 2020a	29.9	12.4	60	30	13.7	60	2.0%	-0.10 [-4.78 , 4.58]
Varelas 2020	47.8	13.7	13	51	7.8	13	0.6%	-3.20 [-11.77 , 5.37]
Subtotal (95% CI)			**213**			**207**	**18.3%**	**-2.97 [-7.84 , 1.90]**
Heterogeneity: Tau² = 25.84; Chi² = 37.78, df = 4 (P < 0.00001); I² = 89%								
Test for overall effect: Z = 1.19 (P = 0.23)								
Total (95% CI)			**1620**			**1502**	**100.0%**	**0.73 [0.05 , 1.41]**
Heterogeneity: Tau² = 0.37; Chi² = 459.40, df = 12 (P < 0.00001); I² = 97%								
Test for overall effect: Z = 2.12 (P = 0.03)								
Test for subgroup differences: Chi² = 3.16, df = 1 (P = 0.08), I² = 68.3%								

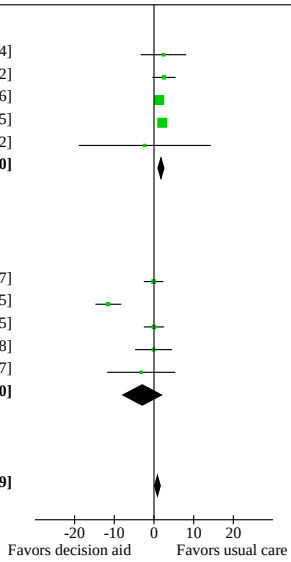


Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 13.2. Comparison 13: Consultation length, Outcome 2: Consultation length - subgroup by timing of intervention - studies without high risk of bias

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Risk of Bias A B C D E F G
13.2.1 In consultation									
Ozanne 2007	24.3	7.5	15	21.9	8.51	15	1.5%	2.40 [-3.34 , 8.14]	? ? ? + + ? ?
Loh 2007	29.2	10.7	191	26.7	12.5	96	5.2%	2.50 [-0.42 , 5.42]	+ + ? ? ? ? +
Hess 2016	4.4	0.4	264	3.1	0.29	272	36.3%	1.30 [1.24 , 1.36]	+ + ? + + + ?
Hess 2018	7.6	0.4	267	5.5	0.2	249	36.3%	2.10 [2.05 , 2.15]	+ + ? + + + +
Tilburt 2022	56.7	20.23	32	59	54.37	50	0.2%	-2.30 [-18.92 , 14.32]	? ? ? + + + ?
Subtotal (95% CI)			**769**			**682**	**79.4%**	**1.75 [1.00 , 2.50]**	
Heterogeneity: Tau² = 0.32; Chi² = 382.60, df = 4 (P < 0.00001); I² = 99%									
Test for overall effect: Z = 4.57 (P < 0.00001)									
13.2.2 In preparation for consultation									
Bozic 2013	20.9	6.8	61	21	7.2	62	6.8%	-0.10 [-2.57 , 2.37]	+ + ? + ? + +
Berger-Hoger 2019	12.8	6.6	34	24.3	6.3	27	4.3%	-11.50 [-14.75 , -8.25]	+ + ? + + + +
Wilkens 2019	11	6.7	45	11	5.6	45	6.5%	0.00 [-2.55 , 2.55]	+ + ? + + ? +
Politi 2020a	29.9	12.4	60	30	13.7	60	2.2%	-0.10 [-4.78 , 4.58]	+ ? ? + + + +
Varelas 2020	47.8	13.7	13	51	7.8	13	0.7%	-3.20 [-11.77 , 5.37]	+ ? + + ? ? ?
Subtotal (95% CI)			**213**			**207**	**20.6%**	**-2.97 [-7.84 , 1.90]**	
Heterogeneity: Tau² = 25.84; Chi² = 37.78, df = 4 (P < 0.00001); I² = 89%									
Test for overall effect: Z = 1.19 (P = 0.23)									
Total (95% CI)			**982**			**889**	**100.0%**	**0.87 [0.15 , 1.59]**	
Heterogeneity: Tau² = 0.37; Chi² = 452.03, df = 9 (P < 0.00001); I² = 98%									
Test for overall effect: Z = 2.37 (P = 0.02)									
Test for subgroup differences: Chi² = 3.52, df = 1 (P = 0.06), I² = 71.6%									

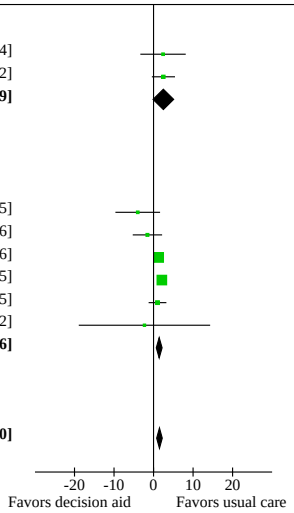


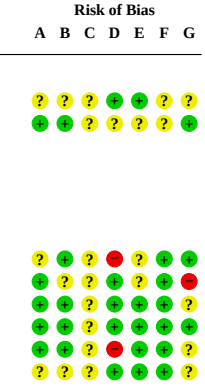
Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 13.3. Comparison 13: Consultation length, Outcome 3: Consultation length - old vs new studies (in consultation)

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
13.3.1 Older studies								
Ozanne 2007	24.3	7.5	15	21.9	8.51	15	1.5%	2.40 [-3.34 , 8.14]
Loh 2007	29.2	10.7	191	26.7	12.5	96	5.1%	2.50 [-0.42 , 5.42]
Subtotal (95% CI)			**206**			**111**	**6.5%**	**2.48 [-0.13 , 5.09]**
Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.98); I² = 0%								
Test for overall effect: Z = 1.86 (P = 0.06)								
13.3.2 Newer studies								
LeBlanc 2015b	44	22	158	48	27	139	1.5%	-4.00 [-9.65 , 1.65]
Perestelo-Perez 2016	18.1	8.07	61	19.65	12.61	63	3.3%	-1.55 [-5.26 , 2.16]
Hess 2016	4.4	0.4	264	3.1	0.29	272	40.3%	1.30 [1.24 , 1.36]
Hess 2018	7.6	0.4	267	5.5	0.2	249	40.3%	2.10 [2.05 , 2.15]
Kunneman 2020	32	16	419	31	17	411	7.9%	1.00 [-1.25 , 3.25]
Tilburt 2022	56.7	20.23	32	59	54.37	50	0.2%	-2.30 [-18.92 , 14.32]
Subtotal (95% CI)			**1201**			**1184**	**93.5%**	**1.43 [0.70 , 2.16]**
Heterogeneity: Tau² = 0.32; Chi² = 389.66, df = 5 (P < 0.00001); I² = 99%								
Test for overall effect: Z = 3.83 (P = 0.0001)								
Total (95% CI)			**1407**			**1295**	**100.0%**	**1.50 [0.79 , 2.20]**
Heterogeneity: Tau² = 0.32; Chi² = 389.98, df = 7 (P < 0.00001); I² = 98%								
Test for overall effect: Z = 4.16 (P < 0.0001)								
Test for subgroup differences: Chi² = 0.58, df = 1 (P = 0.45), I² = 0%								

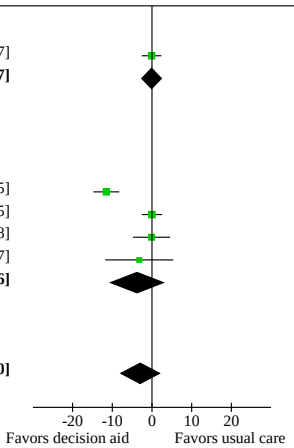


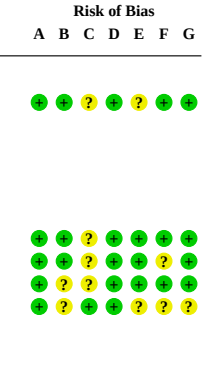


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 13.4. Comparison 13: Consultation length, Outcome 4: Consultation length - old vs new studies (in preparation for consultation)

Study or Subgroup	Decision aid Mean	SD	Total	Usual care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
13.4.1 Older studies								
Bozic 2013	20.9	6.8	61	21	7.2	62	22.5%	-0.10 [-2.57 , 2.37]
Subtotal (95% CI)			**61**			**62**	**22.5%**	**-0.10 [-2.57 , 2.37]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.08 (P = 0.94)								
13.4.2 Newer studies								
Berger-Hoger 2019	12.8	6.6	34	24.3	6.3	27	21.6%	-11.50 [-14.75 , -8.25]
Wilkens 2019	11	6.7	45	11	5.6	45	22.5%	0.00 [-2.55 , 2.55]
Politi 2020a	29.9	12.4	60	30	13.7	60	19.6%	-0.10 [-4.78 , 4.58]
Varelas 2020	47.8	13.7	13	51	7.8	13	13.8%	-3.20 [-11.77 , 5.37]
Subtotal (95% CI)			**152**			**145**	**77.5%**	**-3.78 [-10.41 , 2.86]**
Heterogeneity: Tau² = 39.49; Chi² = 32.48, df = 3 (P < 0.00001); I² = 91%								
Test for overall effect: Z = 1.11 (P = 0.26)								
Total (95% CI)			**213**			**207**	**100.0%**	**-2.97 [-7.84 , 1.90]**
Heterogeneity: Tau² = 25.84; Chi² = 37.78, df = 4 (P < 0.00001); I² = 89%								
Test for overall effect: Z = 1.19 (P = 0.23)								
Test for subgroup differences: Chi² = 1.03, df = 1 (P = 0.31), I² = 3.3%								





Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

ADDITIONAL TABLES

Table 1. Outcome measures

Outcome	How often is it measured*	How is it usually measured/examples	Ideal timing to collect	Rationale for timing
Attributes of the choice made:				
Does the patient decision aid improve the match between the chosen option and the features that matter most to the informed patient?				
Informed values-choice congruence	Less often: 35/209 studies	Most often measured using the Multi-Dimensional Measure of Informed Choice (MMIC) instrument, which comprises 3 dimensions: knowledge, attitude, and uptake (Michie 2002). It can be measured other ways (e.g. "percent match" procedures by Sepucha et al (2007; 2008)).	We collected and reported data, however it is measured. We carefully reviewed how it was measured and standardized and pooled data if there was consistency across studies.	It is less often measured, so we included all timings.
Attributes of the decision process:				
Does the decision aid help patients know the options and their features (knowledge and feeling informed), be clear about the features that matter most to them (clear values), improve communication with their clinician (patient-clinician communication), become involved in their preferred ways (participation in decision-making), be more prepared to make decisions, and more satisfied with the decision-making process?				
Knowledge	Very often: 149/209 studies	Customized tests based on information contained in the decision aid. The proportion of accurate responses is transformed to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).	Soon after exposure to the decision aid.	An outcome of the decision aid but knowledge decreases over time.
Accurate risk perceptions (i.e. perceived probabilities of outcomes)	Less often: 37/209 studies	Based on the accuracy of perceived outcome probabilities according to the percentage of individuals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar people. For studies that elicited risk perceptions using multiple items, we averaged the proportion of accurate risk perceptions.	Soon after exposure to the decision aid.	An outcome of the decision aid.
Decisional conflict subscale – feeling uninformed	Often: 75/209 studies	Subscale of the original Decisional Conflict Scale - 16 Items (O'Connor 1995)	Soon after exposure to the decision aid.	An outcome of the decision aid.
Decisional conflict subscale – feeling unclear values	Often: 71/209 studies	Subscale of the original Decisional Conflict Scale - 16 Items (O'Connor 1995)	Soon after exposure to the decision aid.	An outcome of the decision aid.
Patient-clinician communication	Less often: 36/209 studies	Most studies evaluated the extent of shared decision-making communication by analyzing the audio or video recordings. Common instruments include the OPTION scale (Elwyn 2005), the Shared Decision Making Questionnaire, patient (SDMQ9-patient) and GP (SDM-Q9-doc) (Kris-	It is usually measured during the consultation using audio or video recordings or soon after the consul-	As an outcome of the consultation.

Table 1. Outcome measures *(Continued)*

		ton 2010), the CollaboRATE-SDM (Elwyn 2013b), and the MAPPIN'SDM (Kasper 2012). Other studies measured the proportion of patients who discussed the decision with the clinician.	tation. There may be multiple measurements to extract. We extracted whether the outcome was patient-reported, clinician-reported, or observer-reported.	
Participation in decision-making	Often: 42/209 studies	Defined as clinician-controlled decision-making (passive role) or active patient involvement (patient-controlled decision-making and shared decision-making). Common instruments include the Control Preferences Scale (Degner 1992) and COMRADE (Edwards 2003). Other studies may use similar researcher-developed response statements to measure perceived involvement.	Soon after the consultation with the physician and whether it was actual or preferred participation.	As an outcome of the consultation.
Proportion undecided	Often: 46/209 studies	Sometimes measured using the Stage of Decision-making scale: "How far along are you with your decision?" (O'Connor 2000). Other examples include: asking participants which option they were leaning toward (Arterburn 2011) and reporting which option was chosen, including “undecided” (Berry 2013).	We collected data in 2 subgroups: 1) Soon after exposure to the decision aid but prior to consultation. 2) Post-consultation (or if decision aid was used during the consultation).	An outcome of the decision aid and consultation.
Satisfaction with the decision-making process	Rarely: 16/209	Sometimes measured using the Satisfaction with the Decision Making Process (SDMP), a 12-item scale (Barry 1997), or ‘‘How satisfied were you with this consultation?”, with response scale 0 to 10 (Bozic 2013).	We collected and reported data however it was measured	It is rarely measured, so we included all timings.
Preparation for decision-making	Rarely: 17/209	Preparation for Decision Making Scale (Bennett 2010b).	Soon after exposure to the decision aid.	An outcome of the decision aid.
Secondary outcomes				
Behavior				
Choice	Very often: 165/209 studies	Choice is defined as the actual choice implemented. However, when studies did not report the actual choice, we used the patients' preferred option as a surrogate measure.	Usually measured post-consultation.	Given we want actual choice, it needs to ideally be anytime after the consultation.
Confidence	Rarely: 27/209 studies	Most often measured using the Decisional Self-efficacy Scale (O'Connor 2002). Sometimes referred to as “empowerment”.	We collected and reported data however it was measured.	It is rarely measured, so we included all timings.
Adherence (continuance/compli-	Rarely: 25/209 studies	We grouped adherence according to adherence to the baseline choice and adherence to the treatment. It is usually measured a while after	We collected and reported data how-	It is rarely measured, so we in-

Table 1. Outcome measures *(Continued)*

ance) with chosen option		the decision has been made (e.g. 3 to 12 months post).	ever it was measured.	cluded all timings.
Health outcomes				
Preference-linked health outcomes	Never: 0/209 studies	The study needs to report health outcomes analyzed considering those the patient prefers to have versus those the patient prefers to avoid.	—	To our knowledge, it has never been measured.
Healthcare system effects				
Consultation length	Rarely: 23/209 studies	Usually measured by analyzing recordings of the consultation.	—	—
Cost	Rarely: 8/209 studies	Costs as related to the decision aid measured, using cost-effectiveness analysis or total estimated costs.	We collected and reported data however it was measured	It is rarely measured, so we included all timings.
Healthcare resource use	Rarely: 7/209 studies	Healthcare resource use as related to decision aid use, for example outcomes such as the scheduling of initial or repeat consultations, length of hospital stay, and hospital admissions.	We collected and reported data however it was measured.	It is rarely measured, so we included all timings.
Adverse events				
Decision regret	Less often: 30/209 studies	Measured using the Decision Regret Scale (Brehaut 2003), which measures "distress or remorse after a [health care] decision."	A while after the decision has been made (e.g. 6 to 24 months post decision).	A longer-term outcome of the decision-making process.
Emotional distress	Rarely: 5/209 studies	Emotional distress is sometimes measured using the Impact of Events Scale (Horowitz 1979). For example, “Trouble staying asleep (because of having to make the decision)?”	We collected and reported data however it was measured.	It is rarely measured, so we included all timings.

*Based on the number of studies that measured the outcome in the current review: e.g. > 40 studies = often.

