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

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[Intervention Review]

Decision aids for people facing health treatment or screening decisions

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ABSTRACT

Background

Decision aids are interventions that support patients by making their decisions explicit, providing information about options and associated benefits/harms, and helping clarify congruence between decisions and personal values.

Objectives

To assess the effects of decision aids in people facing treatment or screening decisions.

Search methods

Updated search (2012 to April 2015) in CENTRAL; MEDLINE; Embase; PsycINFO; and grey literature; includes CINAHL to September 2008.

Selection criteria

We included published randomized controlled trials comparing decision aids to usual care and/or alternative interventions. For this update, we excluded studies comparing detailed versus simple decision aids.

Data collection and analysis

Two reviewers independently screened citations for inclusion, extracted data, and assessed risk of bias. Primary outcomes, based on the International Patient Decision Aid Standards (IPDAS), were attributes related to the choice made and the decision-making process.

Secondary outcomes were behavioural, health, and health system effects.

We pooled results using mean differences (MDs) and risk ratios (RRs), applying a random-effects model. We conducted a subgroup analysis of studies that used the patient decision aid to prepare for the consultation and of those that used it in the consultation. We used GRADE to assess the strength of the evidence.

Main results

We included 105 studies involving 31,043 participants. This update added 18 studies and removed 28 previously included studies comparing detailed versus simple decision aids. During the 'Risk of bias' assessment, we rated two items (selective reporting and blinding of participants/personnel) as mostly unclear due to inadequate reporting. Twelve of 105 studies were at high risk of bias.

With regard to the attributes of the choice made, decision aids increased participants' knowledge (MD 13.27/100; 95% confidence interval (CI) 11.32 to 15.23; 52 studies; N = 13,316; high-quality evidence), accuracy of risk perceptions (RR 2.10; 95% CI 1.66 to 2.66; 17 studies; N = 5096; moderate-quality evidence), and congruency between informed values and care choices (RR 2.06; 95% CI 1.46 to 2.91; 10 studies; N = 4626; low-quality evidence) compared to usual care.

Regarding attributes related to the decision-making process and compared to usual care, decision aids decreased decisional conflict related to feeling uninformed (MD −9.28/100; 95% CI −12.20 to −6.36; 27 studies; N = 5707; high-quality evidence), indecision about personal values (MD −8.81/100; 95% CI −11.99 to −5.63; 23 studies; N = 5068; high-quality evidence), and the proportion of people who were passive in decision making (RR 0.68; 95% CI 0.55 to 0.83; 16 studies; N = 3180; moderate-quality evidence).

Decision aids reduced the proportion of undecided participants and appeared to have a positive effect on patient-clinician communication. Moreover, those exposed to a decision aid were either equally or more satisfied with their decision, the decision-making process, and/or the preparation for decision making compared to usual care.

Decision aids also reduced the number of people choosing major elective invasive surgery in favour of more conservative options (RR 0.86; 95% CI 0.75 to 1.00; 18 studies; N = 3844), but this reduction reached statistical significance only after removing the study on prophylactic mastectomy for breast cancer gene carriers (RR 0.84; 95% CI 0.73 to 0.97; 17 studies; N = 3108). Compared to usual care, decision aids reduced the number of people choosing prostate-specific antigen screening (RR 0.88; 95% CI 0.80 to 0.98; 10 studies; N = 3996) and increased those choosing to start new medications for diabetes (RR 1.65; 95% CI 1.06 to 2.56; 4 studies; N = 447). For other testing and screening choices, mostly there were no differences between decision aids and usual care.

The median effect of decision aids on length of consultation was 2.6 minutes longer (24 versus 21; 7.5% increase). The costs of the decision aid group were lower in two studies and similar to usual care in four studies. People receiving decision aids do not appear to differ from those receiving usual care in terms of anxiety, general health outcomes, and condition-specific health outcomes. Studies did not report adverse events associated with the use of decision aids.

In subgroup analysis, we compared results for decision aids used in preparation for the consultation versus during the consultation, finding similar improvements in pooled analysis for knowledge and accurate risk perception. For other outcomes, we could not conduct formal subgroup analyses because there were too few studies in each subgroup.

Authors' conclusions

Compared to usual care across a wide variety of decision contexts, people exposed to decision aids feel more knowledgeable, better informed, and clearer about their values, and they probably have a more active role in decision making and more accurate risk perceptions. There is growing evidence that decision aids may improve values-congruent choices. There are no adverse effects on health outcomes or satisfaction. New for this updated is evidence indicating improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation. Further research is needed on the effects on adherence with the chosen option, cost-effectiveness, and use with lower literacy populations.

PLAIN LANGUAGE SUMMARY

Decision aids to help people who are facing health treatment or screening decisions

Review question

We reviewed the effects of decision aids on people facing health treatment or screening decisions. In this update, we added 18 new studies for a total of 105.

Background

Making a decision about the best treatment or screening option can be hard. People can use decision aids when there is more than one option and neither is clearly better, or when options have benefits and harms that people value differently. Decision aids may be pamphlets, videos, or web-based tools. They state the decision, describe the options, and help people think about the options from a personal view (e.g. how important are possible benefits and harms).

Study characteristics

For research published up to April 2015, there were 105 studies involving 31,043 people. The decision aids focused on 50 different decisions. The common decisions were about: surgery, screening (e.g. prostate cancer, colon cancer, prenatal), genetic testing, and medication treatments (e.g. diabetes, atrial fibrillation).The decision aids were compared to usual care that may have included general information or

no intervention. In the 105 studies, 89 evaluated a patient decision aid used by people in preparation for the visit with the clinician, and 16 evaluated its use during the visit with the clinician.

Key results with quality of the evidence

When people use decision aids, they improve their knowledge of the options (high-quality evidence) and feel better informed and more clear about what matters most to them (high-quality evidence). They probably have more accurate expectations of benefits and harms of options (moderate-quality evidence) and probably participate more in decision making (moderate-quality evidence). People who use decision aids may achieve decisions that are consistent with their informed values (evidence is not as strong; more research could change results). People and their clinicians were more likely to talk about the decision when using a decision aid. Decision aids have a variable effect on the option chosen, depending on the choice being considered. Decision aids do not worsen health outcomes, and people using them are not less satisfied. More research is needed to assess if people continue with the option they chose and also to assess what impact decision aids have on healthcare systems.

SUMMARY OF FINDINGS

Summary of findings for the main comparison.

Patient decision aids compared with usual care for adults considering 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)	Quality of the evidence (GRADE)	Comments
	Assumed benefit	Corresponding benefit				
	Usual care	Patient decision aid				
Knowledge - all studies Standardized on score from 0 (no knowledge) to 100 (perfect knowledge), soon after exposure to the decision aid	The mean knowledge score was 56.9% across control groups, ranging from 27.0% to 85.2%	The mean knowledge score in the intervention groups was 13.27 higher (11.32 to 15.23 higher)	—	13,316 (52 studies)	⊕⊕⊕⊕ **High** [a,b]	Higher scores indicate better knowledge. 46 out of 52 studies showed a statistically significant improvement in knowledge
Accurate risk perceptions - all studies Assessed soon after exposure to the decision aid	**269 per 1000** [c]	**565 per 1000** (447 to 716 per 1000)	**RR 2.10** (1.66 to 2.66)	5096 (17 studies)	⊕⊕⊕⊖ **Moderate** [a,d]	—
Congruence between the chosen option and informed values - all studies Assessed soon after exposure to the decision aid	**289 per 1000** [c]	**595 per 1000** (422 to 841 per 1000)	**RR 2.06** (1.46 to 2.91)	4626 (10 studies)	⊕⊕⊖⊖ **Low** [a,d,e,f]	—
Decisional conflict: uninformed subscale - all studies	The mean for outcome 'feeling uninformed'	The mean feeling uninformed in the intervention groups was	—	5707 (27 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling more informed

Standardized on score from 0 (not uninformed) to 100 (uninformed) Assessed soon after exposure to the decision aid	ranged across control groups from 11.1 to 61.1. Scores ≤ 25 associated with following through on decisions. Scores > 38 associated with delay in decision making	9.28 lower (12.20 to 6.36 lower)				
Decisional conflict: unclear about personal values subscale - all studies Standardized on score from 0 (not unclear) to 100 (unclear) Assessed soon after exposure to the decision aid	The mean for outcome 'feeling unclear about personal values' ranged across control groups from 15.5 to 53.2. Scores ≤ 25 associated with follow-through with decisions. Scores > 38 associated with delay in decision making	The mean feeling unclear values in the intervention groups was 8.81 lower (11.99 to 5.63 lower)	—	5068 (23 studies)	⊕⊕⊕⊕ **High** [a,b]	Lower scores indicate feeling clearer about values
Participation in decision making: clinician-controlled decision making - all studies Assessed soon after consultation with clinician	**228 per 1000** [c]	**155 per 1000 (125 to 189 per 1000)**	**RR 0.68** (0.55 to 0.83)	3180 (16 studies)	⊕⊕⊕⊖ **Moderate** [a,e]	Patient decision aids aim to increase patient involvement in making decisions; lower proportion of clinician-controlled decision making is better
Adverse events	There were no adverse effects on health outcomes or satisfaction, and no other adverse effects reported.					

*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 quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: 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 quality: we are very uncertain about the estimate.

[a]The vast majority of studies measuring this outcome were not at high risk of bias.
[b]The GRADE ratings for these outcomes were not downgraded for 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]The GRADE rating was downgraded given the lack of precision.
[e]The GRADE rating was downgraded given the lack of consistency.
[f]The GRADE rating was downgraded given the lack of directness. As well, the outcome was measured using various approaches with no gold standard approach.

BACKGROUND

Many health treatment and screening decisions have no single 'best' choice. These types of decisions are considered 'preference-sensitive' because there is insufficient evidence about outcomes or there is a need to trade off known benefits and harms. *Clinical Evidence* analyzed 3000 treatments, classifying 50% as having insufficient evidence, 24% as likely to be beneficial, 7% as requiring trade-offs between benefits and harms, 5% as unlikely to be beneficial, 3% as likely to be ineffective or harmful, and only 11% as being clearly beneficial (Clinical Evidence 2013). Not only does one have to take into account the strength of the evidence, but even for the 11% of treatments that show beneficial effects for populations, physicians need to translate the probabilistic nature of the evidence for individual patients to help them reach a decision based on informed values. Patient decision aids are an intervention that can be used to present such evidence (Brouwers 2010). This review is an update of the review last published in 2014 of the comparisons between patient decision aids and usual care (Stacey 2014b). To provide a more focused review, we removed 28 studies that compared detailed versus simple decision aids.

Description of the intervention

According to the International Patient Decision Aids Standards (IPDAS) Collaboration (Elwyn 2006; IPDAS 2005a; Joseph-Williams 2013), decision aids are evidence-based tools designed to help patients make specific and deliberated choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options. The specific aims of decision aids and the type of decision support they provide may vary slightly, but in general they:

1. explicitly state the decision that needs to be considered;
2. provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties;
3. help patients to recognize the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value they place on the benefits and harms. (To accomplish this, patient decision aids may describe the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects, or they may guide clients to consider which benefits and harms are most important to them.)

Decision aids differ from usual health education materials. Decision aids make the decision being considered explicit, providing a detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making. In contrast, health education materials help people to understand their diagnosis, treatment, and management in general terms, but given their broader perspective, these materials are not focused on decision points and thus do not necessarily help them to participate in decision making. Many decision aids are based on a conceptual model or theoretical framework (Durand 2008; Mulley 1995; O'Connor 1998b; Rothert 1987).

In response to concerns about variability in the quality of patient decision aids, the IPDAS Collaboration reached agreement on criteria for judging their quality (Elwyn 2006). More than 100 researchers, clinicians, patients, and policymakers from 14 countries participated. Participants addressed three domains of quality: clinical content, development process, and evaluation of a patient decision aid's effectiveness. A series of background papers informing the original IPDAS criteria were updated in 2013 (IPDAS 2013). Subsequently, an international team of researchers reached consensus on a shorter set of qualifying and certifying criteria (Joseph-Williams 2013). Informed by IPDAS, the Washington State Health Authority launched the first programme for certifying patient decision aids in 2016 (Washington State 2016).

How the intervention might work

Decision aids can be used before, during, or after a clinical encounter to enable patients to become active, informed participants. Providing the patient decision aid in preparation for the consultation allows people more time to digest the information and be ready to discuss the decision, but this may not be feasible in some health decisions (e.g. antibiotics for upper respiratory infections). Decision aids can also facilitate shared decision making. Shared decision making is defined as a process through which clinicians and patients make healthcare choices together (Charles 1997; Makoul 2006), representing the crux of people-centred care (Weston 2001). However, the way the clinician provides information may strongly affect people's preferences (Hibbard 1997), prompting the need for standardized information such as patient decision aids. Patients who are more active in making decisions about their health have better health outcomes and healthcare experiences (Hibbard 2013; Kiesler 2006). In summary, patient decision aids may help clinicians and patients come to quality decisions, grounded in patients' values and taking into account the potential trade-offs in benefits and risks of different options.

Why it is important to do this review

Given the broad range of stakeholders interested in patient decision aids and the rapidly expanding field of research, there was a need to update this review to identify studies on new decisions or conducted in new countries and to strengthen the synthesized evidence supporting use of patient decision aids for outcomes that do not yet have high-quality evidence. In fact, the 2014 publication was the most cited Cochrane Review in 2015 based on 1888 reviews published in 2013 and 2014. With growing development of patient decision aids for use in the consultation, we wanted to conduct a subgroup analysis of patient decision aids used in preparation for versus within the consultation.

Results from previous reviews were used to inform clinical practice guidelines such as Patient Experience in Adult NHS Services (NCGC/NICE 2012) and Decision Support for Adults Living with Chronic Kidney Disease (RNAO 2009). Subgroup analyses of included studies have focused on anxiety (Bekker 2003), adherence (Trenaman 2016), values congruence (Munro 2016), participant trial identity (Brown 2015), and heterogeneity (Gentles 2013).

Other systematic reviews have been 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; Legare 2010; Legare 2014).

OBJECTIVES

To assess the effects of decision aids in people facing treatment or screening decisions.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published studies that used a randomized controlled trial (RCT) design evaluating patient decision aids.

Types of participants

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

Types of interventions

We included studies that evaluated a patient decision aid as part of the intervention. Decision aids were defined as interventions designed to help people make specific and deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as implicit methods to clarify values. The 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' opinions; a personalized recommendation on the basis of clinical characteristics and expressed preferences; 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, clinical trial entry, or general advance directives (e.g. do not resuscitate); education programmes not geared to a specific decision; and interventions designed to promote adherence or elicit informed consent regarding a recommended option. We also excluded studies when the relevant decision aid(s) were not available to us and not adequately described in the article(s), because we could not determine the aids' characteristics and whether or not they met the minimum criteria to qualify as patient decision aids.

Types of comparisons

We included studies that compared patients exposed to a patient decision aid to patients in comparison groups that were exposed to usual care, general information, clinical practice guideline, placebo intervention, or no intervention. For the purposes of this review, we refer to all such control comparisons as 'usual care'.

We excluded studies that compared two different types of patient decision aids.

Types of outcome measures

To ascertain whether the decision aids achieved their objectives, we examined a broad range of outcomes. Although the decision aids focused on diverse clinical decisions, many had similar objectives such as improving knowledge scores, the accuracy of risk perceptions, and participation in decision making. Many of these evaluation criteria mapped onto the International Patient Decision Aids Standards (IPDAS) criteria for evaluating the effectiveness of decision aids (Elwyn 2006; IPDAS 2005b; Sepucha 2013). The IPDAS criteria were attributes related to the choice (e.g. match between the chosen option and the features that matter most to the informed patient) and to the decision-making process (e.g. helps patients to recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the features that matter most; discuss values with their clinician; and become involved in their preferred ways). A complete list of outcomes, specified in advance of the review, included primary and secondary outcomes.

Primary outcomes

Evaluation criteria that map onto the IPDAS criteria

- 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 (demonstrated by outcomes such as knowledge, accurate risk perceptions, values-choice congruence)?
- Attributes of the decision-making process: does the patient decision aid help patients to recognize that a decision needs to be made, feel informed about the options and their features, be clear about the option features that matter most, discuss values with their clinician, and become involved in decision making?

Other decision-making process variables

- Decisional conflict
- Patient-clinician communication
- Participation in decision making
- Proportion undecided
- Satisfaction with the choice, with the process of decision making, and with the preparation for decision making

Secondary outcomes

Behaviour

- Choice (the actual choice implemented; if not reported, the participants' preferred option was used as a surrogate measure)
- Adherence to chosen option

Health outcomes

- Health status and quality of life (generic and condition-specific)
- Anxiety, depression, emotional distress, regret, confidence

Healthcare system

- Costs, cost-effectiveness
- Consultation length
- Litigation rates

Search methods for identification of studies

Our search strategy for the review included:

1. searching electronic medical and social science databases; and
2. searching other resources.

Electronic searches

For this update, we used the same search strategy that was revised by the Trials Search Coordinator at the Cochrane Consumers and Communication Group in the last update (Stacey 2014b).

Therefore, the cumulative search of electronic databases is as follows.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 6) in the Cochrane Library (searched to 24 April 2015).
- MEDLINE Ovid (1966 to 24 April 2015).
- Embase Ovid (1980 to 24 April 2015).
- PsycINFO Ovid (1806 to 24 April 2015).
- CINAHL Ovid (1982 to September 2008), then in Ebsco (to 24 April 2015).

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

Searching other resources

On 18 December 2015 we also searched trial registries (World Health Organization, ClinicalTrials.gov), the Internet using Google and Google Scholar, and the Decision Aid Library Inventory (decisionaid.ohri.ca). Finally, reference lists of all newly included trials were searched.

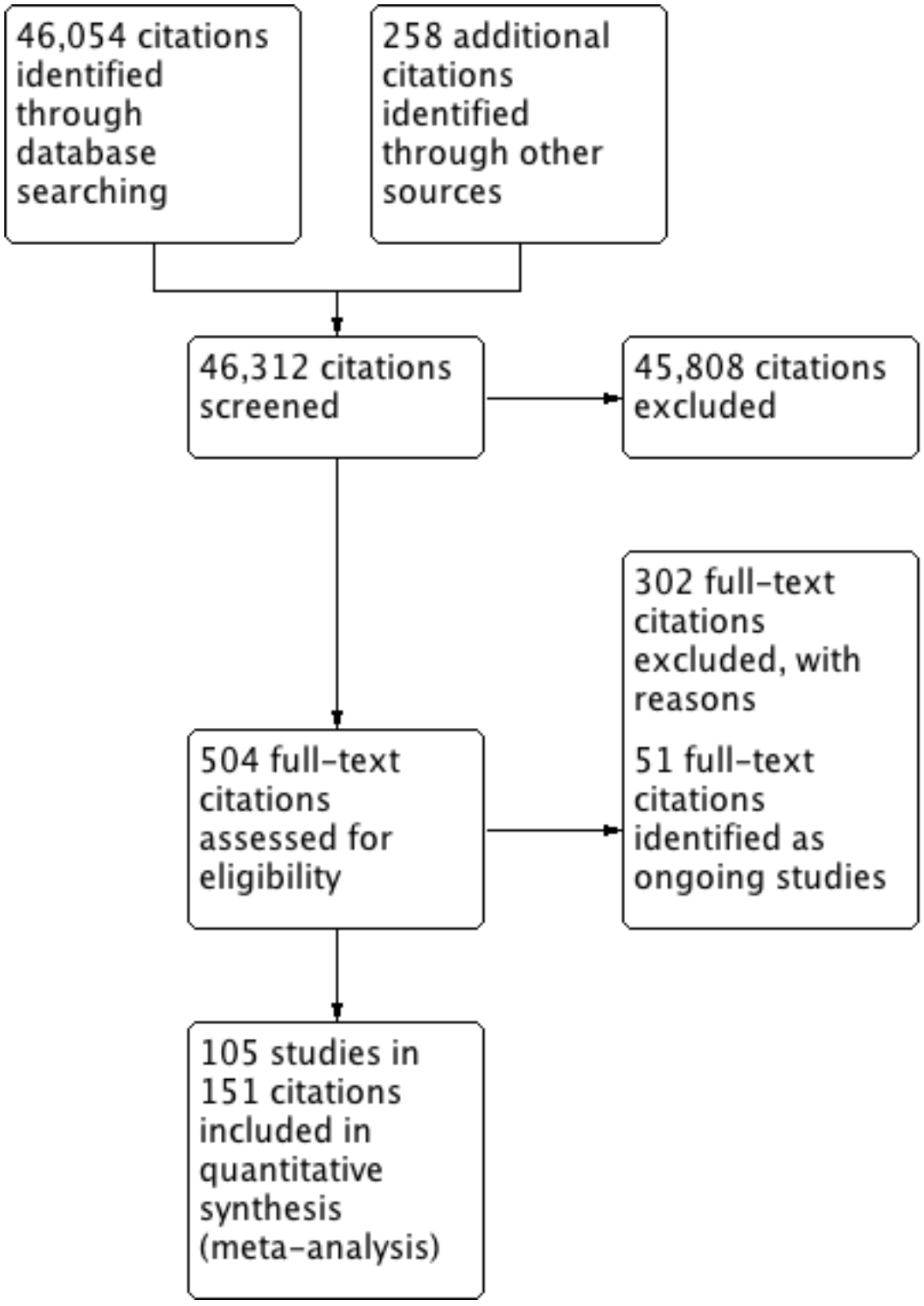
Data collection and analysis

For this current update, we focused only on new publications that had appeared since the previous publication (Stacey 2014b), and we limited the inclusion to patient decision aids versus usual care. As such, we removed studies from the previous reviews that compared detailed versus simple patient decision aids to provide a more focused review.

Selection of studies

Pairs of eight review authors (CB, DS, RT, MB, MHR, KE, NC, DR) screened all identified citations. We retrieved the full text of any papers identified as potentially relevant by at least one author, listing all papers excluded from the review at this stage, with reasons, in the 'Characteristics of excluded studies' table. We also provided citation details and any available information about ongoing studies, and we collated and reported details of additional publications, so that each study (rather than each report) was the unit of interest. We report the screening and selection process in Figure 1.

Figure 1. Study flow diagram.



Data extraction and management

Two research assistants extracted data independently (KL, IS). We compared findings and resolved inconsistencies through discussion with the principal investigator (DS) and, when necessary, with a co-author (CB). No review authors extracted data for their own studies in this update nor in any other versions of this review.

One review author entered all extracted data into Review Manager 5 (RevMan 5), and a second one worked independently to check for accuracy against the data extraction sheets (RevMan 2014).

Assessment of risk of bias in included studies

Two research assistants independently appraised studies using the Cochrane 'Risk of bias' tool (current update: KL, IS) (Higgins 2011, Chapter 8). 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 judgement for each item in the 'Risk of bias' table. 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 postconsultation, whether clustering was accounted for in the analysis; and potential sources of bias reported by the authors in the study limitations.

We resolved inconsistencies by discussion with the principal investigator (DS) and, when necessary, with a co-author (CB). No review authors appraised risk of bias for their own studies in this update nor in any other versions of this review.

Studies were deemed to be at the highest risk of bias if they were scored as at high risk on any of the items of the risk of bias tool (Higgins 2011).

Measures of treatment effect

For dichotomous outcomes, we analyzed data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analyzed data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI.

First, we described study characteristics individually. The a priori comparison was usual care versus decision aids. For studies in which there were more than one intervention group, we extracted data from the groups that provided the strongest contrast between the intervention and control groups. We pooled results across studies in cases where investigators used similar outcome measures and the effects were expected to be independent of the type of decision studied. For example, we expected decision aids to improve knowledge and create accurate percetions 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 analysing the effects of decision aids on choices, we pooled outcomes on more homogeneous subgroups of decisions (choice of major surgery versus conservative options; screening test or not, etc.).

Unit of analysis issues

We checked 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 intracluster correlation (ICC). We obtained estimates of the ICC by contacting authors of included studies, or we imputed them using estimates from external sources. For two studies (Kupke 2013; Lewis 2010), 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. We made no adjustments to the data based on these two studies that were included in meta-analysis for knowledge only.

Dealing with missing data

We contacted authors to obtain missing data. Where possible, we conducted analysis 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

For this update and in previous versions of the review, we grouped studies together across populations and settings. The aim was to enable an assessment of the effectiveness of decision aids across conditions, rather than to focus on disease-specific contexts. Given that 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 populations and decision aid elements, we anticipated that there would be a substantial degree of heterogeneity in our pooled effect estimates. However, we decided that we would consider the direction of effects and variability in these rather than variability in the size of effects, as the major basis for our interpretation of heterogeneity. This meant that for those pooled effect estimates where the direction of effect was consistent across studies, we did not downgrade for inconsistency, despite some variability in the size of effects across individual studies. We did downgrade for inconsistency for one outcome: congruence between the chosen option and informed values. This was because there is no accepted gold standard measure for assessing this outcome, and we considered that variability in measurement by the included studies added further uncertainty about the effects of decision aids for this outcome.

Where heterogeneity was present in pooled effect estimates, we explored possible reasons for variability by conducting subgroup analysis in the 2009 update (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 type of media of the 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 informedness and clarity of values). We analyzed the effect of removing the biggest outlier(s) (defined by visual inspection of forest plots). Given that the post hoc analysis did not alter the findings from the 2009 update, we did not re-conduct the post hoc analysis for the IPDAS effectiveness criteria.

Assessment of reporting biases

We used funnel plots to assess publication bias.

Data synthesis

We used RevMan 5 software to estimate a weighted intervention effect with 95% confidence intervals (RevMan 2014). For continuous measures, we used mean differences (MD); for dichotomous outcomes, we calculated pooled relative risks (RR). 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. We summarized all of the results for the primary outcomes and rated

the strength of evidence using GRADE (Andrews 2013), presenting these in a 'Summary of findings' table (Higgins 2011).

Subgroup analysis and investigation of heterogeneity

For this update, we conducted a subgroup analysis to compare the effects of the intervention when used in preparation for the consultation with the effects of those used during the consultation to usual care.

Sensitivity analysis

We performed post hoc sensitivity analyses to examine the effect of excluding studies of lower methodological quality. The analysis excluded studies that were at high risk of bias for any of the categories in the 'Risk of bias' assessment (Higgins 2011).

'Summary of findings' table

We prepared a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We presented the results of meta-analysis for the major comparison of the review for each of the key outcomes. We provided a source and rationale for each assumed risk cited in the table and used the GRADE criteria to rank the quality of the evidence for each outcome on each of the following domains: risk of bias, inconsistency, imprecision, indirectness, and publication bias. Two authors independently assessed the quality of the evidence using the GRADEprofiler (GRADEpro) software (GRADEpro GDT).

RESULTS

Description of studies

The current version of our review updates our 2014 version, Stacey 2014b, with 18 new studies (Bozic 2013; Brazell 2014; Chabrera 2015; Fraenkel 2012; Knops 2014; Köpke 2014; Kuppermann 2014; Lam 2013; LeBlanc 2015; Legare 2012; Lepore 2012; Mathers 2012; Mott 2014; Sawka 2012; Shourie 2013; Stacey 2014a; Taylor 2006; Williams 2013). For this update, we excluded 28 previously included studies due to the comparisons being limited to detailed versus simple patient decision aids (Deschamps 2004; Deyo 2000; Dodin 2001; Goel 2001; Green 2004; Hunter 2005; Kuppermann 2009; Labrecque 2010; Lalonde 2006; Legare 2003; Leung 2004; Myers 2005a; Myers 2011; O'Connor 1998a; O'Connor 1999a; Raynes-Greenow 2010; Rostom 2002; Rothert 1997; Schapira 2000; Schapira 2007; Solberg 2010; Street 1995; Tiller 2006; Van Roosmalen 2004; Volk 2008; Wakefield 2008a; Wakefield 2008b; Wakefield 2008c).

Results of the search

In total, we identified 46,054 citations from the electronic database searches and 258 citations from other sources. Of these, we assessed 504 citations for eligibility using the full text (see Figure 1).

Included studies

The remaining 151 citations provided data on 105 studies that met our inclusion criteria, 18 of which are new for this update. The 105 RCTs, involving 31,043 participants, presented results from 10 countries: Australia (10 studies), Canada (15 studies), China (1 study), Finland (2 studies), Germany (6 studies), Netherlands (2 studies), Spain (1 study), Sweden (1 study), the UK (16 studies), the USA (50 studies), and Australia plus Canada (1 study). We present study details below and in the Characteristics of included studies table.

Unit of randomization

Ninety studies randomized individual patients, and 15 randomized clusters. For cluster trials, Allen 2010 randomized 12 company worksites; Fraenkel 2012, 2 groups of primary care physicians; Hamann 2006, 12 inpatient psychiatric units; Kupke 2013, 49 dental students; Legare 2011, 4 family medicine group practices; Legare 2012, 12 family medicine group practices; Lewis 2010, 32 family medicine group practices; Loh 2007, 30 general practitioners; Mathers 2012, 49 general medicine practices; McAlister 2005, 102 primary care practices; Mullan 2009, 40 clinicians; Nagle 2008, 60 general practitioners; Shourie 2013, 50 general medicine practices; Weymiller 2007, 21 endocrinologists; and Whelan 2004, 27 surgeons.

For 10 studies (Allen 2010; Legare 2011; Legare 2012; Loh 2007; Mathers 2012; Mullan 2009; Nagle 2008; Shourie 2013; Weymiller 2007; Whelan 2004), 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 intracluster correlation coefficient (ICC)). For Fraenkel 2012, the authors stated that adding a random effect for physician clusters did not contribute to better-fitting regression models, and we removed it from the analysis. The analysis by Kupke 2013 and Lewis 2010 did not account for clustering.

Decision aids and comparisons

The 105 included studies evaluated decision aids that focused on 50 different decisions (Table 1). The most common decisions were about prostate cancer screening (14 studies), colon cancer screening (10 studies), medication for diabetes (4 studies), breast cancer genetic testing (4 studies), prenatal screening (4 studies), medication for atrial fibrillation (4 studies), and surgery (mastectomy for breast cancer, 4 studies; hysterectomy, 3 studies; prostate cancer treatment, 4 studies). New decision topics added in this update included surgery for prolapsed pelvic organs (1 study) and asymptomatic aortic abdominal aneurysm (1 study); restoration for tooth decay (1 study); measles, mumps, and rubella vaccine for infants (1 study); treatment of post-traumatic stress disorder (1 study); and radioactive iodine treatment for thyroid cancer (1 study).

The decision aids used different formats and were compared to a variety of control interventions (e.g. usual care, general information, no intervention, guideline, placebo intervention). We noted the nature of usual care when reported (see Characteristics of included studies table). For this review, we have grouped control interventions and refer to them as 'usual care'.

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 (90.5%) as well as outcome probabilities (89.5%). Fewer patient decision aids provided guidance in the steps of decision making (65.7%), explicit

methods to clarify values (57.1%), and/or examples of others' experiences (41.0%) (see table Characteristics of included studies).

Excluded studies

We excluded 302 studies upon close perusal of the relevant papers (see Characteristics of excluded studies). The reasons for exclusion were: the study was not a randomized controlled trial; the decision was hypothetical, with participants not actually at a point of decision making; the intervention was not focused on making a choice; the intervention offered no decision support in the form of a decision aid or did not provide enough information about the decision aid; no comparison outcome data were provided; the study did not evaluate the decision aid; the study was a protocol; the decision aid was about clinical trial entry, lifestyle choice, or advanced care planning; the study involved testing the presentation of the decision aid, but with no difference in the content of the decision aid between study groups; or the study compared a detailed versus simple decision aid.

We also identified 61 ongoing RCTs through trial registration databases, personal contact, and published protocols in the electronic database searches (see references to Ongoing studies and table 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 2 and Figure 3.

Figure 2. Risk of bias summary as percentages across all included studies.

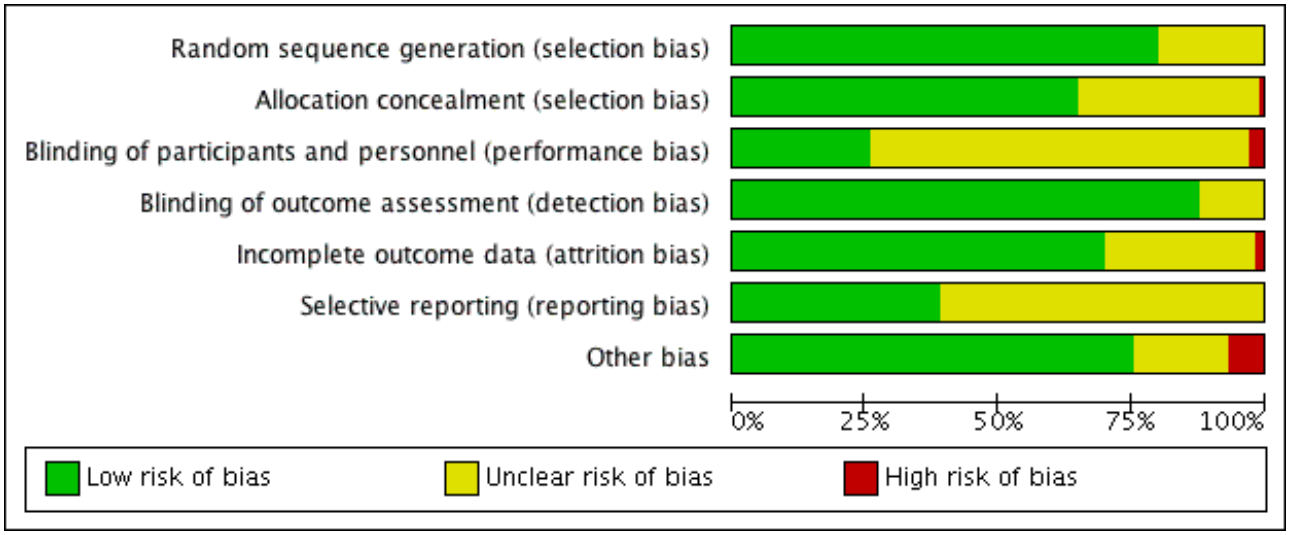


Figure 3. Risk of bias summary for each included study.