Table 2. Values congruent with chosen option

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Allen 2018	Concordance between single-item value score and patient-reported treatment choice	1 month after enrollment	104	3.33 (SD 0.32)	132	2.37 (SD 0.28)	P = 0.03 favoring the DA group
		6 months after enrollment	104	3.65 (SD 0.39)	132	3.12 (SD 0.33)	No difference, P = 0.32
Arterburn 2011	Percent match procedures described by Sepucha et al (2007; 2008). For values items were most predictive and used to specify logistic models to estimate predicted probability of selecting surgery > 0.5.	Post-intervention	75	—	77	—	The intervention group experienced a more rapid early improvement in values concordance immediately after the intervention compared to control.
Berry 2013	Concordant when men reported: a) sexual function influenced decision and they had radiation therapy; b) bowel function influenced decision and they had surgery; c) all effects influenced decision and they had surveillance	6 months post-intervention	239	—	209	—	No difference OR = 0.82, 95% CI 0.56 to 1.2
Beulen 2016	Value-consistency prenatal test decision (attitudes were combined with prenatal test utilization to assess whether decision-making regarding prenatal testing was value-consistent)	Post-intervention	123	92.7%	120	94.2%	P = 0.641
Durand 2021 (in consult)	Decision Quality Instrument concordance subscale	Immediately post consultation	60	—	220	—	There was no effect of the intervention on the Decision Quality Instrument concordance subscale in comparison with usual care.
Frosch 2008a	Concordance between participant's preferences and values for potential outcomes related to the decision and the choice made	Within weeks	155	—	151	—	Men assigned to the decision aid who chose not to have a PSA test rated their concern about prostate cancer lower than did men who

Table 2. Values congruent with chosen option *(Continued)*

							requested a PSA test. Men assigned to usual care provided similar ratings of concern about prostate cancer regardless of their PSA decision. There was no statistically significant difference between groups.
Legare 2008a	—	—	—	—	—	—	Women's valuing of non-chemical aspects of natural health products was positively associated with their choice of nature health products, P = 0.006. No difference between groups.
Lerman 1997	Association between values and choice	—	—	—	—	—	No difference; between-group differences were not reported.
Lewis 2021	Values-choice concordance was analyzed descriptively because of the small sample size and insufficient outcome variability in actual/preferred choice	—	—	—	—	—	"Lower your chances of sudden cardiac arrest", 96.6%; "Peace of mind", 90.0%; "Avoid risks", 51.7%; "Allow a natural death", 51.7%
McGrath 2017	Value congruence measured using a single item, ''If you have already made your decision, to what degree have you made it based on what is important to you?'' (response scale not reported)	2 weeks post-intervention	—	2.76 (SD 0.63)	—	2.77 (SD 0.43)	No difference P = 0.838
McIlvennan 2018 (in consult)	Concordance between caregiver values for their loved one and stated caregiver treatment choice (1 to 10 scale)	1 month post-intervention	53	3.63 (SE 0.43)	89	2.79 (SE 0.34)	No difference P = 0.15
		6 months post-intervention	50	4.27 (SE 0.44)	78	3.05 (SE 0.35)	P = 0.045

Table 2. Values congruent with chosen option *(Continued)*

Pereste-lo-Perez 2017	Concordance between patients' goals/concerns and their treatment intention using a "simple match" approach.	Immediately post-intervention	62	23 (37.1%)	69	27 (39.1%)	No difference P = 0.811
Pereste-lo-Perez 2019	Concordance between patients' goals/concerns about the screening procedure and their intention to be screened as described by Sepucha 2014	Immediately post-intervention	—	—	—	—	Patients' goals and concerns regarding the screening did not significantly predict their intention, and therefore the authors could not calculate a measure of concordance between the two constructs.
Vandemheen 2009	Congruence between personal values and decision	3 weeks	70	—	70	—	Patient choices were consistent with their values across both randomized groups.
Wallace 2021	Congruence between personal values (1 to 10 scale from "not important" to "very important") and values-trade off (1 to 10 scale from "Die quickly from any cause" to "Live as long as possible")	1 month post-intervention	6	5 (83.3%)	3	0 (0%)	P = 0.048

CI : confidence interval; **DA** : decision aid; **OR** : odds ratio; **SD** : standard deviation; **SE** : standard error

Table 3. Knowledge

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Bailey 2016	17 true or false questions. Change in knowledge from baseline.	4 to 6 weeks after enrollment	114	35 (SD 22.3)	111	9.9 (22.2)	P < 0.0001
Beulen 2016	Sufficient knowledge: participants with a score of ≥ 12	Post-intervention	131	88.5%	130	70.8%	P < 0.001
Bozic 2013	Decision quality instrument, 19 items re knowledge (> 50%)	After 1st consultation with surgeon	60	58.3%	60	33.3%	P = 0.01

Table 3. Knowledge *(Continued)*

Chen S 2021	15 items (true, false, or unsure) with points deducted for incorrect answers	Post-intervention	29	9.86 (SD not reported)	30	9.77 (SD not reported)	P = 0.89
Crew 2022	8 multiple choice items. Adequate knowledge defined as at least 50% correct responses.	1 month post-intervention	120	58 (49%)	133	36 (27%)	P < 0.001
Evans 2010	12 true or false questions; scores ranging from -12 to 12	Immediately post	89	4.9	103	2.17	P < 0.001
Fagerlin 2011	Insufficient (≤ 50% correct)	Immediately post	383	31.8%	102	93.1%	P < 0.001
	Sufficient	Immediately post	383	61.9%	102	6.9%	—
Fraenkel 2012	Open-ended questions about medication options to reduce stroke - knows medications	Post-intervention	66	61%	62	31%	OR 3.5 (95% CI 1.6 to 7.7, P = 0.001)
	Open-ended questions about side effects of medications - knows side effects	Post-intervention	53	49%	46	37%	OR 1.9 (95% CI 0.9 to 4.0; P = 0.07)
Fraenkel 2015	Change in knowledge from baseline	2 weeks post-intervention	60	Median 1.0 (IQR -1.0 to 2.0)	61	Median 0 (IQR -2.0 to 1.0)	P = 0.007
Fung 2021	23 true/false items; linearly transformed score range 0 (poor) to 100 (outstanding)	Post-intervention	36	75.1 (SD not reported)	37	65.3 (SD not reported)	P = 0.04
Gabel 2020b	Change in knowledge from baseline	90 days post-invitation	863	0.44 (CI 0.33 to 0.54)	860	0.34 (CI 0.24 to 0.45)	No difference (scale score differences: 0.09, 95% CI -0.05 to 0.24)
Gagne 2017	37 items with response options labeled true, false, and don't know, with points deducted for incorrect answers (range -37 to +37)	2 months post-intervention	26	25.1 (95% CI 23.1 to 27.0)	25	26.0 (95% CI 24.0 to 28.0)	No difference between groups
Gokce 2019	10-item questionnaire	Immediately post-intervention	58	Median 8/10 (range 5 to 10)	57	Median 6/10 (range 3 to 10)	P = 0.045

Table 3. Knowledge *(Continued)*

	Adequate knowledge defined as 8 or more correct answers	Immediately post-intervention	58	43 (74.1%)	57	32 (56.1%)	P = 0.04
Hamann 2006	7-item multiple choice knowledge test (unable to standardize results)	On discharge (~ 1 month)	49	15 (4.4 SD)	58	10.9 (5.4 SD)	P = 0.01
Heller 2008	12-item multiple choice	Pre-operatively	66	14%*	67	8%*	*Mean increase from baseline P = 0.02
Ibrahim 2013	Change in proportion answering 3 of 4 questions correctly	1 month post-intervention	168 + 163	—	167	—	Significant increase for patients who received the DA P < 0.05
Ickenroth 2016	20 true or false questions with points deducted for incorrect answers (range -20 to +20). Diabetes/cholesterol.	Immediately post-intervention	224 217	10.5 (SD 3.56) 8.58 (SD 4.22)	241 240	9.81 (3.71) 8.43 (4.11)	P = 0.031 P = 0.682
	Sufficient knowledge (score of 10 or above). Diabetes/cholesterol.		224 217	150 (67.0%) 102 (47.0%)	241 240	129 (53.5%) 101 (42.1%)	P = 0.003 P = 0.301
Korteland 2017	5-item questionnaire (proportion with all items correct)	Post-intervention/pre-operatively	67	57 (85%)	71	48 (68%)	P = 0.004
Krishnamurti 2019	25-item questionnaire (0 to 100; low to high)	3 months post-intervention	23	52.90 (SD not reported)	19	52.90 (SD not reported)	P = 0.12
Kukafka 2022	Change in knowledge from baseline	1 month post-intervention	101	1.1 (SD 2.3)	86	0.3 (SD 2.3)	P = 0.03
Kunneman 2020 (in consultation)	6-item questionnaire (number of items correct)	Post-intervention	445	≤ 3: 24 (5.4%) 4: 76 (17.1%) 5: 207 (46.5%) 6: 138 (31.0%)	433	≤3: 30 (6.9%) 4: 88 (20.3%) 5: 191 (44.1%) 6: 124 (28.6)	No difference Effect (95% CI) 1.01 (1.0 to 1.02)
LeBlanc 2015	13-item questionnaire (median, IQR) total score	Immediately post	32	7 (4.5 to 9.0)	45	5.5 (2.5 to 8.0)	P = 0.11

Table 3. Knowledge *(Continued)*

(in consultation)	9-item knowledge based on decision aid	Immediately post	32	6 (3.5 to 6.5)	45	4 (2.0 to 8.0)	P = 0.01
LeBlanc 2015b (in consultation)	Tailored to information in the decision aid (0 = no correct, 100 = all correct) Mean (95% CI)	Immediately post	137	58.1 (53.6 to 62.6)	116	46.6 (42.6 to 50.5)	P < 0.001
	Generic (i.e. depression in general)	Immediately post	137	72.5 (68.0, 77.0)	116	72.4 (67.3 to 77.5)	P = 0.65
Legare 2008a	10-item yes/no/unsure general knowledge test about natural health products (not specific to outcomes of options)	Change scores from baseline to 2 weeks	43	0.86 ± 1.77 P = 0.002	41	0.51 ± 1.47 P = 0.031	No difference between groups (P = 0.162)
Mann D 2010 (in consultation)	14-item survey	Immediately post	—	—	—	—	No difference in level of knowledge between groups
Mathers 2012	Correctly answers question about best option to lower blood sugar	6 months post-intervention	95	51.6%	80	28.8%	P < 0.001
	Correctly answers question about best option to lower complications	6 months post-intervention	95	31.0%	80	29%	P = 0.90
Mathieu 2007	9-item - 4 concept questions and 5 numeric questions	—	351	—	357	—	Significantly higher mean increase for the intervention group (2.62) compared to the control group (0.68) from baseline, P < 0.001
Miller 2005	8-item survey	2-week, 2-month, and 6-month follow-ups	—	—	—	—	Intervention type had no impact on general or specific knowledge
Nagle 2008	Good level knowledge was scored higher than the mid-point of the knowledge scale (greater than 4)	—	—	—	—	—	88% (147/167) in DA group compared to 72% (123/171) in pamphlet group. OR

Table 3. Knowledge *(Continued)*

							3.43 (95% CI 1.79 to 6.58).
Ozanne 2007 (in consultation)	Change in knowledge from baseline	Post-test	15	48% to 64%	15	45% to 57%	Change in knowledge score was significant for decision aid (P = 0.01) but not control (P = 0.13)
Partin 2004	10-item knowledge index score	2 weeks	308	7.44	290	6.9	P = 0.001
Perez-Lacasta 2019	22-item: 11 conceptual questions and 5 numerical questions	2 to 4 weeks post DA	203	13.3 (SD not reported)	197	7.83 (SD not reported)	P < 0.001
Reuland 2017	6-item survey	Post-consultation	131	4.6 (SD not reported)	131	2.8 (SD not reported)	P < 0.001
Rubel 2010	24 items adapted from existing prostate cancer knowledge measures	Immediately post	100	—	100	—	The total mean standardized knowledge score was 84.38 (SD 12.38)
Schott 2021 (in consultation)	4-item survey: ordinal logistic mixed-effect model (odds ratio and 95% confidence interval)	Immediately post	33	3.88 (95% CI 1.39 to 10.78)	33	1.0 (reference group)	P = 0.009
Stubenrouch 2022	Disease-specific knowledge test (median and IQR)	Post-intervention/consultation	173	Median 80.0 (IQR 60 to 91.7)	138	Median 66.7 (IQR 50 to 80)	P = 0.025
Trevena 2008	Adequate knowledge (positive score: understanding benefits/harms)	1 month	134	28/134	137	8/137	P = 0.0001
Watson 2006	12-item true/false/don't know	Post-test	468	75% (range 0 to 100)	522	25% (range 0 to 100)	P < 0.0001
Weymiller 2007 (in consultation)	14-item - 9 were addressed by decision aid; 5 were not	Immediately post	52	—	46	—	Mean difference between groups 2.4 (95% CI 1.5 to 3.3) P < 0.05 (when decision aid administered during the consultation only - not if

Table 3. Knowledge *(Continued)*

							prior to the consultation)
Wise 2019	15-item true/false/unsure questionnaire - change in knowledge from baseline	34 weeks gestation (2 to 3 months post-intervention)	146	Increase of 2 points	148	Increase of 1.6 points	No difference P = 0.20
Wyld 2021 (in consultation)	8-item - disease-specific knowledge test (median and IQR)	6 weeks post-intervention	67	Median 5/8 (IQR 45)	58	Median 3/8 (IQR 2 to 5)	P < 0.001
Ye 2021	Adequate knowledge n (%) using 12-item questionnaire with 3 subscales	2 weeks post-intervention	386	142 (36.8%)	387	34 (8.79%)	P < 0.001

CI : confidence interval; **DA** : decision aid; **IQR** : interquartile range; **OR** : odds ratio; **SD** : standard deviation.

Table 4. Accurate risk perceptions

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Cox 2019	Clinician-surrogate concordance scale ("What percent chance do you think [the patient/your loved one] has of being alive 1 year from now if the current treatment plan is continued?". Scores range from 0 to 100; higher values indicate greater discordance)	3 days post-intervention	132	27.1 (95% CI 22.8 to 31.4)	134	29.5 (95% CI 25.1 to 33.9)	P = 0.60
Fraenkel 2012	Accuracy of stroke risk (reported by taking the absolute value of the difference between the participant's risk as estimated by the DA and the estimate provided by the participant - out of 100; lower score indicates more accurate estimation of risk)	Post-intervention	69	9.1 (SD 13.3)	66	14.2 (SD 13)	P = 0.002
	Accuracy of bleeding risk (reported same as above)	Post-intervention	69	8.7 (SD 12.5)	66	13.1 (SD 12.2)	P = 0.004
Hanson 2011	Expectation of benefit index 11-item score from 1 to 4 with lower score indicating better knowledge	Post (after reviewing DA)	127	2.3	129	2.6	P = 0.001

Table 4. Accurate risk perceptions *(Continued)*

Ibrahim 2013	Hospital for Special Surgery Knee Expectations Survey 19-item	1 month post-intervention	168 +163	—	167	—	No difference between groups P = 0.97
Kuppermann 2014	Correct estimate of amniocentesis miscarriage risk	3 to 6 months post-intervention	357	263 (73.8%)	353	208 (59.0%)	P < 0.001
	Correct estimate of Down syndrome risk	3 to 6 months post-intervention	357	210 (58.7%)	353	163 (46.1%)	P = 0.001
Mann E 2010	3 of 8 multiple choice items in the knowledge test (question 4, 5, 7)	2 weeks post	—	—	—	—	Total knowledge reported only
Manne 2020	Perceived risk of contralateral breast cancer after unilateral mastectomy and radiation (mean (SE)). Scale not reported.	2 to 4 weeks after surgery	46	6.44 (SE 1.97)	47	5.10 (SE 1.98)	No difference
	Perceived risk for chest wall recurrence after contralateral prophylactic mastectomy (mean (SE)). Scale not reported.	2 to 4 weeks after surgery	46	11.95 (SE 2.52)	47	12.12 (SE 2.26)	No difference
Mathieu 2010	5-item numerical questions (max = 5)	Post	113	3.02	189	2.45	P < 0.001
Miller 2005	—	2-week, 2-month, and 6-month follow-ups	—	—	—	—	Intervention type had no impact on risk perceptions
Oostendorp 2017 (in consultation)	Accuracy of chances of experiencing severe diarrhea (mean (SD) 0% to 100%)	1 week post-intervention	68	30.9 (SD 22.1)	40	34.9 (SD 22.1)	No difference P = 0.366
	Accuracy of chances of achieving partial or complete tumor response (mean (SD) 0% to 100%)	1 week post-intervention	68	30.0 (SD 20.8)	40	32.5 (SD 14.3)	No difference P = 0.463
Schapira 2019	Difference between perceived risk and risk determined by the National Cancer Institute Breast Cancer Risk Assessment Tool	6 weeks post-intervention	54	3.3% (95% CI -2.7 to 9.3)	59	9.3% (95% CI 2.3 to 16.3)	Both study arms overestimated lifetime breast cancer risk

Table 4. Accurate risk perceptions *(Continued)*

							P = 0.2
Smith 2010	8 numerical questions (max = 8)	—	357	2.93 (SD 2.91)	173	0.58 (SD 1.28)	P < 0.001
Weymiller 2007 (in consultation)	—	Immediately	52	—	46	—	Difference between groups OR 22.4 (95% CI 5.9 to 85.8) when decision aid administered during the consultation only (not if prior to) OR 6.7 (95% CI 2.2 to 19.7) when the decision aid administered prior to or during the consultation

CI : confidence interval; **DA** : decision aid; **OR** : odds ratio; **SD** : standard deviation; **SE** : standard error.

Table 5. Decisional Conflict Score

Study	Scale u sed	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Bailey 2016	Decisional conflict scale - change from baseline to 4 to 6 weeks post enrollment (standardized values)	Uninformed	114	Mean -29.9 SD 26.5	111	Mean -8.4 (SD 27.4)	P < 0.0001
		Unclear values	114	Mean -27.1 SD 24.4	111	Mean -8.9 (SD 22.1)	P < 0.0001
Berry 2013	Decisional conflict scale	Uninformed	—	—	—	—	No significant difference
		Unclear values	—	-3.57 units	—	—	P = 0.002
Chen S 2021	Decisional conflict (1 to 5 scale) post-intervention	Uninformed	29	1.63 (SD not reported)	30	1.63 (SD not reported)	No difference P = 0.99

Table 5. Decisional Conflict Score *(Continued)*

		Unclear values	29	1.54 (SD not reported)	30	1.56 (SD not reported)	No difference P = 0.91
Fraenkel 2012	Decisional conflict subscales low-literacy version - immediately post	Informed	69	13.0	66	24.8	P = 0.01
		Values	69	6.4	66	21.0	P < 0.001
Fraenkel 2015	Decisional conflict scale - change from baseline to 2 weeks post-intervention	Uninformed	60	Median 16.7 (IQR 0 to 33.3)	61	Median 8.3 (IQR -8.3 to 25.0)	P = 0.04
		Unclear values	60	Median 16.7 (IQR 4.2 to 37.5)	61	Median 0 (IQR -16.7 to 16.7)	P = 0.001
Frosch 2008a	Decisional conflict - subscales only	Feeling uninformed	155	23.37	151	29.68	P < 0.05
		Feeling unclear values	155	32.25	151	37.93	P < 0.05
Fung 2021	Decisional conflict scale	Feeling uninformed - post-intervention	36	18.3 (SD not reported)	37	43 (SD not reported)	P < 0.001
		Feeling unclear values - post-intervention	36	16.3 (SD not reported)	37	31.9 (SD not reported)	P = 0.002
Gagne 2017	Decisional conflict subscale scores that underwent a natural log transformation	Feeling uninformed (2 months post)	26	3.5 (95% CI 1.9 to 6.6)	25	3.7 (95% CI 1.9 to 7.0)	No difference
		Feeling unclear values (2 months post)	26	3.8 (95% CI 1.9 to 7.4)	25	4.8 (95% CI 2.4 to 9.5)	No difference
Gokce 2019	Decisional conflict score ≤ 25 or > 25	Feeling uninformed (immediately post-intervention)	58	≤ 25 48 (82.8%) > 25 10 (17.2%)	57	≤ 25 37 (64.9%) > 25 20 (35.1%)	P = 0.03
		Feeling unclear values (immediately post-intervention)	58	≤ 25 47 (81.1%) > 25 11 (18.9)	57	≤ 25 40 (70.2%) > 25 17 (29.8%)	No difference P = 0.17

Table 5. Decisional Conflict Score *(Continued)*

Karagiannis 2016 (in consult)	Decisional conflict subscale feeling uninformed with scale inverted (higher score = higher comfort)	Immediately post	101	78.8 (95% CI 60.9 to 96.8)	103	65.4 (95% CI 44.3 to 86.5)	No difference P = 0.19
Korteland 2017	Decisional conflict scale - post-intervention/pre-operatively	Uninformed	66	Median 8 (range 0 to 100)	70	Median 17 (range 0 to 100)	P < 0.05
		Unclear values	66	Median 28 (range 0 to 72)	70	Median 27 (range 0 to 93)	No difference
Krishnamurti 2019	Decisional conflict - change from baseline to 3 months	Uninformed	—	-14.65	—	1.75	P = 0.003
		Unclear values	—	-4.17	—	-4.39	No difference P = 0.97
LeBlanc 2015 (in consult)	Informed subscale	Immediately post	28	4.2 (95% CI 0 to 25)	36	20.8 (95% CI 0 to 33.3)	P = 0.14
	Values subscale	Immediately post	28	16.7 (95% CI 0 to 25)	36	25.0 (95% CI 8.3 to 33.3)	P = 0.25
Mathieu 2010	Based on approaches suggested by Marteau et al (informed choice)	Immediately after intervention	91	71%	110	64%	P = 0.24
Perez-Lacasta 2019	Decisional conflict subscales low-literacy version	Feeling uninformed (2 to 4 weeks post-intervention)	203	18.56 (SD not reported)	197	28.26 (SD not reported)	P = 0.002
		Unclear values (2 to 4 weeks post-intervention)	203	14.16 (SD not reported)	197	18.02 (SD not reported)	P = 0.157
Singh 2019	Decisional conflict subscales low literacy version - change from baseline to immediately post intervention	Uninformed	151	30.6 (SD 40.6)	147	21.7 (SD 33.9)	P = 0.04
		Unclear values	151	27.2 (SD 41.8)	147	16.8 (SD 37.6)	P = 0.03
Van Peperstraten 2010	15-item questionnaire (1 to 5) - informed (includes some items from DCS)	Post-intervention, pre-IVF	124	77.5	128	87.5	P = 0.001

Table 5. Decisional Conflict Score *(Continued)*

Weymiller 2007 (in consult)	Informed subscale	Administered during consultation	52	-17.3 (95% CI -22.6 to -12.0)	46	—	Mean difference indicates statistically significantly lower decisional conflict for decision aid compared to usual care.
		Administered prior to consultation	52	-6.6 (95% CI -14.3 to -1.1)	46	—	
	Values subscale	Immediately post	52	-8.5 (95% CI -15.7 to -1.3)	46		

CI : confidence interval; **DA** : decision aid; **DCS** : Decisional Conflict Scale; **IQR** : interquartile range; **IVF** : in vitro fertilization; **SD** : standard deviation.

Table 6. Participation in decision-making

Study	Scale used	Timing	N decision **aid**	**Decision aid - mean**	**N comparison**	**Comparison - mean**	**Notes**
Allen 2010	Control preferences - patients choosing active/collaborative decision-making	Post-intervention	291	95%	334	92%	No difference
	Control preferences did not change	Post-intervention	291	92%	334	87%	No difference
	Control preferences changed to passive	Post-intervention	291	3%	334	5%	No difference
	Control preferences changed to active/collaborative	Post-intervention	291	3%	334	7%	No difference
Aoki 2019 (in consult)	COMRADE used to measure patients' perceived involvement in decisions	Post-intervention	32	88.0 median; 9 IQR	53	76.0 median; 7 IQR	P < 0.001
Cuypers 2018	Problem-Solving Decision-Making Scale (perceived role)	Post-consultation	235	3.6 (SD 0.9)	101	3.5 (SD 0.8)	No difference P = 0.5
Fisher 2020	Experienced preferred level of involvement in decisions ('yes' n (%))	Post-treatment decision 3 to 4 weeks Post-intervention	79	30 (38%)	72	28 (39%)	No difference OR 0.96 (95% CI 0.50 to 1.86)

Table 6. Participation in decision-making *(Continued)*

		3 months' post-decision follow-up	36	12 (33%)	47	15 (32%)	No difference OR 1.07 (95% CI 0.45 to 2.55)
Fraenkel 2015	COMRADE used to measure patients' perceived involvement in decisions	2 weeks post-intervention	60	Median 40.0 (IQR 26.5 to 43.0)	61	Median 35.0 (IQR 23.0 to 42.0)	No difference P = 0.1
Hamann 2006	COMRADE used to measure patients' perceived involvement in decisions	Post-consultation	49	79.5 (SD 18.6) 76.8 (SD 20.9)	58	69.7 (SD 20.0) 73.5 (SD 19.3)	Increased patient involvement in decision aid group post-intervention compared to usual care at baseline. At discharge there was no difference between groups.
Hanson 2011	Surrogates feeling somewhat or very involved in decision-making	Post-intervention	—	83%	—	77%	P = 0.18
Kostick 2018	Control Preferences Scale - match in control preferences over time	1 month post-intervention	27	48%	31	52%	No difference P = 1.0
Leighl 2011	Achieved decision involvement	Post-intervention	—	32%	—	35%	No difference
Loh 2007 (in consult)	Patients' perceived involvement in decision-making	Post-consultation	191	26.3 pre 28.0 post	96	24.5 pre 25.5 post	Improved patient participation from baseline to post exposure to the decision aid (P = 0.010) and in comparison to the usual care group (P = 0.003), but there was no change in the control group for the pre-post comparison
Oostendorp 2017 (In consultation)	Decision control (1 to 5)	1 week post-intervention	68	4.2 (SD 0.7)	40	4.3 (SD 0.6)	No difference
	Decision control (1 to 5)	8 weeks post-intervention	58	4.3 (SD 0.6)	33	4.3 (SD 0.6)	No difference

Table 6. Participation in decision-making *(Continued)*

	Problem-Solving Decision-Making Scale (perceived role) (1 to 5)	1 week post-intervention	68	3.1 (SD 1.0)	40	2.8 (SD 0.9)	No difference
	Problem-Solving Decision-Making Scale (perceived role) (1 to 5)	8 weeks post-intervention	58	2.9 (SD 1.0)	33	2.9 (SD 0.8)	No difference
	Perception of being offered a choice (yes/no)	1 week post-intervention	68	45 (66%)	40	26 (67%)	No difference
	Perception of being offered a choice (yes/no)	8 weeks post-intervention	58	41 (71%)	33	20 (61%)	No difference
	Perception of whether patient's opinion mattered (yes/no)	1 week post-intervention	68	51 (75%)	40	30 (77%)	No difference
	Perception of whether patient's opinion mattered (yes/no)	8 weeks post-intervention	58	47 (81%)	33	25 (76%)	No difference
Politi 2020a	Decision process (DQI subscale 0 to 100)	Post-consultation	60	65.1 (SD 21.5)	60	58.2 (SD 20.7)	No difference P = 0.06
Rubel 2010	Adapted from the Control Preferences Scale	Post-intervention	—	—	—	—	The total mean scores were: 2.74 (SD 1.25) (N = 99) pre and 2.83 (SD 1.16) (N = 199) post; no statistically significant difference
Schonberg 2020	Control Preferences Scale (merged Active Role and Collaborative Role)	Post-consultation	280	247 (88.1%)	256	208 (81.2%)	P = 0.02
Sheridan 2011	Patient participation: 'Any'	Immediately post	79	79%	78	51%	Absolute difference 28% (95% CI 9 to 45; P = 0.01)
	'None'	Immediately post	79	21%	78	49%	Absolute difference -28% (95% CI -45 to -9)
Singh 2019	Concordance between desired vs actual role using the Control Preferences Scale	Post-consultation	35	94%	33	85%	No difference P = 0.25

Table 6. Participation in decision-making *(Continued)*

Van Peperstraten 2010	Decision Evaluation scale (15 item questionnaire), Decision Control subscale	Post-consultation	124	85	128	87.5	P = 0.33

CI : confidence interval; **COMRADE** : Combined Outcome Measure for Risk communication And treatment Decision making Effectiveness; **DA** : decision aid; **DQI** : Decision Quality Index; **IQR** : interquartile range; **OR** : odds ratio; **SD** : standard deviation.

Table 7. Adverse events

Author	Item	N decision aid	Proportion or mean (SD)	N control	Proportion or mean (SD)	Notes
Decision regret						
Brown 2019	Decision Regret Scale at 1 and 3 months post-intervention	16	—	21	—	No difference - authors say likely measured too soon
Hanson 2011	5-item Decisional Regret Index	126	11.9	127	14.3	No difference P = 0.14
Korteland 2017	Decision Regret Scale 3 months postoperatively (proportion who experienced regret)	71	30%	67	36%	No difference P = 0.513
Krishnamurti 2019	Decision Regret Scale (out of 100) post decision	—	—	—	—	All had low levels of regret (n = 11) ranging from 0 to 25
Legare 2011	Proportion of patients with decisional regret	—	7%	—	9%	No difference P = 0.91
Mathers 2012	Decision Regret Scale at 6 months postintervention	95	44.63	80	44.57	No difference P = 0.872
McLean 2020	Decision Regret Scale (individual items) at 10 days postintervention. Proportion who who indicated "agreement" or "strong agreement". 'It was the right decision' 'I would make the same choice if I had to do it over again' 'The decision was a wise one'	9	6 (66.67) 7 (77.78) 7 (77.78)	5	5 (100.00) 4 (80.00) 3 (60.00)	No difference P = 0.48
Perez-Lacasta 2019	Anticipated regret (2 to 4 weeks post DA) Might later regret if do not screen • Strongly agree • Agree • Neither agree nor disagree • Disagree or strongly disagree	203	85 (41.9%) 68 (33.5%) 46 (22.7%) 4 (2%)	197	90 (45.7%) 65 (33%) 37 (18.8%) 5 (2.5%)	No difference P = 0.733
	Might later regret if do screen • Strongly agree	203	14 (6.9%) 49 (24.1%)	197	21 (10.7%) 40 (20.3%)	No difference P = 0.246

Table 7. Adverse events *(Continued)*

	• Agree • Neither agree nor disagree • Disagree or strongly disagree		77 (37.9%) 63 (31%)		65 (33%) 71 (36%)	
Emotional distress						
Cox 2019	Post-traumatic stress symptom inventory (range 10 to 70 points, with higher scores indicating greater distress) • 3 days post-intervention • 3 months post-intervention • 6 months post-intervention	409 161 154	26.6 (24.5 to 28.7) 24.8 (22.4 to 27.1) 24.5 (22.0 to 27.1)	426 173 172	27.0 (24.8 to 29.3) 26.4 (24.1 to 28.6) 25.4 (23.0 to 27.7)	No difference P = 0.91 P = 0.42 P = 0.83
Lewis 2010	Intrusive thoughts - 3 items, 4-point scale • Not at all • Sometimes • Often	210	139 (66.2%) 66 (31.4%) 5 (2.4%)	231	157 (68.0%) 69 (29.9%) 5 (2.2%)	No difference P = 0.92
McCaffery 2010	Intrusive thoughts - measured using 1 item from the impact of events scale	77	43%	71	32%	No difference
McIlvennan 2018	Perceived stress scale (0 to 40)	50	12.7 (1.24)	78	12.1 (1.00)	No difference P = 0.71
Metcalfe 2017	Impact of Event Scale • 3 months post-intervention • 6 months post-intervention • 12 months post-intervention	—	24.6 (13.9) 9.3 (13.2) 17.7 (14.7)	—	26.8 (12.8) 25.2 (14.5) 22.4 (15.5)	P = 0.33 P = 0.01 P = 0.05

DA : decision aid; **SD** : standard deviation

Table 8. Proportion undecided

Study	Scale used	Timing	N decision **aid**	**Decision aid - mean**	**N comparison**	**Comparison - mean**	**Notes**
Arterburn 2011	Single item asking which option they were leaning towards. Proportion who were "unsure"	Immediately post-intervention, 3 months post-intervention	—	—	—	—	No difference
Kasper 2008	Single item - ranging from '0 = completely undecided' to '100 = made my decision'	—	—	—	—	—	No difference
Krishnamurti 2019	Stage of Decision Making survey (10 multiple choice questions). Six-point Likert scale ranging from, “I haven’t thought about the decision,” to “I have made my decision and am unlikely to change my mind.”	3 and 6 months post-intervention	—	—	—	—	No difference
Metcalfe 2017	15-point scale: 1 = not leaning toward a breast cancer prevention option, 8 = unsure, and 15 = leaning toward a breast cancer prevention option. A total score of 6 to 10 was classified as undecided. • Prophylactic mastectomy • Prophylactic oophorectomy • Tamoxifen	3 months post-intervention	72	19 (26.4%) 8 (11.3%) 15 (20.8%)	69	15 (21.7%) 2 (2.9%) 15 (21.7%)	P = 0.52 P = 0.05 P = 0.89
Sawka 2012	Answer "I don't know" to question "I favor taking adjuvant radioactive iodine"	Immediately post - treatment preference	37	10.8%	37	21.6%	—
		6.3 months (mean) post - actual decision	37	13.5%	37	8.1%	—
	Answer "I don't know" to question "I favor not taking adjuvant radioactive iodine"	Immediately post - treatment preference	37	43.2%	37	37.8%	—
		6.3 months (mean) post - actual decision	37	40.5%	37	51.4%	—

DA : decision aid

Table 9. Patient-clinician communication

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Berger-Hoger 2019	MAPPIN-O $_{dyad}$ Total	Analysis of the consultation using video-recordings	36	2.29 (95% CI 1.77 to 2.81)	28	0.42 (SD 0.51) (95% CI 0.0 to 0.88)	Significantly higher in the intervention arm P < 0.0001
	MAPPIN-O $_{patient}$ Total	Analysis of the consultation using video-recordings	36	1.78 (95% CI 1.40 to 2.16)	28	0.30 (95% CI 0.0 to 0.68)	No difference 1.48 (95% CI 1.00 to 1.95)
	MAPPIN-O $_{professionals}$ Total	Analysis of the consultation using video-recordings	36	2.23 (95% CI 1.79 to 2.67)	28	0.32 (95% CI 0.0 to 0.68)	Significantly higher in the intervention arm 1.91 (95% CI 1.42 to 2.40)
	MAPPIN-Q $_{physician}$	Physician reported immediately post consultation	36	3.42 (95% CI 3.09 to 3.74)	28	3.44 (95% CI 3.04 to 3.83)	No difference 0.02 (95% CI -0.47 to 0.43)
	MAPPIN-Q $_{patient}$	Patient-reported immediately post consultation	36	3.87 (95% CI 3.78 to 3.96)	28	3.82 (95% CI 3.68 to 3.96)	No difference 0.05 (95% CI -0.10 to 0.20)
Cox 2019	Quality of communication questionnaire (range 0 to 110 points, with higher scores indicating better communication)	3 days post-intervention	121	91.9 (95% CI 89.1 to 94.7)	125	90.3 (95% CI 87.1 to 93.5)	No difference P = 0.149
Coylewright 2016 (in consult)	OPTION Scale	Analysis of the consultation using video-recordings	34	21.3%	20	16.0%	No difference P = 0.071

Table 9. Patient-clinician communication *(Continued)*

Durand 2021 (in consult)	Decision Quality Instrument decision process subscale	Immediately post consultation	66	80.9 (SD 17.7)	257	65.3 (SD 30.1)	Significantly higher in the intervention arm P = 0.01
	CollaboRATE-SDM (dichotomized grouping participants scoring 9 on all 3 items versus all others)	Patient-reported immediately post consultation	59	46 (78.0%)	216	126 (58.3%)	No effect of the intervention
Fraenkel 2012	Discussed risk of stroke	Immediately post	69	71%	66	12%	P < 0.001
	Discussed risk of major bleeding	Immediately post	69	69%	66	20%	P < 0.001
Hanson 2011	Discussed feeding with physician, nurse clinician, or physician's assistant	3 months	126	46%	127	33%	P = 0.04
	Discussed feeding with other nursing home staff	3 months	126	64%	127	71%	P = 0.42
Ibrahim 2013	Discussed knee pain with primary care doctor	Patient-reported within 1 year of intervention	168 + 163	92%	167	85%	P = 0.007
Kostick 2018	CollaboRATE-SDM	Patient-reported 1 month post-intervention	26	90.4 (SD 14.3)	31	89.8 (SD 17.2)	No difference P = 0.94
	SDM-9	Patient-reported 1 month post-intervention	25	87.5 (SD 12.8)	31	85.2 (SD 15.0)	No difference P = 0.74
Kunneman 2020 (in consult)	Quality of communication (The Consumer Assessment of Healthcare Providers and Systems Clinician and Group Survey with 3 subscales: Easy to understand, Listens carefully, Shows respect)	Patient-reported immediately post consultation	432 430 428	431 (99.8%) 428 (99.5%) 426 (99.5%)	425 427 427	422 (99.3%) 427 (100%) 427 (100%)	High in both groups
Lepore 2012	Discussed PSA testing with physician post-intervention	8 months post-intervention	215	15.8%	216	8.3%	P < 0.001
Lewis 2018	Discussed colorectal cancer screening	Patient-reported immediately post consultation	209	58.4%	209	41.6%	P < 0.001