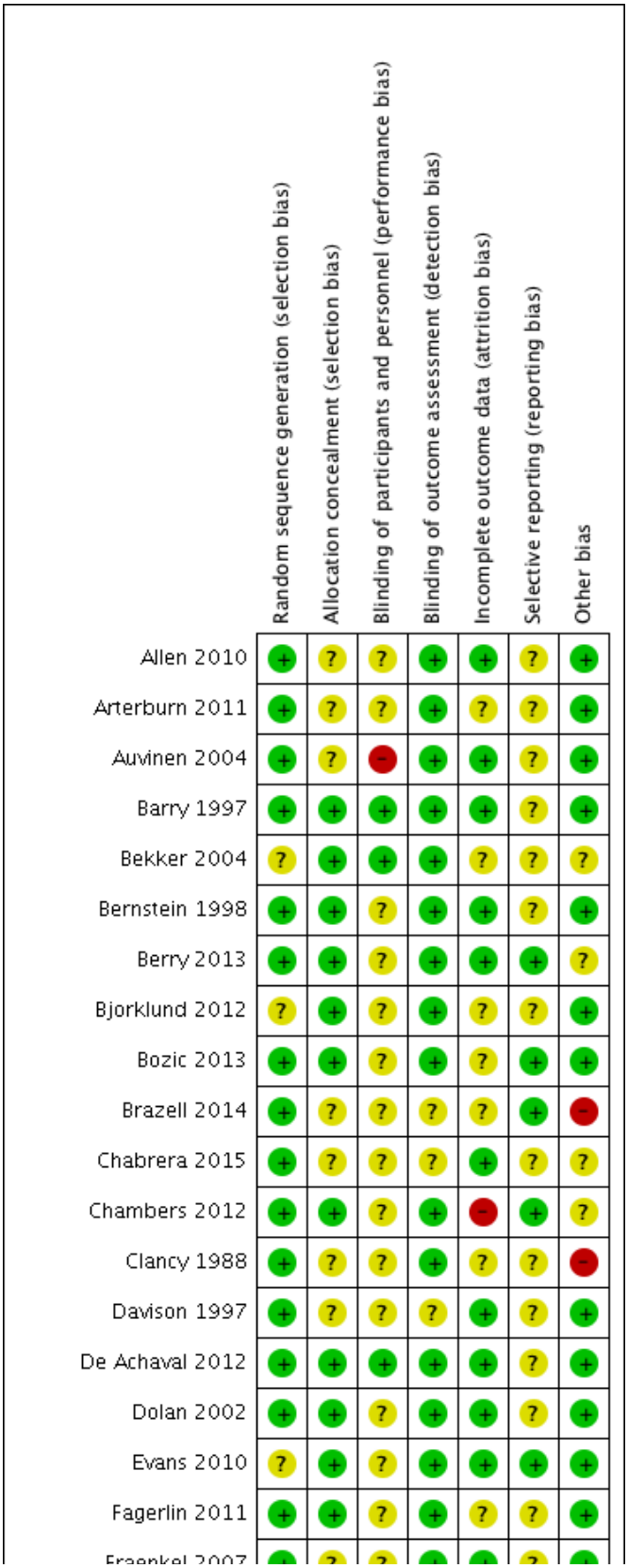
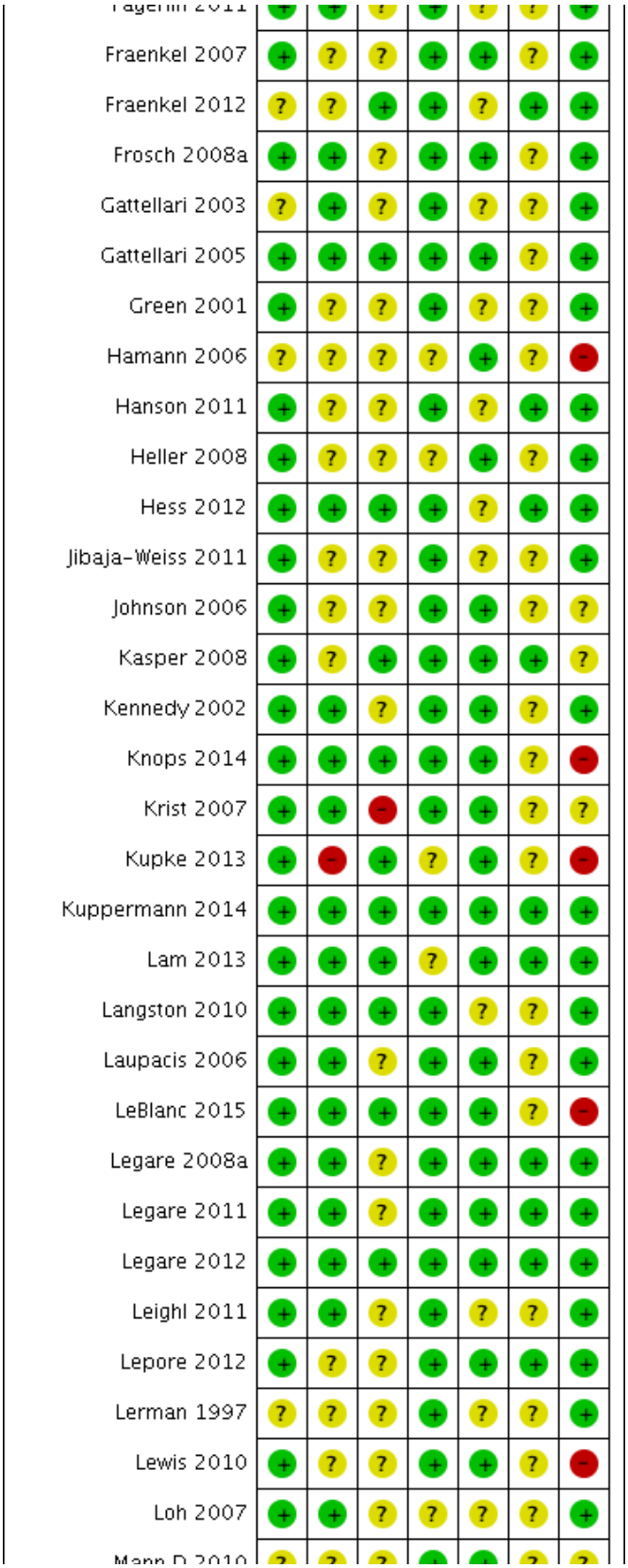


Figure 3. (Continued)



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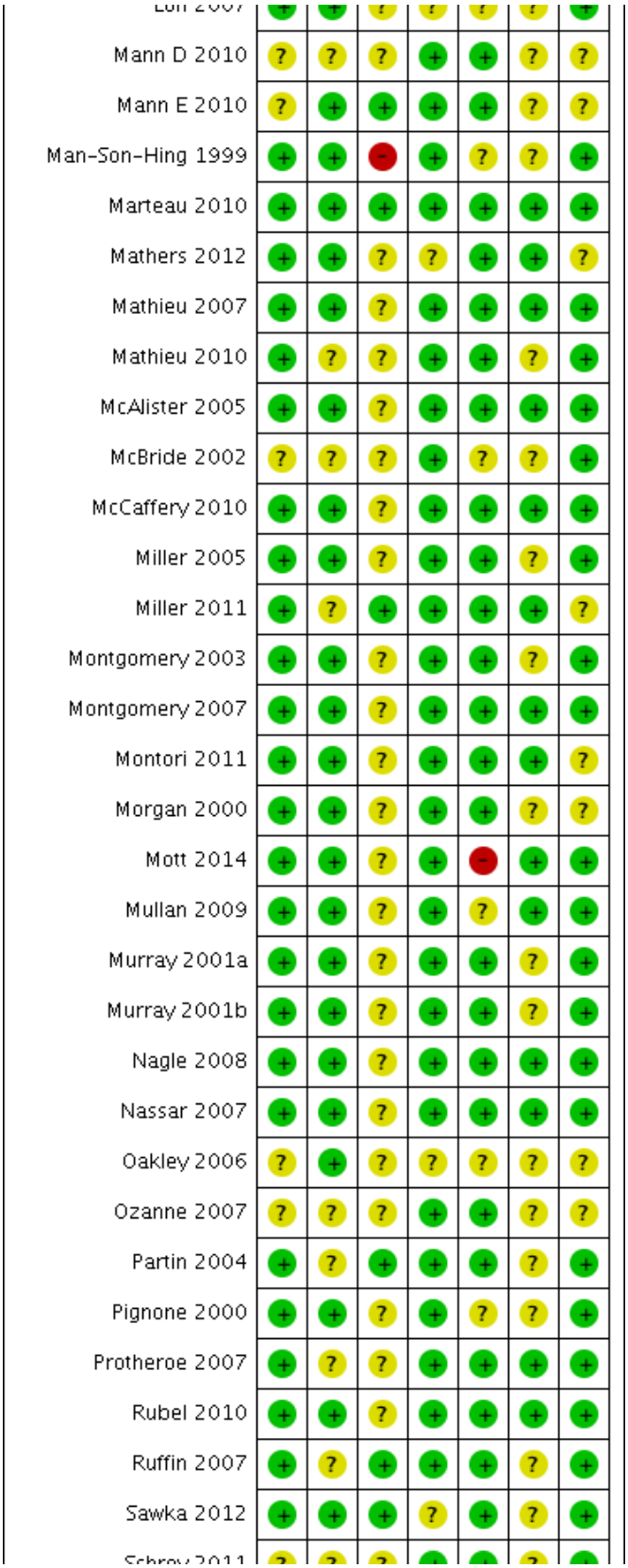

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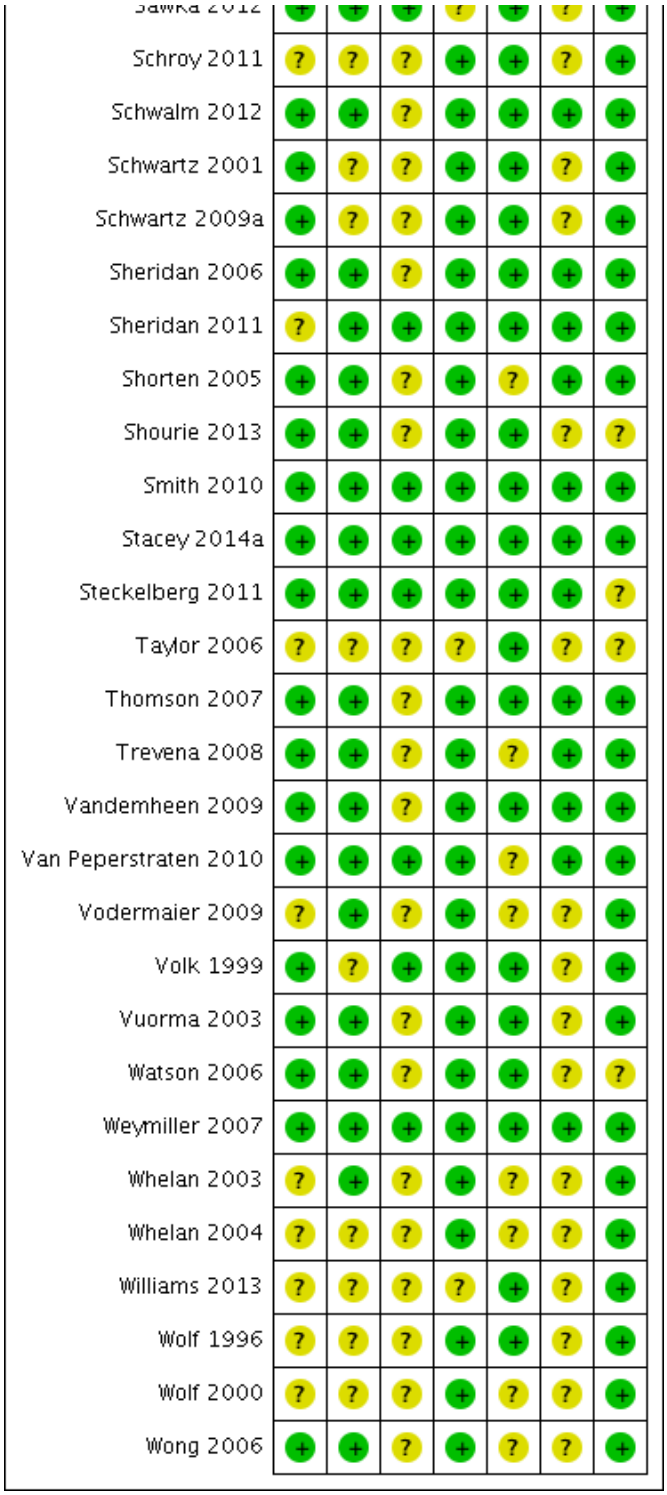


Allocation

When assessing risk of selection bias, we rated all 105 studies as being at low or unclear risk of bias. Allocation concealment methods prompted a rating of low or unclear risk of bias in 104 studies and high risk of bias in 1 study (Kupke 2013).

Blinding

We judged 102 studies to be at low or unclear risk of performance and detection bias for the blinding of participants and personnel, while 3 (2.9%) studies were at high risk of bias. High risk of bias was due to lack of blinding of physicians to the status of patients randomized to the patient decision aid and alternative interventions (Auvinen 2004; Krist 2007; Man-Son-Hing 1999).

We rated the blinding of outcome assessment as leading to low or unclear risk of bias in all 105 studies.

Incomplete outcome data

For 103 studies, aspects related to incomplete outcome data conferred low or unclear risk of bias. In two (1.9%) studies (Chambers 2012; Mott 2014), there was high risk of bias due to high attrition rates.

Selective reporting

We rated all 105 studies as being at either low risk of bias because the protocol was registered publicly or at unclear risk of bias because we could not assess the extent or the impact of any reporting bias.

Other potential sources of bias

Of 105 studies, we rated 98 as being at low or unclear risk of other potential sources of bias. The other seven (6.7%) discussed other potential risks of bias (Brazell 2014; Clancy 1988; Hamann 2006; Knops 2014; Kupke 2013; LeBlanc 2015; Lewis 2010). We rated Brazell 2014 and LeBlanc 2015 as being at high risk of bias given that the same physicians provided consultation to both intervention and control groups, and measures were taken after physician consultation. Clancy 1988 describes a potential for selection bias because non-randomized medical residents were added to the decision aid group, and there was a low response rate among those offered decision aid. We rated Knops 2014 as being at high risk of bias given that a large number of potential participants did not participate in the study. Hamann 2006, Kupke 2013, and Lewis 2010 did not account for clustering in their analyses.

Effects of interventions

See: **Summary of findings for the main comparison**

In addition to Summary of findings for the main comparison, see the Data and analyses figures for pooled data and Additional tables for outcome data that we did not pool. This section presents the attributes of the choice made, the attributes of the decision process, and secondary outcomes.

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?

The randomized controlled trials used three measures that correspond to this outcome: knowledge scores, accuracy of risk perceptions, and congruence between the chosen option and the patient's values.

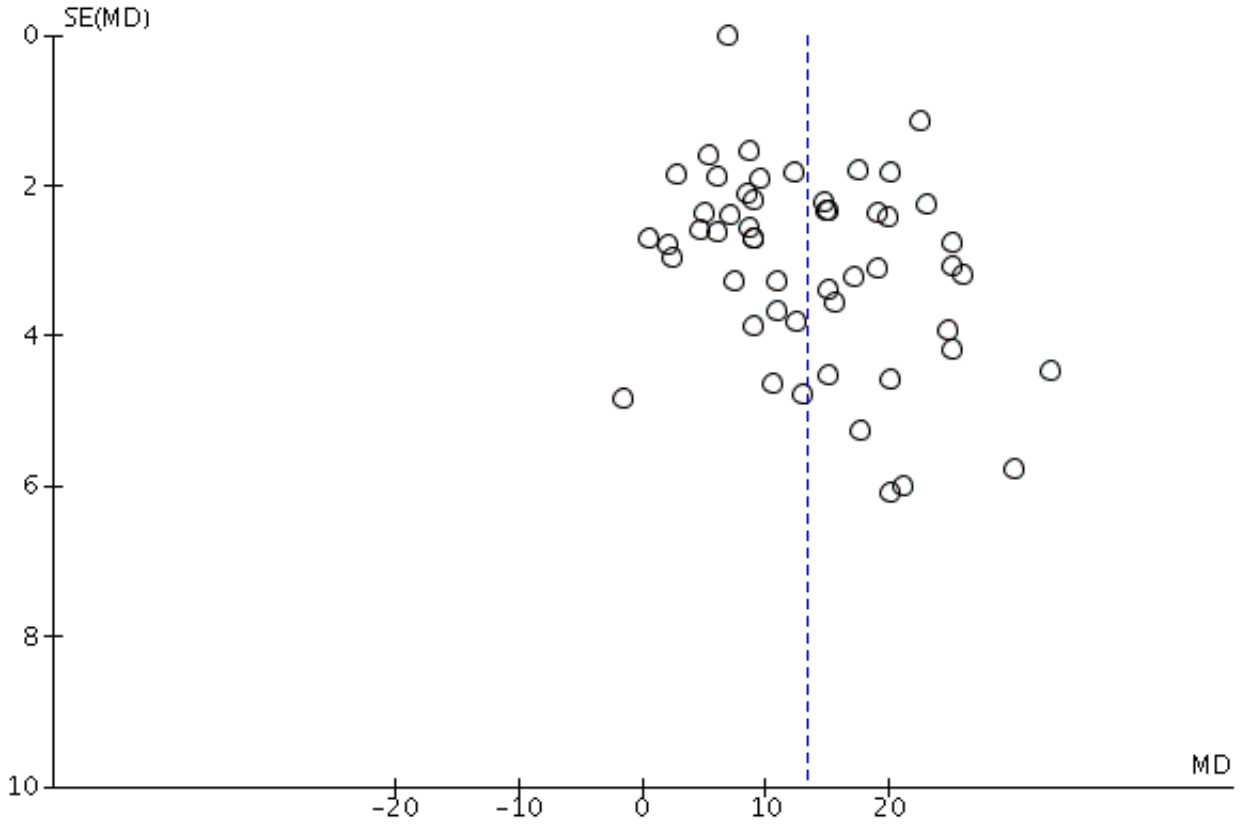
Knowledge

Seventy-one of the 105 studies (67.6%) assessed the effects of decision aids on knowledge. The studies' knowledge tests were based on information contained in the decision aid. The proportion of accurate responses was transformed to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).

There is high-quality evidence that patient decision aids were more effective than usual care (52 studies) on knowledge scores (MD 13.27, 95% CI 11.32 to 15.23; Analysis 1.1). In absolute terms the group receiving usual care had, on average, 57 of 100 answers correct. Those in the decision aid group scored better, with 70 of 100 answers correct on average (from 68 to 72 correct).

Nineteen additional studies presented knowledge scores that could not be included in the pooled outcome (see Table 2). Most of these other studies reported statistically-significantly higher knowledge scores for those exposed to the decision aid compared to usual care. The funnel plot for knowledge as an outcome in studies comparing decision aid to usual care shows that these studies are at low risk for publication bias (Figure 4).

Figure 4. Funnel plot of comparison: 1 Knowledge, outcome: 1.1 Knowledge - all studies.



Accurate risk perceptions (i.e. perceived probabilities of outcomes)

Of 105 studies, 25 (23.8%) examined the effects of patient decision aids on the accuracy of patients' perceived probabilities of outcomes (see Analysis 2.1; Table 3). We classified 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.

There is moderate-quality evidence that patient decision aids were more effective than usual care for transmitting accurate risk perceptions (risk ratio (RR) 2.10, 95% CI 1.66 to 2.66, 17 studies; Analysis 2.1). This means that for every 1000 people receiving usual care, 269 were likely to accurately interpret risk, whereas far more people (565 people per 1000; from 447 to 716) accurately interpreted risk after using a decision aid.

Eight studies reported results that were not amenable to pooling (see Table 3). Fraenkel 2012; Hanson 2011; Kuppermann 2014; Mathieu 2010; and Smith 2010 reported a statistically significant improvement in accurate perceptions of outcomes for the decision aid group compared to usual care, and Miller 2005 reported no effect on risk perception. In another study, Weymiller 2007 reported participants allocated to the decision aid had a significantly more accurate perception of their estimated cardiovascular risk without statin therapy compared to the usual care group; this effect was greater when the clinician used the decision aid during the consultation rather than when the researcher used the decision aid in preparation for the consultation ($P_{interaction}$= 0.03). For the final study by Mann E 2010, three of eight knowledge test items measured accurate risk perceptions, but results were presented for total knowledge and not individual items.The funnel plot for accurate risk perception as an outcome in studies comparing decision aid to usual care shows low risk for publication bias.

Congruence between chosen option and values

Of 105 studies, 16 (15.3%) measured congruence between the chosen options and the patients' values. Six measured values-choice congruence without considering knowledge (Arterburn 2011; Berry 2013; Frosch 2008a; Legare 2008a; Lerman 1997; Vandemheen 2009). Of 10 studies that measured informed values-choice congruence, eight used the Multi-Dimensional Measure of Informed Choice (Bjorklund 2012; Fagerlin 2011; Mathieu 2007; Mathieu 2010; Nagle 2008; Smith 2010; Steckelberg 2011; Trevena 2008), which assesses the extent to which the choice is based on relevant knowledge, is consistent with a person's values/attitudes, and is behaviourally implemented (Michie 2002). These studies operationalized the measure in terms of knowledge scores higher than the mid-point of the scale, attitude scale scores higher than the mid-point, and choice being congruent with attitude.Two other studies measured informed values-based choice: Schwalm 2012 assessed the extent to which the choice was based on knowledge score ≥ 60% and a score for three values-importance ratings that matched the choice; and Stacey 2014a assessed the extent to which the choice was based on knowledge score ≥ 66% and measured values-choice congruence using a logistic regression model. For the 10 studies that measured informed values-choice congruence, two

used preferred choice (Mathieu 2010; Trevena 2008), and the other eight used actual choice.

There is low quality evidence that patient decision aids were more effective than usual care for selecting an option that was congruent with their informed values (RR 2.06, 95% CI 1.46 to 2.91, 10 studies; Analysis 3.1). Of the 10 studies, 8 individually showed statistically higher congruence scores for the patient decision aid compared to usual care, and 2 showed no difference (Bjorklund 2012; Mathieu 2010). Repeating this analysis using the studies that measured actual choice and not preferred choice revealed a pooled RR of 2.13 (95% CI 1.44 to 3.14; 8 studies). A sub-analysis of studies using the Multi-Dimensional Measure of Informed Choice revealed a pooled RR of 2.08 (95% CI 1.40 to 3.08, 8 studies; Analysis 3.3).

There was no difference between patient decision aid and usual care for the six studies that measured values-choice congruence without considering knowledge scores (Arterburn 2011; Berry 2013; Frosch 2008a; Legare 2008a; Lerman 1997; Vandemheen 2009; see Table 4). We did not pool these studies because of how they reported results. Arterburn 2011 reported that, compared to the control group, those exposed to the decision aid experienced a more rapid early improvement of value-choice concordance immediately after exposure. Legare 2008a reported that women's valuing of the non-chemical aspect of natural health products was positively associated with their choice of natural health products in managing menopausal symptoms (P = 0.006). The other four studies reported no differences between groups. However, Frosch 2008a observed that men exposed to the decision aid who chose not to have a prostate-specific antigen (PSA) test rated their concern about prostate cancer lower than men who requested a PSA test, while men assigned to the usual care group provided similar ratings of concern regardless of their PSA choice.

Attributes of the decision process: does the decision aid help patients to recognize that a decision needs to be made, know the options and their features, understand that values affect the decision, be clear about the features that matter most to them, discuss values with their clinician, and become involved in their preferred ways?

In relation to the International Patient Decision Aids Standards (IPDAS) decision process criteria, no studies evaluated the extent to which patient decision aids helped participants to recognize that a decision needed to be made or understand that values affect the decision. Some studies measured participants' self-reports about feeling informed and clear about personal values. The measures used to evaluate these criteria were two subscales of the previously validated Decisional Conflict Scale (DCS) (O'Connor 1995).

Decisional conflict

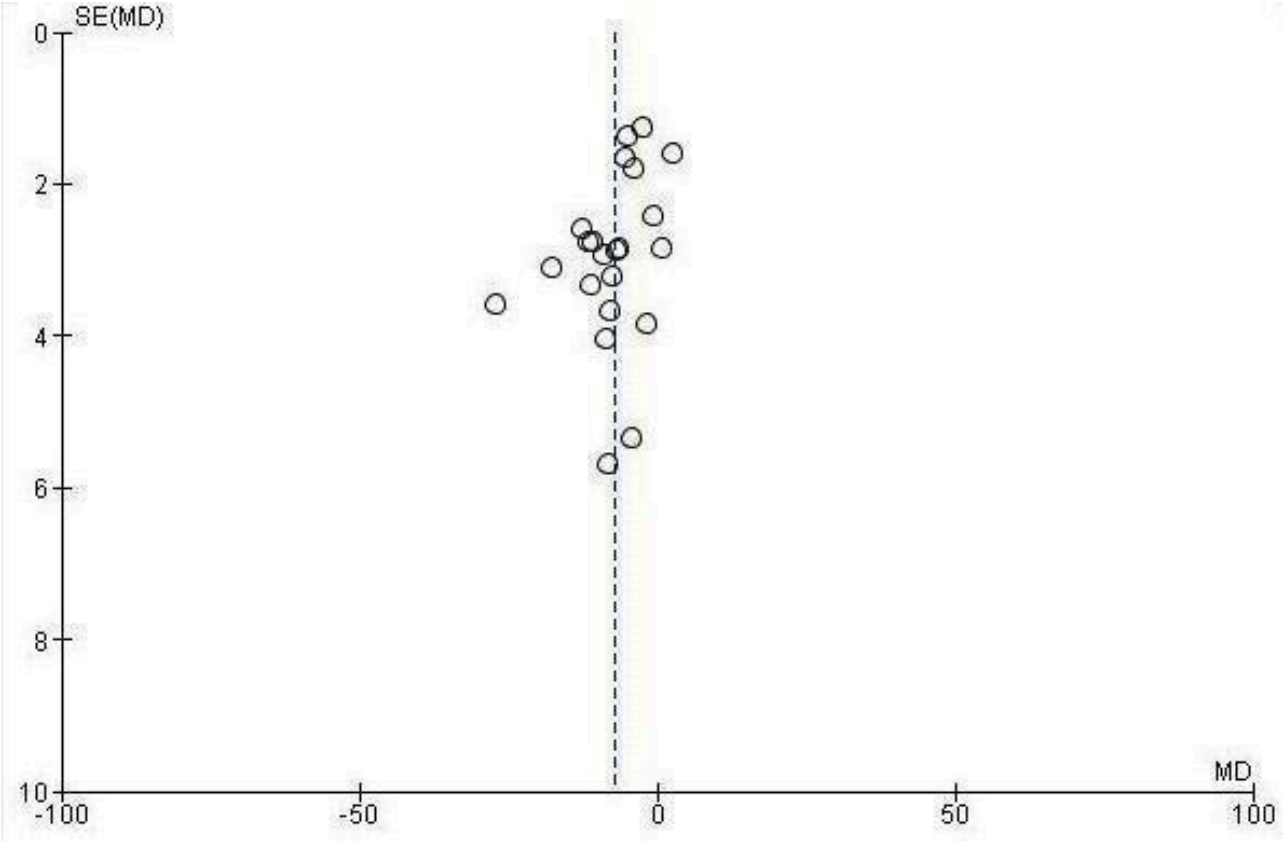
Of 105 studies, 63 (60.0%) evaluated decisional conflict using the DCS (O'Connor 1995). The DCS is reliable, discriminates between those who make or delay decisions, is sensitive to change, and discriminates between different decision support interventions (Morgan 2000; O'Connor 1995; O'Connor 1998b). The scale measures the constructs of overall decisional conflict and the particular factors contributing to uncertainty (e.g. feeling uncertain, uninformed, unclear about values, and unsupported in decision making). A final subscale measures perceived effective decision making. The scores were standardized to range from 0 (no decisional conflict) to 100 points (extreme decisional conflict). Scores of 25 or lower are associated with follow-through with decisions, whereas scores that exceed 38 are associated with delay in decision making (O'Connor 1998b). When decision aids are compared to usual care, a negative score indicates a reduction in decisional conflict, favouring the decision aid.

Analysis 4.1.1 summarizes the decisional conflict results for the 42 studies that compared decision aids to usual care. We report on 21 studies that were not amenable to pooling in Table 5 (original DCS), Table 6 (low literacy version), and Table 7 (SURE test version).

The mean difference (MD) for total DCS scores was −7.22 points out of 100, favouring the patient decision aid over usual care groups (95% CI −9.12 to −5.31; see Analysis 4.1.1). Sixteen studies that could not be pooled (Table 5) reported mixed results on the original DCS. Of four studies that used the low literacy version (Fraenkel 2012; Smith 2010; Taylor 2006; Williams 2013), all reported statistically significant improvement (i.e. reduced) in total (or subscale) decisional conflict scores in the decision aid group, compared to usual care (Table 6). Stacey 2014a reported no difference between groups using the SURE test version.

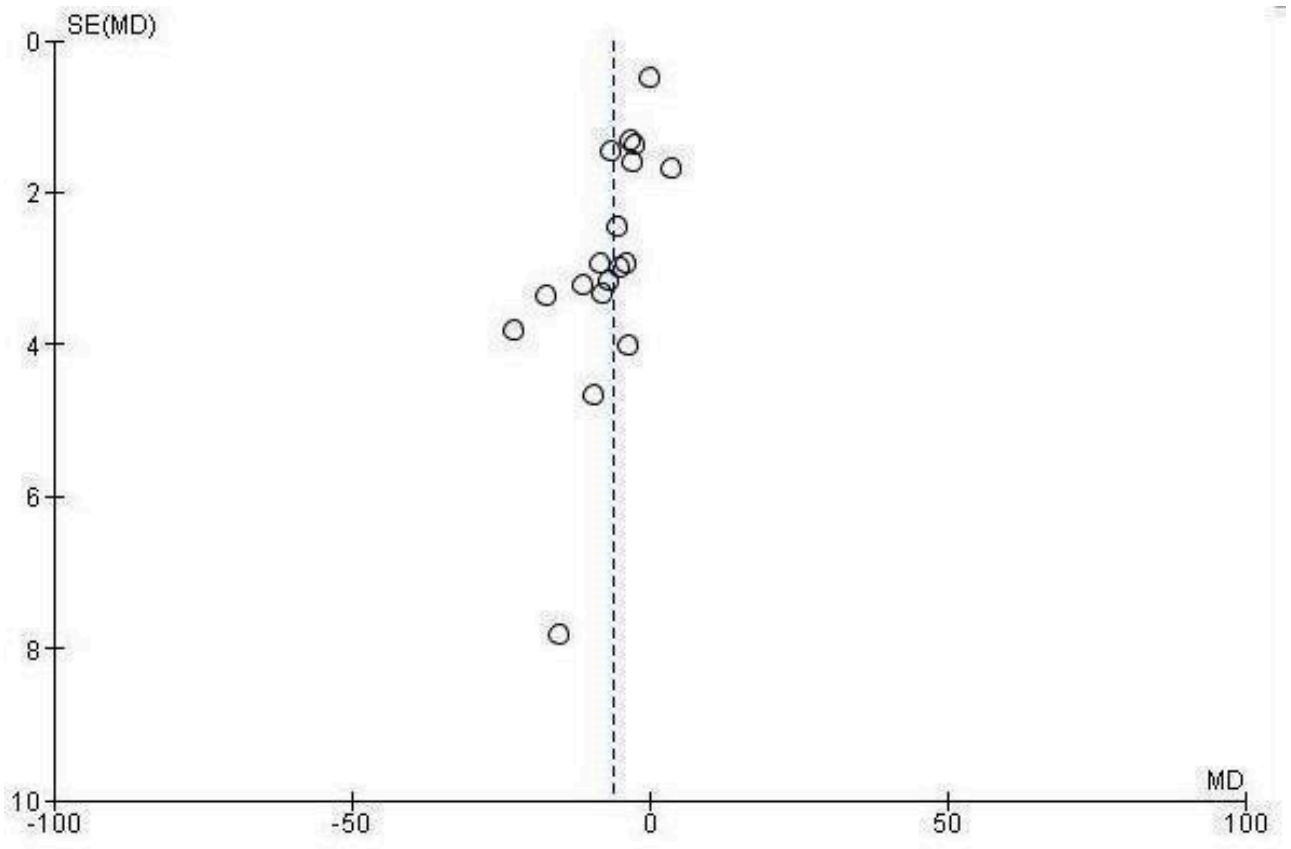
The 'feeling uninformed' subscale of the DCS measures self-reported comfort with knowledge, not actual knowledge. We elected to consider this as a process measure and to reserve the gold standard of objective knowledge tests for assessing decision quality. There was high-quality evidence that patient decision aids were more effective than usual care in reducing patients' 'feeling uninformed' about options, benefits, and harms (MD −9.28, 95% CI −12.20 to −6.36; 27 studies; Analysis 4.1.2). The funnel plot for 'feeling uninformed' as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 5).

Figure 5. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.2 Uninformed subscale



There was high-quality evidence that patient decision aids were more effective than usual care for reducing patients' 'feeling unclear about values' subscale of the DCS (MD −8.81; 95% CI −11.99 to −5.63; 23 studies; Analysis 4.1.3). The funnel plot for using 'feeling unclear about values' as an outcome in studies comparing decision aid to usual care shows low risk for publication bias (Figure 6).

Figure 6. Funnel plot of comparison: 4.1 Decisional conflict: DA vs usual care - all studies, outcome: 4.1.3 Unclear subscale



Patient-clinician communication

Of 105 studies, 10 (9.5%) measured the effect of decision aids on patient-clinician communication. Of these 10 studies, 5 evaluated a patient decision aid used primarily within the consultation with the clinician, and 5 evaluated a patient decision aid used in preparation for the consultation.

Five studies compared the effect of usual care versus a decision aid used within the clinical encounter (or, in Weymiller 2007, half the decision aid participants were exposed just prior to the encounter), evaluating the extent of shared decision making communication by analyzing the audio recordings using the OPTION scale (Hess 2012; LeBlanc 2015; Montori 2011; Mullan 2009; Weymiller 2007). The OPTION scale measures the extent to which healthcare providers use behaviours that involve patients in decision making (Elwyn 2005). All five studies reported statistically higher mean OPTION scores in the patient decision aid group compared to usual care (see Table 8).

Four of five studies reported that compared to those in the usual care group, significantly higher proportions of participants exposed to the patient decision aid in preparation for the consultation reported that they discussed the decision with their clinician (Fraenkel 2012; Hanson 2011; Lepore 2012; Sheridan 2011; see Table 8). The fifth study showed no between-group difference in discussion of cardiovascular disease with the clinician (Sheridan 2006; see Table 8).

Participation in decision making

Of 105 studies, 24 (22.9%) measured the effect of decision aids on patients' perceived participation in decision making (Analysis 5.1; Table 9). Davison 1997 used the Control Preferences Scale (Degner 1992). This scale uses five response statements to measure the role in decision making: two represent an active or patient-controlled role; one a shared or collaborative role; and two response statements represent a passive or clinician-controlled role. Most other studies used comparable response statements that could be classified within each of the three groupings of the Control Preferences Scale, except for Hamann 2006, which used the COMRADE instrument to measure patient perception of involvement, and two others that used other measures of perceived involvement (Hanson 2011; Loh 2007; see Table 9).

Using the groupings of the Control Preferences Scale, 16 of 24 studies reported on clinician-controlled decision making. Consistent with the hypothesis that patient decision aids increase patient participation in decision making, there was moderate-quality evidence that patient decision aids were more effective than usual care for reducing clinician-controlled decision making (RR 0.68; 95% CI 0.55 to 0.83; Analysis 5.1.1). In this field, there is no consensus on the hypothesized effects of decision aids on measures of patient-controlled decision making or shared decision making. Of 24 studies, 15 reported on participants assuming an active (patient-controlled) role in decision making and were pooled for analysis. Compared to usual care, decision aid use increased patient-controlled decision making (RR 1.28, 95% CI 1.05 to 1.55;

Analysis 5.1.2). The 15 studies that reported on a shared decision-making role showed no difference between decision aid and usual care (RR 0.95; 95% CI 0.83 to 1.10; Analysis 5.1.3).

Of eight studies that could not be pooled, Allen 2010, Leighl 2011, Rubel 2010, and Van Peperstraten 2010 reported no between-group differences in these roles (Table 9). Three studies reported that a statistically significant proportion of patients exposed to the decision aid either participated (Sheridan 2011) – or at least felt involved – in decision making (Hamann 2006; Loh 2007). However, Hamann 2006 did not analyze results accounting for the use of design clusters. Hanson 2011 reported that a higher proportion described feeling involved (83% vs. 77%), but the difference between groups was not statistically significant.

Proportion undecided

Of 105 studies, 24 (22.9%) measured the proportion of participants remaining undecided: of these, 22 studies could be pooled. A significantly lower proportion of people remained undecided after exposure to a decision aid (RR 0.64; 95% CI 0.52 to 0.79; Analysis 6.1).

Kasper 2008 measured progress in decision making using a single item ranging from '0 = completely undecided' to '100 = made my decision'. Given the difference in the measure Kasper used, these results were not included in the meta-analysis. In this study, both the patients exposed to a decision aid and the usual care group progressed in their decision making, with no difference between the groups (Table 10). Sawka 2012 reported that 10.8% in the patient decision aid group versus 21.6% in the usual care group reported not knowing if they preferred taking adjuvant radioactive iodine.

Satisfaction

Nineteen included studies (18.1%) measured satisfaction as it relates to the choice and the preparation for and the process of decision making. When possible, we standardized the scores to a 0 to 100 point scale, with higher scores reflecting greater satisfaction.

Nineteen studies (18.1%) measured satisfaction with the choice. Of these 19 studies, 4 reported that people exposed to the decision aid had higher satisfaction with their choice compared to usual care, and the other 15 reported no statistically significant differences (Chabrera 2015; Heller 2008; Laupacis 2006; Montgomery 2007; see Analysis 7.1 and Table 11). For results that used a similar measure (Analysis 7.1), there was high satisfaction for all participants, with a median score of 82.5% for the decision aid and 80.0% for the usual care groups.

Of 105 total studies, 11 (10.5%) measured satisfaction with the decision, 11 (10.5%) measured satisfaction with the decision-making process (see Analysis 7.6; plus Hess 2012 and Vodermaier 2009 in Table 12), 4 measured satisfaction with information provided (LeBlanc 2015; Laupacis 2006; Montori 2011; Oakley 2006), 3 measured satisfaction with the clinician (Laupacis 2006; Miller 2005; Vodermaier 2009), and 1 measured satisfaction with participating in decision making (Kennedy 2002). There were mixed results, but no studies reported that those exposed to patient decision aids were significantly less satisfied compared to usual care. For results that used a similar measure of satisfaction with the decision-making process (Analysis 7.4), there was high satisfaction for all participants, with median scores of 83.8% for the decision aid and 77.8% for the usual care groups. Although there were no differences between participant groups in satisfaction with the information in the Montori 2011, clinicians using the decision aid had higher satisfaction.

Three studies (2.9%) measured satisfaction with preparation for decision making using the Preparation for Decision Making Scale (Bennett 2010) (Table 13). Compared to usual care, two studies reported significant improvements in people's satisfaction with their preparation for making decisions: in Fraenkel 2007 after using decision aids about management of knee osteoarthritis, and in Vandemheen 2009 regarding referral to a lung transplant centre. The third study found no statistically significant difference on this subscale's four items (Stacey 2014a).

Secondary outcomes

Behaviour

Choice

Choice was 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. Actual choices or preferences were reported as the percentage of individuals actually implementing or stating a preference for the most intensive or most invasive option.

In summary, patient decision aids decreased the number of patients choosing elective surgical procedures (excluding prophylactic mastectomy) and PSA testing in multiple studies. Single studies showed that decision aids increased the number of people choosing hepatitis B vaccination, psycho-educational therapies for mental health conditions, and medication for cardiovascular disease prevention. In contrast, decision aids decreased the rate of cardiac stress testing, the number of embryos being transplanted, and the rate of antibiotic use for upper respiratory infections. The effect on patients' choice in other situations was more variable. There were mixed results for the choice of colon cancer screening, genetic testing, prenatal testing, anti-thrombosis therapy, breast screening, and diabetes medications. There was no difference between groups for choices about natural health products, hypertension therapy, breast cancer chemotherapy, schizophraenia medication, immunotherapy for multiple sclerosis, vaccines (for flu or measles, mumps, rubella), diabetes screening, birth control, osteoporosis treatment, chemotherapy for advanced cancer, chemopreventive medications, use of blood transfusions, childbirth procedures, treatment of prolapsed pelvic organs, or radioactive iodine treatment for thyroid cancer.

Choice for major elective surgery

Eighteen studies (17.1%) focused on choices regarding major elective surgery (Analysis 8.1).

Using intention-to-treat analysis, there was a non-significant reduction in the number of patients choosing major elective surgery in the group receiving the decision aid compared to usual care (RR 0.86; 95% CI 0.75 to 1.00, 18 studies; Analysis 8.1.2). Schwartz 2009a reported a statistically significant uptake of prophylactic mastectomy for women who are BRCA1/2 gene carriers (114%). And after removing this study from the pooled results, there was a statistically significant reduction in the number

of patients choosing major elective surgery (RR 0.84 95% CI 0.73 to 0.97; 17 studies; Analysis 8.1.3).

Four other studies showed statistically significant reductions in surgery rates: −29% for cardiac revascularization and bariatric surgery (Arterburn 2011; Morgan 2000), −33% for orchiectomy (Auvinen 2004), and −74% for mastectomy (Whelan 2004). The other 15 studies showed no difference between the decision aid or usual care groups.

Choice for other elective surgery

Two studies evaluated the effect of decision aids versus usual care on other elective surgical decisions. Decision aids did not significantly influence surgical abortion rates in Wong 2006 or feeding tube insertions in Hanson 2011 (Table 14).

Choice for prostate-specific antigen screening

The effects of decision aids on prostate-specific antigen (PSA) screening decisions were variable in 13 studies (12.4%) that compared decision aids to usual care. The pooled RR for 10 studies was 0.88 (95% CI 0.80 to 0.98; Analysis 8.2.1); Frosch 2008a, Lepore 2012, and Williams 2013 could not be included in the pooled data (Table 14). Frosch reported a reduction in screening rates and the other two reported no difference.

Choice for colon cancer screening

Of 10 studies (9.5%) on colon cancer screening, 3 reported statistically significant differences in choices, and 7 showed no difference. Two studies reported that compared to usual care, the decision aid significantly increased the screening rates by 64% and 70% (Pignone 2000; Ruffin 2007). The other study reported a statistically significant reduction of 21% for screening (Smith 2010). There was an increase in screening rates in five studies, by 6% to 39%, but the difference was not statistically significant (Lewis 2010; Miller 2011; Schroy 2011; Steckelberg 2011; Wolf 2000). In two studies (Dolan 2002; Trevena 2008), there was a 73% and 4% decrease in screening rates that was not statistically significant. The pooled RR was 1.12 (95% CI 0.95 to 1.31, 10 studies; Analysis 8.2.2).

Choice for cancer genetic screening

Four studies reported preferences or uptake rates for breast cancer genetic screening (3.8%). The decision aid did not significantly affect preferences for breast cancer genetic screening when compared to usual care. The pooled RR was 0.99 (95% CI 0.71 to 1.38, 3 studies; Analysis 8.2.3). One study reported an increase in screening rates by 14% (Lerman 1997), a second study reported an increase of 18% (Green 2001), and a third study reported a decrease of 29% (Schwartz 2001). Miller 2005 reported that women exposed to the decision aid who were at higher risk of breast cancer increased their intention to obtain genetic testing, while those at average risk decreased their intention (Table 14).

Choice for breast screening

There were lower mammography screening rates among women aged 38 to 45 years of age (Mathieu 2010), but no between-group difference in women aged 70 or older who were exposed to a decision aid versus usual care (Mathieu 2007; Table 14).

Choice for prenatal screening

In all four studies focusing on decisions around prenatal screening, prenatal testing rates were not affected by a decision aid compared to usual care (Bekker 2004; Bjorklund 2012; Kuppermann 2014; Nagle 2008). Meta-analysis included two studies, showing no effect (RR 0.99, 95% CI 0.91 to 1.09, 2 studies; Bjorklund 2012; Kuppermann 2014; Analysis 8.2.4).

Choice for stress test for chest pain

Compared to usual care, adults presenting with chest pain in the emergency department who received the decision aid had significantly lower rates of stress testing (58% versus 77%) (Hess 2012; Table 14).

Choice for screening for diabetes

Compared to usual care, there was no difference in diabetes screening rates in Marteau 2010 or preferences for screening in Mann E 2010 in adults exposed to a decision aid (Table 14).

Choice to take antibiotics for upper respiratory infection

Compared to usual care, using a decision aid in the consultation decreased prescriptions for antibiotics for upper respiratory infections in Legare 2012, although this difference was not statistically significant in Legare 2011 (Table 14).

Choice for atrial fibrillation treatment

Three studies evaluated the effect of a decision aid on the use of anti-thrombotic therapy for atrial fibrillation versus usual care (Table 14). One study demonstrated a non-significant reduction in warfarin use of 25% (Man-Son-Hing 1999). The second study evaluated the proportions of patients choosing the option that was appropriate relative to their level of risk, and found no significant difference between the groups (McAlister 2005). Thomson 2007 reported that patients in the usual care group (guided by practice recommendations) were much more likely to start warfarin (15/16; 93.8%) compared to the decision aid group (4/16; 25%; RR 0.27; 95% CI: 011 to 0.63).

Choice to take breast cancer prevention medication

There was no difference in medication use among women at risk of breast cancer who were exposed to the decision aid versus usual care (Fagerlin 2011; Table 14).

Choice for cardiovascular disease prevention

There was an increase in patient preferences for any effective cardiovascular disease risk-reducing strategy (including medication) when using a decision aid versus usual care (63% versus 42%) (Sheridan 2011; Table 14).

Choice for chemotherapy for cancer

There was no statistically significant difference in the rates of chemotherapy for adults with advanced colorectal cancer (77% versus 71%) (Leighl 2011; Table 14). Whelan 2003 also found no significant effect on preferences for adjuvant chemotherapy versus no chemotherapy for early stage breast cancer.

Choice for diabetes treatment with new medications

Four studies evaluated patient decision aids compared to usual care on decisions about starting new medications for diabetes (Mann D 2010; Mathers 2012; Mullan 2009; Weymiller 2007). Although there was no statistically significant difference between groups for individual studies, pooled results indicated a significant

increase in starting new medications (RR 1.65, 95% CI 1.06 to 2.56; Analysis 8.3).

Choice to take hypertension medication

Montgomery 2003 found no significant effect for decision aids over usual care on the initiation of medication for hypertension (Table 14).

Choice for menopausal symptom treatment

In a study comparing a decision aid to usual care (Murray 2001b), there was a non-significant decrease of 8% in hormone therapy (Table 14). Preferences for natural health products in women experiencing menopausal symptoms were no different for women exposed to the decision aid compared to women exposed to the usual education materials (Legare 2008a).

Choice for multiple sclerosis immunotherapy

Kasper 2008 reported no difference in the uptake of immunotherapy in people with multiple sclerosis who were exposed to a decision aid compared to usual care based on practice guidelines (Table 14).

Choice to take osteoporosis treatment

There was no difference in prescriptions for bisphosphonates for osteoporosis treatment (LeBlanc 2015; Table 14). Montori 2011 found no significant effect of decision aids over usual care on the uptake of medication for osteoporosis treatment.

Mental health

Hamann 2006 found no difference in prescription rates for antipsychotic medications but reported a statistically significant increase in the uptake in psycho-education (P = 0.003) in people with schizophraenia exposed to the decision aid compared to usual care (Table 14). Mott 2014 reported that a higher proportion of participants in the decision aid group with post-traumatic stress disorder completed psychotherapy sessions (4 of 9) compared to usual care (1 of 11).

Obstetrical choices

Childbirth procedures

Three studies focused on childbirth issues, using a decision aid compared to usual care. There was no difference in preference for vaginal birth in Shorten 2005 or actual vaginal mode of delivery in Montgomery 2007 following a previous cesarean section. Another study found no difference in actual choice to undergo external cephalic version for women with breech presentation (Nassar 2007).

Birth control approaches

There was no difference in the birth control methods chosen for those in the decision aid versus usual care groups (Langston 2010).

Embryo transplantation

Compared to usual care, those in the decision aid group were significantly more likely to choose a single embryo transplant (43% versus 32%) (Van Peperstraten 2010).

Vaccines

Compared to usual care, there was a non-significant increase in intentions to get the flu vaccine in those exposed to the decision aid (46% versus 27%) (Chambers 2012), a statistically significant increase in uptake of hepatitis B vaccination with decision aids (Clancy 1988), and no difference in uptake of measles, mumps, rubella vaccine in infants (Shourie 2013).

Other choices

Blood transfusions

There was no difference in the uptake of preoperative autologous blood donation when a decision aid was compared to usual care (Laupacis 2006).

Lung transplant referral

There was no difference in referral rates for consideration of lung transplant in people with advanced cystic fibrosis exposed to a decision aid versus usual care (Vandemheen 2009).

Pelvic organ prolapse treatment

There was no difference in treatment rates for prolapsed pelvic organs (Brazell 2014).

Thyroid cancer radioactive iodine treatment

There was no difference in the rates of adjuvant radioactive iodine treatment for thyroid cancer (Sawka 2012).

Adherence (continuance/compliance) with chosen option

Of 105 studies, 16 (15.2%) measured adherence using various approaches (Table 15).

Based on the measurement framework by Trenaman 2016, we grouped adherence according to adherence to the baseline choice and adherence to the treatment. Six studies measured only adherence to the baseline choice (Langston 2010; Legare 2012; Lepore 2012; Man-Son-Hing 1999; Mathers 2012; Trevena 2008), 6 studies measured only adherence to treatment (Loh 2007; Mann D 2010; Mott 2014; Mullan 2009; Oakley 2006; Sheridan 2011), and 4 studies measured both (LeBlanc 2015; Montgomery 2003; Montori 2011; Weymiller 2007).

For the 10 studies that measured adherence to choice, two studies reported that patients exposed to decision aids had higher adherence compared to usual care (Mathers 2012; Montori 2011), and 8 reported no difference between groups. For example, Mathers 2012 asked participants, 6 months after their decision, whether or not they had changed their initial choice about starting insulin for type II diabetes (decision aid 68.1% versus 56.3% usual care; P = 0.041). Montori used pharmacy records to determine if participants who chose bisphosphonates actually took their medication on more than 80% of the days for which it was prescribed (100% decision aid versus 74% usual care; P = 0.009).

For the 10 studies that measured adherence to treatment, 2 studies reported that patients exposed to decision aids had higher adherence compared to usual care (Mott 2014; Sheridan 2011), 1 study reported that patients exposed to decision aids had lower adherence (Mullan 2009), and 7 reported no difference. Mott reported the percentage of participants at four months who engaged in nine or more psychotherapy sessions (4 of 4 decision aid group participants versus 1 of 5 usual care). Sheridan measured the

percentage of participants who, 3 months after initiating therapy, were continuing (59% decision aid versus 34% usual care; P < 0.01). Mullan used pharmacy records to determine the days covered by medication use (97.5% decision aid versus 100% usual care).

Health outcomes

General health outcomes

Eleven studies (10.5%) compared a decision aid to usual care in terms of general health outcomes (Table 16). Ten of these used either the previously validated Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) or the 12-item Short-Form Health Survey (SF-12) (Stewart 1992), while Vuorma 2003 used the RAND-36 (Hays 1993). As shown in Table 16, there were no significant differences for mental health function or social function in any of the seven studies. In one study (Barry 1997), general health and physical function outcome scores were significantly better in the decision aid group compared to usual care for men considering treatments for benign prostatic disease. Of the two studies evaluating the effect of a decision aid for women considering treatment for abnormal uterine bleeding, Kennedy 2002 found a statistically significant improvement in role physical function, and Vuorma 2003 found a statistically significant improvement in emotional role functioning for women.

In two studies measuring health utilities using the Euroqol EQ-5D (Murray 2001a; Murray 2001b), there was no difference between the decision aid and usual care groups. There was also no between-group difference in the LeBlanc 2015 study, which used the Euroqol 5D health thermometer.

Condition-specific health outcomes

Seven studies (6.7%) used various measures to assess condition-specific health outcomes (Table 17). Outcomes included urinary symptoms (Barry 1997; Murray 2001a), angina (Bernstein 1998), functional assessment of cancer therapy (Leighl 2011), menopausal symptoms (Murray 2001b), and menstrual symptoms (Protheroe 2007; Vuorma 2003). Five studies found no significant effects on condition-specific health outcomes (Bernstein 1998; Leighl 2011; Murray 2001a; Murray 2001b; Vuorma 2003). Protheroe 2007 reported significantly higher menorrhagia-related quality of life scores in women exposed to the decision aid compared to usual care. Barry 1997 showed an improvement in urinary symptoms in favour of the decision aid group, but it was not statistically significant.

Other health outcomes

Seven studies (6.7%) reported on other health outcomes (Table 18), including death (Auvinen 2004; Knops 2014), glycated haemoglobin (Mathers 2012), angina (Morgan 2000), stroke (Thomson 2007), successful pregnancy (Van Peperstraten 2010), and pain (Vuorma 2003). There were no statistically significant differences between groups.

Preference-linked health outcomes

None of the 105 studies measured preference-linked health outcomes – that is, whether the patients experienced the outcomes they preferred and avoided the outcomes they wanted to avoid.

Anxiety

Of 105 studies, 31 (29.5%) measured anxiety, with 24 using the previously validated State Trait Anxiety Inventory (Spielberger 1970), 2 using the anxiety subscale of the Hospital Anxiety and Depression Scale (Knops 2014; Lam 2013), 2 using questions about worry (Fraenkel 2012; Smith 2010), 2 measuring intrusive thoughts (Lewis 2010; McCaffery 2010), and 1 using a single question on a seven-point Likert scale (Johnson 2006; see Table 19). Of 18 studies that used the State Trait Anxiety inventory within 1 month postintervention, 2 (11.1%) reported that the decision aid group had significantly lower anxiety scores for people considering birthing options after a previous caesarean (Montgomery 2007) and for women considering options for the treatment of menorrhagia (Protheroe 2007). None of the studies demonstrated significant differences in effects on people's state anxiety at one month (2 studies), three months (6 studies), six months (4 studies), or one year (2 studies). There was no significant difference between groups for the other instruments that measured anxiety.

Depression

Of 105 studies, 6 (5.7%) measured the effect of decision aids on depression using various instruments (Table 20). None of the studies reported a statistically significant difference between groups for decisions about cancer treatment (Davison 1997; Whelan 2004), depression (Loh 2007), prenatal genetic testing (Nagle 2008), or for women considering the number of embryos to transplant (Van Peperstraten 2010). At 10 months' postintervention, there were lower levels of depression in women deciding about breast cancer surgery who were exposed to the patient decision aid versus the usual care, but no differences at 1 week, 1 month, or 4 months postintervention (Lam 2013).

Regret

Of 105 studies, 7 (6.7%) measured the effect of decision aids on decision regret, using the five-item Decisional Regret scale (Brehaut 2003; see Table 21). At 4 and 10 months postintervention, women with breast cancer who were considering surgery and used a decision aid reported lower regret scores compared to women receiving usual care (Lam 2013). There was no statistically significant between-group difference in the other six studies.

Confidence

Of 105 studies, 8 (7.8%) measured the effect of decision aids on confidence levels (see Table 22). Four of these studies used the Decisional Self-efficacy Scale (Allen 2010; Arterburn 2011; Fraenkel 2007; Smith 2010). Four studies reported a statistically significant improvement in confidence or self-efficacy with decision making in the decision aid compared to the usual care groups (Chambers 2012; Fraenkel 2007; Gattellari 2003; McBride 2002), and the other studies reported no difference between groups.

Healthcare system effects

Cost and resource use

Of eight studies (7.6%) examining cost and resource use, one conducted a cost-effectiveness analysis (Kennedy 2002), five evaluated the effect of decision aids compared to usual care on total costs (Montgomery 2007; Murray 2001a; Murray 2001b; Van Peperstraten 2010; Vuorma 2003), and two measured resource use (Legare 2012; Thomson 2007) (see Table 23).

The cost-effectiveness analysis (Kennedy 2002) was conducted from the healthcare system perspective, using USD values from 1999 to 2000 and calculating costs over two years. The decision aid with nurse coaching demonstrated the lowest mean cost (USD 1566) compared to decision aid alone (USD 2026) or usual care (USD 2751).

Of the five studies that evaluated total costs, two reported no statistically significant difference in the patient decision aid compared to usual care (Montgomery 2007; Vuorma 2003). Two studies reported higher costs for the patient decision aid group when including the cost of the interactive video disc equipment (USD 216 at 1999 prices) and no statistically significant difference between groups when removing this cost (Murray 2001a; Murray 2001b). The fifth study reported that the mean total savings in the decision aid group versus usual care was EUR 169.75 per couple (Van Peperstraten 2010).

For healthcare resource use in upper respiratory infection, Legare 2012 reported no difference in the rates of repeat consultations for the same reason, and Thomson 2007 reported no difference in the rates of general clinician consultations in the three months following the intervention. Both studies used the patient decision aid in the consultation.

Consultation length

Of 105 studies, 10 (9.5%) evaluated the effect of a decision aid compared to usual care on consultation length (see Table 23). The median consultation length was 24 minutes (range 3.8 to 68.3) for patient decision aid compared to 21 minutes (range 4.2 to 65.7) for usual care. The difference was 2.6 minutes longer (7.5% increase) than usual care consultations (range 0.4 minutes shorter to 23 minutes longer). The length of consultation was significantly longer for the patient decision aid group in two studies (Bekker 2004; Thomson 2007), and eight studies reported no difference. Bekker 2004 reported that consultations about prenatal diagnostic testing were 5.9 minutes longer, and Thomson 2007 reported consultations about treatment for atrial fibrillation were 23 minutes longer when using a computerized decision aid with standard gamble method within the consultation.

Litigation rates

None of the 105 studies examined the effect of decision aids on litigation.

Adverse events

There were no adverse effects on health outcomes or satisfaction, and no other adverse events reported.

Subgroup analysis - in preparation for versus during the consultation

Of 105 studies, 89 (84.8%) primarily evaluated the patient decision aid when used by the patient in preparation for the consultation, and 16 (15.2%) primarily evaluated the patient decision aid when used within the consultation. The patient decision aids used during the consultation focused on prenatal screening (Bekker 2004); cardiac stress testing (Hess 2012); dental surgery (Johnson 2006); restoration of tooth decay (Kupke 2013); antibiotics for upper respiratory infection (Legare 2011; Legare 2012); medication use for depression (Loh 2007), diabetes (Mann D 2010; Mullan 2009; Weymiller 2007), osteoporosis (LeBlanc 2015; Montori 2011), prevention of breast cancer (Ozanne 2007), and atrial fibrillation (Thomson 2007); surgery for breast cancer (Whelan 2004); and chemotherapy for breast cancer (Whelan 2003).

Knowledge

When considered separately by subgroups, there was no difference between knowledge scores for those exposed to the decision aid in preparation for the consultation compared to those used in the consultation itself (Analysis 1.2: MD 13.77% versus 10.57%, test for subgroup difference P = 0.31, I^2: 3%). Weymiller 2007 reported a higher mean difference when the decision aid was administered during the consultation but not if it was administered by research staff in preparation for the consultation. For the studies evaluating decision aids used in the consultation not included in the pooled outcome, two showed a statistically significant improvement in knowledge (LeBlanc 2015; Ozanne 2007), and two showed no difference (Mann D 2010; Thomson 2007).

Accurate risk perceptions

When analyzing pre-consultation and in-consultation decision aids further, accurate risk perceptions were not different between studies that used the decision aid in preparation for the consultation and those where the intervention occurred during the consultation (Analysis 2.2: RR 2.25 versus RR 1.79, test for subgroup differences: P = 0.33, I^2: 0%). The only study evaluating a decision aid within the consultation that was not included in the meta-analysis, Weymiller 2007, reported a higher proportion with accurate risk perception when the decision aid was administered during the consultation, but found no difference between groups when administered by research staff in preparation for the consultation.

Decisional conflict uninformed subscale

Too few studies measured the uninformed subscale in those exposed to decision aid within the consultation to be able to compare with those who used decision aids in preparation for the consultation. Weymiller 2007 reported that participants felt less uninformed when the decision aid was administered during the consultation, but not if it was administered by research staff in preparation for the consultation.

Decisional conflict unclear values subscale

Too few studies measured the unclear values subscale in those exposed to decision aid within the consultation to be able to compare with those who used decision aids in preparation for the consultation. Weymiller 2007 reported that participants felt less unclear about values when the decision aid was administered during the consultation, but not if it was administered by research staff in preparation for the consultation.

Patient-clinician communication

Due to variation in the reporting of data for this outcome, we were unable to investigate the effect of intervention timing on the variation in the effect on communication. Five studies evaluated a patient decision aid primarily used within the consultation with the clinician, and five evaluated a patient decision aid used in preparation for the consultation (see Table 8). All five studies that used the decision aid during consultations reported statistically higher mean OPTION scores in the patient decision aid group compared to usual care (Hess 2012; LeBlanc 2015; Montori 2011;

Mullan 2009; Weymiller 2007). Four of five studies assessing the effects of pre-consultation decision aid delivery (Fraenkel 2012; Hanson 2011; Lepore 2012; Sheridan 2011) reported that, compared to those in the usual care group, significantly higher proportions of participants exposed to the patient decision aid in preparation for the consultation reported that they discussed the decision with their clinician, and the fifth study showed no between-group difference (Sheridan 2006).

Participation in decision making

There were too few studies on decision aids used during the consultation to interpret findings from the subgroup analysis (Analysis 5.2; Analysis 5.3).

Length of the consultation

Due to variation in the reporting of data for this outcome, we were unable to investigate the effects of intervention timing on the length of consultation. Of seven studies that evaluated decision aids used within the consultation (Bekker 2004; LeBlanc 2015; Loh 2007; Ozanne 2007; Thomson 2007; Weymiller 2007; Whelan 2003), two reported that the length of the consultation was significantly longer for the patient decision aid group (Bekker 2004; Thomson 2007). There was no difference for the other studies. The three studies that evaluated decision aids used in preparation for the consultation reported no between group difference in the length of the consultation (Bozic 2013; Krist 2007; Vodermaier 2009).

Other outcomes

For values-choice congruence and proportion undecided, none of the studies of patient decision aids used during the consultation measured these outcomes. For satisfaction, there were a range of different approaches to measuring this outcome with mixed results and too few studies to make any descriptive comparisons. For choice, there were too few studies to conduct a subgroup analysis of pooled comparisons.

Post hoc analysis

Effects of study quality

To examine the potential bias arising from including studies of low methodological quality, we excluded 12 studies with a high risk of bias for any of the seven risk of bias criteria from the analysis (Auvinen 2004; Brazell 2014; Chambers 2012; Clancy 1988; Hamann 2006; Knops 2014; Krist 2007; Kupke 2013; LeBlanc 2015; Lewis 2010; Man-Son-Hing 1999; Mott 2014; see Figure 3). Overall, the results remained the same (Table 24; Analysis 1.3; Analysis 2.3; Analysis 3.5; Analysis 4.4).

Heterogeneity

When comparing patient decision aids to usual care, there was statistically significant heterogeneity in five of six of the IPDAS effectiveness criteria: knowledge scores, accurate risk perceptions, congruence between values and choice; feeling uninformed, and feeling unclear regarding personal values. There was no statistically significant heterogeneity for participation in decision making. 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 25). 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 18 new studies for a total of 105 studies comparing patient decision aids to usual care. This update also removed 28 studies that compared detailed versus simple patient decision aids that were included in the previous update. Based on the GRADE assessment (Summary of findings for the main comparison), there is high-quality evidence that compared to usual care, decision aids improve people's knowledge regarding options and reduce the decisional conflict stemming from feeling uninformed and unclear about their personal values. There is moderate-quality evidence that decision aids stimulate people to take a more active role in decision making and increase the accuracy of their risk perceptions. There is lower-quality evidence that decision aids improve congruence between the chosen option and personal values. This outcome is measured using a variety of different approaches, and the evidence could be strengthened by more standardized measurement. Moreover, decision aids decreased the proportion of people remaining undecided.

Although not a primary outcome of the review, the effect of decision aids on patients' choosing particular options continues to be variable. The numbers of patients choosing to have major elective surgery continues to decrease in favour of more conservative options, except when the baseline rates are low (e.g. surgery for benign prostate hyperplasia, prophylactic mastectomy for women who are carriers of the BRCA gene). The numbers of men choosing prostate-specific antigen (PSA) testing were fewer after exposure to decision aids.

Decision aids do no better than usual care in terms of their effects on people's satisfaction with decision making or health outcomes such as general quality of life or condition-specific quality of life. However, no studies measured preference-linked health outcomes, nor were adverse events reported. There was also no difference in anxiety. For length of consultation, eight studies found no difference, while two studies found a median increase of 2.6 minutes (7.5%) in the decision aid group compared to usual care consultations.There continue to be too few studies to determine the effects of decision aids on costs/resource use (Trenaman 2014). Although there may be additional costs involved in delivering decision aids, an independent review of decision aid studies with economic outcomes concluded that "this was likely to be small relative to the benefit to patients in terms of improved decision quality when effective decision aids are used" (NCGC/NICE 2012). Given the variability in measurement strategies, it difficult to determine the effect of patient decision aids on adherence to the chosen option or treatment.

New for this update, we analyzed the pooled data for decision aids used in preparation for the consultation separately from decision aids used in the consultation, and we found that there were similar improvements in knowledge, accurate risk perceptions, and patient-clinician communication.

Overall completeness and applicability of evidence

Main effects of decision aids

The largest and most consistent benefits of decision aids, relative to usual care, are better knowledge of options and outcomes, and more accurate perceptions of outcome probabilities. These

observations are clinically important because the usual care groups' scores for knowledge and perception of outcome probabilities were lower than the intervention groups'; both knowledge and perception of outcome probabilities are important for ensuring informed decision making. These effects suggest that current 'usual care' may not be good enough when informing people about these complex, values-sensitive decisions. People need to comprehend the options and outcome probabilities in order to consider and communicate to their clinicians the personal value they place on the benefits versus the harms. Likewise, pooling results from additional studies in this update shows a significant increase in informed values-based choice when decision aids were compared to usual care, and the results appear to be similar across subgroup analyses of studies that used the same composite measure.

Decision aids also help people feel more comfortable with their choices than usual care. This is revealed by the reduced scores for overall decisional conflict and for the decisional conflict subscales. People who use decision aids generally feel more informed about options and clearer regarding their personal values.

Compared to usual care strategies, decision aids improve individuals' perception of involvement in decision making. This observation suggests that the International Patient Decision Aids Standards 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. People may have a mistaken preference for passivity because they believe that the best choice relies on the expertise of the clinician (which option is medically reasonable?) rather than understand the importance of their own preferences for outcomes of options (which outcomes matter most to me?).

Evidence continues to build that decision aids have a positive effect on the patient-clinician consultation (in 9 of the 10 studies that assessed this effect). Of the studies that measured patient-clinician communication, five involved using decision aids within the consultation and five in preparation for the consultation. At the same time, evidence on length of consultation indicates either no difference (8 studies) or slightly longer (2 studies) consultations in the decision aid group compared to usual care consultations.

However, few studies have reported on the impact of the context in which the patient decision aids are used. A previous subgroup analysis of 29 studies evaluating patient decision aids for treatment decisions reported greater improvement in knowledge scores (P = 0.03) when the patient decision aid was evaluated within the clinical pathway of care, compared to when patients volunteered to participate in the study independent of their clinician (Brown 2015).

Variable effects of decision aids

There may be several reasons for the variable effect of decision aids on the outcome of choices. First, most studies were under-powered to detect important differences in the outcome of choices. Second, not enough is known about baseline rates for optimal use of specific options. Third, in the studies reporting the outcome 'choices' at baseline and postdecision 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 people become better informed and more involved in decision making.