Table 9. Patient-clinician communication *(Continued)*

	Patient initiated screening discussion	Patient-reported immediately post consultation	120	61.7%	87	41.4%	P = 0.004
Madden 2020	Discussed contraception with provider	Patient-reported immediately post consultation	161	96.9%	80	97.5%	No difference P = 0.79
McGrath 2017	Perceived ability to discuss concerns and values/preferences with the doctor (0 to 8 scale; not very able to very able)	Patient-reported 2 weeks post-intervention	30	6.3 (2.04)	37	6.95 (1.43)	No difference P = 0.20
Meier 2019 (in consult)	SDM-Q-9	Patient-reported immediately post consultation	51	Median 88.89 (SE 1.84)	48	Median 90.74 (SE 1.92)	No difference P = 0.845
Miller 2018	Discussed screening with provider	Patient-reported 1 day post consultation	197	150 (76%)	213	103 (48%)	P < 0.001
Montori 2011 (in consult)	OPTION 100-point scale	Analysis of the consultation using video-recorded consultations	38	49.8	32	27.3	P < 0.001
Politi 2020a	CollaboRATE (% with top score)	Patient-reported immediately post consultation	60	58.9%	60	62.7%	P = 0.681
Schonberg 2020	Discussed mammography with doctor	Analysis of consultation notes 6 months post	279	146 (52.3%)	260	111 (42.7%)	No difference RR 1.16 (95% CI 0.95 to 1.42)
Schott 2021 (in consult)	CollaboRATE 3-item: dichotomized as "every effort" and "not every effort"	Patient-reported immediately post consult	32	20 (62.5%)	32	22 (68.75%)	No difference
Sheridan 2006	Discussed CHD with doctor	Patient-reported immediately post	16/41 decision aid pre-consultation with summary report to bring to consultation	—	8/34 usual care	—	Absolute difference 16% (95% CI -4 to 37)

Table 9. Patient-clinician communication *(Continued)*

	Plan to reduce CHD risk and discussed with doctor	Patient-reported immediately post	15/41 decision aid pre-consultation with summary report to bring to consultation	—	8/34 usual care	—	Absolute difference 13% (95% CI -7 to 34)
	Plan to reduce CHD risk and not discussed with doctor	Patient-reported immediately post	37/41 decision aid pre-consultation with summary report to bring to consultation	—	25/34 usual care	—	Absolute difference 16% (95% CI -1 to 33)
Sheridan 2011	Had CHD discussion with provider	Patient-reported immediately post	79	89%	78	58%	Absolute difference 31% (95% CI 15 to 45; P < 0.001)
	Patient-raised discussion	Patient-reported immediately post	79	63%	78	35%	Absolute difference 28% (95% CI 9 to 45; P = 0.02)
	Modified Healthcare Climate Questionnaire: 1. "My provider provided me with choices and options about lowering my chances of heart disease"	Patient-reported immediately post	79	91%	78	76%	Absolute difference 15% (95% CI -0.1 to 31; P = 0.02)
	2. "My provider understands how I see things with respect to lowering my chances of heart disease."	Patient-reported immediately post	79	95%	78	86%	Absolute difference 9% (95% CI -7 to 25; P = 0.21)
	3. "My provider conveyed confidence in my ability to make changes regarding lowering my chances of heart disease"	Patient-reported immediately post	79	88%	78	77%	Absolute difference 11% (95% CI -5 to 27; P = 0.15)
	4. "My provider encouraged me to ask questions"	Patient-reported immediately post	79	78%	78	67%	Absolute difference 11% (95% CI -4% to 27%; P = 0.13)

Table 9. Patient-clinician communication *(Continued)*

	5. "My provider listened to how I would like to do things"	Patient-reported immediately post	79	92%	78	71%	Absolute difference 21% (CI 95% 6 to 37; P < 0.01)
	6. "My provider tried to understanding how I see things before suggesting new ways to lower my chances of heart disease."	Patient-reported immediately post	79	84%	78	69%	Absolute difference 15% (CI 95% -0.3 to 31; P = 0.05)
Singh 2019	Interpersonal Processes of Care short form - 18 items	Patient-reported 3 months post	—	83.6 (SD 7.7)	—	83.1 (SD 7.3)	No difference P = 0.50
	Active Patient Participation Coding Scheme (APPC)	Analysis of audio recordings		8.1 (SD 7.2)	—	9.2 (SD 7.3)	No difference P = 0.80
	Patient-centered communication by the doctor using APPC	Analysis of audio recordings	—	5.1 (SD 2.1)	—	3.7 (SD 1.9)	No difference P = 0.06
Smallwood 2017	4 yes/no items scored 0 to 4 (follow-up discussion with a primary care physician, whether alternative treatment options were provided, discussed reasons for and against taking medication, and asked what they wanted to do regarding treatment)	Patient-reported 3 months post, based on chart review	29	3.19 (SD 1.2)	21	2.91 (SD 1.3)	No difference P = 0.566
Stubenrouch 2022	SDM-Q-9	Patient-reported immediately post-intervention/ consultation	171	Median 93.3% (IQR 82.2% to 100%)	138	93.3% (IQR 79.4% to 100%)	No difference P = 0.71
	CollaboRATE	Patient-reported immediately post-intervention/ consultation	171	Median 83.3% (IQR 80.0% to 90.0%)	137	Median 86.7% (80.0% to 90.0%)	No difference P = 0.61
	SDM-Q-Doc	Clinician-reported immediately post consultation	175	Median 80% (IQR 71.1 to 86.7%)	143	Median 73.3% (IQR 64.4 to 84.4%)	P = 0.002
Tebb 2021	Discussed contraception with provider	Patient-reported 48 hours post-intervention	320	285 (89.1%)	436	301 (69.0%)	No difference

Table 9. Patient-clinician communication *(Continued)*

Weymiller 2007 (in consult)	OPTION Scale	Analysis of the consultation using video-recorded consultations	1/2 used decision aid prior to consultation and 1/2 used it during consultation	—	Usual care	—	Greater patient participation (MD 4.4, 95% CI 2.9 to 6.0) in decision aid compared to usual care group
Wyld 2021 (in consult)	CollaboRATE	Patient-reported after decision-making	71	Median 100 (IQR 96 to 100)	77	Median 100 (IQR 93 to 100)	No difference P = 0.729

CHD : coronary heart disease; **CI** : confidence interval; **DA** : decision aid; **DCS** : decisional conflict scale; **ICC** : intraclass correlation coefficient; **IQR** : interquartile range; **MD** : mean difference; **OPTION scale** : observing patient involvement scale; **RR** : risk ratio; **SD** : standard deviation

Table 10. Satisfaction with the decision-making process

Study	Scale used	Timing	N decision **aid**	**Decision aid - mean**	**N comparison**	**Comparison - mean**	**Notes**
Satisfaction with the decision-making process							
Case 2019	Satisfaction with decision-making process (1 for strongly disagree to 5 for strongly agree)	Post consultation	43	—	48	—	High satisfaction with no difference by group P = 0.42
Hess 2012 (in consult)	Satisfaction with decision process (0 for strongly agree to 5 for strongly disagree)	—	101	—	103	—	Patients in DA group reported greater satisfaction with the DM process (strongly agree, 61% DA vs 40% usual care)
Kunneman 2020 (in consult)	Satisfaction with the information-sharing approach (proportion who would recommend to others)	Post consultation	429	390 (90.9%)	425	378 (88.9%)	No difference Effect size 1.0 (0.97 to 1.1)
Vodermaier 2009	Satisfied with process	1 week follow-up	53	42	56	50	High satisfaction with no difference by group

Table 10. Satisfaction with the decision-making process *(Continued)*

Satisfaction with participating in decision-making							
Kennedy 2002	Measured satisfaction with opportunities to participate in decision-making using a single item	—	—	—	—	—	Compared to usual care, women who received the decision aid followed by nurse coaching were significantly more satisfied with the opportunities to participate in decision-making (OR 1.5, 95% CI 1.1 to 2.0).
Satisfaction with the information provided							
Cuypers 2018	Satisfaction with Cancer Information Profile (SCIP)	Post consultation	235	3.8 (SD 0.8)	101	4.1 (0.6)	P = 0.04
Hess 2016 (in consult)	Amount of information was just right	Post consultation	441	416 (94%)	438	401 (92%)	P = 0.133
	Information received was extremely clear	Post consultation	440	335 (76%)	438	296 (68%)	P = 0.011
	Information received was extremely helpful	Post consultation	441	320 (73%)	438	303 (69%)	P = 0.506
	Would recommend method to others	Post consultation	440	387 (88%)	437	349 (80%)	P = 0.004
	Would use for other decisions	Post consultation	440	346 (79%)	437	335 (77%)	P = 0.813
Hess 2018 (in consult)	Amount of information	Post consultation	476	455 (92%)	469	441 (92%)	P = 0.29
	Clarity of information	Post consultation	476	382 (78%)	466	342 (72%)	P = 0.02

Table 10. Satisfaction with the decision-making process *(Continued)*

	Helpfulness of the information	Post consultation	478	377 (77%)	468	344 (72%)	P = 0.05
	Would recommend to others	Post consultation	479	376 (76%)	469	343 (72%)	P = 0.08
	Would want to use for other decisions	Post consultation	478	327 (66%)	471	290 (61%)	P = 0.04
Kleiss 2021	Understood all received information and felt adequately educated to make a decision	2 weeks post consultation	52	44 (84%)	49	42 (86%)	P = 0.99
LeBlanc 2015 (in consult)	Amount of information was just right	Post consultation	29	25 (86%)	37	34 (92%)	P = 0.69
	Information received was clear	Post consultation	27	17 (63%)	36	26 (72%)	P = 0.43
	Information received was helpful	Post consultation	28	21 (75%)	34	23 (68%)	P = 0.53
	Would recommend method to others	Post consultation	28	24 (86%)	35	27 (77%)	P = 0.52
LeBlanc 2015b (in consult)	Right amount of information given	Post consultation	132	124 (92.5%)	109	102 (91.9%)	P = 0.81
	Information given was extremely clear	Post consultation	132	92 (68.7%)	109	64 (58.7%)	P = 0.09
	Information given was extremely helpful	Post consultation	132	92 (69.2%)	109	57 (52.8%)	P = 0.01
	Strongly desire to receive information this way for other treatment decisions	Post consultation	132	90 (68.2%)	109	55 (50.5%)	P = 0.005
	Strongly recommend the way information was shared to others	Post consultation	132	104 (77.6%)	109	65 (59.1%)	P = 0.002
Laupacis 2006	Satisfaction with information received subscale 4-item (0 to 100; low to high)	Average 10 days	54	76 (15.5 SD)	56	59 (23.3 SD)	P = 0.001

Table 10. Satisfaction with the decision-making process *(Continued)*

McLean 2020	Information about treatment options good or excellent	Post-intervention	16	16 (100%)	15	10 (66.67)	P = 0.04
	Amount of information was just right	Post-intervention	16	13 (81.25%)	15	11 (73.33)	P = 0.45
	Information was useful when making a decision	Post-intervention	16	16 (100%)	15	11 (73.33)	P = 0.05
	Information made it easy to make a decision	Post-intervention	16	16 (100%)	15	10 (66.67)	P = 0.04
Montori 2011 (in consult)	(7-point scales) *Participants' satisfaction with knowledge transfer* • Amount of information • Clarity of information • Helpfulness of the information • Would want other decisions • Recommend to others	Post-intervention	49	6.6 6 6 6.1 6.4	46	6.3 6 5.8 5.8 6.2	P = 0.798 P = 0.296 P = 0.624 P = 0.248 P = 0.435
	Clinicians' satisfaction with knowledge transfer • Helpfulness of the information • Would want other decisions • Recommend to others	Post-intervention	39	5.8 6.1 5.9	33	5.2 4.9 4.8	P = 0.006 P < 0.001 P < 0.001
Oakley 2006	Satisfaction with information about medicines	4 months post	16	10.4 (SD 2.9)	17	10.1 (SD 2.2)	No difference
Oostendorp 2017 (in consult)	Amount of information (1 to 7 from too little - too much)	1 week post 8 weeks post	68 58	3.8 (0.7) 3.8 (0.5)	40 33	4.0 (0.4) 3.9 (0.3)	No difference
	Undesired information (yes/no)	1 week post	68	6 (10%)	40	7 (18%)	No difference P = 0.244
	Satisfaction with quality of information for severe adverse events, tumor response,	1 week post 8 weeks post	68 58	—	40 33	—	No difference for all items measured

Table 10. Satisfaction with the decision-making process *(Continued)*

	and survival (1 to 6 from not satisfied - very much satisfied)						
	Balanced presentation (1 to 5 from clearly in favor of chemotherapy plus best supportive care to clearly in favor of best supportive care alone)	1 week post	68	2.7 (0.7)	40	2.4 (1.1)	No difference 0.201
Perez-Lacasta 2019	Length • Too long • Just right • Too short	2 to 4 weeks post-intervention	203	12.3% 82.8% 4.9%	197	6.1% 83.2% 10.7%	P = 0.008
	Balance • Clearly slanted • A little slanted • Completely balanced	2 to 4 weeks post-intervention	203	26.6% 16.7% 47.3%	197	42.6% 14.2% 42.6%	P < 0.001
	Easy to understand (strongly agree/agree)	2 to 4 weeks post-intervention	203	91%	197	94%	P = 0.002
	Helpful in decision-making (strongly agree/agree)	2 to 4 weeks post-intervention	203	76%	197	86%	P = 0.076
Roberto 2020	Amount of information (too much, too little, fair)	7 to 10 days post-intervention	468	3.6% 4.1% 92.3%	517	1.2% 6.0% 92.8%	P = 0.01
	Clear information	7 to 10 days post-intervention	469	92.5%	517	91.3%	P = 0.47
	Balanced information	7 to 10 days post-intervention	469	36.9%	517	33.7%	P = 0.37

Table 10. Satisfaction with the decision-making process *(Continued)*

	Helped to decide	7 to 10 days post-intervention	469	70.4%	517	69.6%	P = 0.85
	Recommend to others	7 to 10 days post-intervention	469	96.8%	517	98.1%	P = 0.21
van Dijk 2021	Satisfaction with the given information (0 to 10 scale; low to high)	Post consultation	66	8.6 (SD 1.1)	65	7.6 (SD 1.8)	P = 0.00
Varelas 2020	Satisfaction with information provided (15 to 60 scale; low to high)	Post consultation	13	56.8 (SD 4.2)	13	47.9 (SD 8.2)	P = 0.0017
Satisfaction with the clinician							
Karagiannis 2016 (in consult)	Satisfaction with conversation with clinician • Strongly agree • Agree • Neither agree nor disagree • Disagree • Strongly disagree	Post consultation	101	66 (65.3%) 31 (30.7%) 4 (4.0%) 0 (0%) 0 (0%)	103	58 (56.3%) 44 (42.7%) 1 (1.0%) 0 (0%) 0 (0%)	No difference P = 0.54
Kleiss 2021	Satisfaction with the visit (11-point scale; low to high)	2 weeks post consultation	52	9.2 (SD 1.4)	49	8.8 (SD 1.7)	No difference P = 0.216
Madden 2020	Satisfaction with counseling from the provider and visit overall, 5-point scale (1 to 5; low to high)	Post consultation	161	—	80	—	High satisfaction with no difference by group
Laupacis 2006	Satisfaction with practitioner treatment during decision process subscale 4-item (0 to 100; low to high)	Average 10 days	54	69 (25.3 SD)	56	54 (26.7 SD)	P = 0.004
Miller 2005	Satisfaction with cancer information service 1-item (1 to 5; low to high)	2 weeks	—	4.37 (0.84 SD)	—	4.38 (0.86 SD)	No difference
		6 months	—	4.51 (0.75 SD)	—	4.51 (0.64 SD)	No difference
van Dijk 2021	Satisfaction with physician (0 to 10 scale; low to high)	Post consultation	66	8.9 (SD 0.9)	65	8.3 (SD 1.7)	P = 0.01

Table 10. Satisfaction with the decision-making process *(Continued)*

Vodermaier 2009	• Physician helped me understand • Physician understood important to me • Physician answered questions • Satisfied with involvement • Satisfied with physician's involvement	1 week follow-up	53	49 (92.5%) 47 47 44 36	56	53 (94.6%) 50 51 45 36	High satisfaction with no difference by group

CI : confidence interval; **DA** : decision aid; **DM** : decision-making; **OR** : odds ratio; **SD** : standard deviation.

Table 11. Preparation for decision-making

Study	Scale used	Timing	N decision **aid**	**Decision aid - mean**	**N comparison**	**Comparison - mean**	**Notes**
Fraenkel 2007	Preparation for Decision Making Scale	Pre-consultation	43	35 (median)	40	20.5 (median)	P < 0.001
Fung 2021	Preparation for Decision Making Scale	Post-intervention	36	87.8 (SD not reported)	37	66.2 (SD not reported)	P < 0.001
Krishnamurti 2019	Preparation for Decision Making Scale (difference in change in preparedness)	3 months post-intervention	23	—	19	—	No difference P = 0.16
		6 months post-intervention	22	—	17	—	P < 0.001
Lewis 2018	Prepared for individualized decision-making (proportion having adequate knowledge (≥ 3 of 5 questions correct) and adequately clarified values (a score of ≤ 25 on the unclear values subscale, range 0 to 100))	Post-intervention; pre-consultation	212	67.6%	210	31.9%	P < 0.001
Manne 2020	Preparation for Decision Making Scale	2 to 4 weeks after surgery	46	3.46 (0.61)	47	3.42 (0.55)	No difference
McLean 2020	Preparation for Decision Making Scale Helped you recognize that a decision needs to be made	Post-intervention	16	11 (68.75)	15	6 (40.00)	P < 0.01

Table 11. Preparation for decision-making *(Continued)*

	Prepared you to make a better decision	Post-intervention	16	14 (87.50)	15	4 (26.67)	
	Helped you think about the pros and cons of each option	Post-intervention	16	14 (87.50)	15	4 (26.67)	
	Helped you think about which pros and cons are most important	Post-intervention	16	13 (81.25)	15	6 (40.00)	
	Helped you know that the decision depends on what matters most to you	Post-intervention	16	13 (81.25)	15	8 (53.33)	
	Helped you organize your own thoughts about the decision	Post-intervention	16	9 (56.25)	15	6 (40.00)	
	Helped you think about how involved you want to be in this decision	Post-intervention	16	11 (68.75)	15	10 (66.67)	
	Helped you identify questions you want to ask your physician	Post-intervention	16	11 (68.75)	15	9 (60.00)	
	Prepared you to talk to your physician about what matters most to you	Post-intervention	16	14 (87.50)	15	10 (66.67)	
	Prepared you for a follow-up visit with your physician	Post-intervention	16	13 (81.25)	15	8 (53.33)	
Stacey 2014a	Preparation for Decision Making Scale item (5-point scale from: 1 not at all to 5 a great deal) 'Help recognize decision to be made'	Post-intervention; pre-consultation	66	4.12 (SD 1.21)	64	3.78 (SD 1.25)	No difference
	Preparation for Decision Making Scale item 'Help know decision depends on what matters most'	Post-intervention; pre-consultation	66	4.48 (SD 0.85)	64	4.14 (SD 1.10)	No difference
	Preparation for Decision Making Scale item 'Help think about how involved you want to be in decision'	Post-intervention; pre-consultation	66	4.48 (SD 0.81)	64	4.25 (SD 1.05)	No difference
	Preparation for Decision Making Scale item	Post-intervention; pre-consultation	66	4.36 (SD 0.91)	64	4.23 (SD 1.04)	No difference

Table 11. Preparation for decision-making *(Continued)*

	'Prepare you to talk to your doctor about what matters most'						
Stacey 2016	Preparation for Decision Making Scale (4 of 10 items; 5-point scale from: 1 not at all to 5 a great deal) Help recognize decision to be made	2 weeks post-intervention; pre-consultation	156	4.16 (SD 1.01)	157	3.91 (1.17)	No difference 0.070
	Help know decision depends on what matters most	2 weeks post-intervention; pre-consultation	156	4.40 (SD 0.84)	157	4.03 (1.14)	0.003
	Help think about how involved you want to be in decision	2 weeks post-intervention; pre-consultation	156	4.40 (SD 0.88)	157	4.27 (1.05)	No difference 0.426
	Prepare to talk to your doctor about what matters most	2 weeks post-intervention; pre-consultation	156	4.47 (SD 0.68)	157	4.10 (1.14)	0.014

DA : decision aid; **SD:** standard deviation.

Table 12. Choice

Study	Type of comparison	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Surgery - elective major surgery						
Ibrahim 2013	Preference (knee replacement). Odds ratio of increased willingness at 1 month (5-point scale; higher score indicates higher willingness)	162	OR 2.46	161	OR 1.79	No difference
Korteland 2017	Actual choice (heart valve prosthesis type) - mechanical vs biological	67	23.9%	71	21.1%	No difference
Luan 2016	Preference (breast reconstruction) - prosthetic vs autologous or combined	8	2 (25%)	8	1 (13%)	No difference
Surgery - elective more minor surgery						
Carroll 2017	Actual choice (ICD replacement)	41	24	41	24	No difference
Lewis 2021	Actual choice (ICD replacement) • 2 to 4 weeks • 6 months • 12 months	14 13 12	0 4 8	15 15 14	0 7 10	No difference
Wallace 2021	Actual choice (ICD implanted)	15	6	6	4	No difference
Hanson 2011	Actual choice (feeding tube)	127	1	129	3	No difference
Love 2016	Preference (skin cancer) • Conventional excision • Electrodessication and curettage • Imiquimod cream	13	50.0% 33.3% 16.7%	16	62.5% 25.0% 6.25%	No difference
Wilkens 2019	Preference (trapeziometacarpal arthritis)	45	3	45	3	No difference
Wong 2006	Actual choice (abortion)	—	—	—	—	No difference
Ye 2021	Preference (cataract surgery) - definitely or likely	386	87	387	132	Intervention decreased preference for surgery. P < 0.001
Screening - breast cancer genetic testing						
Miller 2005	Preference	—	—	—	—	Intervention decreased intention for genetic testing in women at av-

Table 12. Choice *(Continued)*

						erage risk; increased in women at high risk
Screening - breast screening						
Mathieu 2010	Preference of women who were decided	96	52%	127	65%	P = 0.05
Screening - cardiac stress testing						
Hess 2012 (in consult)	Actual choice	101	58%	100	77%	P < 0.001
Screening - colorectal cancer						
Pereste-lo-Perez 2019	Preference • Fecal occult blood test • Colonoscopy	53	96.2% 94.3%	52	86.5% 84.6%	No difference between groups after correcting for attenuation
Screening - cervical cancer						
Elliott 2022	Actual choice	3080	35.8%	4402	37.7%	No difference P = 0.55
Screening - diabetes						
Marteau 2010	Actual choice	633	353	639	368	P = 0.51
Mann E 2010	Preference	273	—	134	—	No difference
Screening - lung cancer						
Elliott 2022	Actual choice	459	20.2%	781	23.6%	No difference P = 0.55
Volk 2020	Actual choice	67	85.1%	85	80.0%	No difference P = 0.60
Screening - prenatal						
Bekker 2004 (in consult)	Actual choice	—	—	—	—	No difference
Nagle 2008	Actual choice	—	—	—	—	No difference
Screening - prostate cancer testing						
Frosch 2008a	Actual choice	—	—	—	—	The experimental interventions led to significant reductions in requests for prostate-specific antigen tests (~2 times greater decline).

Table 12. Choice *(Continued)*

Lepore 2012	Actual choice 2 years postintervention	215	62.7%	216	66.7%	No difference Exp (B) = 0.829 CI 95% 0.564 to 1.218
Williams 2013	Actual choice	—	—	—	—	No difference (P > 0.3)
Lepore 2012	Preference	215	80.9%	216	80.1%	No difference Exp (B) = 0.994 95% CI 0.614 to 1.610
Diagnostic testing - cardiac testing for chest pain						
Hess 2016	Actual choice	451	38.1%	447	45.6%	P = 0.013
Diagnostic testing - computerized tomography (CT) scan for brain injury						
Hess 2018	Actual choice	493	22%	478	24%	No difference
Diagnostic testing - prenatal genetic testing						
Kuppermann 2014	Invasive diagnostic testing without screening test	357	11 (3.0%)	353	16 (4.6%)	P = 0.37
	Screening test followed by invasive diagnostic test	357	10 (2.9%)	353	27 (7.7%)	Not reported
Medication - antibiotics for upper respiratory infections						
Legare 2011 (in consult)	Actual choice	81	33	70	49	P = 0.08
Legare 2012 (in consult)	Actual choice	—	27.2%	—	52.2%	Absolute difference 25.0; RR 0.5 (95% CI 0.3 to 0.7)
Medication - atrial fibrillation anti-thrombosis - uptake						
Man-Son-Hing 1999	Actual choice	—	—	—	—	25% decrease in DA group, not statistically significant
McAlister 2005	Actual choice	—	—	—	—	No difference
Schott 2021	Actual choice	—	—	—	—	No difference
Thomson 2007 (in consult)	Actual choice	—	93.8%	—	25%	RR 0.27 (95% CI 0.11 to 0.63)
Medication - autoimmune disease						

Table 12. Choice *(Continued)*

Fraenkel 2015	Actual choice (rheumatoid arthritis)	60	73%	61	72%	No difference
Singh 2019	Preferred choice (lupus nephritis)	151	72.9%	147	59.9%	P = 0.01
Medication - breast cancer prevention						
Crew 2022	Actual choice	115	3	131	5	No difference
Fagerlin 2011	Actual choice	383	0.5%	102	0%	No difference
Medication - cardiovascular disease prevention						
Bonner 2022	1 (strongly disagree) to 7 (strongly agree) • Change lifestyle • Take medication • Take supplements	285	4.7 (1.2) 2.5 (1.4) 3.1 (1.6)	290	4.5 (1.4) 2.5 (1.4) 3.2 (1.6)	No difference No difference No difference
Sheridan 2011	DA versus usual care. Any effective CHD risk reducing strategy	79	63%	78	42%	Absolute difference 21%, 95% CI 5 to 37
	Blood pressure medication, if hypertensive (n = 55)	—	26%	—	29%	Absolute difference -3%, 95% CI -30 to 25
	Cholesterol medication, if abnormal cholesterol (n = 69)	—	39%	—	9%	Absolute difference 30%, 95% CI 14 to 46
	Smoking cessation, if smoking (n = 21)	—	80%	—	50%	Absolute difference 30%, 95% CI -16 to 76
	Aspirin, if CHD risk > 6% (n = 140)	—	43%	—	24%	Absolute difference 19%, 95% CI -1 to 39
	Diet low in saturated fat	79	29%	78	40%	Absolute difference -11%, 95% CI -27 to 6
	Regular exercise	79	53%	78	54%	Absolute difference -1%, 95% CI -17 to 16
Medication - chemotherapy						
Leighl 2011	For advanced cancer	107	77%	100	71%	No difference
Oostendorp 2017	For advanced cancer	57	88%	31	84%	No difference
Whelan 2003 (in consult)	For early breast cancer	—	—	—	—	No difference
Wyld 2021	For adjuvant therapy	526	69	547	99	P = 0.013

Table 12. Choice *(Continued)*

Medication - diabetes management insulin						
Mathers 2012	Preference for insulin	92	18.5%	78	11.5%	P = 0.41
Medication - hypertension						
Montgomery 2003	Uptake	—	—	—	—	No difference
Medication - menopausal symptom treatment						
Murray 2001b	Uptake hormone therapy	—	—	—	—	8% decrease in DA group, not statistically significant
Legare 2008a	Preference for natural health products		41%		41%	No difference
Medication - multiple sclerosis immunotherapy						
Kasper 2008	Uptake	—	—	—	—	No difference
Medication - osteoporosis						
LeBlanc 2015 (in consult)	Preference Prescription during encounter	29 29	12 (41%) 13 (41%)	38 38	11 (29%) 12 (27%)	P = 0.57 P = 0.2
Montori 2011 (in consult)	Uptake	52	44%	48	40%	No difference
Smallwood 2017	Uptake	29	15.4%	21	50.0%	No difference P = 0.111
Medication - pain						
Omaki 2021	Prescription during encounter • Opioid • Non-opioid • None	65	18% 37% 45%	59	20% 34% 46%	No difference P = 0.93
Mental health treatment						
Fisher 2020	Uptake medication and/or psychoeducation	77	61.0%	71	67.6%	No difference
Hamann 2006	Uptake prescribed medication Uptake psychoeducation	— —	— —	— —	— —	No difference Higher uptake in DA group (P = 0.003)
Mott 2014	Uptake of 9 psychoeducation sessions	9	44%	11	9%	All 4 decision aid participants received 9 or

Table 12. Choice *(Continued)*

						more sessions. 1 of 5 usual care received 9 or more sessions.
Pereste-lo-Perez 2017	Preference • Medication • Psychotherapy • Combined	64	5 15 42	79	7 13 49	No difference
Watts 2015	Uptake evidence-based treatment	63	75%	65	57%	P = 0.04
Treatment - dialysis						
Subraman-ian 2019	Preference • Hemodialysis • Peritoneal dialysis • Other	53	42.8% 36.5% 4.8%	42	22.9% 31.4% 5.7%	No difference after re-moving those who were undecided
Treatment - obstructive sleep apnea						
Bergeron 2018	Actual choice • Observation • Medical • Surgery • No change	24	4.2% 20.8% 16.7% 58.3%	26	11.6% 23.1% 19.2% 46.2%	No difference P = 0.86
Treatment - skin disorder						
McLean 2020	Preference (hidradenitis sup-purativa - many treatment options e.g. none, topical, systemic, biological, laser, etc.)	18	—	16	—	No difference in pre-ferred treatment op-tions between groups

CI : confidence interval; **CHD** : congenital heart disease; **DA** : decision aid; **ICD** : implantable cardioverter defibrillator; **OR** : odds ratio; **RR** : risk ratio.

Table 13. Choice (continued)

Study	Type of comparison	N decision aid	Decision aid - mean	N compari-son	Compari-son - mean	Notes
Obstetrics - birth control method						
Langston 2010	Preference	114	—	108	—	No difference in the meth-ods chosen between groups; participants in the intervention group were not more likely to initi-ate the requested method immediately compared to those in the usual care

Table 13. Choice (continued) *(Continued)*

						group (OR 0.65, 95% CI 0.31 to 1.34)
Madden 2020	Uptake	161	—	80	—	No difference in the methods chosen between groups
Stephenson 2020	Uptake long-acting reversible contraception	349	30.4%	364	31.0%	No difference
Tebb 2021	Uptake non-barrier contraception • 3 months • 6 months	257 295	63.0% 62.7%	359 379	44.8% 43.8%	Greater increase in uptake for DA group from baseline at 3 months (P = 0.04) and 6 months (P = 0.005)
Obstetric - childbirth procedure						
Chen S 2021	Uptake - vaginal birth after cesarean	29	3	30	3	No difference
Kuppermann 2020	Uptake - vaginal birth after cesarean	727	231	732	233	No difference
Montgomery 2007	Uptake	—	—	—	—	No difference
Nassar 2007	Uptake	—	—	—	—	No difference
Shorten 2005	Preference	—	—	—	—	No difference
Wise 2019	Attempted vaginal birth after cesarean	146	56.9%	148	60.8%	No difference
Obstetric - embryo preservation						
Ehrbar 2019	Preference	24	91.7%	27	55.6%	P = 0.014
Obstetric - embryo transplant						
Van Peperstraten 2010	Uptake - single embryo transfer	152	43%	156	32%	P = 0.05
Obstetric - rooming-in						
Wang 2021	Actual choice • Separated • 12h rooming-in • 24h rooming-in	75	88.0% 10.7% 1.3%	75	76.0% 8.7% 5.3%	No difference P = 0.129
Other - organ transplant						
Gordon 2017	Kidney - willingness to accept increased risk donor kidney (1 to 5 scale; lower scores reflect greater willingness)	133	2.57 (95% CI 2.34 to 2.81)	155	2.78 (95% CI 2.58 to 2.97)	No difference P = 0.22

Table 13. Choice (continued) *(Continued)*

Patzer 2018	Kidney - living donor inquiry, placement on transplant waiting list, receipt of a living or deceased donor transplant	226	—	217	—	No difference P = 0.49
Vandemheen 2009	Lung transplant referral	—	—	—	—	No difference
Other - pre-operative blood transfusion						
Laupacis 2006	Uptake	—	—	—	—	No difference
Other - pelvic organ prolapse treatment						
Brazell 2014	Uptake	—	—	—	—	No difference; P = 0.835
Other - thyroid cancer adjuvant radioactive iodine treatment						
Sawka 2012	Preferred treatment immediately post	37	35.1%	37	32.4%	—
	Uptake at follow-up (~ 6.3 months post)	37	29.7%	37	18.9%	No difference (Chi ^{2} = 1.18; df = 1; P = 0.28)
Vaccines						
Chambers 2012	Uptake flu shot	48	46%	59	27%	No difference
Clancy 1988	Uptake hepatitis B	—	—	—	—	Significant increase of 76% in the DA group
Lin 2020	Uptake rotavirus vaccine	90	79	90	64	P = 0.01
Saunier 2020	Uptake flu shot	—	38.7% (95% CI 36.5 to 40.9)	—	31% (95% CI 28.7 to 33.3)	P < 0.005
Shourie 2013	Measles, mumps, rubella in infant	48	48 (100%)	71	70 (99%)	No difference

CI : confidence interval; **DA** : decision aid; **OR** : odds ratio

Table 14. Confidence

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Aoki 2019 (in consult)	COMRADE confidence subscale	Post-intervention	32	Median 41 (6 IQR)	53	Median 37 (7 IQR)	P = 0.005
Arterburn 2011	Decisional self-efficacy	Changes from baseline	75	+ 3.0 (95% CI 0.6 to 5.4)	77	+ 2.8 (95% CI 0.9 to 4.8)	No difference P = 0.78
Bailey 2016	Decisional self-efficacy scale (change from baseline to follow-up)	4 to 6 weeks after enrollment	114	3.7 (SD 16.7)	111	-3.9 (SD 19.2)	P = 0.0018
Chambers 2012	Mean confidence with decision: scale from 1 (low confidence) to 5 (high confidence)	Post-intervention	48	4	59	3.6	P = 0.02
Fraenkel 2007	Decisional self-efficacy scale	Pre-consultation	43	32 (median)	40	27 (median)	P = 0.001
Fraenkel 2015	COMRADE confidence subscale	2 and 8 weeks post-intervention	—	—	—	—	No difference
Gattellari 2003	Perceived ability to make an informed choice 1-item; 5-point Likert scale	3 days post	106	—	108	—	P = 0.008; DA group more likely to agree that they could make an informed choice about PSA screening
Gattellari 2005	Perceived ability to make an informed choice 1-item; 5-point Likert scale	Immediately post	131	—	136	—	No difference
Hoffman 2017	12-item Patient Self-Advocacy Scale (Yes = 1, Unsure = 2, No = 3), summed, and divided by 12 for an average score, with lower scores indicating greater self-advocacy	Immediately post-intervention	58	1.6 (SD 0.3)	28	1.8 (SD 0.3)	P = 0.01
Krishnamurti 2019	Decisional self-efficacy scale - change from baseline	3 months post-intervention	23	—	18	—	Study reports higher change for DA group

Table 14. Confidence *(Continued)*

							P = 0.05
		6 months post-intervention	23	—	18	—	P = 0.06
Kukafka 2022	Decisional self-efficacy scale - change from baseline	1 month post-intervention	101	1.6 (10.6)	86	0.4 (12.8)	No difference P = 0.52
		6 months post-intervention	88	0.0 (12.0)	75	-0.6 (13.8)	No difference P = 0.89
Lin 2020 (in consult)	Information provided can help me to have more confidence in deciding whether or not to let the baby receive the vaccine (1 to 5; strongly disagree to strongly agree)	Post-intervention	90	4.58 (SD 0.65)	90	3.76 (SD 0.96)	P < 0.001
Manne 2020	Confidence in the decision made rated on a scale from 0 (not confident at all) to 10 (extremely confident)	2 to 4 weeks after surgery	46	9.1 (SE 0.35)	47	8.5 (SE 0.33)	Small to moderate effect size (Cohen's d -0.30)
	Confidence in the ability to manage worries and uncertainty (e.g. recurrence, future surveillance)	2 to 4 weeks after surgery	46	4 (SE 0.16)	47	3.85 (SE 0.14)	Small effect size (Cohen's d -0.16)
McBride 2002	Confidence with ability to understand outcomes of hormone therapy, make a decision, engage in discussion with practitioner, 3 items (0 to 10; low to high confidence)	1 month post	273	78% (18% SD)	284	70% (19% SD)	P < 0.001
		9 months post	261	80% (17% SD)	278	75% (20% SD)	P = 0.0004
Meade 2015	Decision Self-efficacy (Arthritis self-efficacy scale (ASES) Scores range from 1 to 10 with higher scores indicating higher levels of self-efficacy)	Baseline	78	5.43 (SD 1.87)	66	5.74 (SD 2.00)	
		2 to 4 weeks post-intervention	78	5.81 (SD 1.92)	66	5.56 (SD 2.03)	P = 0.030
Miller 2018	Self-efficacy to complete CRC screening with a 1-item validated instrument from Vernon et al 1997 (scale not reported)	Post-intervention	223	3.89 (0.84)	227	3.64 (1.00)	P = 0.004

Table 14. Confidence *(Continued)*

Politi 2020a	Patient Activation Measure (PAM 13) - 3 of 13 items: • I am confident I can tell my healthcare provider concerns even when he or she does not ask • I am confident I can find trustworthy sources of information • I know the different options available	Post-intervention	57	96.5%	60	98.3%	P = 0.612
		Post-intervention	57	100%	60	96.7%	P = 0.496
		Post-intervention	57	98.3%	60	83.3%	P = 0.009
Perez-Lacasta 2019	Confidence in the decision made: 3 questions with 5 response options ranging from 1 = very little to 5 = very much	2 to 4 weeks post-intervention	203	4.23/5 (SD 0.83)	197	4.2/5 (SD 0.86)	No difference P = 0.761
Smith 2010	3 items adapted from the Decisional Self-efficacy Scale	2-week follow-up	357	4.67 (0.54 SD)	173	4.61 (0.62 SD)	No difference P = 0.26
Tebb 2021	Study specific 3-items: "How confident are you that you can: (1) “talk to your doctor about what birth control method(s) to use?” (2) “use birth control correctly so you do not get pregnant?” and (3) “have the information you need to choose the most appropriate birth control method for you?”" (0 = not at all confident to 10 = completely confident; total score range = 0 to 30)	48 hours post-intervention	320	25.2 (SD 5.1)	437	23.0 (SD 6.4)	Greater increase from baseline for DA group but not controls
		3 months post-intervention	282	25.2 (4.9)	379	23.4 (6.1)	No difference
		6 months post-intervention	292	26.1 (4.4)	379	23.4 (6.0)	DA group reported greater increase from baseline (P = 0.01)
Ye 2021	Decision Self-efficacy Scale	2 weeks post-intervention	371	Mean 73.5	376	Mean 72.4	No difference P = 0.33

CI : confidence interval; **CRC** : colorectal cancer; **DA** : decision aid; **IQR** : interquartile range; **PSA** : prostate-specific antigen; **SD** : standard deviation; **SE** : standard error.