Relatively under-used options at baseline were prostate surgery for benign prostatic hyperplasia and prophylactic mastectomy for breast cancer gene carriers. In this prostate-related example, there was a shortage of urologists and low referral rates for benign prostatic hyperplasia, whereas the breast-related example reflects the growing number of women who test gene positive and become aware of their options for preventing breast cancer. Hence, under-use of an option may be corrected with exposure to a decision aid.

In the other surgical decision aid studies, there were higher numbers of people choosing surgery in the control group (e.g. cardiac revascularization, back surgery, hysterectomy, orchiectomy, mastectomy). The procedure may have been chosen due to people's inflated perceptions of the probabilities of benefits, lack of appreciation of the probabilities of harms, and lack of awareness of alternatives (Hoffman 2015). Exposure to the decision aid reduced the number of people choosing elective surgery in favour of more conservative alternatives.

Limited effects of decision aids

The limited effects of decision aids on reported satisfaction with the decision-making process and with the actual choice made may indicate that decision aids have a limited effect on satisfaction. The null effects may also be due to measurement insensitivity. This is especially likely when satisfaction with usual care is already quite high (e.g. ceiling effects) and when choices are inherently difficult to make because of competing benefits and harms. Furthermore, once the decision is made, people may find it psychologically more comforting to say that they are satisfied rather than entertain doubts about what they have chosen (Gruppen 1994).

There is a need to establish the 'essential ingredients' in decision aids and to identify the people who are most likely to benefit from them. As the body of available research grows, it will become easier and more important to assess the usefulness of different components of decision support for different clinical contexts, decision problems, and groups of people. For example, an analysis of decision aids used in higher versus lower socioeconomic groups indicated greater improvements for those of lower socioeconomic status (Durand 2014). Recently, the IPDAS Collaboration completed a set of evidence reviews underlying the IPDAS checklist (IPDAS 2013), proposing criteria for defining the intervention as a patient decision aid and minimal certifying criteria (Joseph-Williams 2013). These are being used to inform the certification of patient decision aids in the USA, England, and Norway.

It is not surprising that decision aids had limited effects on health outcomes. One reason for using a decision aid is that there is often no option with a clear health outcome advantage. For example, when men with localized prostate cancer consider active treatment options, their health outcomes can be different, depending on whether they choose surgery with higher risks of impotence or radiation therapy with higher risks of longer term bowel irritation. Therefore, if health outcomes are used in future investigations of decision aids in situations in which there is clearly no health outcome advantage, the key question to pose is: do patients experience the health outcomes they prefer and avoid the outcomes to which they are averse?

More recently, decision aids are being used in situations in which there may be a longer-term health advantage, for example, in preventive decisions about the management of type II diabetes and/or hypertension, when the longer-term health outcome may be to avoid stroke (Mann D 2010; Mathers 2012; Montgomery 2003; Mullan 2009; Weymiller 2007). Interestingly, the pooled results showed a statistically significant increase in medication initiation when participants were exposed to the decision aid compared to usual care.

Unknown effects of decision aids

The effect of patient decision aids on adherence to the chosen option is an area of uncertainty. The adherence results are difficult to interpret due to incomplete data, primarily self-reported data, varying length of follow-ups, and small sample sizes. Moreover, studies reporting this outcome such as Man-Son-Hing 1999 had very little variation in choice (over 90% of long-term aspirin users decided to stay on aspirin). 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 involving the management of side effects and in a manner that separates those choosing to change versus those remaining with the status quo.

Despite the positive effects of decision aids on patient-clinician communication, some authors are concerned about the potential negative influence that decision aids may have on the relational aspects of the decision-making process; this concern highlights the need for further evaluation when decision aids are implemented as part of the routine process of care (Charles 2010; LeBlanc 2010).

In the context of decision aid use, cost-effectiveness and health utilities are other secondary outcome measures about which little is known and further evaluation is required (Trenaman 2014). We also need to establish ways of measuring preference-linked health outcomes to better determine the effect on quality of life. It is unlikely that we will observe the effect of decision aids on litigation rates in studies of decision aids, given the time delay to litigation and the rarity of this type of event. There do not appear to be any adverse events from using decision aids, but this could be more clearly examined in future studies. In fact, a mock trial that used a patient decision aid for prostate-specific antigen testing found that the majority of jurors (94%) would indicate that the standard of care had been met (Barry 2008). A recent systematic review concluded that there was insufficient evidence to determine if patient decision aids could reduce medical malpractice litigation (Durand 2014).

Quality of the evidence

Risk of bias ratings reveal between-study variability. We rated few studies as being at low risk of bias for blinding of participants and personnel and most studies as being at unclear risk of bias. Likewise, the majority of studies were rated as being at unclear risk of bias for selective reporting. When we conducted a post hoc analysis that involved removing studies at high risk of bias from the meta-analysis, there was no effect on the results. The conclusions of this review are limited by inadequate power to detect important between-subgroup differences in effectiveness and by the wide variability in the decision contexts, the elements within the patient decision aids, the type of comparison delivered (collectively referred to as usual care here), the targeted outcomes, and the evaluation procedures. The small number of studies for most outcomes did not allow for analysis of publication bias due to failure to publish negative studies. Moreover, most studies were at unclear risk of selective outcome reporting, indicating that there may have been bias arising from a failure to report all negative findings.

We rated the six primary outcomes in the 'Summary of findings' table using GRADE and assessed outcomes as high quality (knowledge, feeling uninformed, feeling unclear values), moderate quality (accurate risk perception, clinician-controlled role in decision making), and low quality (values-choice congruence). For values-choice congruence, the GRADE rating was downgraded for lack of consistency, directness, and precision. More specifically, congruence was measured using various approaches, as there is no gold standard measurement approach (Munro 2016). Several of the outcomes demonstrated statistically significant levels of heterogeneity. For the outcome of knowledge, for example, heterogeneity would be expected, given that the knowledge tests themselves were not standardized. However, we did not downgrade the ratings for knowledge, feeling uninformed, and feeling unclear values based on heterogeneity given the consistent direction of findings across studies. Moreover, the heterogeneity found in the various outcomes reflects differences across clinically diverse studies; 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.

Potential biases in the review process

The strength of this systematic review is that patient decision aids improve several key primary outcomes across a wide variety of populations and decision contexts. The potential biases in the review process are due to limitations associated with having inadequate power to detect potentially important differences in effectiveness between subgroups, to differentiate between the most effective elements within the patient decision aid, and to investigate any differences associated with the type of comparison interventions used in studies. Several of the outcomes demonstrated statistically significant heterogeneity. This reflects differences across clinically diverse studies; 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 the Gentles 2013 subgroup analysis exploring three potential sources of heterogeneity (e.g. type of control intervention, decision aid IPDAS quality score, participants' baseline accurate risk perception), participants' baseline accurate risk perception was an important variable for explaining heterogeneity. Authors reported that when participants' baseline scores for accurate risk perception were lower, decision aids led to great improvement. Furthermore, 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 decision aid interventions.

Agreements and disagreements with other studies or reviews

Our results confirm many of the observations reported in the previous versions of our review and in a comparative effectiveness review that focused on studies evaluating oncology-specific patient decision aids (Trikalinos 2014). We published the first systematic review of 17 randomized trials of decision aids in 1999 (O'Connor

1999b; O'Connor 2001), followed by updates in 2003 with a total of 35 studies (O'Connor 2003), in 2009 with a total of 55 studies (O'Connor 2009b), in 2011 with a total of 86 studies (Stacey 2011), and 2014 with a total of 115 studies (Stacey 2014b).

AUTHORS' CONCLUSIONS

Implications for practice

The positive effects of decision aids on improving people's knowledge of risks and benefits, feeling informed, and feeling clear about their values across a wide variety of decision contexts provides sufficient evidence for using them in clinical practice. They probably also facilitate accurate risk perception and active participation in decision making. However, several conditions may be necessary for successful implementation, including: good quality decision aids that meet the needs of the population; clinicians who are willing to use decision aids in their practice; effective systems for delivering decision support; and clinicians and healthcare consumers who are skilled in shared decision making. Although there have been some strides in achieving these conditions (Elwyn 2013; O'Connor 2007), the use of patient decision aids will not occur without adequate attention to implementation barriers to implementation and careful design of effective strategies for introducing and maintaining their use in routine clinical practice (Elwyn 2013; Gravel 2006; Legare 2008b; Legare 2010 ; Legare 2014).

New in this update was a subgroup analysis of the findings based on timing of decision aid used either before or during a consultation. Although knowledge scores and accurate risk perceptions were significantly higher in the decision aid group compared to the usual care, there was no difference in these outcomes when comparing decision aids used in preparation for versus during the consultation.

Implications for research

Studies are needed to deepen our understanding of interactions between patient decision aid use and the patterns of patient-clinician communication; format issues such as the web-based delivery of patient decision aids; and downstream effects on cost, resource use, and adherence. Although this update shows new studies conducted in Spain and China, most studies have taken place in North America, the UK, Europe, and Australia. There were far fewer studies of patient decision aids used within the consultation than those delivered pre-consultation, and this is an area of further research given the important issue of implementation.

With the addition of more studies in the systematic review, it may be possible to tease out the reasons for heterogeneity of results, including variability in: study quality; comparison intervention; elements within patient decision aids; decision type; setting where it was used; and format of decision aid (e.g. video, Internet, booklet). Research should also explore the degree of detail in patient decision aids that is required for positive effects according to the IPDAS criteria. In particular, evaluation is needed to compare the effect of those decision aids that meet the minimal IPDAS criteria for certification versus those that meet the full roster of IPDAS quality criteria (Joseph-Williams 2013).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Allen 2010

Methods	Cluster-randomized to decision aid vs usual care
Participants	398 + 414 men considering prostate cancer screening in the USA
Interventions	DA: computer tailored programme on clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision; interactive computer programme: 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) 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	—

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)

Arterburn 2011

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) 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
Notes	—

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 programme 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

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

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	—

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

Barry 1997

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 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	—

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 coordinator opening 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
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 of 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

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 Comparator: routine consultation on options' outcomes, outcome probability

Bekker 2004 *(Continued)*

Outcomes	Primary outcome: anxiety Secondary outcomes: uptake of option, knowledge, decisional conflict, informed decision making, satisfaction with consultation, consultation length
Notes	—

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 & intervention. Tape recorded sessions to ensure no bias
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unclear blinding but outcomes were objectively measured
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Bekker 2003 flow diagram indicates postrandomization 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

Bernstein 1998

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 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	—

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 subjects 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 group
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

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) Comparator: usual care
Outcomes	Primary outcome: decisional conflict Secondary outcome: preferred/actual treatment choice (pre- and post-DA), proportion undecided Other outcomes (Bosco 2012): choice concordance (6 months post-DA). (Data from 239 + 209 men)
Notes	—

Risk of bias

Berry 2013 *(Continued)*

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

Bjorklund 2012

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) Comparator: usual care using pamphlet
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	—

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)

Bjorklund 2012 *(Continued)*

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

Bozic 2013

Methods	Randomized to decision aid vs usual care
Participants	95 + 103 participants with hip and/or knee osteoarthritis considering hip/knee surgery
Interventions	DA: DVD and booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinions, and guidance/coaching with health coach 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

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' favourable 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.

Bozic 2013 *(Continued)*

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

Brazell 2014

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
Interventions	DA: paper-based or web-based DA on clinical problem, options' outcomes, outcome probabilities, patient stories and standard counselling Comparator: standard counselling alone
Outcomes	Primary outcomes: decisional conflict (immediately postconsultation) Secondary outcomes: choice (3 months after making decision), decisional regret (3 months after making decision)
Notes	—

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 PtDA and physician consult

Chabrera 2015

Methods	Randomized to DA vs usual care
Participants	73 + 74 men recently diagnosed with prostate cancer considering treatment options
Interventions	DA: 2-part decision support booklet with clinical problem, options' outcomes, outcome probabilities, patient stories, explicit values clarification, and guidance Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict, satisfaction with decision-making process Secondary outcome: coping Outcomes assessed at 3 months postintervention
Notes	—

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 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	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

Methods	Randomized to DA vs usual care

Chambers 2012 *(Continued)*

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 Comparator: usual care using pamphlet
Outcomes	Primary outcomes: confidence in decision (post-DA) Secondary outcomes: impact on immunization intent (post-DA), proportion undecided
Notes	—

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
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

Clancy 1988

Methods	Randomized to decision aid vs usual care
Participants	753 + 263 health physicians considering Hep B vaccine in the USA
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, explicit values clarification (personal decision analysis), guidance/coaching Comparator: usual care (no information provided)
Outcomes	Uptake of option

Clancy 1988 *(Continued)*

Notes	—

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)
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

Davison 1997

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 Comparator: usual care (general information pamphlets on clinical problem)
Outcomes	Primary outcomes: role in decision making Secondary outcomes: anxiety, depression
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Davison 1997 *(Continued)*

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

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) Comparator: usual care receiving generic booklet
Outcomes	Decisional conflict (baseline and postintervention)
Notes	—

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)	Low risk	Likely not blinded, but low threat of bias in study (p 231)

De Achaval 2012 *(Continued)*

All outcomes		
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

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 Comparator: usual care with information on options, clinical problem
Outcomes	Primary outcomes: uptake of option, decisional conflict Secondary outcomes: role in decision making
Notes	—

Risk of bias

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

Dolan 2002 *(Continued)*

Other bias	Low risk	Appears to be free of other sources of bias

Evans 2010

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 programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer programme; summary) Comparator: paper version of online DA on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion, guidance (interactive computer programme; 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
Notes	—

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

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 Comparator 1: given DA after 3-month follow-up Comparator 2: given DA after all outcome measures were taken
Outcomes	Decisional conflict (post-DA), behavioural intent (post-DA), actual behaviour (post-DA), proportion undecided, perception of benefits (post-DA), perception of risk (post-DA) 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), behavioural intent (post-DA), actual behaviour (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

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

Fraenkel 2007

Methods	Randomized to decision aid vs usual care
Participants	47 + 40 patients with knee pain considering treatment options in the USA
Interventions	DA: interactive computer tool options' outcomes, outcome probability, explicit values clarification Comparator: usual care using the Arthritis Foundation information pamphlet
Outcomes	Decisional self-efficacy, preparation for decision making
Notes	Primary outcome was not specified

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 of trial was registered centrally
Other bias	Low risk	Appears to be free of other potential biases

Fraenkel 2012

Methods	Cluster-randomized control trial of clinics to decision aid versus usual care
Participants	69 + 66 patients with nonvalvular atrial fibrillation considering anticoagulation with aspirin or warfarin
Interventions	DA: computer-based tool on options' outcomes, clinical problem, options' probabilities, guidance, explicit values clarification 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

Fraenkel 2012 *(Continued)*

	encounter as captured on audiotape), change in treatment plan (post intervention), anxiety, accurate risk expectations (stroke, bleeding)
Notes	Trial registration NCT00829478

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	Does not appear to be any other potential sources of bias

Frosch 2008a

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
Interventions	DA: information on options' outcomes, clinical problem, outcome probabilities, others' opinions 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	—

Frosch 2008a *(Continued)*

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

Gattellari 2003

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 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

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)	Unclear risk	Consenting men were blinded to allocation, but unclear if personnel were blinded

Gattellari 2003 *(Continued)*

All 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	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

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 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
Notes	Primary outcome was not specified

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)	Low risk	Minimal attrition that is consistent across groups (figure 1)

Gattellari 2005 *(Continued)*

All outcomes		
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

Green 2001

Methods	Randomized to decision aid + counselling vs counselling 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 counselling on options' outcomes, clinical problem, others' opinions, guidance/coaching Comparator: counselling Comparator: usual care
Outcomes	Primary outcome: preferred options Secondary outcome: knowledge
Notes	—

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 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

Methods	Cluster-randomized trial of decision aid vs usual care
Participants	54 + 59 patients with schizophraenia 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 Comparator: usual care
Outcomes	Knowledge, participation in decision making (COMRADE - doctor gave me a chance to decided 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
Notes	Primary outcome was not specified

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

Hanson 2011

Methods	Randomized to 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)

Hanson 2011 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (3 months post-DA) 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	—

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 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

Heller 2008

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 programme on options' outcomes, others' opinions Comparator: standard patient education
Outcomes	Knowledge, anxiety, satisfaction with treatment choice, satisfaction with decision-making ability
Notes	Primary outcome was not specified

Risk of bias

Bias	Authors' judgement	Support for judgement

Heller 2008 *(Continued)*

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 balanced (p 3). Reasons for incomplete questionnaires and study withdrawals 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

Methods	Randomized to decision aid vs usual care
Participants	103 + 105 patients in the the emergency department with primary symptoms of nontraumatic chest pain and were being considered of admission to the emergency department observation unit for monitoring and cardiac stress testing within 24 hours
Interventions	DA (in consultation): 1-page printout on options' outcomes, clinical problem, and outcome probabilities Comparator: usual care
Outcomes	Primary outcomes: knowledge Secondary outcomes: risk perceptions, decisional conflict, actual choice, satisfaction with decision making process, patient-practitioner communication
Notes	—

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)

Hess 2012 *(Continued)*

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

Jibaja-Weiss 2011

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 programme on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (step-by-step process for making the decision) Comparator: usual care + breast cancer treatment educational materials normally provided to patients
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

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

Jibaja-Weiss 2011 *(Continued)*

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 what was 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

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 Comparator: usual care
Outcomes	Primary outcomes: knowledge, satisfaction with decision making process, anxiety
Notes	—

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 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 useable several residents did not understand need for entering data on the envelope and placing matched questionnaire in it (p 5)
Selective reporting (reporting bias)	Unclear risk	No indication that the trial was registered in a central trials registry

Johnson 2006 *(Continued)*

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

Kasper 2008

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) 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	—

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

Methods	Randomized to decision aid + coaching vs decision aid only vs usual care
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 Comparator: usual care
Outcomes	Primary outcomes: general quality of life Secondary outcomes: uptake of option, satisfaction, menorrhagia severity, cost-effectiveness
Notes	—

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 interventions 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

Knops 2014

Methods	Randomized to decision aid vs usual care
Participants	91 + 87 patients with asymptomatic abdominal aortic aneurysm considering elective surgery vs watchful waiting
Interventions	DA: interactive CD-ROM on options' outcomes, clinical problem, outcome probabilities, explicit values clarification Comparator: usual care with regular information

Knops 2014 *(Continued)*

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

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 medial records.
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.

Krist 2007

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

Krist 2007 *(Continued)*

	Comparator: web-site with same information as paper based DA Comparator: usual care
Outcomes	Primary outcomes: role in decision making Secondary outcomes: knowledge, decisional conflict, time spent discussing screening, choice (PSA test ordered)
Notes	—

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 coordinator (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, ration of 1:3:3 but appears to be free of other potential biases

Kupke 2013

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
Interventions	DA (in consultation): options' outcomes, outcome probabilities 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

Kupke 2013 *(Continued)*

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)
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

Kuppermann 2014

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
Interventions	DA: describes clinical condition, options, outcome probabilities, values clarification 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, DS affected fetus) (3 to 6 months), decisional conflict (3 to 6 months), decisional regret (3 to 6 months)
Notes	—

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)

Kuppermann 2014 *(Continued)*

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) 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)
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

Lam 2013

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
Interventions	DA: take-home booklet on clinical problem, options' outcomes, outcome probabilities, guidance, explicit values clarification 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	—

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)
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)

Lam 2013 *(Continued)*

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

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 counselling) + usual care 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	—

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)
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";

Langston 2010 *(Continued)*

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

Laupacis 2006

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) 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	—

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)
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

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
Interventions	DA (in consultation): clinical problem, individualized risk of condition, options' outcomes, guidance 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	—

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)
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)

Legare 2008a

Methods	Randomized to decision aid vs usual care
Participants	45 + 45 women considering use of natural health products for managing menopausal symptoms
Interventions	DA: booklet with worksheet on options' outcomes, clinical problem, explicit values clarification, guidance/coaching (Ottawa Decision Support Framework) 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	—

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 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

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

Legare 2011 *(Continued)*

	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: • 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	—

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	Appears to be free of other sources of bias

Legare 2012

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)
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). Comparator: usual care

Legare 2012 *(Continued)*

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	—

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)

Leighl 2011

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)

Leighl 2011 *(Continued)*

	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	—

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 them 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

Methods	Randomized to decision support intervention (decision coaching by telephone + educational pamphlet) vs control
Participants	244 + 246 African American men aged 45-70 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) Comparator: attention control (education on fruit and vegetable consumption)
Outcomes	Primary outcomes: knowledge (pretest and post-test at 8 months postrandomization), decisional conflict (posttest), 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

Lepore 2012 *(Continued)*

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

Methods	Randomized to decision aid vs waiting list control
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 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	—

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

Lerman 1997 *(Continued)*

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

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

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

Lewis 2010 *(Continued)*

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

Loh 2007

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 Comparator: usual care
Outcomes	Participation in decision making, adherence, satisfaction with clinical care, depression severity, consultation length
Notes	Primary outcome was not specified

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
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 on outcomes not measured by using a scale (e.g. consultation time was documented in minutes by the physicians following each consultation)

Loh 2007 *(Continued)*

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 pt and physician baseline characteristics). Statistically significant differences were controlled for in outcome analyses

Man-Son-Hing 1999

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) 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	—

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

Man-Son-Hing 1999 *(Continued)*

Other bias	Low risk	No other potential risks of bias

Mann D 2010

Methods	Randomized to decision aid vs usual care
Participants	80 + 70 participants diagnosed with diabetes considering the use of statins to reduce coronary risk
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) Comparator: usual primary care visit + pamphlet
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

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 was 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 magnitude in change of data due to this choice

Mann E 2010

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 Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcomes: preferred option (post-DA) Secondary outcomes: whether invitation type impacts on intention (post-DA), impact on knowledge (post-DA), impact on attitude (post-DA), risk perception
Notes	—

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)

Marteau 2010

Methods	Randomized to decision aid vs usual care
Participants	633 + 639 patients considering diabetes screening in England

Marteau 2010 *(Continued)*

Interventions	DA: screening invitation on clinical problem, outcome probabilities and explicit values clarification Comparator: usual care using screening invitation on clinical problem
Outcomes	Primary outcome: attendance for screening (post-DA and consult) Secondary outcomes: intention to make changes to lifestyle (post-DA and consult), satisfaction with decisions made among attenders (post-DA and consult)
Notes	—

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 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 free of other potential biases

Mathers 2012

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 Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (immediately postintervention), glycaemic control (glycosolated haemoglobin, HbA1c) at 6 months

Mathers 2012 *(Continued)*

	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

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)

Mathieu 2007

Methods	Randomized to decision aid versus usual care
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) 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/intension, attitudes about screening, relationship between objective and perceived risk of breast cancer

Mathieu 2007 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer programme, 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 programme (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 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

Methods	Randomized to decision aid vs usual care
Participants	189 + 223 women considering mammography screening
Interventions	DA: Internet programme + 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) 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	—

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)

Mathieu 2010 *(Continued)*

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 pg.67-68)
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

Methods	Cluster-randomized to decision aid vs usual care
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) Comparator: usual care
Outcomes	Primary outcomes: uptake of (appropriate) option Secondary outcomes: knowledge, decisional conflict, accurate risk perceptions
Notes	—

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

McAlister 2005 *(Continued)*

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 we employed, has been published (p 1, Methods)
Other bias	Low risk	Appears to be free of other potential biases

McBride 2002

Methods	Randomized to decision aid vs usual care
Participants	289 + 292 perimenopausal women considering hormone replacement therapy in the USA
Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching Comparator: delayed intervention
Outcomes	Primary outcome: accurate risk perceptions Secondary outcomes: satisfaction with decision, confidence with knowledge and making/discussing decision
Notes	—

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

McBride 2002 *(Continued)*

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 favoured recruitment of women with higher SES and those who had prior experience with HRT

McCaffery 2010

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
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification, others' opinion and guidance (worksheet) 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 behaviour (post-DA), help seeking behaviour (post-DA), knowledge (post-DA)
Notes	—

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

Miller 2005

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 Comparator: provision of general information about cancer risk
Outcomes	Preferred option, knowledge, perceived risk, satisfaction
Notes	Primary outcome was not specified

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
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 drop-out 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 not able to 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

Methods	Decision aid vs attention placebo
Participants	132 + 132 participants considering colon cancer screening in the USA
Interventions	DA: computer-based web programme on options' outcomes, clinical problem, outcome probabilities, others' opinion, guidance (encourages patient-practitioner communication, summary) Comparator: computer-based web programme 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

Miller 2011 *(Continued)*

Notes	—

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) All outcomes	Low risk	"[C]linical outcome assessors were [blinded]" (p 613, Discussion)
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 participant pool

Montgomery 2003

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 Comparator: decision analysis on options' outcomes, outcome probability, explicit values clarification Comparator: video and leaflet on options' outcomes, clinical problem Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: uptake of option, knowledge, anxiety
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Montgomery 2003 *(Continued)*

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 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

Methods	Randomized to decision aid with values clarification vs decision aid without values clarification vs usual care
Participants	245 + 250 + 247 women with previous caesarean section in the UK
Interventions	DA: options' outcomes, clinical problem, outcome probability, explicit values clarification Comparator: options' outcomes, clinical problem, outcome probability Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: choice, anxiety, knowledge, satisfaction with decision
Notes	—

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)

Montgomery 2007 *(Continued)*

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 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

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) 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

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

Montori 2011 *(Continued)*

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

Morgan 2000

Methods	Randomized to decision aid vs usual care
Participants	120 + 120 patients with ischaemic heart disease considering revascularization surgery in Canada
Interventions	DA: Health Dialog interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinions Comparator: usual care
Outcomes	Primary outcome: satisfaction with the decision making process Secondary outcomes: uptake of option, knowledge
Notes	—

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 *(Continued)*

		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

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
Interventions	DA: booklet on clinical problem, options' outcomes, structured guidance 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

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 (UC = 11; SMD = 9) completed the study (p 146-147). 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 reported on

Mott 2014 *(Continued)*

Other bias	Low risk	Does not appear to be any other sources of bias

Mullan 2009

Methods	Cluster-randomized to decision aid vs usual care
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 Compare: 12-page pamphlet on oral antihyperglycaemic medications
Outcomes	Knowledge, decisional conflict, participation in decision making, acceptability of the information, change in medication, adherence, HbA1C levels, trust in physician, OPTION to analyse audio-taped encounters
Notes	Primary outcome was not specified

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	Appears to be free of other sources of bias

Murray 2001a

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 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	—

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 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

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 Comparator: usual care
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	—

Murray 2001b *(Continued)*

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 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

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) Comparator: standard pamphlet on prenatal testing
Outcomes	Primary outcomes: informed choice, decisional conflict Secondary outcomes: anxiety, depression, attitudes toward pregnancy, acceptability of the intervention, choice
Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Nagle 2008 *(Continued)*

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

Nassar 2007

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) Comparator: usual care counselling 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	—

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)

Nassar 2007 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Womens were not blinded - unclear if this would introduce bias to 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 labour 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

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) Comparator: usual care
Outcomes	Satisfaction with information, decisional conflict (intervention group only), improvement in adherence
Notes	Primary outcome was not specified

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

Oakley 2006 *(Continued)*

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 intervention group and 17 in control group; small sample size.

Ozanne 2007

Methods	Randomized to decision aid + standard counselling vs usual care (standard counselling)
Participants	15 + 15 women considering breast cancer prevention in the USA
Interventions	DA (in consultation): interactive computer decision aid on options outcomes, outcome probability Comparator: standard counselling
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	—

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 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 behaviour (based on doing both intervention and control)

Partin 2004

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 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	—

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 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

Pignone 2000

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 Comparator: video on car safety
Outcomes	Primary outcome: uptake of options

Pignone 2000 *(Continued)*

Notes	—

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

Protheroe 2007

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 Comparator: information leaflet
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, anxiety, condition specific health outcomes, treatment preference, undecided
Notes	—

Risk of bias

Protheroe 2007 *(Continued)*

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 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

Rubel 2010

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 Comparator : booklet on options' outcomes, clinical problem, outcome probabilities, others' opinions + post-test Comparator: pretest + post-test Comparator: post-test
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

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)

Rubel 2010 *(Continued)*

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

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 Comparator: non-interactive website with information on clinical problem
Outcomes	Primary outcome: uptake of option
Notes	—

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.

Ruffin 2007 *(Continued)*

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

Sawka 2012

Methods	Randomized to decision aid vs usual care
Participants	37 + 37 individuals with early-stage papillary thyroid cancer
Interventions	DA: web-based decision aid with clinical problem, options' outcomes, outcome probabilities, guidance, printout summary Comparator: usual care (consultation with a specialized head and neck surgeon, and with 1 or more medical specialist).
Outcomes	Primary outcomes: knowledge (baseline and immediately post intervention) Secondary outcomes: decisional conflict, undecided, treatment decision (baseline, immediately post intervention, 6 to12 months), individual primarily responsible for the treatment decision (6 to 12 months)
Notes	Trial registration: NCT01083550

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), yet 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

Sawka 2012 *(Continued)*

Other bias	Low risk	Appears to be free of other potential sources of bias

Schroy 2011

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 audio-visual DA on options' outcomes, clinical problem, outcome probabilities, others' opinion and guidance 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

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 appears 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

Methods	Randomized to decision aid vs usual care
Participants	76 + 74 patients undergoing coronary angiography

Schwalm 2012 *(Continued)*

Interventions	DA: booklet on options' outcomes, clinical problem, outcome probabilities, explicit values clarification and guidance Comparator: usual care
Outcomes	Primary outcomes: decisional conflict Secondary outcomes: knowledge, risk perception, value congruent with chosen option
Notes	—

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

Methods	Randomized to decision aid vs usual care
Participants	181 + 190 Ashkenazi Jewish women considering genetic testing in the USA
Interventions	DA: 16-page booklet on genetic testing with options' outcomes, clinical problem 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	—

Risk of bias

Schwartz 2001 *(Continued)*

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

Methods	Randomized to decision aid + genetic counselling vs genetic counselling 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/counselling - genetic counselling as usual care (Ottawa Decision Support Framework) Comparator: genetic counselling 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	—

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

Schwartz 2009a *(Continued)*

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

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 Comparator: list of CHD risk factors to present to doctor
Outcomes	Patient-practitioner communication (e.g. discussion with doctor, specific plan to reduce risk discussed with doctor)
Notes	Primary outcome was not specified

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)	Low risk	Results (p 5); Flow diagram (p 10); Baseline characteristics/data included

Sheridan 2006 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	ClinicalTrials.gov NCT00315978
Other bias	Low risk	Appears to have no other potential risk of bias

Sheridan 2011

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 Comparator: usual care using computer programme
Outcomes	Preferred choice (post-DA), adherence Other outcomes (Sheridan 2014): patient-provider communication (post-DA), patient participation (post-DA), patients perceptions of discussions and the health care visit (post-DA), preferred choice (baseline and post-DA) (data from 81 +79 patients).
Notes	Primary outcome was not specified

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 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

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) Comparator: usual care
Outcomes	Primary outcomes: knowledge, decisional conflict Secondary outcomes: preferred option, help with making a decision
Notes	—

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 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

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
Interventions	Web-based DA: clinical problem, options' outcomes, explicit values clarification, guidance MMR leaflet: Health Scotland leaflet, 'MMR: your questions answered'

Shourie 2013 *(Continued)*

	Comparator: usual care
Outcomes	Primary outcomes: decisional conflict (baseline and 2 weeks postintervention) 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)
Notes	Trial registration: UK Clinical Research Network - UKCRN ID 4811

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 don't 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.

Smith 2010

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) 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)

Smith 2010 *(Continued)*

	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	—

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 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

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) Comparator: usual care
Outcomes	Primary outcomes: feasibility (including recruitment, data collection), preliminary effectiveness

Stacey 2014a *(Continued)*

	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

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 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

Steckelberg 2011

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 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Steckelberg 2011 *(Continued)*

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; 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

Taylor 2006

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
Interventions	Print DA: clinical problem; outcome probabilities; guidance (list of questions to ask at next appointment); others' opinions Video DA: clinical problem; others' opinions Wait list comparator: no information provided until 1 month postrandomization (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

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient information related to random sequence generation

Taylor 2006 *(Continued)*

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; however, participants were requested to not share intervention materials with others to prevent contamination between groups (p 2180)
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)

Thomson 2007

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 Comparator: guidelines applied as direct advice
Outcomes	Primary outcome: decisional conflict Secondary outcomes: anxiety, knowledge, resource use, choice, health outcomes (stroke, transient ischaemic attack, bleeding events)
Notes	—

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)

Thomson 2007 *(Continued)*

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

Trevena 2008

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 behaviour) Comparator: consumer guidelines recommending faecal 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
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

Trevena 2008 *(Continued)*

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 Peperstraten 2010

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 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 consult) Secondary outcomes: knowledge (pre, post-DA and consult), empowerment (pre, post-DA and consult), participation in decision making, decisional conflict (post-DA and consult), levels of anxiety (pre, post-DA and consult), depression (pre, post-DA and consult), cost evaluation of empowerment strategy (post-DA and consult), condition-specific health outcomes (pregnancies) (post-DA and consult)
Notes	—

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

Van Peperstraten 2010 *(Continued)*

Selective reporting (reporting bias)	Low risk	Outcomes same as those registered with ClinicalTrials.gov
Other bias	Low risk	The study appear to be free of other sources of bias

Vandemheen 2009

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) Comparator: blank pages
Outcomes	Primary outcomes: knowledge, accurate risk perceptions, decisional conflict Secondary outcomes: preparation for decision making, choice, durability of decision, undecided
Notes	—

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

Vodermaier 2009

Methods	Randomized to decision aid vs usual care
Participants	74 + 78 women with breast cancer considering treatment options in Germany
Interventions	DA: Decision board administered by research psychologists and booklet on options' outcomes, clinical problem, outcome probability 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	—

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

Methods	Randomized to decision aid vs usual care
Participants	80 + 80 men considering PSA testing in the USA
Interventions	DA: Health Dialog videotape and brochure on options' outcomes, clinical problem, outcome probability, others' opinion Comparator: usual care
Outcomes	Primary outcomes: knowledge, preferred/uptake of option

Volk 1999 *(Continued)*

Notes	—

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

Vuorma 2003

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 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement

Vuorma 2003 *(Continued)*

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
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

Watson 2006

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 Comparator: usual care
Outcomes	Primary outcomes: knowledge, screening intention, attitudes Secondary outcomes: preferred role in decision making

Watson 2006 *(Continued)*

Notes	—

Risk of bias

Bias	Authors' judgement	Support for judgement
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)

Weymiller 2007

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 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence (p 2)

Weymiller 2007 *(Continued)*

		Nannenga 2009: no information provided
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

Whelan 2003

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 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	—

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information provided

Whelan 2003 *(Continued)*

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

Whelan 2004

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 Comparator: usual care
Outcomes	Primary outcomes: preferred option, knowledge, decisional conflict, satisfaction Secondary outcomes: accurate risk perceptions, anxiety
Notes	—

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).
Allocation concealment (selection bias)	Unclear risk	Randomly assigned in a concealed fashion, but 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

Whelan 2004 *(Continued)*

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	Appears to be free of other potential biases

Williams 2013

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 40-70 years with no history of prostate cancer who had pre-registered for screening
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 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

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

Williams 2013 *(Continued)*

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

Wolf 1996

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 Comparator: usual care (single sentence)
Outcomes	Preferred option
Notes	—

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 total sample size of 205. Reasons for attrition mentioned; baseline characteristics included Wolf 1998: no information provided except that 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 limited, but overall appears to be free of other potential biases Wolf 1998: appears to be free of other potential biases

Wolf 2000

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 Comparator: usual care (5 sentences)
Outcomes	Primary outcome: preferred option Secondary outcomes: accurate risk perceptions
Notes	—

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

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 Comparator: placebo leaflet on contraception use post pregnancy termination
Outcomes	Primary outcomes: uptake of option, knowledge, decisional conflict, anxiety
Notes	—

Wong 2006 *(Continued)*

Risk of bias

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	Consecutive numbered, opaque trial envelope (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

CHD: coronary heart disease; **CRC**: colorectal cancer; **DA**: decision aid; **HPV**: human papilloma virus; **HRT**: hormone replacement therapy; **NSW**: New South Wales; **OA**: osteoarthritis; **PSA**: prostate-specific antigen; **PTSD**: post-traumatic stress disorder; **RCT**: randomized controlled trial; **SES**: socioeconomic status.

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)
Adab 2003	Hypothetical choice, not at a point of decision making
Al Saffar 2008	Study not focused on making a choice; adhering to medications only
Alegría 2014	Not a patient decision aid
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

Study	Reason for exclusion
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
Bieber 2006	Study did not evaluate the patient decision aid (evaluated shared decision-making process); not a patient decision aid
Branda 2013	2 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
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
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
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)
Costanza 2011	Not a randomized controlled trial
Coulter 2003	Not a randomized controlled trial (editorial)

Study	Reason for exclusion
Cox 2012	Not a randomized controlled trial
Crang-Svalenius 1996	Not a randomized controlled trial
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
Deinzer 2009	Not a patient decision aid
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
Dobke 2008	Not focused on making a choice
Dodin 2001	Simple versus detailed patient decision aid (excluded in update after 2014 publication)
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-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
Emery 2007	Not a patient decision aid

Study	Reason for exclusion
Emmett 2007	Not a randomized controlled trial
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)
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
Genz 2012	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)
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)
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
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

Study	Reason for exclusion
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
Healton 1999	Not a patient decision aid (education to promote compliance)
Henderson 2013	Not a treatment or screening decision
Herrera 1983	Quasi-RCT: assigned to 1 of 2 alternating groups
Hess 2015	Conjoint analysis for values clarification without information on options, pros and cons
Hewison 2001	Not a patient decision aid; no values clarification
Heyn 2013	Not a randomized controlled trial
Hickish 1995	Not a randomized controlled trial (letter)
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
Holbrook 2007	Hypothetical choice, not at the point of decision making
Hollen 2013	Not a treatment or screening decision
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
Hope 2010	Same content
Huijbregts 2013	Not a patient decision aid
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)
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

Study	Reason for exclusion
Jerant 2007	Not focused on making a choice - adherence to screening
Jibaja-Weiss 2006	No comparison outcome data provided (only presents data for intervention group)
Joosten 2009	Not a patient decision aid
Joosten 2011	Not a patient decision aid
Jorm 2003	Hypothetical choice, not at point of decision making - community sample asked to evaluate information booklet on depression
Kakkilaya 2011	Hypothetical choice, not at point of decision making
Kaplan 2014a	Not a patient decision aid
Kaplan 2014b	Not randomized controlled trial results; cross-sectional analysis of baseline data
Kassan 2012	Web arm only, not a randomized controlled trial
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
Kobelka 2009	Not a randomized controlled trial; not a patient decision aid
Koelewijn-van Loon 2009	Lifestyle only
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
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
Köpke 2009	Not a patient decision aid
Köpke 2014	Not a patient decision aid
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
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
Lazcano Ponce 2000	Not a patient decision aid (no values clarification)

Study	Reason for exclusion
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
Lopez-Jornet 2012	Not a patient decision aid/not at point of decision-making
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 DA)
Maisels 1983	Not a patient decision aid (no values clarification)
Mancini 2006	Not about evaluating a patient decision aid
Manne 2009	Not focused on making a choice (about adherence not decision making)
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)
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
Matloff 2006	Not a patient decision aid - genetic counselling only
Mazur 1994	Hypothetical choice, not at the point of decision making
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
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

Study	Reason for exclusion
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)
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
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
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
Powers 2011	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
Ranta 2015	Not a patient decision aid; intended to increase guideline adherence for transient ischaemic 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)
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)
Robinson 2013	Not a patient decision aid
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
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)
Rovner 2004	Not a randomized controlled trial
Rubinstein 2011	Not a patient decision aid
Ruddy 2009	Not a patient decision aid
Ruehlman 2012	Not a patient decision aid
Ruland 2013	No specific decision to be made
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
Scaffidi 2014	Not an RCT
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)

Study	Reason for exclusion
Schwartz 2009b	Hypothetical choice, not at the point of decision making
Sears 2007	About do not resuscitate versus initiating cardiopulmonary resuscitation decision
Sequist 2011	Not a patient decision aid (promotes complying with a recommended option)
Shah 2012	Not a patient decision aid, lifestyle choices
Sheppard 2012	Not a randomized controlled trial
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
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
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)
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
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
Sundaresan 2011	Hypothetical choice, not at the point of decision making, not a randomized controlled trial
Tabak 1995	Not a randomized controlled trial
Taylor 2013	Not a patient decision aid - benefits and harms of screening not included
Ten 2008	Not a patient decision aid; about stopping medication use
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
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
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)
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
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)

Study	Reason for exclusion
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 counselling process, no focused decision
Warner 2015	Not a treatment or screening decision
Watts 2014	Simple versus detailed patient decision aid
Welschen 2012	Not a patient decision aid
Wennberg 2010	Same decision aid in both groups
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
Woltmann 2011	Not a patient decision aid
Wroe 2005	Not focused on making a choice - promotes complying with a recommended option
Yee 2014	Not a patient decision aid
Yun 2011	End-of-life decision
Zajac 2012	Hypothetical
Zapka 2004	Not focused on making a choice - promotes complying with a recommendation
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

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

ACTRN12615000523505

Trial name or title	The motherhood choices decision aid for women with rheumatoid arthritis increases knowledge and reduces decisional conflict: a randomized controlled study
Methods	RCT
Participants	130 women diagnosed with rheumatoid arthritis and currently under the care of a rheumatologist
Interventions	Patient decision aid vs usual care
Outcomes	Decisional conflict, knowledge, anxiety, depression, self-efficacy
Starting date	May 2015
Contact information	Tanya Meade; School of Social Science and Psychology University of Western Sydney; Sydney, Australia
Notes	Trial #: ACTRN12615000523505

ACTRN12615000843550

Trial name or title	Evaluation of decision aids for parents about the benefits and harms of antibiotic use for coughs and colds in children
Methods	Pilot RCT
Participants	108 adult parents or primary caregivers of a child
Interventions	Patient decision aid vs usual care
Outcomes	Informed choice, knowledge, attitudes towards antibiotic use, intention to use antibiotic, decisional conflict, confidence in decision-making, usability and accessibility of the written materials
Starting date	August 2015
Contact information	Mr Peter D Coxeter; pcoxeter@bond.edu.au; Bond University, Queensland, Australia
Notes	ACTRN12615000843550

Al-Itejawi 2015

Trial name or title	(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

Al-Itejawi 2015 *(Continued)*

Contact information	Hoda Al-Itejawi; Afdeling Urologie, Amsterdam, the Netherlands
Notes	Trial #: NTR5177

Anderson 2014

Trial name or title	Shared decision making in the emergency department: Chest Pain Choice Trial (CPC)
Methods	RCT
Participants	Presenting to the emergency department with chest pain
Interventions	Chest Pain Choice decision aid vs usual care
Outcomes	Knowledge, patient engagement, decisional conflict, satisfaction, adverse events, admissions, healthcare utilization
Starting date	October 2013
Contact information	Erik P Hess, Mayo Clinic
Notes	NCT01969240; verified September 2014, estimated study completion March 2016

Aslani 2014

Trial name or title	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	—

Buhse 2013

Trial name or title	Efficacy of an evidence-based informed shared decision making program for prevention of myocardial infarction in type 2 diabetes
Methods	RCT
Participants	154 patients with type 2 diabetes

Buhse 2013 *(Continued)*

Interventions	Shared decision-making programme consisting of a decision aid booklet and a curriculum for group counselling vs placebo counselling
Outcomes	Knowledge, sustainability of knowledge, achievement of individual treatment goals, achievement of treatment goals prioritized by individual patients, medication uptake
Starting date	March 2013
Contact information	Matthias Lenz, University of Hamburg
Notes	ISRCTN84636255

Carroll 2012

Trial name or title	Development of and feasibility testing of decision support for patients who are candidates for an implantable defibrillator
Methods	RCT
Participants	Referred for consideration of an implantable cardioverter-defibrillators (non-cardiac resynchronization therapy) for a primary prevention indication
Interventions	Patient decision aid provided prior to the consultation with the physician, which provides a lay summary that outlines the facts, risks, benefits (including probabilities), specific to the option of an implantable defibrillator or the option of medical management vs usual care
Outcomes	Decision aid development and evaluation, decisional conflict and decision quality, sure test, reparation for decision-making scale, medical outcomes trust short form (SF-36v2)
Starting date	June 2012
Contact information	Sandra Carroll, McMaster University
Notes	Trial #: NCT01876173

Chambers 2008

Trial name or title	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; heathcare utilization; use of healthcare resources; and a return to previous activities
Starting date	Not yet assessed

Chambers 2008 *(Continued)*

Contact information	Suzanne K Chambers, Griffith University
Notes	Trials #: ACTRN012607000233426

Coylewright 2012

Trial name or title	Shared decision making in patients with stable coronary artery disease: PCI Choice
Methods	RCT
Participants	—
Interventions	—
Outcomes	—
Starting date	—
Contact information	Megan Coylewright, Mayo Clinic
Notes	Upcoming RCT

Cuypers 2015

Trial name or title	Prostate cancer patient-centered care: impact of a treatment decision aid in a pragmatic, cluster randomized controlled trial
Methods	Pragmatic RCT
Participants	400 men newly diagnosed with early stage prostate cancer
Interventions	Decision aid (online) vs usual care
Outcomes	Decisional conflict, decisional regret, treatment satisfaction, decision making role, knowledge, satisfaction with decision-making process, preparation for decision-making, health-related quality of life, personality (anxiety, depression, optimism), skills measures (self-efficacy, health literacy, numeracy)
Starting date	May 2014
Contact information	M Cuypers; M.Cuypers@uvt.nl; Tilburg University Social and Behavioral Sciences Tilburg, the Netherlands
Notes	NTR4554

Den Ouden 2015

Trial name or title	Shared decision-making in type 2 diabetes with a support decision tool that takes into account clinical factors, the intensity of treatment and patient preferences
Methods	Cluster RCT
Participants	150 adults with type 2 diabetes mellitus for 8-15 years
Interventions	Patient decision aid with training vs usual care
Outcomes	Achievement of diabetes-specific health goals, satisfaction with treatment, quality of life, well-being, coping, evidence of shared decision-making
Starting date	March 2012
Contact information	h.denouden@umcutrecht.nl; Henk den Ouden; Julius Cntre for Health Sciences and Primary Care, University Medical Centre, Utrecht, the Netherlands
Notes	Trial #: NCT02285881

Dirmaier 2013

Trial name or title	Tailored, dialogue-based health communication application for patients with chronic low back pain
Methods	RCT
Participants	414 patients with self-reported chronic low back pain
Interventions	Web-based interactive health communication application (IHCA) vs control (standard info)
Outcomes	Knowledge, patient empowerment, website usage, preparation for decision making, decisional conflict
Starting date	2012
Contact information	Martin Härter, University Medical Center Hamburg-Eppendorf
Notes	International Clinical Trials Registry DRKS00003322

Geiger 2011

Trial name or title	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 the doctors - intend 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

Hersch 2014

Trial name or title	Effect of information about over detection of breast cancer on women's decision-making about mammography screening
Methods	RCT
Participants	970 women aged 48-50
Interventions	Intervention (evidence-based information booklet including over detection, breast cancer mortality reduction and false positives) vs control information booklet (including mortality reduction and false positives only)
Outcomes	Knowledge, consistency between attitudes and intentions, decision conflict, confidence, regret, anxiety, perceived risk, quality of life
Starting date	June 2014
Contact information	Kirsten McCaffery, University of Sydney
Notes	Australian New Zealand Clinical Trials Registry ACTRN12613001035718

Hess 2014

Trial name or title	Shared decision making in parents of children with head trauma: head CT choice
Methods	RCT
Participants	1004 parent-child dyad, seeking care for a child who had blunt trauma above the eyebrows and is positive for at least 1 PECARN clinical prediction rules
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, engagement in decision-making process, decisional conflict, trust in the physician, satisfaction with the decision-making process, choice, healthcare utilization 7-days post ER visit, rate of clinically important traumatic brain injury
Starting date	April 2014
Contact information	Erik Hess; Mayo Clinic; Rochester, MN
Notes	Trial #: NCT02063087

Jimbo 2012

Trial name or title	Decision aid to technologically enhance shared decision making
Methods	RCT
Participants	Patients who are not current with colorectal cancer screening
Interventions	Web based decision aid + interactive component (preferences and risk assessment) vs web based decision aid only
Outcomes	Uptake of screening on patient determinants/preference/intention before the patient-physician encounter, and on shared decision making, concordance and patient intention during/after the patient-physician encounter
Starting date	May 2012
Contact information	Masahito Jimbo, University of Michigan
Notes	Trial # :NCT01514786; last updated December 2013, estimated study completion October 2014

Layton 2012

Trial name or title	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

LeBlanc 2013

Trial name or title	Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice decision aid to usual care: study protocol for a randomized controlled trial
Methods	RCT
Participants	300 patients
Interventions	Use of the Depression Medication Choice decision aid by patients and their primary care clinician during the clinical encounter vs usual care

LeBlanc 2013 *(Continued)*

Outcomes	Decisional conflict, knowledge, satisfaction, preference in decision making style, patient involvement in decision making, depression outcomes, medication adherence
Starting date	December 2011
Contact information	Victor Montori, Mayo Clinic, USA
Notes	NCT01502891

Mann 2012

Trial name or title	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 behaviour changes
Outcomes	Outcome measurements are designed to detect changes in patient behaviours 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 haemoglobin 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

Trial name or title	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

NCT01077037

Trial name or title	Shared decision making in the emergency department: the Chest Pain Choice Trial
Methods	RCT
Participants	1500 adults admitted to the emergency department for chest pain, being considered by the treating clinical for admission for cardiac testing
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, healthcare utilization (rate of hospital admission, rate of cardiac testing, etc), patient engagement in decision-making process, decisional conflict, trust in the physician, satisfaction with decision, safety (major adverse cardiac events within 30 days)
Starting date	October 2013
Contact information	hess.erik@mayo.edu; Mayo Clinic, Rochester, Minnesota, USA
Notes	Trial #: NCT01969240

NCT01152294

Trial name or title	Measuring quality of decisions about treatment of menopausal symptoms
Methods	RCT
Participants	Patients talked with healthcare provider about ways to manage menopause or seriously considered taking medicine or supplement to manage menopause
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	NCT01152294; completed, study results on clinicaltrials.gov

NCT01152307

Trial name or title	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 counselling)
Interventions	Decision aid (DVD/booklet) vs usual care
Outcomes	Knowledge, value concordance
Starting date	June 2010

NCT01152307 *(Continued)*

Contact information	Karen R Sepucha, Massachusetts General Hospital
Notes	NCT01152307; completed, study results on clinicaltrials.gov

NCT01447186

Trial name or title	Informed decisions about lung cancer screening
Methods	RCT
Participants	500 adults between 55 and 77 years olds who are currently smoking or quit within the past 15 years
Interventions	Patient decision aid vs standard educational information
Outcomes	Decisional conflict: value subscale and informed subscale
Starting date	March 2015
Contact information	MD Anderson Cancer Center; USA
Notes	Trial #: NCT02286713

NCT01618097

Trial name or title	Evaluation of DVD and Internet decision aids for hip and knee osteoarthritis: focus on health literacy
Methods	RCT
Participants	Osteoarthritis patients
Interventions	DVD decision aid vs Internet-based decision aid
Outcomes	Decisional conflict, decision self-efficacy, knowledge
Starting date	January 2012
Contact information	Kelli D Allen, Duke University
Notes	Trial #: NCT01618097; last updated March 2014, study completion date January 2014

NCT01713894

Trial name or title	Utility of a clinically relevant decision aid, for parents facing extremely premature delivery
Methods	RCT
Participants	300 women who are receiving counselling at the limits of viability
Interventions	Decision aid vs usual care

NCT01713894 *(Continued)*

Outcomes	Decisional conflict, knowledge
Starting date	May 2013
Contact information	uguillen@christianacare.org; Ursula Guillen, Christiana Care Health Systems; University of Michigan
Notes	Trial # NCT01713894

NCT01771536

Trial name or title	Study to test use of a decision aid in a clinical visit to help patients choose a diabetes medication. Translating Information on Comparative Effectiveness Into Practice (TRICEP)
Methods	RCT
Participants	Type 2 diabetes mellitus patients
Interventions	Diabetes medication decision aid vs usual care
Outcomes	Patient satisfaction and knowledge. Physician adoption and satisfaction with the decision aid
Starting date	January 2011
Contact information	Nilay D Shah, Mayo Clinic
Notes	NCT01293578; estimated completion date December 2014

NCT01851785

Trial name or title	Behavioral and social science research on understanding and reducing health disparities: African American preference for knee replacement: a patient-centred intervention (ACTION)
Methods	RCT
Participants	African-American participants referred to orthopaedic doctor with presence of knee OA
Interventions	Decision aid video + communication, skill-building intervention vs educational programme (an NIH-developed booklet) that summarizes how to live with knee OA but does not mention joint replacement
Outcomes	Recommendation and receipt of knee joint replacement
Starting date	July 2010
Contact information	Said A Ibrahim, University of Pennsylvania
Notes	Trial #: NCT01851785; last verified May 2013, estimated completion date June 2015

NCT01941186

Trial name or title	A family centered intervention to promote optimal child development
Methods	RCT
Participants	64 parent-child dyad in which the child is aged 0-36 months screening positive for developmental concern
Interventions	Patient decision aid vs usual care
Outcomes	Evaluation by early intervention specialist, attitudes, knowledge, uncertainty, intervention acceptability, intervention feasibility
Starting date	December 2013
Contact information	Children's Hospital of Philadelphia Philadelphia, PN, USA, 19104
Notes	Trial #: NCT01941186

NCT01976325

Trial name or title	Incorporation of the 'Ottawa Malaria Decision Aid' into the pre-travel consultation process
Methods	RCT
Participants	100 adults attending a travel clinic before travelling 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

NCT02026102

Trial name or title	A pilot trial of patient decision aids for implantable cardioverter-defibrillators (ICDs)
Methods	RCT
Participants	60 patients with heart failure referred for primary prevention implantable cardioverter-defibrillators
Interventions	Decision aid toolkit vs usual care
Outcomes	Intervention acceptability, decision quality (knowledge and values concordance), quality of life, depressive symptoms, health status, spiritual well-being

NCT02026102 *(Continued)*

Starting date	September 2014
Contact information	amy.jenkins@ucdenver.edu; University of Colorado Hospital (UCH)
Notes	Trial #: NCT02026102

NCT02084290

Trial name or title	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 programme 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@hitchcock.org; Corey A Siegel; Dartmouth-Hitchcock Medical Center
Notes	Trial #: NCT02084290

NCT02110979

Trial name or title	Validation of a patient decision aid for type 2 diabetes
Methods	RCT
Participants	200 type 2 diabetes patients
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict
Starting date	April 2014
Contact information	EPI-Q Inc, Oak Brook, IL, USA, 60523 www.epi-q.com/our-approach
Notes	Trial #: NCT02110979

NCT02145481

Trial name or title	Decisional quality for patients with stable coronary artery disease
Methods	RCT

NCT02145481 *(Continued)*

Participants	846 adults with stable coronary artery disease
Interventions	Patient decision aid vs standard education
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

NCT02198690

Trial name or title	Randomized trial of a mammography decision aid for women aged 75 and older
Methods	RCT
Participants	550 women aged 75-89 years
Interventions	Decision aid vs usual care
Outcomes	Receipt of mammography screening, acceptability, anxiety, decision-making role, decisional conflict, home safety, home safety discussions, knowledge, preparation for decision-making, screening discussions, screening intentions
Starting date	September 2014
Contact information	Mara A Schonberg, MD, MPH; mschonbe@bidmc.harvard.edu; Beth Israel Deaconess Medical Center; Boston, MA, USA
Notes	NCT02198690

NCT02235571

Trial name or title	iChoose kidney decision aid for treatment options among end-stage renal disease (ESRD) patients
Methods	RCT
Participants	450 adults with end-stage renal disease on dialysis for < 1 year and being evaluated for kidney transplant
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, evidence of shared decision-making, access to transplant, treatment preferences
Starting date	September 2014
Contact information	Rachel Patzer; Emory Transplant Center; Atlanta, GA, USA
Notes	Trial # NCT02235571

NCT02248974

Trial name or title	Development and user testing of a decision aid for left ventricular assist device (LVAD) placement
Methods	RCT
Participants	144 adults who are candidates for a left ventricular assist device
Interventions	Patient decision aid vs. standard education
Outcomes	Knowledge, decisional conflict, control preferences scale, CollaboRATE score, perceived quality of care, satisfaction with decision-making process, decisional regret, satisfaction with life, preparation for decision-making, usability and acceptability of the intervention
Starting date	February 2014
Contact information	Jennifer Blumenthal-Barby; Baylor College of Medicine; Houston, TX
Notes	Trial #: NCT02248974

NCT02259699

Trial name or title	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	lwenzel@uci.edu; Lari Wenzel; University of California, Irvine, USA
Notes	Trial #: NCT02259699

NCT02308592

Trial name or title	Patient decision aid for antidepressant use in pregnancy
Methods	RCT
Participants	50 women aged 18 years or older planning a pregnancy or <30 weeks pregnant
Interventions	Patient decision aid vs standard resource sheet
Outcomes	depression, anxiety, decisional conflict, knowledge, intervention acceptability, choice, satisfaction with DA

NCT02308592 *(Continued)*

Starting date	January 2015
Contact information	simone.vigod@wchospital.ca Women's College Hospital, Toronto, Ontario, Canada
Notes	Trial #: NCT02308592

NCT02319525

Trial name or title	
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	

NCT02326597

Trial name or title	Decision aid for therapeutic options in sickle cell disease
Methods	RCT
Participants	120 individuals with sickle cell disease ages 8 to 80 years
Interventions	Decision aid vs usual care
Outcomes	Knowledge, self-efficacy, decisional conflict, values, realistic expectations, preparation for decision-making, choice predisposition, stage of decision-making, decisional regret
Starting date	September 2014
Contact information	diana.ross@emory.edu; principal investigator Lakshmanan Krishnamurti; Emory University, Atlanta, GA, USA
Notes	Trial # NCT02326597

NCT02344576

Trial name or title	A multicenter trial of a shared decision support intervention for patients and their caregivers offered destination therapy for end-stage heart failure

NCT02344576 *(Continued)*

Methods	RCT
Participants	400 adults advanced heart failure and are being evaluated for destination left ventricular assist device
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, values, decisional conflict, decisional regret, stress, anxiety, depression, quality of life, control preferences scale, illness acceptance, health status
Starting date	May 2015
Contact information	jocelyn.thompson@ucdenver.edu; University of Colorado, Denver
Notes	Trial #: NCT02344576

NCT02488317

Trial name or title	Empowering patients on choices for renal replacement therapy
Methods	RCT
Participants	150 adults with kidney disease
Interventions	Patient decision aid vs usual care
Outcomes	Preference for shared decision-making (CPS), decisional conflict, decision self-efficacy, knowledge, preparation for decision making
Starting date	May 2015
Contact information	Francesca Tentori; Arbor Research Collaborative for Health; Ann Arbor, MI
Notes	Trial #: NCT02488317

NCT02488603

Trial name or title	Utilization of decision aids for tamoxifen treatment in breast cancer patients
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

NCT02492009

Trial name or title	Patient decision aid for antidepressant use in pregnancy
Methods	RCT
Participants	50 women aged 18 years or older planning a pregnancy or < 30 weeks pregnant
Interventions	Patient decision aid vs standard resource sheet
Outcomes	Depression, anxiety, decisional conflict, knowledge, intervention acceptability, choice
Starting date	June 2015
Contact information	hind.khalifeh@kcl.ac.uk or ruth.brauer@kcl.ac.uk Section of Women's Mental Health, King's College London
Notes	Trial #: NCT02492009

NCT02503553

Trial name or title	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	Trial #: NCT02503553

NCT02516449

Trial name or title	Assessment of shared decision making aids in asthma
Methods	RCT
Participants	51 adults with mild to severe asthma
Interventions	Patient decision aid vs usual care
Outcomes	Knowledge, decisional conflict, treatment adherence, asthma control
Starting date	March 2013

NCT02516449 *(Continued)*

Contact information	Centre de recherche de l'Institut universitaire de cardiologie et de pneumologie de Québec, Québec, Canada, G1V 4G5
Notes	Trial # NCT02516449

NCT02540044

Trial name or title	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 behaviours, 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

Trial name or title	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	Trial #: NCT02611050

Oostendorp 2011

Trial name or title	Assessing the information desire of patients with advanced cancer by providing information with a decision aid, which is evaluated in a randomized trial: a study protocol

Oostendorp 2011 *(Continued)*

Methods	RCT
Participants	Patients with advanced colorectal, breast, or ovarian cancer and have started treatment with first-line palliative chemotherapy
Interventions	Patients are randomized to receive either usual care or usual care + decision aid
Outcomes	Not yet assessed
Starting date	Not yet assessed
Contact information	Linda JM Oostendorp, Radbound University
Notes	Netherlands Trial Register (NTR): NTR1113

Yu 2015

Trial name or title	Impact of an interprofessional shared decision-making and goal setting decision aid for patients with diabetes
Methods	Cluster-randomized controlled trial
Participants	112 patients with diabetes
Interventions	Multicomponent patient decision aid toolkit vs patient education pamphlet
Outcomes	Decisional conflict, diabetes distress, health-related quality of life, chronic illness care, intention to engage in SDM
Starting date	April 2015
Contact information	yuca@smh.ca
Notes	Trial # NCT02379078

CA-125: cancer antigen 125; **CAD**: coronary artery disease; **CT**: computerized tomography; **NIH**: National Institutes of Health; **NSW**: New South Wales; **OA**: osteoarthritis; **RCT**: randomized controlled trial; **SDM**: shared decision making.

DATA AND ANALYSES

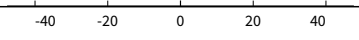
Comparison 1. Knowledge

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge - all studies	52	13316	Mean Difference (IV, Random, 95% CI)	13.27 [11.32, 15.23]
2 Knowledge - subgroup by timing of intervention (in consultation versus in preparation for consultation)	52		Mean Difference (IV, Random, 95% CI)	Subtotals only

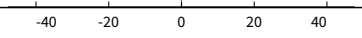
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 In consultation	8	922	Mean Difference (IV, Random, 95% CI)	10.57 [4.79, 16.36]
2.2 In preparation for consultation	44	12394	Mean Difference (IV, Random, 95% CI)	13.77 [11.61, 15.93]
3 Knowledge - studies without high risk of bias	47	12327	Mean Difference (IV, Random, 95% CI)	13.43 [11.37, 15.49]

Analysis 1.1. Comparison 1 Knowledge, Outcome 1 Knowledge - all studies.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.04%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.09%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.28%	21[9.25,32.75]
Bekker 2004	50	74 (14.5)	56	71.5 (16)		1.96%	2.5[-3.31,8.31]
Bernstein 1998	61	83 (16)	48	58 (16)		1.93%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.18%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		1.91%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.12%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.09%	5[0.39,9.61]
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.09%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.32%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.02%	8.9[3.6,14.2]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		2.05%	8.57[3.56,13.58]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.43%	17.63[7.33,27.93]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		1.89%	7.4[0.98,13.82]
Knops 2014	80	76.9 (16.9)	84	72.3 (16.2)		2.04%	4.62[-0.45,9.69]
Krist 2007	196	69 (33.2)	75	54 (33.2)		1.6%	15[6.16,23.84]
Kupke 2013	50	60 (23.3)	31	27 (16.7)		1.61%	33[24.27,41.73]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.23%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		1.82%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		1.76%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.37%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.08%	19.9[15.17,24.63]
Lewis 2010	93	45.1 (34)	107	46.7 (34)		1.52%	-1.6[-11.05,7.85]
Man-Son-Hing 1999	137	75.9 (15.7)	136	66.5 (16.1)		2.18%	9.45[5.68,13.22]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.11%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		1.89%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		1.75%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		1.86%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.19%	12.2[8.61,15.79]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		1.26%	20[8.09,31.91]
Morgan 2000	86	75 (32)	94	62 (32)		1.53%	13[3.63,22.37]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		1.57%	10.5[1.44,19.56]
Nassar 2007	98	88 (19)	90	79 (18)		2.02%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		1.8%	10.9[3.73,18.07]

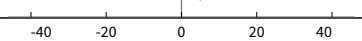


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Sawka 2012	37	97 (6)	37	78 (13)		2.09%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.2%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.58%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.24%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.1%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.19%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		1.73%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.3%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.12%	14.6[10.27,18.93]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		2.01%	0.56[-4.77,5.89]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		1.92%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.68%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		1.9%	17[10.68,23.32]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		2.14%	8.5[4.37,12.63]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.19%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.01%	25[19.6,30.4]
Total ***	**6779**		**6537**			**100%**	**13.27[11.32,15.23]**
Heterogeneity: Tau²=41.98; Chi²=717.6, df=51(P<0.0001); I²=92.89%							
Test for overall effect: Z=13.31(P<0.0001)							



Analysis 1.2. Comparison 1 Knowledge, Outcome 2 Knowledge - subgroup by timing of intervention (in consultation versus in preparation for consultation).

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
1.2.1 In consultation							
Bekker 2004	50	74 (14.5)	56	71.5 (16)		13.35%	2.5[-3.31,8.31]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		13.83%	8.57[3.56,13.58]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		12.96%	7.4[0.98,13.82]
Kupke 2013	50	60 (23.3)	31	27 (16.7)		11.41%	33[24.27,41.73]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		9.32%	20[8.09,31.91]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		11.19%	10.5[1.44,19.56]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		13.64%	0.56[-4.77,5.89]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		14.3%	8.5[4.37,12.63]
Subtotal ***	**465**		**457**			**100%**	**10.57[4.79,16.36]**
Heterogeneity: Tau²=56.4; Chi²=46.7, df=7(P<0.0001); I²=85.01%							
Test for overall effect: Z=3.58(P=0)							
1.2.2 In preparation for consultation							
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.38%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.43%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.51%	21[9.25,32.75]
Bernstein 1998	61	83 (16)	48	58 (16)		2.26%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.54%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		2.24%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.48%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.44%	5[0.39,9.61]

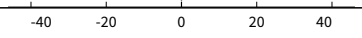


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.44%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.57%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.36%	8.9[3.6,14.2]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.69%	17.63[7.33,27.93]
Knops 2014	80	76.9 (16.9)	84	72.3 (16.2)		2.39%	4.62[-0.45,9.69]
Krist 2007	196	69 (33.2)	75	54 (33.2)		1.88%	15[6.16,23.84]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.6%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2.33%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		2.14%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		2.07%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.75%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.43%	19.9[15.17,24.63]
Lewis 2010	93	45.1 (34)	107	46.7 (34)		1.8%	-1.6[-11.05,7.85]
Man-Son-Hing 1999	137	75.9 (15.7)	136	66.5 (16.1)		2.54%	9.45[5.68,13.22]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.47%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		2.21%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		2.05%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		2.19%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.55%	12.2[8.61,15.79]
Morgan 2000	86	75 (32)	94	62 (32)		1.81%	13[3.63,22.37]
Nassar 2007	98	88 (19)	90	79 (18)		2.36%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		2.11%	10.9[3.73,18.07]
Sawka 2012	37	97 (6)	37	78 (13)		2.44%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.56%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.86%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.61%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.45%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.55%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		2.04%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.67%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.47%	14.6[10.27,18.93]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		2.25%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.97%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		2.22%	17[10.68,23.32]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.55%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.34%	25[19.6,30.4]
Subtotal * **	**6314**		**6080**			**100%**	**13.77[11.61,15.93]**

Heterogeneity: Tau^2=44.14; Chi^2=669.38, df=43(P<0.0001); I^2=93.58%

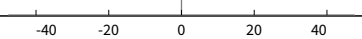
Test for overall effect: Z=12.5(P<0.0001)

Test for subgroup differences: Chi^2=1.03, df=1 (P=0.31), I^2=3.03%



Analysis 1.3. Comparison 1 Knowledge, Outcome 3 Knowledge - studies without high risk of bias.