Table 15. Adherence with chosen option

Reference	Scale used	N decision aid	Mean (SD) Decision aid	N comparison	Mean (SD) Comparison	Notes
Aoki 2019 (in consult)	3 months - medication adherence patient-reported subjectively with VAS (0 to 10)	22	Median 9.0 (2.7 IQR)	22	Median 9.1 (2.3 IQR)	P = 0.91 No difference in adherence to treatment
	6 months VAS (0 to 10)	44	Median 9.2 (4.9 IQR)	44	Median 8.9 (2.3 IQR)	P = 0.872 No difference in adherence to treatment
Bergeron 2018	Post consultation - proportion who contacted the physician to modify their treatment	24	0 (0.0%)	26	4 (15.4%)	Patient DA higher adherence to baseline choice P = 0.04
Karagiannis 2016 (in consult)	No missed medicine in prior week (patient-reported) • Assessed at 12 weeks	70	67 (95.7%)	81	69 (85.2%)	P = 0.35 No difference in adherence to treatment
	• Assessed at 24 weeks	80	75 (93.8%)	63	55 (87.3)	P = 0.61 No difference in adherence to treatment
Langston 2010	3 months - using a contraceptive method that was in the same effectiveness group as the method requested at enrolment, 'very effective', as chosen option - e.g. if chose sterilization and ended up using an IUD counted as adhering	48	85%	52	77%	P = 0.28 No difference in adherence to baseline choice
	3 months - using a contraceptive method that was in the same effectiveness group, 'effective', as chosen option	41	68%	31	68%	P = 0.96 No difference in adherence to baseline choice
LeBlanc 2015 (in consult)	Filled prescription (of those who were given prescriptions), n/N (%)	29	10/13 (83%) (1 missing)	38	4/12 (40%) (2 missing)	P = 0.07 No difference in adherence to baseline choice
	% of days covered out of 180 (median, 95% CI)	29	46.7% (95% CI 39.2 to 46.7)	38	85% (95% CI 55.3 to 92.6)	P = 0.08 No difference in adherence to treatment
LeBlanc 2015b (in consult)	Filled prescription (of those who were given prescriptions), n/N (%)	158	94/109 (86.2%) (4 missing)	139	82/88 (93.2) (5 missing)	P = 0.19

Table 15. Adherence with chosen option *(Continued)*

						No difference in adherence to baseline choice
	Proportion of patients with a percentage of days covered > 80% (of filled prescription)	158	96 (98.0%)	139	85 (97.7%)	P = 0.25 No difference in adherence to treatment
Legare 2012 (in consult)	2 weeks post - single question asking if the patient maintained the decision made, n (%)	163	143 (87.7%)	165	150 (91.5%)	Absolute difference 3.8; RR 1.0 (95% CI 0.9 to 1.0) No difference in adherence to baseline choice
Lepore 2012	Congruence between intention to test and verified PSA test - 1 year	244	55.3%	246	58.1%	No difference in adherence to baseline choice (95% CI 0.62 to 1.28)
	Congruence between intention to test and verified PSA test - 2 year	244	59.0%	246	59.3%	No difference in adherence to baseline choice (95% CI 0.69 to 1.42)
Loh 2007 (in consult)	6 to 8 weeks - patient-reported - 5-point Likert scale on steadiness of following the treatment plan: 1 = very bad to 5 = very good	191	4.3 (0.9)	96	3.9 (1.0)	No difference in adherence to treatment P = 0.073
	6 to 8 weeks - physician-reported - 5-point Likert scale steadiness of following the treatment plan: 1 = very bad to 5 = very good	191	4.8 (0.6)	96	4.3 (1.1)	No difference in adherence to treatment P = 0.56
Mann D 2010 (in consult)	3 months - telephone administration of the 8-item Morisky adherence scale (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviors such as skipping medicines when they have no symptoms)	—	—	—	—	No difference in adherence to treatment 70% reported good adherence to statins; no difference between groups
	6 months - telephone administration of the 8-item Morisky adherence scale (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviors such as skipping medicines when they have no symptoms)	—	—	—	—	No difference in adherence to treatment 80% reported good adherence to statins; no difference between groups
Man-Son-Hing 1999	6 months - self-reported. Measured % of participants taking therapy initially chosen.	129	95.35%	134	93.28%	No difference in adherence to baseline choice

Table 15. Adherence with chosen option *(Continued)*

						P = 0.44
Mathers 2012	6 months - self-reported. Measured % of patients who did not change their initially chosen treatment.	95	68.1%	80	56.3%	Patient DA higher adherence to baseline choice P = 0.041
Miller 2018	24 weeks - completed ordered colonoscopy	72	44 (61%)	47	25 (53%)	No difference in adherence to baseline choice
	24 weeks - completed ordered fecal test	81	21 (26%)	25	8 (32%)	No difference in adherence to baseline choice
Montgomery 2003	~ 3 years - self-reported – 6-item adherence questionnaire: from 'I take all my tablets at the same time of day' to 'I take hardly any of my tablets'	—	—	—	—	No difference in adherence to baseline choice or adherence to treatment
Montori 2011 (in consult)	6 months - percentage of participants that self-reported currently taking medication who have not missed 1 dose within last week	17	65%	19	63%	No difference in adherence to treatment P = 0.92
	6 months - percentage of participants who opted to take bisphosphonates who took their medication on more than 80% of the days for which it was prescribed, based on pharmacy records	23	100%	19	74%	Patient DA higher adherence to baseline choice P = 0.009
Mott 2014	4 months - percentage of participants who engaged in psychotherapy sessions	9	44%	11	45%	—
	4 months - number of participants who engaged in 9 or more psychotherapy sessions	4	100%	5	20%	Adherence to treatment
Mullan 2009 (in consult)	6 months - pharmacy records - days covered (range)	48	97.5% (range 0 to 100)	37	100 (range 73.9 to 100)	Higher adherence to treatment for usual care AMD -8.88 (-13.6% to -4.14%) Statistically significant
	6 months - self-reported by telephone call – did not miss a dose in last week	41	76%	31	81%	No difference in adherence to treatment OR 0.74 (95% CI 0.24 to 2.32)

Table 15. Adherence with chosen option *(Continued)*

Oakley 2006	4 months - extent to which the participants' behavior in taking medications coincides with the clinical prescription	16	10.4% (32) (improvement from baseline)	17	2% (26) (improvement from baseline)	No difference in adherence to treatment
Perestelo-Perez 2016 (in consult)	3 months - sometimes forget to take medicine	56	18 (32.1%)	42	15 (35.7%)	No difference in adherence to treatment P = 0.963
	3 months - all pills taken in the last week	55	51 (92.7%)	42	36 (81%)	No difference in adherence to treatment P = 0.189
Sheridan 2011	3 month - adherence to treatment					
	Any therapy promoted in decision aid	76	45 (59%)	73	25 (34%)	P < 0.01 DA group showed higher adherence to treatment
	Any therapy promoted in decision aid + others (e.g. diet or physical activity)	77	64 (83%)	77	52 (68%)	P = 0.02
	Aspirin	32	30 (94%)	19	11 (58%)	P < 0.01
	Cholesterol medicine	14	12 (86%)	6	5 (83%)	The intervention had little effect blood pressure or cholesterol medication, however, the sample sizes for these estimates were small and underpowered
	Blood pressure medicine	9	9 (100%)	12	11 (92%)	
	Stop smoking	8	25%	5	20%	No effect on smoking, although subgroups were small and underpowered
Stephenson 2020	Use of long-acting reversible contraception at 6 months if using at baseline	97	57 (58.8%)	104	73 (70.2%)	No difference in adherence to baseline choice P = 0.12
Trevena 2008	1 month - fecal occult blood test uptake	134	5.2%	137	6.6%	No difference in adherence to baseline choice P = 0.64
Weymiller 2007 (in consult)	3 months - self-reported – mailed surveys and telephone call to non-respondents	33	93.94%	29	79.31%	No difference in adherence to baseline choice or treatment when analysis adjusted by sex, cardiovas-

Table 15. Adherence with chosen option *(Continued)*

	On adherence to statin use: missed 1 dose or more within the last week					cular disease, and number of medications
Wilkens 2019	Change of treatment defined as choosing a more invasive treatment (e.g. change to surgery after nonsurgical treatment) - 6 weeks post enrolment	45	0 (0%)	45	3 (7%)	No difference in adherence to treatment P = 0.24
	6 months post enrolment	45	3 (7%)	45	5 (11%)	No difference in adherence to treatment P = 0.71
Wise 2019	Adherence to baseline choice of delivery mode at 34 weeks gestation (2 to 3 months post-intervention) • Vaginal • Cesarean	146	77.0% 81.3%	148	85.2% 87.1%	No difference in adherence to baseline choice P = 0.5 P = 0.4

AMD : absolute mean difference; **CI** : confidence interval; **DA** : decision aid; **IQR** : interquartile range; **IUD** : intrauterine device; **OR** : odds ratio; **PSA** : prostate-specific antigen; **RR** : risk ratio; **SD** : standard deviation; **VAS** : visual analogue scale

Table 16. Healthcare system effects

Study	Scale used	N decision **aid**	**Decision aid - mean**	**N comparison**	**Comparison - mean**	**Difference between groups**	**Notes**
Consultation length							
Aoki 2019 (in consultation)	Recording of initial consultation in minutes	35	Median 26 (5 IQR)	53	Median 24 (22 IQR)	+ 2 minutes	No difference between groups P = 0.983
Bekker 2004 (in consultation)	Consultation length using decision analysis in the consultation (minutes)	50	32.2 (SD 13.0)	56	26.3 (SD 11.5)	+ 5.9 minutes	P = 0.01 (longer with decision aid)
Krist 2007	Time spent discussing prostate cancer with practitioner post-DA (minutes) - patient-reported	196	5.3	75	5.2	+ 0.1 minutes	No difference between groups
	Time spent discussing prostate cancer with practitioner post-DA (minutes) - physician-reported	196	3.8	75	4.2	-0.4 minutes	No difference between groups, but physicians thought they spent less time than patients (P < 0.001)
LeBlanc 2015 (in consultation)	Consultation length with practitioner using DA in consultation (median, range in minutes)	29	11.5 (5.4 to 21.4)	37	10.7 (2.5 to 54.9)	+ 0.8 minutes (-33.6 to 3.0)	—
Love 2016	Duration of time for informed consent discussion with physician (minutes)	13	5.5 site 1 1.4 site 2	16	4.9 site 1 6.0 site 2	0.6 minutes -4.6 minutes	No difference overall
Stubenrouch 2022	Duration of consultation (minutes:seconds)	191	Median 16:30 (IQR 11:15 to 22:17)	151	Median 12:30 (IQR 08:55 to 17:18)	+4 minutes	P < 0.001
Thomson 2007 (in consultation)	Consultation length using DA in consultation (minutes)	8	44 (39 to 55)	10	21 (19 to 26)	+23 minutes	P = 0.001 Compared computerized decision aid with standard gamble within the consultation to guideline-driven consultation

Table 16. Healthcare system effects *(Continued)*

Vodermaier 2009	Consultation length with practitioner post-DA						
	5 to 10 min	53	6 (11.3%)	54	5 (9.3%)	—	P = 0.91
	10 to 15 min		17 (32.1%)		19 (35.2%)	—	
	15 to 25 min		15 (28.3%)		14 (25.9%)	—	
	25 to 35 min		7 (13.2%)		5 (9.3%)	—	
	Above 35 min		8 (15.1%)		11 (20.4%)	—	
Whelan 2003 (in consultation)	Consultation length using DA in consultation (minutes)	50	68.3	50	65.7	+ 2.6 minutes	P = 0.53
Weymiller 2007 (in consultation)	Consultation length using DA in consultation (minutes)	52	—	46	—	+ 3.8 minutes in DA group	Not statistically significant 3.8 min (95% CI -2.9 to 10.5)
Cost							
Hollinghurst 2010 ; Montgomery 2007	Total costs in the UK for decision about mode of delivery post previous cesarean	235	GBP 2019 (SD 741)	238	GBP 2033 (SD 677)	—	No difference
Kennedy 2002	Cost-effectiveness in the UK for decision about benign heavy menstruation	296 300	USD 2026 (DA alone) USD 1556 (DA plus nurse coaching	298	USD 2751	—	Mean differences: DA versus usual care USD 461 (95% CI 236 to 696) DA plus coaching versus usual care USD 1184 (95% CI 684 to 2110)
Murray 2001a	Total costs excluding intervention in the UK for decision about treatment of benign enlarged prostate	57	GBP 310.3 (SD 602.0)	48	GBP 188.8 (SD 300.4)	—	Mean difference GBP 121.5 (95% CI −58.9 to 302.0)

Table 16. Healthcare system effects *(Continued)*

	Total costs including intervention (interactive video disk equipment) in the UK for decision about treatment of benign enlarged prostate	57	GBP 594.10 (SD 602)	48	GBP 188.8 (SD 300.4)	—	Mean difference GBP 405.4 (95% CI GBP 224.9 to GBP 585.8) P < 0.001
Murray 2001b	Total costs excluding intervention in the UK for decision about hormone replacement therapy	85	GBP 90.5	84	GBP 90.9 (SD 39.2)	—	No difference
	Total costs including intervention (interactive video disk equipment) in the UK for decision about hormone replacement therapy	85	GBP 306.5 (SD 42.8)	84	GBP 90.9 (SD 39.2)	—	Mean difference GBP 215.5 (95% CI 203.1 to 228.0), P < 0.001
Shourie 2013	National Health Service costs (GBP)	42	35.06 (SD 6.4)	62	44.26 (SD 5.25)		Incremental cost -9.20
	Societal costs (GBP)	42	42.23 (SD 8.07)	62	48.85 (SD 6.29)		Incremental cost -6.62
	Cost-effectiveness (GBP)	42	72% chance of being cost-effective	62	8% chance of being cost-effective		DA has higher chance of being cost-effective
Stacey 2016 ; Trenaman 2017	Mean per-patient costs (2016 CAD), by database	161	CAD 21,965	163	CAD 23,681	—	Similar mean per-patient costs (CAD -1716, 95% CI -5631 to 2198)
	Cost-effectiveness at 2 years	167	CAD 7530 (6876 to 8114)	167	CAD 8033 (7360 to 8557)		The decision aid arm provided greater quality-adjusted life-years per patient (0.05, 95% CI -0.04 to 0.13) at a lower cost (CAD -560, 95% CI -1358 to 426) than the usual care arm
Van Peperstraten 2010	Mean total savings per couple in the Netherlands for decision about embryo transfer for in vitro fertilization	—	—	—	—	—	Mean total savings per couple in the intervention group were EUR 169.75 (USD 219.12)

Table 16. Healthcare system effects *(Continued)*

Vuorma 2003	Total estimated costs in Finland for treatment decision about heavy benign menstruation	184	EUR 2760	179	EUR 3094	—	P = 0.1 No difference between intervention and control
Healthcare resource use							
Cox 2019	Hospital length of stay (days)	138	42.8 (SD 31.6)	139	39.4 (SD 27.3)	+3.4 days	No difference P = 0.84
Hess 2016 (in consultation)	Repeat emergency department visit	447	39 (9.3%)	451	52 (12.5%)		No difference P = 0.156
	Readmission to hospital	447	19 (4.5%)	451	20 (4.8%)		No difference P = 0.884
	Outpatient clinic visit	447	259 (62.0%)	451	266 (64.1%)		No difference P = 0.568
Hess 2018 (in consultation)	Emergency department length of stay (minutes)	493	176 (SD 135)	478	199 (SD 162)	-23 minutes	P = 0.02
	Admitted to hospital	493	9 (2%)	478	9 (2%)	—	P = 0.94
	Emergency department visit within 7 days of discharge	493	10 (2%)	478	18 (4%)	—	P = 0.15
Ibrahim 2013	Attended orthopedic consult	162	~57%	161	~50%	—	No difference P = 0.56
Legare 2012 (in consultation)	Repeat consultation for the same reason, n (%)	163	37 (22.7%)	165	25 (15.2%)	Absolute difference 7.5	RR 1.3 (95% CI 0.7 to 2.3)
Shourie 2013	Resource utilization (actual and intended contacts with the National Health Service)	42	—	62	—	—	No statistically significant differences between groups

Table 16. Healthcare system effects *(Continued)*

Thomson 2007 (in consultation)	GP consultations postintervention	51	39 (76.5%)	54	32 (59.3%)	—	P = 0.35
	Hospital appointments postintervention	51	29 (56.9%)	54	10 (18.5%)	—	P = 0.06
Volk 2020	Scheduled a consultation to discuss screening within 6 months	238	150 (63.0%)	238	158 (66.4%)	-3.4 (-11.9 to 5.2)	P = 0.47

CI : confidence interval; **DA** : decision aid; **GP** : general practitioner; **IQR** : interquartile range; **RR** : risk ratio; **SD** : standard deviation; **SE** : standard error.