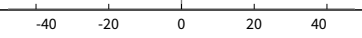
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Allen 2010	291	66 (35.5)	334	60 (29.2)		2.23%	6[0.86,11.14]
Arterburn 2011	75	72 (12)	77	65 (17)		2.29%	7[2.33,11.67]
Barry 1997	104	75 (45)	123	54 (45)		1.41%	21[9.25,32.75]



Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Bekker 2004	50	74 (14.5)	56	71.5 (16)		2.15%	2.5[-3.31,8.31]
Bernstein 1998	61	83 (16)	48	58 (16)		2.12%	25[18.95,31.05]
Bjorklund 2012	182	77 (17)	204	71 (20)		2.4%	6[2.31,9.69]
Chabrera 2015	61	75.7 (19)	61	49.9 (16)		2.1%	25.8[19.57,32.03]
Frosch 2008a	155	81.4 (18.7)	151	72.4 (19.7)		2.33%	9[4.69,13.31]
Gattellari 2003	106	50 (18.4)	108	45 (15.9)		2.3%	5[0.39,9.61]
Gattellari 2005	131	57.2 (21.3)	136	42.2 (16.7)		2.3%	15[10.4,19.6]
Green 2001	29	95 (7)	14	65 (21)		1.46%	30[18.71,41.29]
Hanson 2011	127	88.4 (21.6)	129	79.5 (21.6)		2.21%	8.9[3.6,14.2]
Hess 2012	101	51.4 (18.2)	103	42.9 (18.3)		2.25%	8.57[3.56,13.58]
Jibaja-Weiss 2011	44	61.2 (20.4)	39	43.6 (26.6)		1.57%	17.63[7.33,27.93]
Johnson 2006	32	92.6 (11)	35	85.2 (15.6)		2.07%	7.4[0.98,13.82]
Kuppermann 2014	357	62.7 (21.3)	353	57.3 (21.3)		2.45%	5.4[2.27,8.53]
Lam 2013	113	61 (21)	112	59 (21)		2.19%	2[-3.49,7.49]
Laupacis 2006	53	83 (19.5)	53	67.4 (17)		2%	15.6[8.64,22.56]
Leighl 2011	100	72.5 (26.9)	100	60 (26.9)		1.94%	12.5[5.05,19.95]
Lepore 2012	215	61.6 (0.1)	216	54.7 (0.1)		2.6%	6.9[6.88,6.92]
Lerman 1997	122	68.9 (19)	164	49 (21.7)		2.28%	19.9[15.17,24.63]
Mann E 2010	273	64.1 (21.9)	134	41.3 (21)		2.32%	22.85[18.45,27.25]
Mathieu 2010	113	73.5 (27.6)	189	62.7 (27.6)		2.07%	10.8[4.37,17.23]
McCaffery 2010	77	81 (23.5)	71	72 (23.5)		1.92%	9[1.42,16.58]
Montgomery 2003	50	75 (17)	58	60 (18)		2.05%	15[8.39,21.61]
Montgomery 2007	196	69.7 (18)	202	57.5 (18.5)		2.41%	12.2[8.61,15.79]
Montori 2011	49	63.3 (29.6)	46	43.3 (29.6)		1.39%	20[8.09,31.91]
Morgan 2000	86	75 (32)	94	62 (32)		1.69%	13[3.63,22.37]
Mullan 2009	48	63.5 (24.4)	37	53 (18.2)		1.73%	10.5[1.44,19.56]
Nassar 2007	98	88 (19)	90	79 (18)		2.22%	9[3.71,14.29]
Protheroe 2007	54	59.7 (18.4)	54	48.8 (19.6)		1.97%	10.9[3.73,18.07]
Sawka 2012	37	97 (6)	37	78 (13)		2.3%	19[14.39,23.61]
Schroy 2011	223	89.2 (15)	231	71.7 (22.5)		2.41%	17.5[13.99,21.01]
Schwalm 2012	76	60 (30)	74	40 (26)		1.74%	20[11.02,28.98]
Schwartz 2001	191	65.7 (14.3)	190	57.1 (15.7)		2.46%	8.57[5.55,11.59]
Shorten 2005	99	75.3 (15)	92	60.5 (17.1)		2.3%	14.8[10.23,19.37]
Smith 2010	357	54.2 (27.8)	173	34.2 (14.3)		2.41%	20[16.42,23.58]
Stacey 2014a	66	71.2 (23.7)	66	46.6 (21.4)		1.9%	24.6[16.9,32.3]
Steckelberg 2011	785	53.8 (28.8)	792	31.3 (15)		2.52%	22.5[20.23,24.77]
Taylor 2006	80	77.3 (15.5)	74	62.7 (11.8)		2.33%	14.6[10.27,18.93]
Thomson 2007	53	62.9 (14.3)	56	62.4 (14.1)		2.21%	0.56[-4.77,5.89]
Van Peperstraten 2010	123	62 (28.3)	132	43 (20.5)		2.11%	19[12.9,25.1]
Vandemheen 2009	70	74 (27.1)	79	49 (23.3)		1.84%	25[16.83,33.17]
Volk 1999	78	48 (21.6)	80	31 (18.8)		2.09%	17[10.68,23.32]
Whelan 2003	82	80.2 (14.4)	93	71.7 (13.3)		2.35%	8.5[4.37,12.63]
Williams 2013	196	64.4 (18.5)	185	61.7 (17.8)		2.4%	2.7[-0.95,6.35]
Wong 2006	154	85 (26.7)	159	60 (21.7)		2.2%	25[19.6,30.4]
Total ***	**6223**		**6104**			**100%**	**13.43[11.37,15.49]**

Heterogeneity: Tau^2=42.59; Chi^2=674.45, df=46(P<0.0001); I^2=93.18%

Test for overall effect: Z=12.78(P<0.0001)

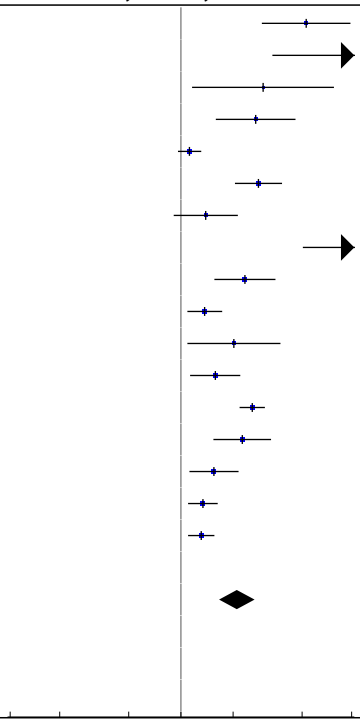


Comparison 2. Accurate risk perceptions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Accurate risk perceptions - all studies	17	5096	Risk Ratio (M-H, Random, 95% CI)	2.10 [1.66, 2.66]
2 Accurate risk perceptions - subgroup by timing of intervention (in consultation versus in preparation for consultation)	17		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 In consultation	6	898	Risk Ratio (M-H, Random, 95% CI)	1.79 [1.28, 2.52]
2.2 In preparation for consultation	11	4198	Risk Ratio (M-H, Random, 95% CI)	2.25 [1.65, 3.07]
3 Accurate risk perceptions - studies without high risk of bias	15	4732	Risk Ratio (M-H, Random, 95% CI)	2.02 [1.57, 2.59]

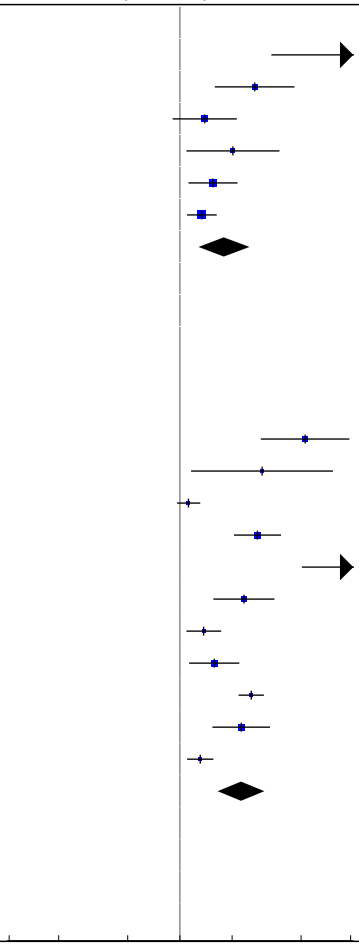
Analysis 2.1. Comparison 2 Accurate risk perceptions, Outcome 1 Accurate risk perceptions - all studies.

Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gattellari 2003	57/106	11/108		5.23%	5.28[2.93,9.5]
Hess 2012	24/101	1/103		1.2%	24.48[3.37,177.53]
Laupacis 2006	14/47	5/50		3.47%	2.98[1.16,7.63]
LeBlanc 2015	23/32	12/45		5.56%	2.7[1.59,4.58]
Lerman 1997	90/122	108/164		7.5%	1.12[0.96,1.31]
Man-Son-Hing 1999	92/139	35/148		6.81%	2.8[2.05,3.83]
Mann D 2010	35/80	22/70		6.18%	1.39[0.91,2.13]
Mathers 2012	67/95	4/75		3.38%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		6.3%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		7.21%	1.37[1.09,1.73]
Montori 2011	23/49	10/43		5.05%	2.02[1.09,3.75]
Schwalm 2012	47/76	29/74		6.7%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		7.45%	2.58[2.18,3.05]
Vandemheen 2009	46/70	23/79		6.43%	2.26[1.54,3.31]
Whelan 2003	47/82	34/92		6.75%	1.55[1.12,2.15]
Whelan 2004	73/94	62/107		7.36%	1.34[1.1,1.63]
Wolf 2000	189/266	72/133		7.43%	1.31[1.1,1.56]
Total (95% CI)	**2584**	**2512**		**100%**	**2.1[1.66,2.66]**
Total events: 1363 (Decision Aid), 676 (Control)					
Heterogeneity: Tau^2=0.19; Chi^2=151.38, df=16(P<0.0001); I^2=89.43%					
Test for overall effect: Z=6.16(P<0.0001)					



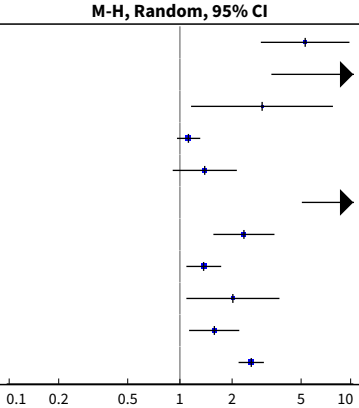
Analysis 2.2. Comparison 2 Accurate risk perceptions, Outcome 2 Accurate risk perceptions - subgroup by timing of intervention (in consultation versus in preparation for consultation).

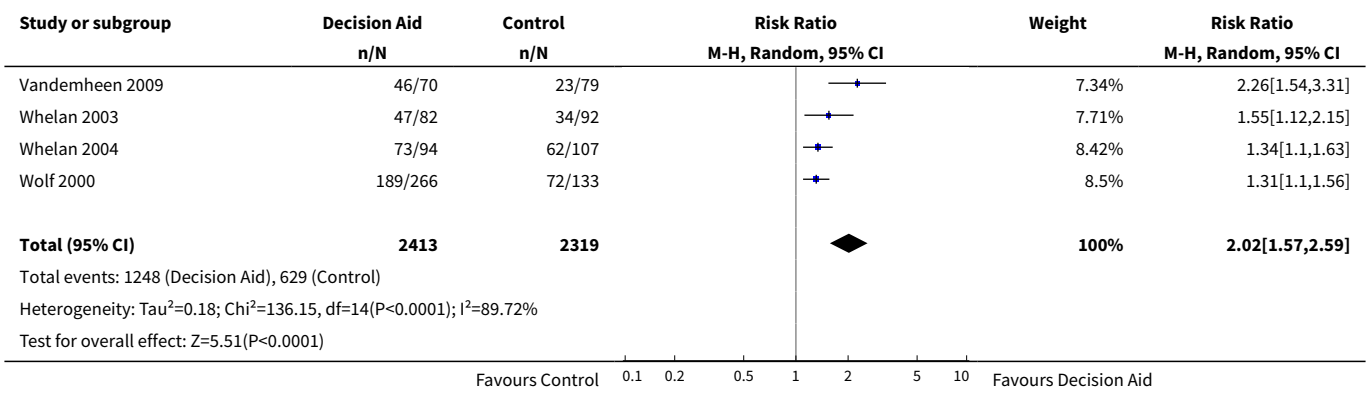
Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
2.2.1 In consultation					
Hess 2012	24/101	1/103		2.65%	24.48[3.37,177.53]
LeBlanc 2015	23/32	12/45		16.47%	2.7[1.59,4.58]
Mann D 2010	35/80	22/70		19.22%	1.39[0.91,2.13]
Montori 2011	23/49	10/43		14.37%	2.02[1.09,3.75]
Whelan 2003	47/82	34/92		21.99%	1.55[1.12,2.15]
Whelan 2004	73/94	62/107		25.29%	1.34[1.1,1.63]
Subtotal (95% CI)	**438**	**460**		**100%**	**1.79[1.28,2.52]**
Total events: 225 (Decision Aid), 141 (Control)					
Heterogeneity: Tau^2=0.11; Chi^2=17.62, df=5(P=0); I^2=71.63%					
Test for overall effect: Z=3.37(P=0)					
2.2.2 In preparation for consultation					
Gattellari 2003	57/106	11/108		7.94%	5.28[2.93,9.5]
Laupacis 2006	14/47	5/50		5.5%	2.98[1.16,7.63]
Lerman 1997	90/122	108/164		10.78%	1.12[0.96,1.31]
Man-Son-Hing 1999	92/139	35/148		9.95%	2.8[2.05,3.83]
Mathers 2012	67/95	4/75		5.37%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		9.31%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		10.43%	1.37[1.09,1.73]
Schwalm 2012	47/76	29/74		9.81%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		10.72%	2.58[2.18,3.05]
Vandemheen 2009	46/70	23/79		9.48%	2.26[1.54,3.31]
Wolf 2000	189/266	72/133		10.7%	1.31[1.1,1.56]
Subtotal (95% CI)	**2146**	**2052**		**100%**	**2.25[1.65,3.07]**
Total events: 1138 (Decision Aid), 535 (Control)					
Heterogeneity: Tau^2=0.23; Chi^2=130.92, df=10(P<0.0001); I^2=92.36%					
Test for overall effect: Z=5.11(P<0.0001)					
Test for subgroup differences: Chi^2=0.94, df=1 (P=0.33), I^2=0%					



Analysis 2.3. Comparison 2 Accurate risk perceptions, Outcome 3 Accurate risk perceptions - studies without high risk of bias.

Study or subgroup	Decision Aid n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Gattellari 2003	57/106	11/108		5.95%	5.28[2.93,9.5]
Hess 2012	24/101	1/103		1.35%	24.48[3.37,177.53]
Laupacis 2006	14/47	5/50		3.93%	2.98[1.16,7.63]
Lerman 1997	90/122	108/164		8.58%	1.12[0.96,1.31]
Mann D 2010	35/80	22/70		7.05%	1.39[0.91,2.13]
Mathers 2012	67/95	4/75		3.83%	13.22[5.05,34.62]
McAlister 2005	66/175	25/155		7.18%	2.34[1.56,3.51]
McBride 2002	109/265	82/274		8.24%	1.37[1.09,1.73]
Montori 2011	23/49	10/43		5.74%	2.02[1.09,3.75]
Schwalm 2012	47/76	29/74		7.65%	1.58[1.13,2.2]
Steckelberg 2011	361/785	141/792		8.53%	2.58[2.18,3.05]

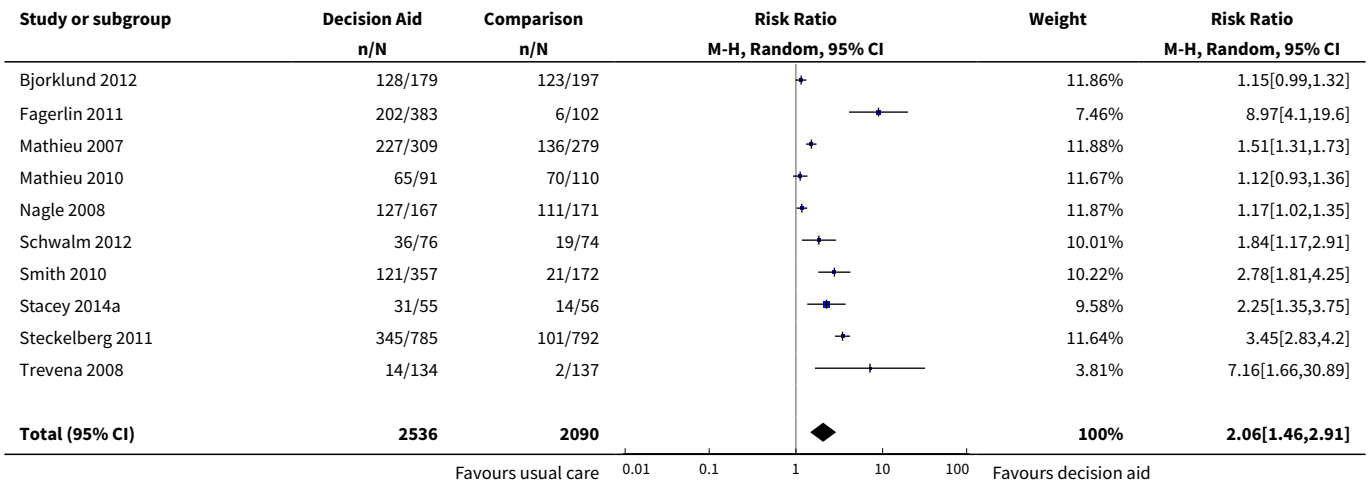


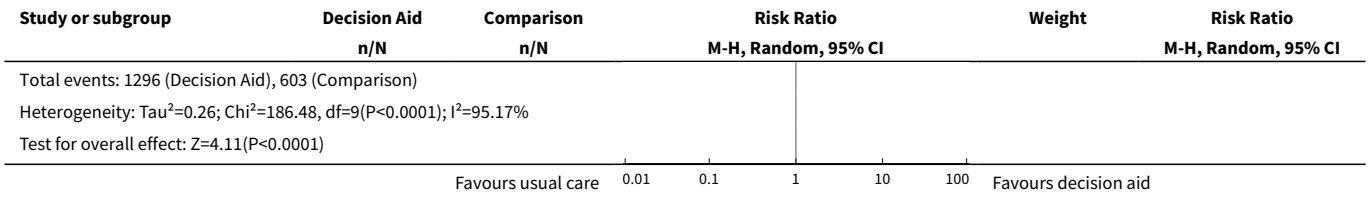


Comparison 3. Informed values-choice congruence

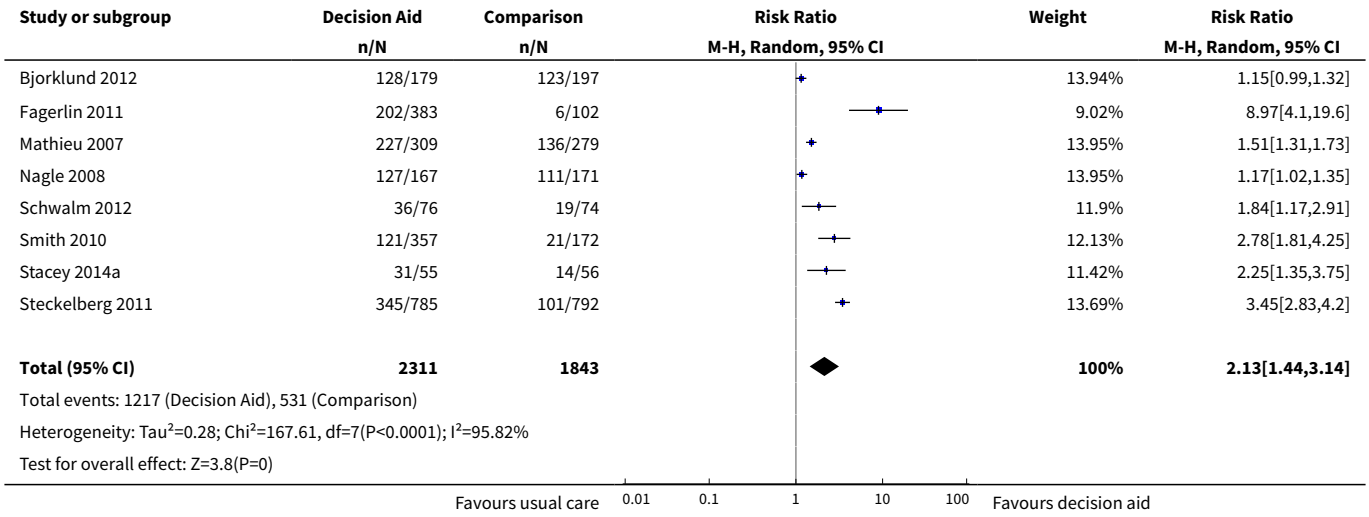
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Informed values-choice congruence - all studies	10	4626	Risk Ratio (M-H, Random, 95% CI)	2.06 [1.46, 2.91]
2 Informed values-choice congruence - actual choice only	8	4154	Risk Ratio (M-H, Random, 95% CI)	2.13 [1.44, 3.14]
3 Informed values-chose congruence -using MMIC	8	4365	Risk Ratio (M-H, Random, 95% CI)	2.08 [1.40, 3.08]
4 Informed values-chose congruence - heterogeneous measures	2	261	Risk Ratio (M-H, Random, 95% CI)	2.02 [1.44, 2.83]
5 Informed values-choice congruence - without studies of high risk of bias	10	4626	Risk Ratio (M-H, Random, 95% CI)	2.06 [1.46, 2.91]

Analysis 3.1. Comparison 3 Informed values-choice congruence, Outcome 1 Informed values-choice congruence - all studies.

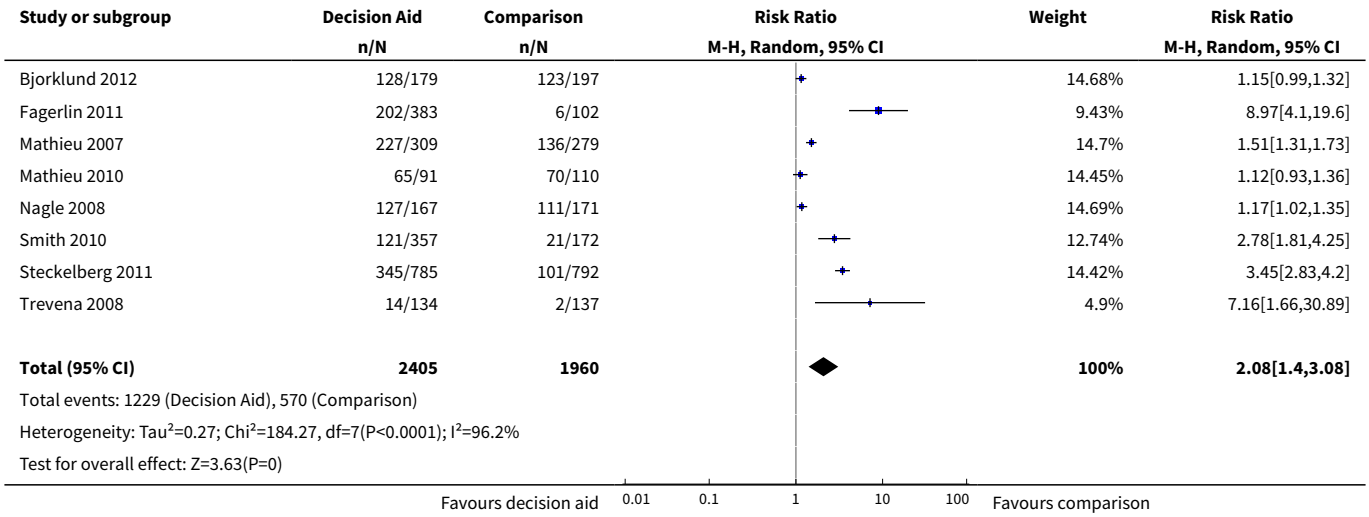




Analysis 3.2. Comparison 3 Informed values-choice congruence, Outcome 2 Informed values-choice congruence - actual choice only.



Analysis 3.3. Comparison 3 Informed values-choice congruence, Outcome 3 Informed values-chose congruence -using MMIC.



Analysis 3.4. Comparison 3 Informed values-choice congruence, Outcome 4 Informed values-chose congruence - heterogeneous measures.

Study or subgroup	Decision Aid n/N	Comparison n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Schwalm 2012	36/76	19/74		55.73%	1.84[1.17,2.91]
Stacey 2014a	31/55	14/56		44.27%	2.25[1.35,3.75]
Total (95% CI)	**131**	**130**		**100%**	**2.02[1.44,2.83]**
Total events: 67 (Decision Aid), 33 (Comparison)					
Heterogeneity: Tau^2=0; Chi^2=0.33, df=1(P=0.56); I^2=0%					
Test for overall effect: Z=4.05(P<0.0001)					

Favours Decision Aid — Favours Comparison

Analysis 3.5. Comparison 3 Informed values-choice congruence, Outcome 5 Informed values-choice congruence - without studies of high risk of bias.

Study or subgroup	Decision Aid n/N	Comparison n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Bjorklund 2012	128/179	123/197		11.86%	1.15[0.99,1.32]
Fagerlin 2011	202/383	6/102		7.46%	8.97[4.1,19.6]
Mathieu 2007	227/309	136/279		11.88%	1.51[1.31,1.73]
Mathieu 2010	65/91	70/110		11.67%	1.12[0.93,1.36]
Nagle 2008	127/167	111/171		11.87%	1.17[1.02,1.35]
Schwalm 2012	36/76	19/74		10.01%	1.84[1.17,2.91]
Smith 2010	121/357	21/172		10.22%	2.78[1.81,4.25]
Stacey 2014a	31/55	14/56		9.58%	2.25[1.35,3.75]
Steckelberg 2011	345/785	101/792		11.64%	3.45[2.83,4.2]
Trevena 2008	14/134	2/137		3.81%	7.16[1.66,30.89]
Total (95% CI)	**2536**	**2090**		**100%**	**2.06[1.46,2.91]**
Total events: 1296 (Decision Aid), 603 (Comparison)					
Heterogeneity: Tau^2=0.26; Chi^2=186.48, df=9(P<0.0001); I^2=95.17%					
Test for overall effect: Z=4.11(P<0.0001)					

Favours usual care — Favours decision aid

Comparison 4. Decisional conflict

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Decisional conflict - all studies	42		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Total decisional conflict score	38	8785	Mean Difference (IV, Random, 95% CI)	-7.22 [-9.12, -5.31]
1.2 Uninformed subscale	27	5707	Mean Difference (IV, Random, 95% CI)	-9.28 [-12.20, -6.36]

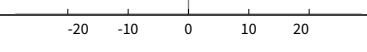
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.3 Unclear values subscale	23	5068	Mean Difference (IV, Random, 95% CI)	-8.81 [-11.99, -5.63]
1.4 Uncertainty subscale	28	6200	Mean Difference (IV, Random, 95% CI)	-4.04 [-6.27, -1.81]
1.5 Unsupported subscale	24	5214	Mean Difference (IV, Random, 95% CI)	-6.27 [-8.86, -3.68]
1.6 Ineffective choice subscale	24	5241	Mean Difference (IV, Random, 95% CI)	-6.31 [-8.93, -3.70]
2 Decisional conflict - in consultation	6		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Uncertainty subscale	2	310	Mean Difference (IV, Random, 95% CI)	-6.45 [-18.29, 5.38]
2.2 Uninformed subscale	4	545	Mean Difference (IV, Random, 95% CI)	-6.37 [-14.58, 1.85]
2.3 Unclear values subscale	1	204	Mean Difference (IV, Random, 95% CI)	-17.2 [-23.77, -10.63]
2.4 Unsupported subscale	2	354	Mean Difference (IV, Random, 95% CI)	-7.16 [-13.28, -1.03]
2.5 Ineffective choice subscale	2	307	Mean Difference (IV, Random, 95% CI)	-2.37 [-7.31, 2.58]
2.6 Total decisional conflict score	5	735	Mean Difference (IV, Random, 95% CI)	-6.46 [-12.78, -0.14]
3 Decisional conflict - in preparation for consultation	36		Mean Difference (IV, Random, 95% CI)	Subtotals only
3.1 Uncertainty subscale	26	5890	Mean Difference (IV, Random, 95% CI)	-3.83 [-6.12, -1.55]
3.2 Uninformed subscale	23	5162	Mean Difference (IV, Random, 95% CI)	-9.81 [-13.00, -6.61]
3.3 Unclear values subscale	22	4864	Mean Difference (IV, Random, 95% CI)	-8.40 [-11.59, -5.21]
3.4 Unsupported subscale	22	4860	Mean Difference (IV, Random, 95% CI)	-6.18 [-8.96, -3.40]
3.5 Ineffective choice subscale	22	4934	Mean Difference (IV, Random, 95% CI)	-6.75 [-9.59, -3.90]
3.6 Total decisional conflict score	33	8050	Mean Difference (IV, Random, 95% CI)	-7.32 [-9.35, -5.28]

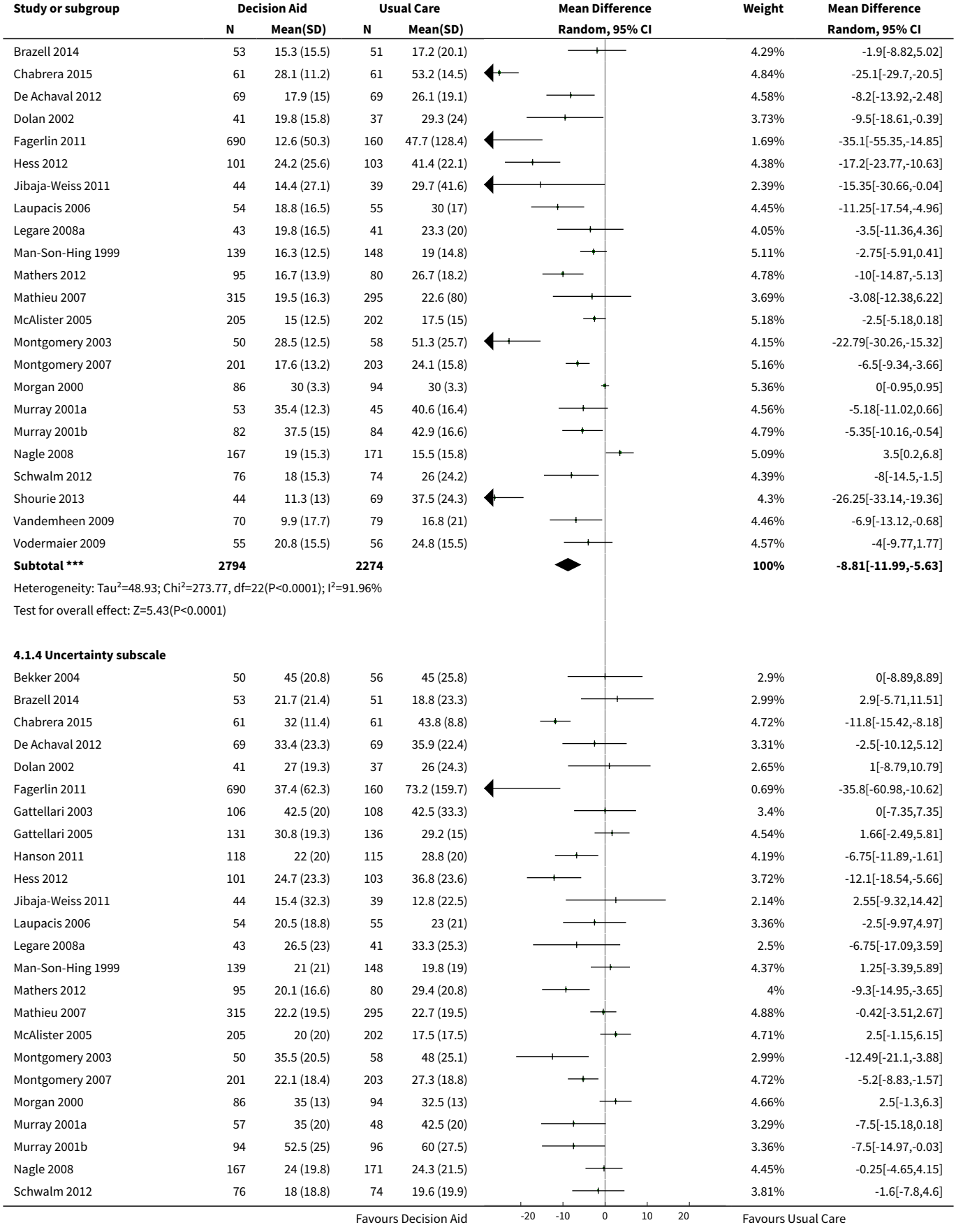
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Decisional conflict - without studies having high risk of bias	39		Mean Difference (IV, Random, 95% CI)	Subtotals only
4.1 Uncertainty subscale	26	5809	Mean Difference (IV, Random, 95% CI)	-4.53 [-6.87, -2.18]
4.2 Uninformed subscale	25	5316	Mean Difference (IV, Random, 95% CI)	-9.96 [-13.13, -6.78]
4.3 Unclear values subscale	21	4677	Mean Difference (IV, Random, 95% CI)	-9.55 [-13.08, -6.02]
4.4 Unsupported subscale	22	4823	Mean Difference (IV, Random, 95% CI)	-7.00 [-9.76, -4.24]
4.5 Ineffective choice subscale	22	4850	Mean Difference (IV, Random, 95% CI)	-6.97 [-9.76, -4.18]
4.6 Total decisional conflict score	35	8240	Mean Difference (IV, Random, 95% CI)	-7.81 [-9.84, -5.77]

Analysis 4.1. Comparison 4 Decisional conflict, Outcome 1 Decisional conflict - all studies.