Table 17. Heterogeneity (based on 55 trials in search to 2006)

Outcome	Overall effect	Treatment decision	Screening decision	Video/computer decision aid	Audio/pamphlet Decision aid	Base risk control	Removal of outliers*
Knowledge - decision aid versus usual care	15.2 (11.7 to 18.7)	16.5 (11.9 to 21.2)	13.1 (7.7 to 18.5)	21.3 (16.3 to 26.2)	11.9 (8.3 to 15.6)	15.5 (11.3 to 19.8)	17.3 (13.6 to 20.9) (* Bekker 2004 , Gattellari 2003 , Johnson 2006)
Accurate risk perceptions - probabilities versus no probabilities	1.6 (1.4 to 1.9)	1.6 (1.4 to 1.9)	1.6 (1.1 to 2.3)	No data	1.6 (1.4 to 1.9)	1.3 (1.2 to 1.5) (P = 0.3)	1.5 (1.3 to 1.7) (* Gattellari 2003)
Uninformed subscale of the Decisional Conflict Scale - decision aid versus usual care	-8.4 (-11.9 to -4.8)	-9.4 (-13.3 to -5.5)	-3.5 (-12.9 to 5.8)	-12.6 (-19.5 to -5.8)	-4.9 (-7.6 to -2.3) (P = 0.06)	-5.4 (-7.7 to -3.2) (P = 0.11)	-6.2 (-8.4 to -4.1) (P = 0.06) (* Montgomery 2003)
Unclear values subscale of the Decisional Conflict Scale - decision aid versus usual care	-6.3 (-10.0 to -2.7)	-6.0 (-9.8 to -2.3)	Insufficient data	-8.0 (-15.1 to -1.0)	-4.5 (-8.4 to -0.6)	-3.6 (-6.8 to -0.5)	-4.0 (-6.7 to -1.3) (* Montgomery 2003)

APPENDICES

Appendix 1. Revised search strategies January 2015 to March 2022

CENTRAL via the Cochrane Library

#1 MeSH descriptor: [Decision Support Techniques] explode all trees

#2 MeSH descriptor: [Decision Making, Shared] explode all trees

#3 MeSH descriptor: [Consensus] explode all trees

#4 ((decision* NEXT (aid* or box* or support* or technolog* or interven*))):ti,ab,kw (Word variations have been searched)

#5 ((option NEXT grid*)):ti,ab,kw (Word variations have been searched)

#6 {OR #1-#5} with Cochrane Library publication date Between Jan 2015 and March 2022, in Trials

MEDLINE via Ovid

1 choice behavior/

2 exp decision making/

3 exp decision support techniques/

4 educational technology/

5 decision*.tw.

6 (choice* or preference*).tw.

7 communication package*.tw.

8 or/1-7

9 exp health education/

10 health knowledge attitudes practice/

11 informed consent.tw,hw.

12 patient.tw,hw.

13 consumer.tw,hw.

14 or/9-13

15 8 and 14

16 ((patient* or consumer*) adj1 (decision* or choice* or preferenc* or participat*)).tw.

17 ((women or men) adj1 (decision* or choice* or preferenc* or participat*)).tw.

18 (parent* adj1 (decision* or choice* or preferenc* or participat*)).tw.

19 ((personal or interpersonal or individual) adj (decision* or choice* or preferenc* or participat*)).tw.

20 shared decision making.tw.

21 decision aid*.tw.

22 informed choice.tw.

23 or/16-22

24 15 or 23

25 (decision* adj (aid* or box* or support* or technolog* or interven*)).ti,ab,kw.

26 (option adj3 grid*).ti,ab,kw.

27 25 or 26

28 randomized controlled trial.pt.

29 controlled clinical trial.pt.

30 randomized.ab.

31 placebo.ab.

32 drug therapy.fs.

33 randomly.ab.

34 trial.ab.

35 groups.ab.

36 or/28-35

37 exp animals/ not humans.sh.

38 36 not 37

39 and/24,27,38

40 limit 39 to yr="2015 -Current"

Embase via Ovid

1 decision support system/

2 patient decision making/ or shared decision making/

3 decision aid/

4 "decision tree"/

5 decision making.hw,kw,tw. and informed consent.hw,kw.

6 ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw,kw.

7 (decision adj (board* or guide* or counseling)).tw,kw.

8 ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw,kw.

9 (computer* adj2 decision making).tw,kw.

10 interactive health communication*.tw,kw.

11 (interactive adj (internet or online or graphic* or booklet*)).tw,kw.

12 (interacti* adj4 tool*).tw,kw.

13 ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw,kw.

14 shared decision making.tw,kw.

15 (informed adj (choice* or decision*)).tw,kw.

16 adaptive conjoint analys#s.tw,kw.

17 or/1-16

18 randomized controlled trial/

19 controlled clinical trial/

20 single blind procedure/ or double blind procedure/

21 crossover procedure/

22 random*.tw.

23 placebo*.tw.

24 ((singl* or doubl*) adj (blind* or mask*)).tw.

25 (crossover or cross over or factorial* or latin square).tw.

26 (assign* or allocat* or volunteer*).tw.

27 or/18-26

28 nonhuman/ not (human/ and nonhuman/)

29 27 not 28

30 17 and 29

31 (decision* adj (aid* or box* or support* or technolog* or interven*)).ti,ab,kw.

32 (option adj3 grid*).ti,ab,kw.

33 or/31-32

34 and/30,33

35 limit 34 to yr="2015 -Current"

PsycINFO via Ovid

1 decision support systems/ or exp Decision Making/

2 (decision making or choice behavior).mp. and (informed consent.sh. or (patient* or parent* or carer* or caregiver* or care giver*).mp.)

3 ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab,id.

4 (decision adj (board* or guide* or counseling)).ti,ab,id.

5 ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab,id.

6 computer assisted therapy/

7 (computer* adj2 decision making).ti,ab,id.

8 interactive health communication*.ti,ab,id.

9 (interactive adj (internet or online or graphic* or booklet*)).ti,ab,id.

10 (interacti* adj4 tool*).ti,ab,id.

11 ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).ti,ab,id.

12 shared decision making.ti,ab,id.

13 (informed adj (choice* or decision*)).ti,ab,id.

14 adaptive conjoint analys#s.ti,ab,id.

15 or/1-14

16 random*.ti,ab,hw,id.

17 intervention.ti,ab,hw,id.

18 trial.ti,ab,hw,id.

19 placebo*.ti,ab,hw,id.

20 ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.

21 (cross over or crossover).ti,ab,hw,id.

22 latin square.ti,ab,hw,id.

23 (assign* or allocat* or volunteer*).ti,ab,hw,id.

24 treatment effectiveness evaluation/

25 mental health program evaluation/

26 exp experimental design/

27 or/16-26

28 (decision* adj (aid* or box* or support* or technolog* or interven*)).ti,ab.

29 (option adj3 grid*).ti,ab.

30 or/28-29

31 and/15,27,30

32. limit 31 to yr="2015 -Current"

CINAHL via EBSCO

S17	S10 AND S15
S16	S10 AND S15
S15	S13 OR S14
S14	(MH "Decision Support Techniques") OR (MH "Decision Making, Computer Assisted") OR (MH "Decision Making, Shared") OR (MH "Decision Making, Patient") OR (MH "Decision Making, Family")
S13	S11 OR S12
S12	TX (decision* N (aid* or box* or support* or technolog* or interven*))
S11	TX (option N3 grid*)
S10	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9
S9	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)
S8	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)
S7	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)
S6	MH Quantitative Studies
S5	MH Placebos

(Continued)

S4	MH Random Assignment
S3	MH Clinical Trials+
S2	PT Clinical Trial
S1	PT "randomi?ed controlled trial"

Appendix 2. Revised search strategies January 2009 to April 2015

CENTRAL via the Cochrane Library

1. (decision-support or decision-aid):kw in Trials
2. decision-tree:kw in Trials
3. patient-decision-making:kw
4. (decision-making or choice-behavior):ti,ab,kw and (informed-consent:kw,ti or (patient or parent* or carer or caregiver or care-giver):ti,ab,kw) in Trials
5. ((decision or decid*) near/4 (support* or aid* or tool or instrument or technolog* or technique or system or program* or algorithm or process or method or intervention or material)):ti,ab,kw
6. (decision next (board or guide or counseling)):ti,ab,kw
7. ((risk-communication or risk-assessment or risk-information) near/4 (tool or method)):ti,ab,kw
8. (computer* near/2 decision-making):ti,ab,kw
9. (interactive-health-communication or (interacti* near/4 tool)):ti,ab,kw
10. (interactive next (internet or online or graphic* or booklet)):ti,ab,kw
11. ((interactiv* or evidence-based) near/3 (risk-information or risk-communication or risk-presentation or risk-graphic*)):ti,ab,kw
12. shared-decision-making:ti,ab,kw
13. (informed next (choice or decision)):ti,ab,kw
14. adaptive-conjoint-analysis:ti,ab,kw
15. (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14), from 2009 to 2015

(Last line **restricted** to “Trials”, and to date range 2009 to 2015)

MEDLINE Ovid

1. decision support techniques/

2. decision support systems clinical/

3. decision trees/

4. (decision making or choice behavior).mp. and informed consent.sh.

5. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw.

6. (decision adj (board* or guide* or counseling)).tw.

7. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw.

8. decision-making computer assisted/

9. (computer* adj2 decision making).tw.

10. interactive health communication*.tw.

11. (interactive adj (internet or online or graphic* or booklet*)).tw.

12. (interacti* adj4 tool*).tw.

13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw.

14. shared decision making.tw.

15. (informed adj (choice* or decision*)).tw.

16. adaptive conjoint analys#s.tw.

17. or/1-16

18. randomized controlled trial.pt.

19. controlled clinical trial.pt.

20. randomized.ab.

21. placebo.ab.

22. clinical trials as topic.sh.

23. randomly.ab.

24. trial.ti.

25. or/18-24

26. exp animals/ not humans.sh.

27. 25 not 26

28. 17 and 27

29. limit 28 to yr="2009 -Current"

Embase Ovid

1. decision support system/

2. patient decision making/

3. decision aid/

4. "decision tree"/

5. decision making.hw,kw,tw. and informed consent.hw,kw.

6. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw,kw.

7. (decision adj (board* or guide* or counseling)).tw,kw.

8. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw,kw.

9. (computer* adj2 decision making).tw,kw.

10. interactive health communication*.tw,kw.

11. (interactive adj (internet or online or graphic* or booklet*)).tw,kw.

12. (interacti* adj4 tool*).tw,kw.

13. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw,kw.

14. shared decision making.tw,kw.

15. (informed adj (choice* or decision*)).tw,kw.

16. adaptive conjoint analys#s.tw,kw.

17. or/1-16

18. randomized controlled trial/

19. controlled clinical trial/

20. single blind procedure/ or double blind procedure/

21. crossover procedure/

22. random*.tw.

23. placebo*.tw.

24. ((singl* or doubl*) adj (blind* or mask*)).tw.

25. (crossover or cross over or factorial* or latin square).tw.

26. (assign* or allocat* or volunteer*).tw.

27. or/18-26

28. nonhuman/ not (human/ and nonhuman/)

29. 27 not 28

30. 17 and 29

31. 30 and 20012:2015.(sa_year).

32. limit 31 to exclude medline journals

PsycINFO Ovid

1. decision support systems/

2. (decision making or choice behavior).mp. and (informed consent.sh. or (patient* or parent* or carer* or caregiver* or care giver*).mp.)

3. ((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab,id.

4. (decision adj (board* or guide* or counseling)).ti,ab,id.

5. ((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab,id.

6. computer assisted therapy/

7. (computer* adj2 decision making).ti,ab,id.

8. interactive health communication*.ti,ab,id.

9. (interactive adj (internet or online or graphic* or booklet*)).ti,ab,id.

10. (interacti* adj4 tool*).ti,ab,id.

11. ((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).ti,ab,id.

12. shared decision making.ti,ab,id.

13. (informed adj (choice* or decision*)).ti,ab,id.

14. adaptive conjoint analys#s.ti,ab,id.

15. or/1-14

16. random*.ti,ab,hw,id.

17. intervention.ti,ab,hw,id.

18. trial.ti,ab,hw,id.

19. placebo*.ti,ab,hw,id.

20. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.

21. (cross over or crossover).ti,ab,hw,id.

22. latin square.ti,ab,hw,id.

23. (assign* or allocat* or volunteer*).ti,ab,hw,id.

24. treatment effectiveness evaluation/

25. mental health program evaluation/

26. exp experimental design/

27. or/16-26

28. 15 and 27

29. limit 28 to yr="2009 -Current"

CINAHL (EBSCO)

#	Query	Limiters/Expanders
S31	S30	**Limiters - Exclude MEDLINE records** Search modes - Boolean/Phrase
S30	S28 and S29	Search modes - Boolean/Phrase
S29	EM 2009-	Search modes - Boolean/Phrase
S28	S17 and S27	Search modes - Boolean/Phrase
S27	S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26	Search modes - Boolean/Phrase
S26	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)	Search modes - Boolean/Phrase
S25	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)	Search modes - Boolean/Phrase
S24	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)	Search modes - Boolean/Phrase
S23	MH Quantitative Studies	Search modes - Boolean/Phrase
S22	MH Placebos	Search modes - Boolean/Phrase
S21	MH Random Assignment	Search modes - Boolean/Phrase
S20	MH Clinical Trials+	Search modes - Boolean/Phrase
S19	PT Clinical Trial	Search modes - Boolean/Phrase
S18	PT "randomi?ed controlled trial"	Search modes - Boolean/Phrase
S17	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16	Search modes - Boolean/Phrase

(Continued)

S16	"informed choice*" or "informed decision*"	Search modes - Boolean/Phrase
S15	"shared decision making"	Search modes - Boolean/Phrase
S14	"adaptive conjoint analys?s"	Search modes - Boolean/Phrase
S13	(interactive N2 "risk information") or (interactive N2 "risk communication") or (interactive N2 "risk presentation") or (interactive N2 "risk graphic*")	Search modes - Boolean/Phrase
S12	"interactive internet" or "interactive online" or "interactive graphic*" or "interactive booklet*" or (interacti* N3 tool*)	Search modes - Boolean/Phrase
S11	"interactive health communication*"	Search modes - Boolean/Phrase
S10	computer* N1 "decision making"	Search modes - Boolean/Phrase
S9	("risk communication" N3 tool*) or ("risk communication" N3 method*) or ("risk information" N3 tool*) or ("risk information" N3 method*) or ("risk assessment" N3 tool*) or ("risk assessment" N3 method*)	Search modes - Boolean/Phrase
S8	"evidence based risk communication" or "evidence based risk information"	Search modes - Boolean/Phrase
S7	"decision board*" or "decision guide*" or "decision counseling"	Search modes - Boolean/Phrase
S6	(decision* N3 support*) or (decision* N3 aid*) or (decision* N3 tool*) or (decision* N3 instrument*) or (decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*) or (decision* N3 algorithm*) or (decision* N3 process*) or (decision* N3 method*) or (decision* N3 intervention*) or (decision* N3 material*)	Search modes - Boolean/Phrase
S5	("decision making" or "choice behavior") and MH consent	Search modes - Boolean/Phrase
S4	MH decision making, computer assisted	Search modes - Boolean/Phrase
S3	MH decision making, patient	Search modes - Boolean/Phrase
S2	MH decision support systems, clinical	Search modes - Boolean/Phrase
S1	MH decision support techniques+	Search modes - Boolean/Phrase

Appendix 3. Search strategies to 2009

CENTRAL

CENTRAL in the Cochrane Library was searched using the MEDLINE search above in Ovid to the end of 2006; for the 2011 update, the CENTRAL search was conducted at www.thecochranelibrary.com to the end of 2009 using the following search strategy:

1. decision.tw,hw.

2. patient.tw,hw.

3. consumer.tw,sh.

4. 1 and (2 or 3)

5. shared decision making.tw.

6. decision aid$.tw.

7. informed choice.tw.

8. or/4-7

9. clinical trial.pt.

10. randomized controlled trial.pt.

11. random$.tw.

12. or/9-11

13. 8 and 12

MEDLINE Ovid (1966 to December 2009)

1. choice behavior/

2. decision making/

3. exp decision support techniques/

4. Educational Technology/

5. decision$.tw.

6. (choic$ or preference$).tw.

7. communication package.tw.

8. or/1-7

9. exp health education/

10. Health Knowledge, Attitudes, Practice/

11. informed consent.tw,hw.

12. patient.tw,hw.

13. consumer.tw,hw.

14. or/9-13

15. 8 and 14

16. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

17. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

18. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

19. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

20. shared decision making.tw.

21. decision aid$.tw.

22. informed choice.tw.

23. or/16-22

24. 15 or 23

25. clinical trial.pt.

26. randomized controlled trial.pt.

27. random$.tw.

28. (double adj blind$).tw.

29. double-blind method/

30. or/25-29

31. 24 and 30

CINAHL Ovid (1982 to September 2008)

1. exp Decision Making/

2. information seeking behavior/

3. Help Seeking Behavior/

4. (choic$ or preference$).tw.

5. decision$.tw.