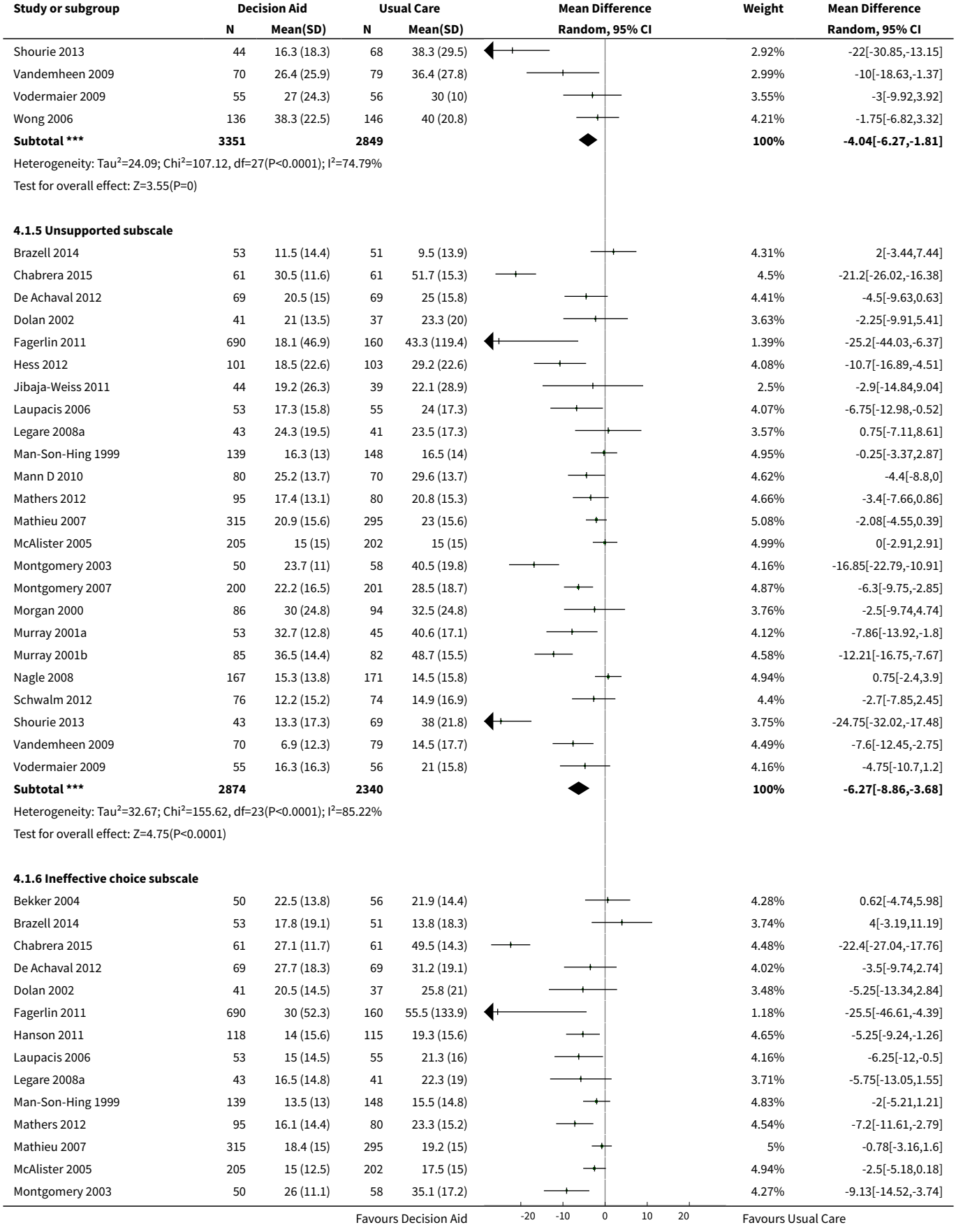
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.1.1 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.6%	-6[-11.66,-0.34]
Brazell 2014	53	15.8 (13.9)	51	14.1 (16.1)		2.57%	1.7[-4.09,7.49]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		2.9%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		2.68%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.19%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.35%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		0.91%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		2.79%	-8[-12.76,-3.24]
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		2.64%	-20[-25.46,-14.54]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		1.77%	-5.63[-15.51,4.25]
Knops 2014	73	22 (17)	81	24 (17)		2.66%	-2[-7.38,3.38]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.23%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		2.91%	-4.1[-8.26,0.06]
Laupacis 2006	53	17.5 (13.8)	54	25.3 (14.3)		2.67%	-7.75[-13.06,-2.44]
Legare 2008a	43	23 (14.3)	41	27 (15.3)		2.46%	-4[-10.32,2.32]
Lepore 2012	215	34.2 (24)	216	39.9 (24)		2.83%	-5.7[-10.24,-1.16]
Man-Son-Hing 1999	139	16.3 (11.3)	148	18.5 (13.5)		3.13%	-2.25[-5.12,0.62]
Mann D 2010	80	25.5 (11.1)	70	28.5 (11.1)		3.02%	-3[-6.57,0.57]
Mathers 2012	95	17.4 (12.6)	80	25.2 (14.9)		2.91%	-7.8[-11.93,-3.67]
Mathieu 2007	315	20.1 (14.5)	295	21.9 (14.5)		3.21%	-1.83[-4.13,0.47]
McAlister 2005	205	15 (12.5)	202	17.5 (12.5)		3.2%	-2.5[-4.93,-0.07]
Montgomery 2003	50	27.1 (10)	58	44.2 (19.3)		2.59%	-17.1[-22.79,-11.41]
Montgomery 2007	198	23.6 (15.1)	201	27.8 (14.6)		3.13%	-4.2[-7.12,-1.28]

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Montori 2011	49	14.4 (24.9)	46	16.2 (24.9)		1.74%	-1.8[-11.83,8.23]
Morgan 2000	86	27.5 (37.5)	94	27.5 (37.5)		1.59%	0[-10.97,10.97]
Mullan 2009	48	14.1 (17.9)	37	15 (12.7)		2.42%	-0.85[-7.35,5.65]
Murray 2001a	57	32.5 (10)	48	40 (12.5)		2.86%	-7.5[-11.89,-3.11]
Murray 2001b	94	37.5 (12.5)	96	45 (15)		2.95%	-7.5[-11.42,-3.58]
Nagle 2008	167	17.8 (12.3)	171	16.3 (13.8)		3.15%	1.5[-1.27,4.27]
Nassar 2007	98	4.6 (9)	98	13.5 (19.2)		2.9%	-8.9[-13.1,-4.7]
Protheroe 2007	69	23.4 (14.3)	69	40.5 (18.3)		2.64%	-17.1[-22.58,-11.62]
Sawka 2012	37	25.2 (13.4)	37	52.1 (21.9)		2.06%	-26.9[-35.17,-18.63]
Schwalm 2012	76	14.8 (10.5)	74	19.5 (16.7)		2.84%	-4.7[-9.18,-0.22]
Shorten 2005	99	23.5 (12.5)	88	29.5 (18.3)		2.83%	-6[-10.54,-1.46]
Shourie 2013	43	14.3 (17.3)	67	37.3 (21.5)		2.26%	-23[-30.29,-15.71]
Vandemheen 2009	70	11.6 (13.6)	79	20.4 (16.9)		2.76%	-8.8[-13.7,-3.9]
Vodermaier 2009	55	20.5 (14.8)	56	24.8 (15.5)		2.61%	-4.25[-9.88,1.38]
Whelan 2004	94	10 (12)	107	15.5 (12.9)		3.04%	-5.5[-8.94,-2.06]
Subtotal * **	**4635**		**4150**			**100%**	**-7.22[-9.12,-5.31]**
Heterogeneity: Tau²=28.03; Chi²=255.34, df=37(P<0.0001); I²=85.51%							
Test for overall effect: Z=7.42(P<0.0001)							
4.1.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		3.85%	0.83[-4.74,6.4]
Brazell 2014	53	12.1 (12.7)	51	11.1 (15.2)		3.89%	1[-4.39,6.39]
Chabrera 2015	61	39.7 (10.6)	61	61.1 (19.7)		3.85%	-21.4[-27.01,-15.79]
De Achaval 2012	69	15.9 (15.8)	69	27.3 (16.6)		3.89%	-11.4[-16.81,-5.99]
Dolan 2002	41	15.8 (13)	37	24.5 (21.3)		3.37%	-8.75[-16.67,-0.83]
Fagerlin 2011	690	8.7 (43.2)	160	57.4 (110.7)		1.72%	-48.7[-66.15,-31.25]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		3.75%	-17.8[-23.89,-11.71]
Jibaja-Weiss 2011	44	15 (22.3)	39	23.4 (28.7)		2.71%	-8.42[-19.58,2.74]
Laupacis 2006	54	16.3 (13.8)	54	27.3 (15)		3.88%	-11[-16.43,-5.57]
Legare 2008a	43	29.8 (22.8)	41	34.3 (26)		2.84%	-4.5[-14.97,5.97]
Man-Son-Hing 1999	139	15.8 (13.3)	148	21 (14.8)		4.25%	-5.25[-8.49,-2.01]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		3.84%	-6.7[-12.35,-1.05]
Mathers 2012	95	18.1 (13.3)	80	26 (16.6)		4.05%	-7.9[-12.41,-3.39]
Mathieu 2007	315	20.8 (15.6)	295	23.3 (15.6)		4.34%	-2.48[-4.96,-0]
McAlister 2005	205	15 (12.5)	202	20 (15)		4.32%	-5[-7.68,-2.32]
Montgomery 2003	50	22.2 (9.5)	58	49.1 (25.4)		3.55%	-26.97[-34.01,-19.93]
Montgomery 2007	199	35.1 (25.6)	203	35.8 (22.7)		4.01%	-0.7[-5.43,4.03]
Morgan 2000	86	20 (21.5)	94	27.5 (21.5)		3.71%	-7.5[-13.79,-1.21]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		3.46%	-1.63[-9.14,5.88]
Murray 2001a	52	27.6 (10.5)	45	38.9 (20)		3.67%	-11.32[-17.83,-4.81]
Murray 2001b	93	29.9 (17.3)	93	38.9 (22.5)		3.82%	-8.96[-14.73,-3.19]
Nagle 2008	167	15.3 (14.5)	171	12.8 (14.8)		4.27%	2.5[-0.62,5.62]
Schwalm 2012	76	15.7 (13.5)	74	22.3 (20.5)		3.85%	-6.6[-12.17,-1.03]
Shourie 2013	44	11.3 (15.3)	69	46.3 (26)		3.44%	-35[-42.61,-27.39]
Vandemheen 2009	70	4.5 (9.6)	79	17.2 (20.6)		3.95%	-12.7[-17.77,-7.63]
Vodermaier 2009	55	22 (15.8)	56	30 (22.5)		3.52%	-8[-15.21,-0.79]
Wong 2006	136	21.8 (15)	146	25.8 (15)		4.21%	-4[-7.5,-0.5]
Subtotal * **	**3116**		**2591**			**100%**	**-9.28[-12.2,-6.36]**
Heterogeneity: Tau²=49.45; Chi²=231.76, df=26(P<0.0001); I²=88.78%							
Test for overall effect: Z=6.23(P<0.0001)							
4.1.3 Unclear values subscale							



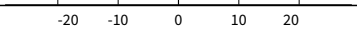


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Brazell 2014	53	15.3 (15.5)	51	17.2 (20.1)		4.29%	-1.9[-8.82,5.02]
Chabrera 2015	61	28.1 (11.2)	61	53.2 (14.5)		4.84%	-25.1[-29.7,-20.5]
De Achaval 2012	69	17.9 (15)	69	26.1 (19.1)		4.58%	-8.2[-13.92,-2.48]
Dolan 2002	41	19.8 (15.8)	37	29.3 (24)		3.73%	-9.5[-18.61,-0.39]
Fagerlin 2011	690	12.6 (50.3)	160	47.7 (128.4)		1.69%	-35.1[-55.35,-14.85]
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		4.38%	-17.2[-23.77,-10.63]
Jibaja-Weiss 2011	44	14.4 (27.1)	39	29.7 (41.6)		2.39%	-15.35[-30.66,-0.04]
Laupacis 2006	54	18.8 (16.5)	55	30 (17)		4.45%	-11.25[-17.54,-4.96]
Legare 2008a	43	19.8 (16.5)	41	23.3 (20)		4.05%	-3.5[-11.36,4.36]
Man-Son-Hing 1999	139	16.3 (12.5)	148	19 (14.8)		5.11%	-2.75[-5.91,0.41]
Mathers 2012	95	16.7 (13.9)	80	26.7 (18.2)		4.78%	-10[-14.87,-5.13]
Mathieu 2007	315	19.5 (16.3)	295	22.6 (80)		3.69%	-3.08[-12.38,6.22]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.18%	-2.5[-5.18,0.18]
Montgomery 2003	50	28.5 (12.5)	58	51.3 (25.7)		4.15%	-22.79[-30.26,-15.32]
Montgomery 2007	201	17.6 (13.2)	203	24.1 (15.8)		5.16%	-6.5[-9.34,-3.66]
Morgan 2000	86	30 (3.3)	94	30 (3.3)		5.36%	0[-0.95,0.95]
Murray 2001a	53	35.4 (12.3)	45	40.6 (16.4)		4.56%	-5.18[-11.02,0.66]
Murray 2001b	82	37.5 (15)	84	42.9 (16.6)		4.79%	-5.35[-10.16,-0.54]
Nagle 2008	167	19 (15.3)	171	15.5 (15.8)		5.09%	3.5[0.2,6.8]
Schwalm 2012	76	18 (15.3)	74	26 (24.2)		4.39%	-8[-14.5,-1.5]
Shourie 2013	44	11.3 (13)	69	37.5 (24.3)		4.3%	-26.25[-33.14,-19.36]
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.46%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		4.57%	-4[-9.77,1.77]
Subtotal * **	**2794**		**2274**			**100%**	**-8.81[-11.99,-5.63]**
Heterogeneity: Tau²=48.93; Chi²=273.77, df=22(P<0.0001); I²=91.96%							
Test for overall effect: Z=5.43(P<0.0001)							
4.1.4 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		2.9%	0[-8.89,8.89]
Brazell 2014	53	21.7 (21.4)	51	18.8 (23.3)		2.99%	2.9[-5.71,11.51]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		4.72%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.31%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.65%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.69%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.4%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.54%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.19%	-6.75[-11.89,-1.61]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		3.72%	-12.1[-18.54,-5.66]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.14%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.36%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.5%	-6.75[-17.09,3.59]
Man-Son-Hing 1999	139	21 (21)	148	19.8 (19)		4.37%	1.25[-3.39,5.89]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		4.88%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		4.71%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		2.99%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		4.72%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		4.66%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.29%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.36%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.45%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		3.81%	-1.6[-7.8,4.6]



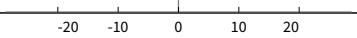
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		2.92%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		2.99%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.55%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.21%	-1.75[-6.82,3.32]
Subtotal ***	**3351**		**2849**			**100%**	**-4.04[-6.27,-1.81]**
Heterogeneity: Tau²=24.09; Chi²=107.12, df=27(P<0.0001); I²=74.79%							
Test for overall effect: Z=3.55(P=0)							
4.1.5 Unsupported subscale							
Brazell 2014	53	11.5 (14.4)	51	9.5 (13.9)		4.31%	2[-3.44,7.44]
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.5%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.41%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		3.63%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.39%	-25.2[-44.03,-6.37]
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		4.08%	-10.7[-16.89,-4.51]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.5%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.07%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.57%	0.75[-7.11,8.61]
Man-Son-Hing 1999	139	16.3 (13)	148	16.5 (14)		4.95%	-0.25[-3.37,2.87]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		4.62%	-4.4[-8.8,0]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		4.66%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.08%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		4.99%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.16%	-16.85[-22.79,-10.91]
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		4.87%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		3.76%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.12%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		4.58%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		4.94%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.4%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		3.75%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.49%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.16%	-4.75[-10.7,1.2]
Subtotal ***	**2874**		**2340**			**100%**	**-6.27[-8.86,-3.68]**
Heterogeneity: Tau²=32.67; Chi²=155.62, df=23(P<0.0001); I²=85.22%							
Test for overall effect: Z=4.75(P<0.0001)							
4.1.6 Ineffective choice subscale							
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		4.28%	0.62[-4.74,5.98]
Brazell 2014	53	17.8 (19.1)	51	13.8 (18.3)		3.74%	4[-3.19,11.19]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.48%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.02%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.48%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.18%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		4.65%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.16%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		3.71%	-5.75[-13.05,1.55]
Man-Son-Hing 1999	139	13.5 (13)	148	15.5 (14.8)		4.83%	-2[-5.21,1.21]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.54%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		4.94%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.27%	-9.13[-14.52,-3.74]

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Morgan 2000	86	20 (32)	94	22.5 (32)		3.12%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.38%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.48%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		4.88%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.53%	-4.6[-9.04,-0.16]
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.12%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.11%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		3.62%	-6.75[-14.33,0.83]
Whelan 2004	94	12.5 (12)	107	17 (13)		4.78%	-4.5[-7.96,-1.04]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		4.72%	-17.29[-21,-13.58]
Subtotal * **	**2861**		**2380**			**100%**	**-6.31[-8.93,-3.7]**
Heterogeneity: Tau²=34.12; Chi²=175.19, df=23(P<0.0001); I²=86.87%							
Test for overall effect: Z=4.73(P<0.0001)							

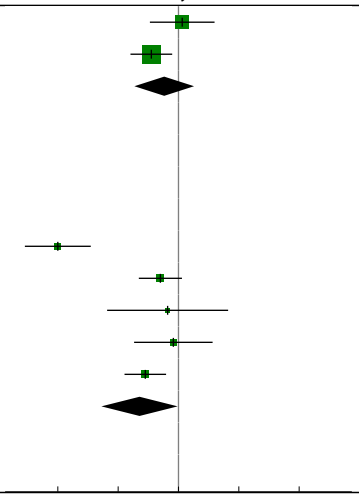


Analysis 4.2. Comparison 4 Decisional conflict, Outcome 2 Decisional conflict - in consultation.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.2.1 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		46.65%	0[-8.89,8.89]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		53.35%	-12.1[-18.54,-5.66]
Subtotal * **	**151**		**159**			**100%**	**-6.45[-18.29,5.38]**
Heterogeneity: Tau²=57.51; Chi²=4.67, df=1(P=0.03); I²=78.56%							
Test for overall effect: Z=1.07(P=0.28)							
4.2.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		25.73%	0.83[-4.74,6.4]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		25.16%	-17.8[-23.89,-11.71]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		25.65%	-6.7[-12.35,-1.05]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		23.46%	-1.63[-9.14,5.88]
Subtotal * **	**279**		**266**			**100%**	**-6.37[-14.58,1.85]**
Heterogeneity: Tau²=60.19; Chi²=21.5, df=3(P<0.0001); I²=86.04%							
Test for overall effect: Z=1.52(P=0.13)							
4.2.3 Unclear values subscale							
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		100%	-17.2[-23.77,-10.63]
Subtotal * **	**101**		**103**			**100%**	**-17.2[-23.77,-10.63]**
Heterogeneity: Not applicable							
Test for overall effect: Z=5.13(P<0.0001)							
4.2.4 Unsupported subscale							
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		43.78%	-10.7[-16.89,-4.51]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		56.22%	-4.4[-8.8,0]
Subtotal * **	**181**		**173**			**100%**	**-7.16[-13.28,-1.03]**
Heterogeneity: Tau²=12.33; Chi²=2.64, df=1(P=0.1); I²=62.15%							
Test for overall effect: Z=2.29(P=0.02)							
4.2.5 Ineffective choice subscale							

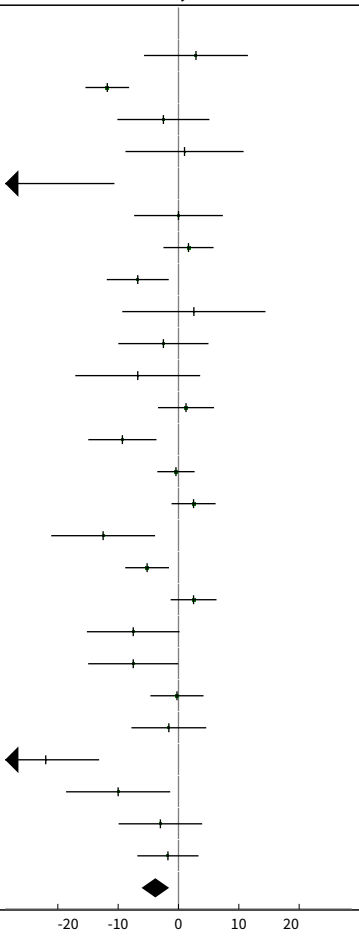


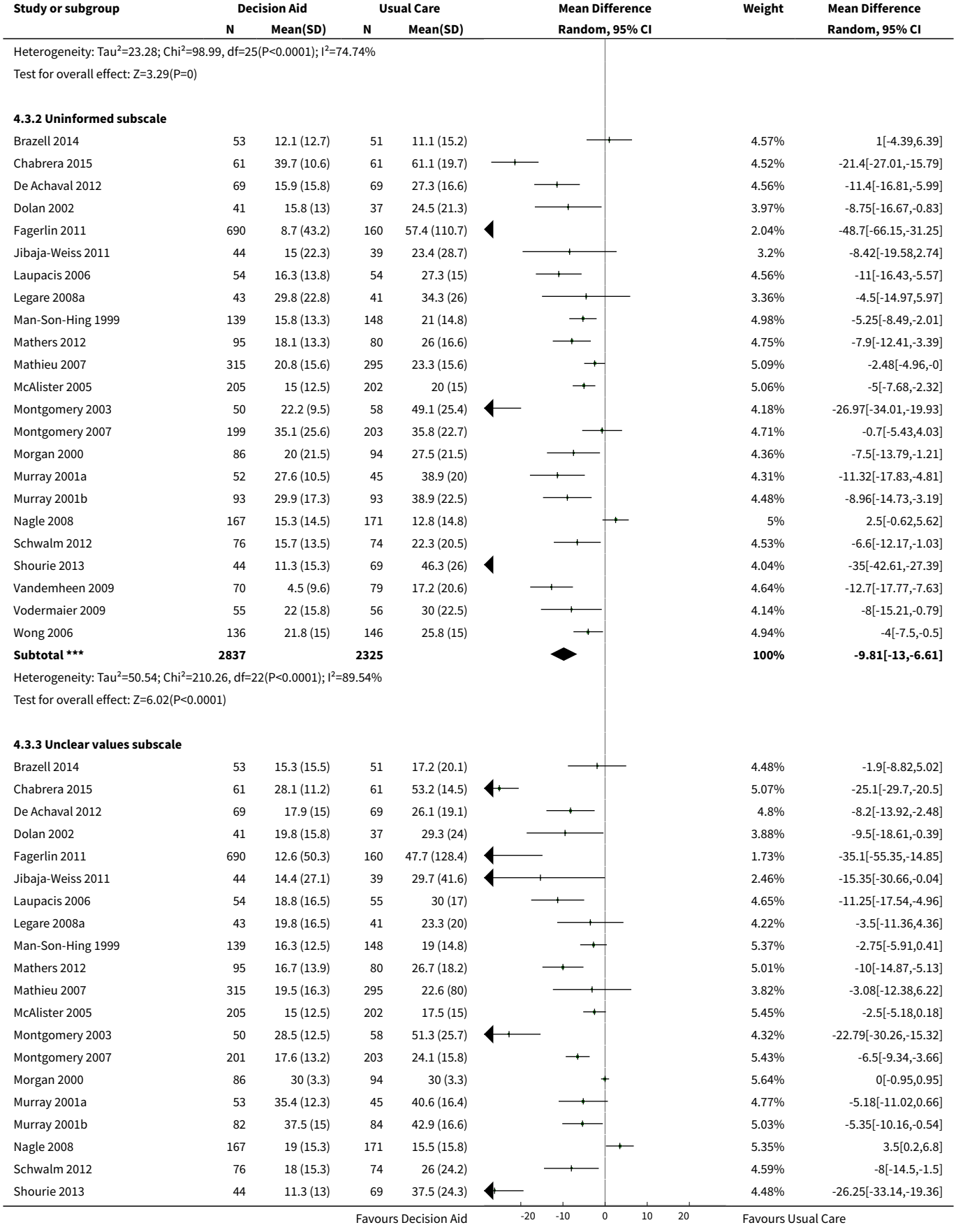
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		41.68%	0.62[-4.74,5.98]
Whelan 2004	94	12.5 (12)	107	17 (13)		58.32%	-4.5[-7.96,-1.04]
Subtotal ***	**144**		**163**			**100%**	**-2.37[-7.31,2.58]**
Heterogeneity: Tau²=7.81; Chi²=2.48, df=1(P=0.12); I²=59.62%							
Test for overall effect: Z=0.94(P=0.35)							
4.2.6 Total decisional conflict score							
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		20.53%	-20[-25.46,-14.54]
Mann D 2010	80	25.5 (11.1)	70	28.5 (11.1)		22.5%	-3[-6.57,0.57]
Montori 2011	49	14.4 (24.9)	46	16.2 (24.9)		15.06%	-1.8[-11.83,8.23]
Mullan 2009	48	14.1 (17.9)	37	15 (12.7)		19.29%	-0.85[-7.35,5.65]
Whelan 2004	94	10 (12)	107	15.5 (12.9)		22.62%	-5.5[-8.94,-2.06]
Subtotal ***	**372**		**363**			**100%**	**-6.46[-12.78,-0.14]**
Heterogeneity: Tau²=42.94; Chi²=31.11, df=4(P<0.0001); I²=87.14%							
Test for overall effect: Z=2(P=0.05)							



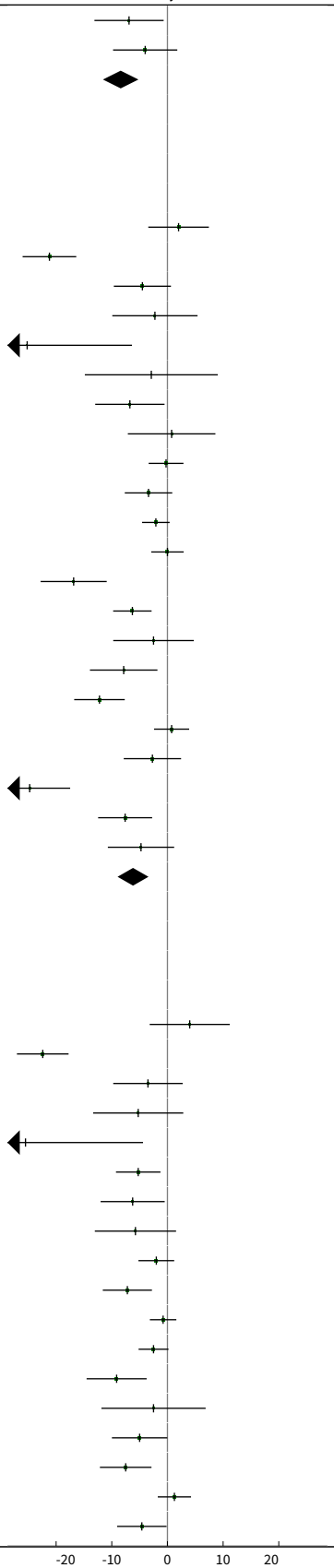
Analysis 4.3. Comparison 4 Decisional conflict, Outcome 3 Decisional conflict - in preparation for consultation.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.3.1 Uncertainty subscale							
Brazell 2014	53	21.7 (21.4)	51	18.8 (23.3)		3.19%	2.9[-5.71,11.51]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		5.08%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.53%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.81%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.72%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.63%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.88%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.5%	-6.75[-11.89,-1.61]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.26%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.59%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.65%	-6.75[-17.09,3.59]
Man-Son-Hing 1999	139	21 (21)	148	19.8 (19)		4.69%	1.25[-3.39,5.89]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4.29%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		5.26%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		5.07%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		3.19%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		5.08%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		5.01%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.51%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.59%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.79%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		4.07%	-1.6[-7.8,4.6]
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		3.11%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		3.18%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.79%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.52%	-1.75[-6.82,3.32]
Subtotal ***	**3200**		**2690**			**100%**	**-3.83[-6.12,-1.55]**

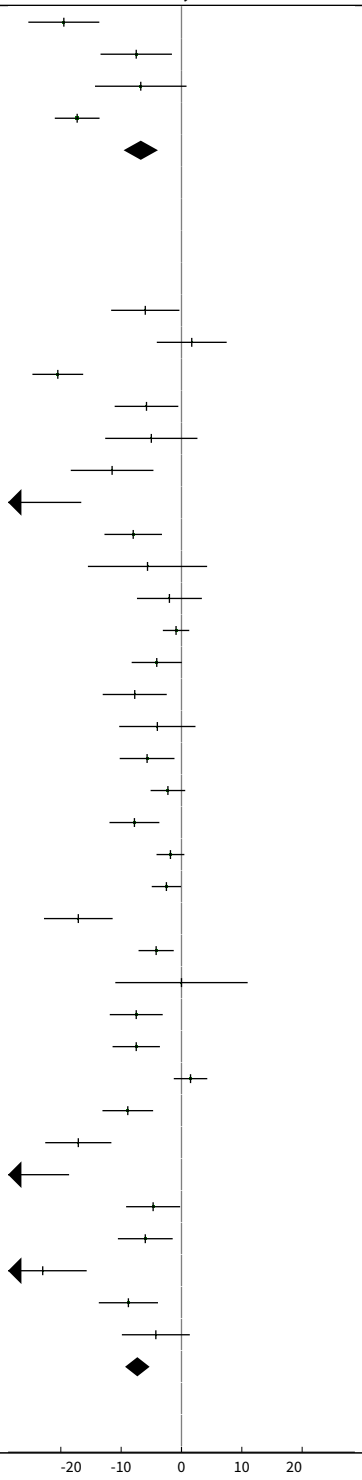




Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.67%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		4.78%	-4[-9.77,1.77]
Subtotal ***	**2693**		**2171**			**100%**	**-8.4[-11.59,-5.21]**
Heterogeneity: Tau²=46.63; Chi²=255.5, df=21(P<0.0001); I²=91.78%							
Test for overall effect: Z=5.17(P<0.0001)							
4.3.4 Unsupported subscale							
Brazell 2014	53	11.5 (14.4)	51	9.5 (13.9)		4.73%	2[-3.44,7.44]
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.92%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.82%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		4.01%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.58%	-25.2[-44.03,-6.37]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.79%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.47%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.95%	0.75[-7.11,8.61]
Man-Son-Hing 1999	139	16.3 (13)	148	16.5 (14)		5.38%	-0.25[-3.37,2.87]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		5.08%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.52%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		5.43%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.57%	-16.85[-22.79,-10.91]
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		5.3%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		4.15%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.53%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		5%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		5.37%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.82%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		4.13%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.91%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.56%	-4.75[-10.7,1.2]
Subtotal ***	**2693**		**2167**			**100%**	**-6.18[-8.96,-3.4]**
Heterogeneity: Tau²=34.85; Chi²=151.76, df=21(P<0.0001); I²=86.16%							
Test for overall effect: Z=4.36(P<0.0001)							
4.3.5 Ineffective choice subscale							
Brazell 2014	53	17.8 (19.1)	51	13.8 (18.3)		4.15%	4[-3.19,11.19]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.91%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.44%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.87%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.37%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		5.08%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.58%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		4.12%	-5.75[-13.05,1.55]
Man-Son-Hing 1999	139	13.5 (13)	148	15.5 (14.8)		5.26%	-2[-5.21,1.21]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.97%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5.43%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.37%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.69%	-9.13[-14.52,-3.74]
Morgan 2000	86	20 (32)	94	22.5 (32)		3.5%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.81%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.91%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		5.31%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.96%	-4.6[-9.04,-0.16]

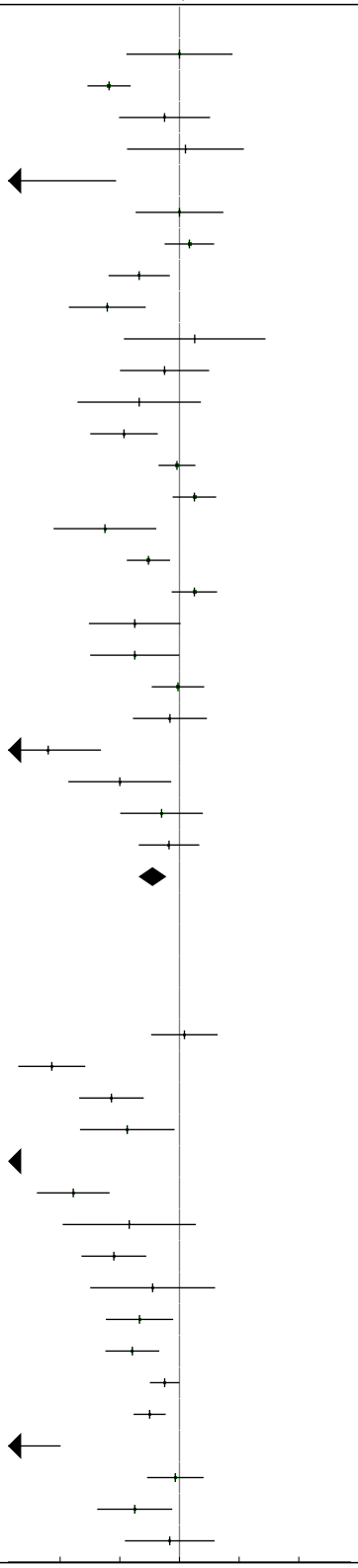


Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.55%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.54%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		4.03%	-6.75[-14.33,0.83]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		5.15%	-17.29[-21,-13.58]
Subtotal * **	**2717**		**2217**			**100%**	**-6.75[-9.59,-3.9]**
Heterogeneity: Tau²=37.39; Chi²=170.48, df=21(P<0.0001); I²=87.68%							
Test for overall effect: Z=4.65(P<0.0001)							
4.3.6 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.98%	-6[-11.66,-0.34]
Brazell 2014	53	15.8 (13.9)	51	14.1 (16.1)		2.95%	1.7[-4.09,7.49]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		3.33%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		3.08%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.51%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.69%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		1.04%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		3.2%	-8[-12.76,-3.24]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		2.03%	-5.63[-15.51,4.25]
Knops 2014	73	22 (17)	81	24 (17)		3.05%	-2[-7.38,3.38]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.71%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		3.34%	-4.1[-8.26,0.06]
Laupacis 2006	53	17.5 (13.8)	54	25.3 (14.3)		3.07%	-7.75[-13.06,-2.44]
Legare 2008a	43	23 (14.3)	41	27 (15.3)		2.82%	-4[-10.32,2.32]
Lepore 2012	215	34.2 (24)	216	39.9 (24)		3.25%	-5.7[-10.24,-1.16]
Man-Son-Hing 1999	139	16.3 (11.3)	148	18.5 (13.5)		3.6%	-2.25[-5.12,0.62]
Mathers 2012	95	17.4 (12.6)	80	25.2 (14.9)		3.34%	-7.8[-11.93,-3.67]
Mathieu 2007	315	20.1 (14.5)	295	21.9 (14.5)		3.69%	-1.83[-4.13,0.47]
McAlister 2005	205	15 (12.5)	202	17.5 (12.5)		3.67%	-2.5[-4.93,-0.07]
Montgomery 2003	50	27.1 (10)	58	44.2 (19.3)		2.98%	-17.1[-22.79,-11.41]
Montgomery 2007	198	23.6 (15.1)	201	27.8 (14.6)		3.59%	-4.2[-7.12,-1.28]
Morgan 2000	86	27.5 (37.5)	94	27.5 (37.5)		1.82%	0[-10.97,10.97]
Murray 2001a	57	32.5 (10)	48	40 (12.5)		3.29%	-7.5[-11.89,-3.11]
Murray 2001b	94	37.5 (12.5)	96	45 (15)		3.39%	-7.5[-11.42,-3.58]
Nagle 2008	167	17.8 (12.3)	171	16.3 (13.8)		3.62%	1.5[-1.27,4.27]
Nassar 2007	98	4.6 (9)	98	13.5 (19.2)		3.33%	-8.9[-13.1,-4.7]
Protheroe 2007	69	23.4 (14.3)	69	40.5 (18.3)		3.03%	-17.1[-22.58,-11.62]
Sawka 2012	37	25.2 (13.4)	37	52.1 (21.9)		2.36%	-26.9[-35.17,-18.63]
Schwalm 2012	76	14.8 (10.5)	74	19.5 (16.7)		3.26%	-4.7[-9.18,-0.22]
Shorten 2005	99	23.5 (12.5)	88	29.5 (18.3)		3.25%	-6[-10.54,-1.46]
Shourie 2013	43	14.3 (17.3)	67	37.3 (21.5)		2.59%	-23[-30.29,-15.71]
Vandemheen 2009	70	11.6 (13.6)	79	20.4 (16.9)		3.16%	-8.8[-13.7,-3.9]
Vodermaier 2009	55	20.5 (14.8)	56	24.8 (15.5)		2.99%	-4.25[-9.88,1.38]
Subtotal * **	**4263**		**3787**			**100%**	**-7.32[-9.35,-5.28]**
Heterogeneity: Tau²=27.77; Chi²=223.37, df=32(P<0.0001); I²=85.67%							
Test for overall effect: Z=7.05(P<0.0001)							

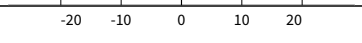


Analysis 4.4. Comparison 4 Decisional conflict, Outcome 4 Decisional conflict - without studies having high risk of bias.