6. Educational Technology/

7. or/1-6

8. exp Health Behavior/

9. consumer participation/

10. exp Health Education/

11. health knowledge/ or exp professional knowledge/

12. exp Consent/

13. informed consent.tw.

14. patient.tw,hw.

15. consumer.tw,sh.

16. or/8-15

17. 7 and 16

18. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

19. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

20. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

21. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

22. shared decision making.tw.

23. decision aid$.tw.

24. informed choice.tw.

25. or/18-24

26. 17 or 25

27. exp clinical trials/

28. Clinical trial.pt.

29. (clinic$ adj trial$1).tw.

30. random$.tw.

31. Random assignment/

32. placebo$.tw,sh.

33. Quantitative studies/

34. Allocat$ random$.tw.

35. ((singl$ or doubl$ or trebl$ or tripl$) adj (blind$3 or mask$3)).tw.

36. or/27-35

37. 26 and 36

Embase Ovid (1980 to December 2009)

1. decision making/

2. decision theory/

3. decision$.tw.

4. Educational Technology/

5. or/1-4

6. exp health behavior/

7. exp Patient Attitude/

8. exp health education/

9. informed consent.tw,sh.

10. patient.tw,sh.

11. consumer.tw,sh.

12. or/6-11

13. 5 and 12

14. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

15. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

16. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

17. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

18. shared decision making.tw.

19. decision aid$.tw.

20. informed choice.tw.

21. or/14-20

22. 13 or 21

23. Controlled Study/

24. Randomized Controlled Trial/

25. Clinical Study/

26. Clinical Trial/

27. Major Clinical Study/

28. Prospective Study/

29. Multicenter Study/

30. Randomization/

31. Double Blind Procedure/

32. Single Blind Procedure/

33. Crossover Procedure/

34. Placebo.tw,sh.

35. random$.tw.

36. (double adj blind$).tw.

37. or/23-36

38. 22 and 37

PsycINFO Ovid (1806 to December 2009)

1. decision$.tw.

2. (choic$ or preference$).tw.

3. exp decision making/

4. computer assisted instruction/

5. or/1-4

6. exp health education/

7. exp health personnel attitudes/

8. informed consent.tw,sh.

9. patient.tw,hw.

10. consumer.tw,hw.

11. exp health behavior/

12. or/6-11

13. 5 and 12

14. ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.

15. ((women or men) adj1 (decision$ or choice or preference or participation)).tw.

16. (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.

17. ((personal or interpersonal or individual) adj (decision$ or choice or preference$ or participat$)).tw.

18. shared decision making.tw.

19. decision aid$.tw.

20. informed choice.tw.

21. or/14-20

22. 13 or 21

23. random$.tw.

24. (double adj blind$).tw.

25. placebo$.tw,hw.

26. or/23-25

27. 22 and 26

WHAT'S NEW

Date	Event	Description
29 January 2024	New citation required and conclusions have changed	New for this update is higher-certainty evidence that patient decision aids improve all the primary outcomes compared to usual care.
29 January 2024	New search has been performed	We updated the search in March 2022 and added 104 new studies comparing decision aids to usual care. For this update, we conducted a subgroup analysis for studies published since 2015 (n = 104 studies) (i.e. new studies included in this update) versus studies published prior to 2015 (n = 105 studies).

HISTORY

Protocol first published: Issue 1, 1999
Review first published: Issue 3, 2001

Date	Event	Description
6 April 2017	New search has been performed	We updated the search in April 2015 and added 18 new studies comparing decision aids to usual care. For this update, we removed 28 studies that were focused on detailed versus simple decision aids. We also conducted a subanalysis of decision aids used within the consultation and those used in preparation for the consultation.
6 April 2017	New citation required and conclusions have changed	New for this update is growing evidence that decision aids may improve informed, values-congruent choices and the subanalysis indicated improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.
5 December 2013	New citation required and conclusions have changed	This update added 33 new studies for a total of 115 studies involving 34,444 participants. GRADE was used to summarize the quality of the evidence, and findings were reported using a summary of findings table. We excluded three previously included trials on the basis of their quasi-randomized controlled trial (q-RCT) design, identified using the more rigorous risk of bias assessment tool, as well as one other study that used the same decision aid content for both groups but varied the format used. Overall, the results are similar to the previous update, but this update indicates the quality of the evidence to support the reported outcomes (high-quality evidence that decision aids com-

Date	Event	Description
		pared to usual care improve people's knowledge and reduce their decisional conflict related to feeling uninformed and unclear about their personal values; moderate-quality evidence that decision aids compared to usual care stimulate people to take a more active role in decision-making and improve accurate risk perceptions when probabilities are included; and low-quality evidence that decision aids improve the congruence between the chosen option and their values). We added two new authors to the review, LT in Sydney and JW in Ottawa who helped co-ordinate this update.
30 June 2012	New search has been performed	Search strategies were updated and new searches run in June 2012.
18 January 2012	Amended	Minor change to wording, Plain Language Summary.
5 September 2011	New search has been performed	An update of this review was conducted in 2010 and published in Issue 10, 2011 of *The Cochrane Library* . Citations were searched from 2006 to December 2009.
5 September 2011	New citation required but conclusions have not changed	This update added 31 new studies, and all 86 included studies were assessed for risk of bias. Overall, the results were consistent with the previous update. New in this update is the meta-analysis of informed, values-based choices for decision aids including explicit values-clarification compared to those with no explicit values-clarification. We have also conducted a post hoc analysis to evaluate the effect of risk of bias assessment ratings on outcomes.
29 April 2009	New search has been performed	See the 'History' items dated 29 April 2009 and 28 July 2006.
29 April 2009	New citation required and conclusions have changed	A substantially updated version of this review was published in Issue 1, 2009 of *The Cochrane Library* . The changes are outlined in the 'History' (date 28 July 2006). The updated review ought to have had a new citation to reflect the new authorship and substantial changes to the review and its conclusions; however, because of a technical error this new citation was not given to the updated review. The new citation for this review for Issue 3, 2009 (O'Connor 2009b) reflects the updated review contents as actually published from Issue 1, 2009 onwards.
28 April 2009	Amended	Corrected mislabeled table 'Summary of pooled outcomes'.
17 July 2008	Amended	Converted to new review format.
28 July 2006	New search has been performed	Changes for the 2006 update (first published in Issue 1, 2009 of *The Cochrane Library)* : • Outcomes focus on the new effectiveness criteria of the International Patient Decision Aids Standards (IPDAS) Collaboration. • There are now 55 randomized controlled trials evaluating decision aids in the review. Twenty-five new randomized controlled trials have been added for this update. Four trials that were previously included were excluded from this review as the decision

Date	Event	Description
		support intervention was not available to determine whether it met the inclusion criteria - a requirement for this update in light of the new IPDAS standards. There are an additional 15 trials in progress. • The number of included countries has doubled from the last update. We now have results from seven countries (AU, CA, China, Finland, Netherlands, US, UK). Findings from the 2006 update (*new to this update): • *Thirty-eight trials used at least one measure that mapped onto an IPDAS effectiveness criterion. No trials evaluated the extent to which patient decision aids achieve the IPDAS decision process criteria: helped patients to recognize that a decision needs to be made, understand that values affect the decision, or discuss values with their practitioner. • *Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions; the effect was stronger when probabilities were measured quantitatively rather than qualitatively. • Compared to usual care, exposure to decision aids improved knowledge, decreased decisional conflict, reduced the proportion of people who were passive in decision-making, reduced the proportion who remained undecided, and reduced rates of elective invasive surgery. • Detailed decision aids (compared to simpler decision aids) improved knowledge and reduced the uptake of hormone replacement therapy. • *Compared to usual care, exposure to decision aids reduced prostate-specific antigen (PSA) screening. • There are too few studies to comment on the effects of decision aids on length of the consultation, patient-practitioner communication, persistence with chosen option, costs, and resource use.
21 February 2003	New search has been performed	For the 2002 update (O'Connor 2003), the following changes were made: • There are now 221 decision aids (increased from 87) that have been identified for the inventory with 131 available and up-to-date, many of which are available on the Internet. However, few have undergone any form of evaluation for impact on decision-making. • There are now 35 randomized controlled trials evaluating decision aids in the review. Eleven new randomized controlled trials have been added for this update, including one large-scale trial that evaluated a suite of eight decision aids in a number of health services. • There are an additional six trials pending publication and 24 trials in progress. • In conjunction with the benefits reported in the earlier reports, there is now evidence that decision aids compared to usual care also help with making actual choices and there is a statistically significant reduction in major elective surgery by a quarter. Detailed compared to simple decision aids also show an improved agreement between values and actual choice.

Date	Event	Description
		• There continue to be too few studies to comment on the effects of decision aids on persistence with chosen therapy, costs, resource use, or efficacy of dissemination.

CONTRIBUTIONS OF AUTHORS

1999 Review (O'Connor 1999b):
AO, AR, VF, JT, VE, HLT, MHR, VF, MB, and JJ contributed to the design of the protocol, the interpretation of results, and the revision and approved the final paper.
AO led the team, and JT co-ordinated the project.
AO, MH-R, AR, VF, and JT pilot-tested the data extraction forms.
AR, VF, and JT screened studies and extracted data.
AR, JT, and AO analyzed the results.

2001 Review (O'Connor 2001):
AO, DS, DR, MHR, HLT, VE, MB, JT, VF, and AR contributed to the interpretation of results and the revision, and approved the final paper.
AO led the team, and DS co-ordinated the update.
AO, DR, MHR, HLT, JT, DS, and JP screened studies and extracted data.
DS and JP evaluated decision aids using the CREDIBLE criteria.
AO and DS analyzed the results.

2002 Review (O'Connor 2003):
AO, DS, DR, MHR, HLT, VE, MB, JT, and VF contributed to the interpretation of results and the revision, and approved the final paper.
AO led the team, and DS co-ordinated the update.
DS, JP, VT, and JT screened studies and extracted data.
DS, JP, VT, and SK evaluated decision aids using the CREDIBLE criteria.
AO and DS analyzed the results.

2006 Review (O'Connor 2009b):
AO, CB, DS, MB, NC, KE, VE, VF, MHR, SK, HLT, and DR contributed to the interpretation of results, and the revision and final approval of the paper.
AO led the team and CB co-ordinated the update.
CB, SK, DS, AO, and VF screened studies and extracted data.
AO and CB analyzed the results.

2009 Review (Stacey 2011):

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, and RT contributed to the interpretation of results and the revision, and approved the final paper.
DS led the team, and CB co-ordinated the update.
CB and DS screened studies; SM and AD extracted data; CB entered the data; DS verified the data entered.
DS and CB analyzed the results.

2013 Review (Stacey 2014b):

DS, CB, MB, NC, KE, FL, AL, MHR, HLT, RT, and LT contributed to the interpretation of results and the revision, and approved the final paper.
DS led the team with help co-ordinating the update from SB and JW.
CB, DS, RT, MB, MHR, NC, KE, BV, DR, and AS screened studies; SB, RW, JW, and CC extracted data; SB and JW entered the data; DS verified the data entered.
DS and JW analyzed the results.

2017 Review (Stacey 2017):

DS, CB, MB, KE, FL, AL, MHR, HLT, RT, LT, and KL contributed to the interpretation of results and the revision, and approved the final paper.
DS led the team with help co-ordinating the update from KL.
CB, DS, RT, MB, MHR, KE, DR, and AS screened studies; KL and IS extracted data; KL entered the data; DS verified the data entered.
DS analyzed the results.

2023 Review (Current):

DS, KBL, MS, MC, RJV, EED, LPB, JF, JG, MJB, CLB, PB, KS, AG, IDG, SEK, FL, HS, RT, LoT, and LyT contributed to decisions about changes in the outcomes included in this update, the interpretation of results, and revisions to the paper, and approved the final paper.
DS and KBL led the team with help co-ordinating the update from MC.

CB, MB, MC, KDS, ED, JF, AG, KBL, LPB, DS, RT, and RJV screened studies; LBP extracted data on all newly included studies; DS, KBL, RJV, EED, and PB (and graduate students in acknowledgments) extracted data on some of the newly included studies; MC entered the data; DS and KBL verified the data entered.
DS, KBL, and MC analyzed the results.

DECLARATIONS OF INTEREST

Several of the investigators have developed patient decision aids, but none made study eligibility decisions about, extracted data from, performed risk of bias assessment for, or assessed GRADE certainty of their own studies where they were included in this review update.

DS: no relevant interests; Professor in the School of Nursing (no clinical work); Co-chair, International Patient Decision Aid Standards Collaboration; involved in conducting a study that is eligible for inclusion in this review (to evaluate a patient decision aid produced by the Foundation in Ottawa in a RCT; funded by Foundation for Informed Decision Making); involved in conducting a study that is eligible for inclusion (Patient Decision Aid, University of Ottawa Heart Institute; funded by Canadian Institutes of Health Research; Canadian Council of Cardiovascular Nurses).

KBL: Canadian Cardiovascular Society (Grant/Contract); Canadian Institutes for Health Research (Grant/Contract); Cardiac Arrhythmia Network of Canada (Grant/Contract); Heart and Stroke Foundation of Canada (Grant/Contract); licensed Registered Nurse in Ontario, Canada; involved in conducting a study that is eligible for inclusion (Patient Decision Aid, University of Ottawa Heart Institute; funded by Canadian Institutes of Health Research; Canadian Council of Cardiovascular Nurses).

MS: none known.

MC: none known.

RJV: no relevant interests; involved in a randomized trial of a patient decision aid for lung cancer screening (JAMA Network Open. 2020;3(1):e1920362. doi:10.1001/jamanetworkopen.2019.20362. Funding source: Patient-Centered Outcomes Research Institute); involved in a randomized trial of a patient decision aid about prostate cancer screening (Archives of Family Medicine 1999;8(4):333-40. [CRS ID: 3133593]. Funding source: internally funded). Both studies are included in this review update.

EED: none known.

LP-B: no relevant interests; registered physiotherapist with the Ordre Professionnel de la Physiothérapie du Québec, but has never worked as a physiotherapist; is a recipient of the Arthritis Society PhD Salary Award supporting PhD studies from September 2021 to September 2023.

JF: no relevant interests; Clinical Nurse Specialist at Aarhus University Hospital.

JG: none known.

MB: Healthwise (Employment, end date: 31 March 2017; grantee, end date: 30 June 2021); National Cancer Institute (Consultant, end date: 6 January 2017); United States Preventive Services Task Force (Chair, ongoing); Indiana University (Consultant, end date: 25 August 2017); multiple publications on shared decision-making; Informed Medical Decisions Foundation (pre-2017), Healthwise had statements supporting SDM (both nonprofits; USPSTF has supported and published on SDM); recipient of AHRQ grant for an RCT of a BPH decision aid, many years ago, included in the review.

CLB: none known.

PB: no relevant interests; podcasts for CDC Empowerment related to shared decision-making; board member of the International Shared Decision Making Society.

KDS: none known.

AG: none known.

IDG: none known.

SEK: none known.

FL: no relevant interests; family medicine doctor in the public healthcare system in Canada; involved in conducting a study that is eligible for inclusion (funded by the Canadian Institute of Health Research and FRSQ).

HS: no relevant interests; volunteer at the Danish Kidney Association, a not-for-profit, patient-run patient organization.

RT: no relevant interests; number of publications related to decision aids and shared decision-making; RCT of PDA carried out at Newcastle University (Thomson R, Eccles M, Steen N, Greenaway J, Stobbart L, Murtagh M, May C. A patient decision aid to support shared decision making on antithrombotic treatment of patients with atrial fibrillation: randomised controlled trial. QSHC 2007; 16: 216-223. Funded NHS UK R&D).

LoT: no relevant interests; published work on the development and evaluation of patient decision aids. This includes publishing work as a member of the International Patient Decision Aids Standards Collaboration (unpaid); conducted a cost-effectiveness analysis of an RCT led by Dawn Stacey. This included a trial-based economic evaluation and a longitudinal resource use/cost analysis. The RCT was funded by the Informed Medical Decisions Foundation (conducted analysis while being funded through a CIHR doctoral award; both analyses were published in *Osteoarthritis and Cartilage* while at the University of British Columbia as a PhD student).

LyT: Australian Commission on Safety and Quality in Health Care (Member of the Patients as Partners Committee); University of Sydney (Employment); Agency for Clinical Innovation (Consultant); peer reviewed publications on shared decision-making; pro bono clinical work as a GP with refugees; involved in National Health and Medical Research Foundation (NHMRC)-funded trial of decision aids for antibiotic use with respiratory infections (excluded from this review update) and also a NHMRC-funded trial of decision aid for colon cancer screening (included study).

SOURCES OF SUPPORT

Internal sources

- University of Ottawa, Canada

  University Research Chair in Knowledge Translation to Patients
- Ottawa Hospital Research Institute, Canada

  Scientific Director, Patient Decision Aids Research Group

External sources

- Canadian Institutes of Health Research, Canada

  Operating Grant from the Canadian Institutes of Health Research

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are three main differences between the original protocol and the review. We re-structured the 2009 update, O'Connor 2009b , to organize the long list of outcomes into primary and secondary outcomes based on the new effectiveness criteria of the International Patient Decision Aid (IPDAS) Collaboration (Elwyn 2006). For the 2011 update, Stacey 2011 , we changed the study quality assessment to the risk of bias tool (Higgins 2011). For the 2014 update, Stacey 2014b , we used GRADE to summarize the quality of the evidence and reported the results using Summary of findings 1 . For the 2017 update, we removed 28 studies that compared detailed versus simple decision aids and limited comparisons to patient decision aids versus usual care to provide a more focused review.

For the 2023 (current) update, we stopped reporting on some outcomes, including anxiety, depression, quality of life, other condition-specific health outcomes, total decisional conflict (SURE test and subscales of unsupported, uncertainty, ineffective choice), and litigation rates. The reduction in outcomes was based on the guidance from the *Cochrane Handbook for Systematic Reviews of Interventions* on staying focused on the most relevant outcomes (Higgins 2022).

INDEX TERMS

Medical Subject Headings (MeSH)

Communication; Conservative Treatment; *Decision Support Techniques; Elective Surgical Procedures; *Health Knowledge, Attitudes, Practice; Patient Education as Topic [*methods]; *Patient Participation; Physician-Patient Relations; Publication Bias; Randomized Controlled Trials as Topic

MeSH check words

Humans