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
4.4.1 Uncertainty subscale							
Bekker 2004	50	45 (20.8)	56	45 (25.8)		3.15%	0[-8.89,8.89]
Chabrera 2015	61	32 (11.4)	61	43.8 (8.8)		5.07%	-11.8[-15.42,-8.18]
De Achaval 2012	69	33.4 (23.3)	69	35.9 (22.4)		3.58%	-2.5[-10.12,5.12]
Dolan 2002	41	27 (19.3)	37	26 (24.3)		2.87%	1[-8.79,10.79]
Fagerlin 2011	690	37.4 (62.3)	160	73.2 (159.7)		0.75%	-35.8[-60.98,-10.62]
Gattellari 2003	106	42.5 (20)	108	42.5 (33.3)		3.68%	0[-7.35,7.35]
Gattellari 2005	131	30.8 (19.3)	136	29.2 (15)		4.88%	1.66[-2.49,5.81]
Hanson 2011	118	22 (20)	115	28.8 (20)		4.52%	-6.75[-11.89,-1.61]
Hess 2012	101	24.7 (23.3)	103	36.8 (23.6)		4.02%	-12.1[-18.54,-5.66]
Jibaja-Weiss 2011	44	15.4 (32.3)	39	12.8 (22.5)		2.33%	2.55[-9.32,14.42]
Laupacis 2006	54	20.5 (18.8)	55	23 (21)		3.63%	-2.5[-9.97,4.97]
Legare 2008a	43	26.5 (23)	41	33.3 (25.3)		2.71%	-6.75[-17.09,3.59]
Mathers 2012	95	20.1 (16.6)	80	29.4 (20.8)		4.32%	-9.3[-14.95,-3.65]
Mathieu 2007	315	22.2 (19.5)	295	22.7 (19.5)		5.24%	-0.42[-3.51,2.67]
McAlister 2005	205	20 (20)	202	17.5 (17.5)		5.06%	2.5[-1.15,6.15]
Montgomery 2003	50	35.5 (20.5)	58	48 (25.1)		3.24%	-12.49[-21.1,-3.88]
Montgomery 2007	201	22.1 (18.4)	203	27.3 (18.8)		5.07%	-5.2[-8.83,-1.57]
Morgan 2000	86	35 (13)	94	32.5 (13)		5.01%	2.5[-1.3,6.3]
Murray 2001a	57	35 (20)	48	42.5 (20)		3.56%	-7.5[-15.18,0.18]
Murray 2001b	94	52.5 (25)	96	60 (27.5)		3.64%	-7.5[-14.97,-0.03]
Nagle 2008	167	24 (19.8)	171	24.3 (21.5)		4.79%	-0.25[-4.65,4.15]
Schwalm 2012	76	18 (18.8)	74	19.6 (19.9)		4.11%	-1.6[-7.8,4.6]
Shourie 2013	44	16.3 (18.3)	68	38.3 (29.5)		3.16%	-22[-30.85,-13.15]
Vandemheen 2009	70	26.4 (25.9)	79	36.4 (27.8)		3.24%	-10[-18.63,-1.37]
Vodermaier 2009	55	27 (24.3)	56	30 (10)		3.84%	-3[-9.92,3.92]
Wong 2006	136	38.3 (22.5)	146	40 (20.8)		4.54%	-1.75[-6.82,3.32]
Subtotal * **	**3159**		**2650**			**100%**	**-4.53[-6.87,-2.18]**
Heterogeneity: Tau²=24.77; Chi²=101.56, df=25(P<0.0001); I²=75.38%							
Test for overall effect: Z=3.79(P=0)							
4.4.2 Uninformed subscale							
Bekker 2004	50	32.5 (15)	56	31.7 (14.2)		4.19%	0.83[-4.74,6.4]
Chabrera 2015	61	39.7 (10.6)	61	61.1 (19.7)		4.18%	-21.4[-27.01,-15.79]
De Achaval 2012	69	15.9 (15.8)	69	27.3 (16.6)		4.22%	-11.4[-16.81,-5.99]
Dolan 2002	41	15.8 (13)	37	24.5 (21.3)		3.7%	-8.75[-16.67,-0.83]
Fagerlin 2011	690	8.7 (43.2)	160	57.4 (110.7)		1.96%	-48.7[-66.15,-31.25]
Hess 2012	101	22.8 (22.8)	103	40.6 (21.5)		4.08%	-17.8[-23.89,-11.71]
Jibaja-Weiss 2011	44	15 (22.3)	39	23.4 (28.7)		3.01%	-8.42[-19.58,2.74]
Laupacis 2006	54	16.3 (13.8)	54	27.3 (15)		4.21%	-11[-16.43,-5.57]
Legare 2008a	43	29.8 (22.8)	41	34.3 (26)		3.16%	-4.5[-14.97,5.97]
Mann D 2010	80	27.1 (17.6)	70	33.8 (17.6)		4.17%	-6.7[-12.35,-1.05]
Mathers 2012	95	18.1 (13.3)	80	26 (16.6)		4.38%	-7.9[-12.41,-3.39]
Mathieu 2007	315	20.8 (15.6)	295	23.3 (15.6)		4.67%	-2.48[-4.96,-0]
McAlister 2005	205	15 (12.5)	202	20 (15)		4.65%	-5[-7.68,-2.32]
Montgomery 2003	50	22.2 (9.5)	58	49.1 (25.4)		3.89%	-26.97[-34.01,-19.93]
Montgomery 2007	199	35.1 (25.6)	203	35.8 (22.7)		4.34%	-0.7[-5.43,4.03]
Morgan 2000	86	20 (21.5)	94	27.5 (21.5)		4.04%	-7.5[-13.79,-1.21]
Mullan 2009	48	13.7 (19.8)	37	15.3 (15.5)		3.79%	-1.63[-9.14,5.88]



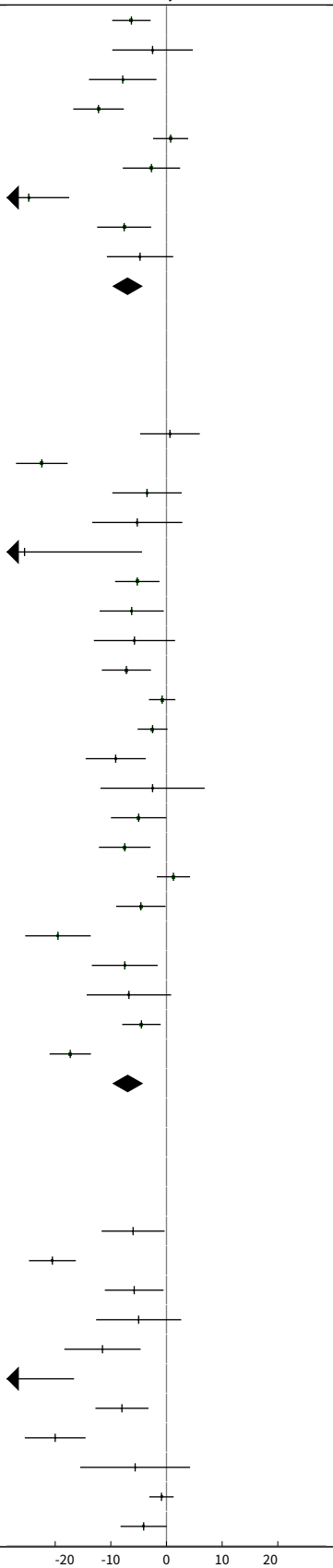
Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Murray 2001a	52	27.6 (10.5)	45	38.9 (20)		4%	-11.32[-17.83,-4.81]
Murray 2001b	93	29.9 (17.3)	93	38.9 (22.5)		4.15%	-8.96[-14.73,-3.19]
Nagle 2008	167	15.3 (14.5)	171	12.8 (14.8)		4.59%	2.5[-0.62,5.62]
Schwalm 2012	76	15.7 (13.5)	74	22.3 (20.5)		4.19%	-6.6[-12.17,-1.03]
Shourie 2013	44	11.3 (15.3)	69	46.3 (26)		3.77%	-35[-42.61,-27.39]
Vandemheen 2009	70	4.5 (9.6)	79	17.2 (20.6)		4.28%	-12.7[-17.77,-7.63]
Vodermaier 2009	55	22 (15.8)	56	30 (22.5)		3.85%	-8[-15.21,-0.79]
Wong 2006	136	21.8 (15)	146	25.8 (15)		4.54%	-4[-7.5,-0.5]
Subtotal * **	**2924**		**2392**			**100%**	**-9.96[-13.13,-6.78]**
Heterogeneity: Tau²=54.55; Chi²=223.82, df=24(P<0.0001); I²=89.28%							
Test for overall effect: Z=6.15(P<0.0001)							
4.4.3 Unclear values subscale							
Chabrera 2015	61	28.1 (11.2)	61	53.2 (14.5)		5.29%	-25.1[-29.7,-20.5]
De Achaval 2012	69	17.9 (15)	69	26.1 (19.1)		5.05%	-8.2[-13.92,-2.48]
Dolan 2002	41	19.8 (15.8)	37	29.3 (24)		4.19%	-9.5[-18.61,-0.39]
Fagerlin 2011	690	12.6 (50.3)	160	47.7 (128.4)		2%	-35.1[-55.35,-14.85]
Hess 2012	101	24.2 (25.6)	103	41.4 (22.1)		4.84%	-17.2[-23.77,-10.63]
Jibaja-Weiss 2011	44	14.4 (27.1)	39	29.7 (41.6)		2.78%	-15.35[-30.66,-0.04]
Laupacis 2006	54	18.8 (16.5)	55	30 (17)		4.91%	-11.25[-17.54,-4.96]
Legare 2008a	43	19.8 (16.5)	41	23.3 (20)		4.52%	-3.5[-11.36,4.36]
Mathers 2012	95	16.7 (13.9)	80	26.7 (18.2)		5.24%	-10[-14.87,-5.13]
Mathieu 2007	315	19.5 (16.3)	295	22.6 (80)		4.14%	-3.08[-12.38,6.22]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.63%	-2.5[-5.18,0.18]
Montgomery 2003	50	28.5 (12.5)	58	51.3 (25.7)		4.62%	-22.79[-30.26,-15.32]
Montgomery 2007	201	17.6 (13.2)	203	24.1 (15.8)		5.61%	-6.5[-9.34,-3.66]
Morgan 2000	86	30 (3.3)	94	30 (3.3)		5.79%	0[-0.95,0.95]
Murray 2001a	53	35.4 (12.3)	45	40.6 (16.4)		5.02%	-5.18[-11.02,0.66]
Murray 2001b	82	37.5 (15)	84	42.9 (16.6)		5.25%	-5.35[-10.16,-0.54]
Nagle 2008	167	19 (15.3)	171	15.5 (15.8)		5.53%	3.5[0.2,6.8]
Schwalm 2012	76	18 (15.3)	74	26 (24.2)		4.86%	-8[-14.5,-1.5]
Shourie 2013	44	11.3 (13)	69	37.5 (24.3)		4.76%	-26.25[-33.14,-19.36]
Vandemheen 2009	70	9.9 (17.7)	79	16.8 (21)		4.93%	-6.9[-13.12,-0.68]
Vodermaier 2009	55	20.8 (15.5)	56	24.8 (15.5)		5.04%	-4[-9.77,1.77]
Subtotal * **	**2602**		**2075**			**100%**	**-9.55[-13.08,-6.02]**
Heterogeneity: Tau²=55.88; Chi²=273.66, df=20(P<0.0001); I²=92.69%							
Test for overall effect: Z=5.3(P<0.0001)							
4.4.4 Unsupported subscale							
Chabrera 2015	61	30.5 (11.6)	61	51.7 (15.3)		4.95%	-21.2[-26.02,-16.38]
De Achaval 2012	69	20.5 (15)	69	25 (15.8)		4.85%	-4.5[-9.63,0.63]
Dolan 2002	41	21 (13.5)	37	23.3 (20)		4.02%	-2.25[-9.91,5.41]
Fagerlin 2011	690	18.1 (46.9)	160	43.3 (119.4)		1.57%	-25.2[-44.03,-6.37]
Hess 2012	101	18.5 (22.6)	103	29.2 (22.6)		4.51%	-10.7[-16.89,-4.51]
Jibaja-Weiss 2011	44	19.2 (26.3)	39	22.1 (28.9)		2.79%	-2.9[-14.84,9.04]
Laupacis 2006	53	17.3 (15.8)	55	24 (17.3)		4.5%	-6.75[-12.98,-0.52]
Legare 2008a	43	24.3 (19.5)	41	23.5 (17.3)		3.95%	0.75[-7.11,8.61]
Mann D 2010	80	25.2 (13.7)	70	29.6 (13.7)		5.08%	-4.4[-8.8,0]
Mathers 2012	95	17.4 (13.1)	80	20.8 (15.3)		5.12%	-3.4[-7.66,0.86]
Mathieu 2007	315	20.9 (15.6)	295	23 (15.6)		5.57%	-2.08[-4.55,0.39]
McAlister 2005	205	15 (15)	202	15 (15)		5.48%	0[-2.91,2.91]
Montgomery 2003	50	23.7 (11)	58	40.5 (19.8)		4.59%	-16.85[-22.79,-10.91]

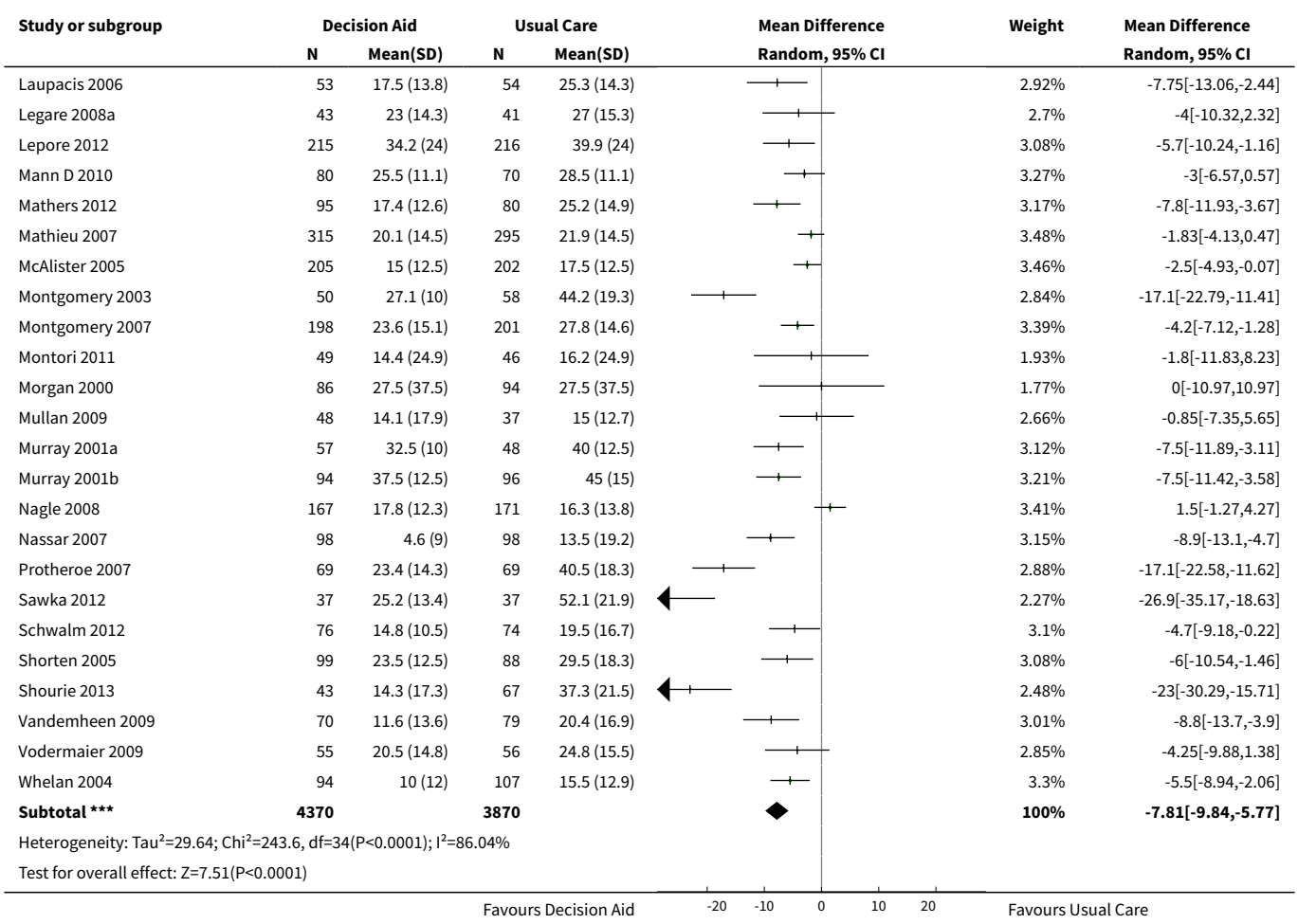


Favours Decision Aid

Favours Usual Care

Study or subgroup	Decision Aid N	Decision Aid Mean(SD)	Usual Care N	Usual Care Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Montgomery 2007	200	22.2 (16.5)	201	28.5 (18.7)		5.34%	-6.3[-9.75,-2.85]
Morgan 2000	86	30 (24.8)	94	32.5 (24.8)		4.16%	-2.5[-9.74,4.74]
Murray 2001a	53	32.7 (12.8)	45	40.6 (17.1)		4.55%	-7.86[-13.92,-1.8]
Murray 2001b	85	36.5 (14.4)	82	48.7 (15.5)		5.04%	-12.21[-16.75,-7.67]
Nagle 2008	167	15.3 (13.8)	171	14.5 (15.8)		5.42%	0.75[-2.4,3.9]
Schwalm 2012	76	12.2 (15.2)	74	14.9 (16.9)		4.85%	-2.7[-7.85,2.45]
Shourie 2013	43	13.3 (17.3)	69	38 (21.8)		4.15%	-24.75[-32.02,-17.48]
Vandemheen 2009	70	6.9 (12.3)	79	14.5 (17.7)		4.94%	-7.6[-12.45,-2.75]
Vodermaier 2009	55	16.3 (16.3)	56	21 (15.8)		4.58%	-4.75[-10.7,1.2]
Subtotal * **	**2682**		**2141**			**100%**	**-7[-9.76,-4.24]**
Heterogeneity: Tau²=33.9; Chi²=141.02, df=21(P<0.0001); I²=85.11%							
Test for overall effect: Z=4.98(P<0.0001)							
4.4.5 Ineffective choice subscale							
Bekker 2004	50	22.5 (13.8)	56	21.9 (14.4)		4.68%	0.62[-4.74,5.98]
Chabrera 2015	61	27.1 (11.7)	61	49.5 (14.3)		4.89%	-22.4[-27.04,-17.76]
De Achaval 2012	69	27.7 (18.3)	69	31.2 (19.1)		4.41%	-3.5[-9.74,2.74]
Dolan 2002	41	20.5 (14.5)	37	25.8 (21)		3.83%	-5.25[-13.34,2.84]
Fagerlin 2011	690	30 (52.3)	160	55.5 (133.9)		1.33%	-25.5[-46.61,-4.39]
Hanson 2011	118	14 (15.6)	115	19.3 (15.6)		5.07%	-5.25[-9.24,-1.26]
Laupacis 2006	53	15 (14.5)	55	21.3 (16)		4.56%	-6.25[-12,-0.5]
Legare 2008a	43	16.5 (14.8)	41	22.3 (19)		4.08%	-5.75[-13.05,1.55]
Mathers 2012	95	16.1 (14.4)	80	23.3 (15.2)		4.95%	-7.2[-11.61,-2.79]
Mathieu 2007	315	18.4 (15)	295	19.2 (15)		5.43%	-0.78[-3.16,1.6]
McAlister 2005	205	15 (12.5)	202	17.5 (15)		5.37%	-2.5[-5.18,0.18]
Montgomery 2003	50	26 (11.1)	58	35.1 (17.2)		4.67%	-9.13[-14.52,-3.74]
Morgan 2000	86	20 (32)	94	22.5 (32)		3.45%	-2.5[-11.86,6.86]
Murray 2001a	57	25 (10)	48	30 (15)		4.79%	-5[-9.97,-0.03]
Murray 2001b	94	30 (15)	96	37.5 (17.5)		4.89%	-7.5[-12.13,-2.87]
Nagle 2008	167	16.3 (13.8)	171	15 (14.3)		5.31%	1.25[-1.74,4.24]
Schwalm 2012	76	11.3 (11.4)	74	15.9 (15.9)		4.95%	-4.6[-9.04,-0.16]
Shourie 2013	44	11 (12.3)	68	30.5 (19.5)		4.52%	-19.5[-25.38,-13.62]
Vandemheen 2009	70	10.4 (16.4)	79	17.9 (20.4)		4.51%	-7.5[-13.42,-1.58]
Vodermaier 2009	55	28.3 (20.8)	56	35 (20)		3.99%	-6.75[-14.33,0.83]
Whelan 2004	94	12.5 (12)	107	17 (13)		5.2%	-4.5[-7.96,-1.04]
Wong 2006	136	19.4 (13.1)	159	36.7 (19.2)		5.14%	-17.29[-21,-13.58]
Subtotal * **	**2669**		**2181**			**100%**	**-6.97[-9.76,-4.18]**
Heterogeneity: Tau²=35.8; Chi²=164.67, df=21(P<0.0001); I²=87.25%							
Test for overall effect: Z=4.9(P<0.0001)							
4.4.6 Total decisional conflict score							
Allen 2010	291	14 (34.3)	334	20 (37.8)		2.84%	-6[-11.66,-0.34]
Chabrera 2015	61	31.2 (10.2)	61	51.7 (13.3)		3.15%	-20.5[-24.71,-16.29]
De Achaval 2012	69	23.4 (15)	69	29.2 (16.6)		2.93%	-5.8[-11.07,-0.53]
Dolan 2002	41	20.8 (13)	37	25.8 (20.3)		2.41%	-5[-12.64,2.64]
Evans 2010	89	38.1 (24.2)	103	49.6 (24.2)		2.58%	-11.5[-18.35,-4.65]
Fagerlin 2011	690	22 (42.2)	160	55.7 (108.4)		1.02%	-33.7[-50.79,-16.61]
Hanson 2011	118	16.3 (18.6)	115	24.3 (18.6)		3.04%	-8[-12.76,-3.24]
Hess 2012	101	23.3 (20.8)	103	43.3 (19)		2.89%	-20[-25.46,-14.54]
Jibaja-Weiss 2011	44	16.5 (19.9)	39	22.2 (25.3)		1.96%	-5.63[-15.51,4.25]
Kuppermann 2014	357	12.9 (14.1)	353	13.8 (15.6)		3.49%	-0.9[-3.09,1.29]
Lam 2013	113	15.8 (15.5)	112	19.9 (16.3)		3.16%	-4.1[-8.26,0.06]





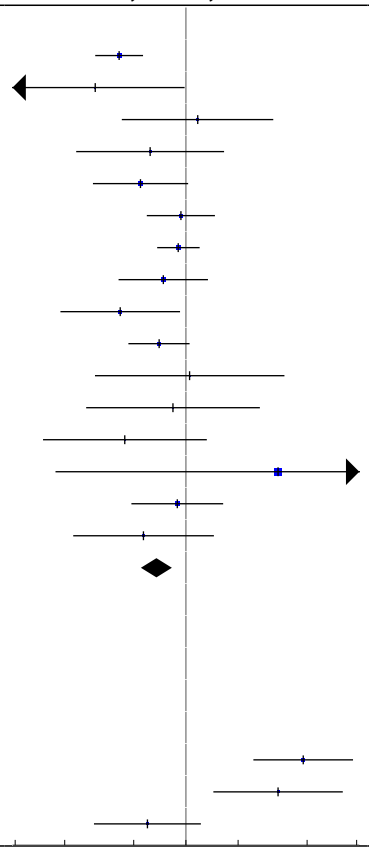
Comparison 5. Participation in decision making

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Participation in decision making - all studies	16		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Clinician-controlled decision making	16	3180	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.55, 0.83]
1.2 Patient-controlled decision making	15	3009	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.05, 1.55]
1.3 Shared decision making	15	2973	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.83, 1.10]
2 Participation in decision making - in consultation	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 Clinician-controlled decision making - in consultation	3	650	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.70, 1.12]

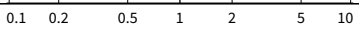
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.2 Patient-controlled decision making - in consultation	2	479	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.80, 1.27]
2.3 Shared decision making - in consultation	2	479	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.84, 1.55]
3 Participation in decision making - in preparation for consultation	13		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Clinician-controlled decision making	13	2530	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.48, 0.75]
3.2 Patient-controlled decision making	13	2530	Risk Ratio (M-H, Random, 95% CI)	1.37 [1.08, 1.73]
3.3 Shared decision making	13	2494	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.80, 1.09]

Analysis 5.1. Comparison 5 Participation in decision making, Outcome 1 Participation in decision making - all studies.

Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
5.1.1 Clinician-controlled decision making					
Auvinen 2004	31/103	73/100		13.89%	0.41[0.3,0.57]
Davison 1997	3/30	10/30		2.62%	0.3[0.09,0.98]
Dolan 2002	7/43	6/43		3.48%	1.17[0.43,3.19]
Kasper 2008	6/134	10/139		3.6%	0.62[0.23,1.66]
Krist 2007	20/196	14/75		7.05%	0.55[0.29,1.03]
Legare 2011	26/81	24/70		10.33%	0.94[0.59,1.47]
Legare 2012	58/163	65/165		14.99%	0.9[0.68,1.2]
Man-Son-Hing 1999	16/137	23/146		7.59%	0.74[0.41,1.34]
Mathers 2012	8/92	16/77		5.08%	0.42[0.19,0.92]
Morgan 2000	25/86	39/94		11.42%	0.7[0.47,1.05]
Murray 2001a	5/57	4/48		2.37%	1.05[0.3,3.7]
Murray 2001b	5/94	6/95		2.76%	0.84[0.27,2.67]
Sawka 2012	4/37	9/37		3.05%	0.44[0.15,1.32]
Smith 2010	3/357	0/173		0.47%	3.4[0.18,65.5]
Vodermaier 2009	14/53	16/54		7.36%	0.89[0.48,1.64]
Whelan 2003	6/80	12/91		3.93%	0.57[0.22,1.45]
Subtotal (95% CI)	**1743**	**1437**		**100%**	**0.68[0.55,0.83]**
Total events: 237 (Decision Aid), 327 (Usual Care)					
Heterogeneity: Tau^2=0.05; Chi^2=23.59, df=15(P=0.07); I^2=36.42%					
Test for overall effect: Z=3.74(P=0)					
5.1.2 Patient-controlled decision making					
Auvinen 2004	44/103	9/100		4.83%	4.75[2.45,9.2]
Davison 1997	17/30	5/30		3.5%	3.4[1.44,8.03]
Dolan 2002	9/43	15/43		4.46%	0.6[0.29,1.22]

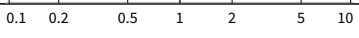


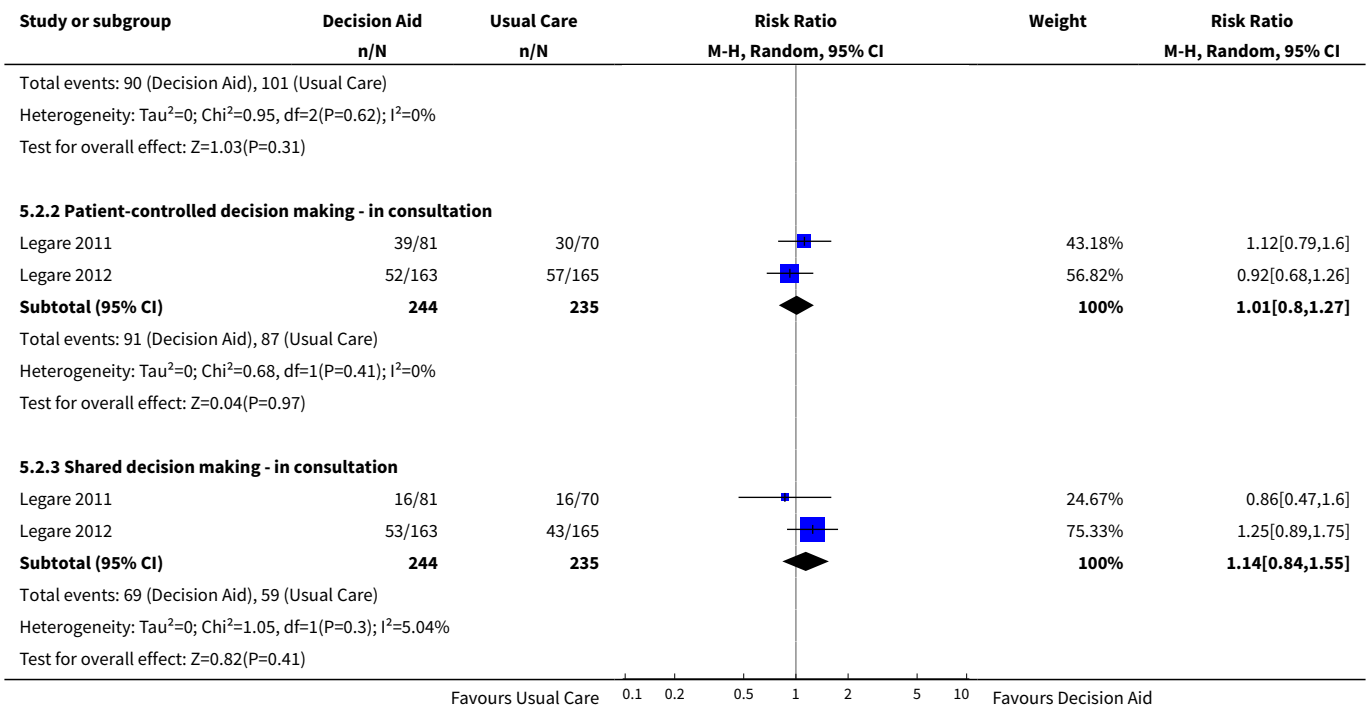
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Kasper 2008	109/134	103/139		10.44%	1.1[0.97,1.25]
Krist 2007	106/196	35/75		8.99%	1.16[0.88,1.52]
Legare 2011	39/81	30/70		8.05%	1.12[0.79,1.6]
Legare 2012	52/163	57/165		8.59%	0.92[0.68,1.26]
Man-Son-Hing 1999	85/137	80/146		9.83%	1.13[0.93,1.38]
Mathers 2012	59/92	33/77		8.68%	1.5[1.11,2.02]
Morgan 2000	17/86	14/94		4.98%	1.33[0.7,2.53]
Murray 2001a	18/57	2/48		1.63%	7.58[1.85,31.03]
Murray 2001b	49/94	53/95		9.11%	0.93[0.72,1.22]
Sawka 2012	17/37	9/37		4.79%	1.89[0.97,3.68]
Smith 2010	335/357	166/173		10.88%	0.98[0.94,1.02]
Vodermaier 2009	4/53	2/54		1.23%	2.04[0.39,10.66]
Subtotal (95% CI)	**1663**	**1346**		**100%**	**1.28[1.05,1.55]**
Total events: 960 (Decision Aid), 613 (Usual Care)					
Heterogeneity: Tau^2=0.09; Chi^2=109.06, df=14(P<0.0001); I^2=87.16%					
Test for overall effect: Z=2.47(P=0.01)					
5.1.3 Shared decision making					
Auvinen 2004	25/103	17/100		4.64%	1.43[0.82,2.48]
Davison 1997	10/30	15/30		3.91%	0.67[0.36,1.24]
Dolan 2002	27/43	22/43		7.6%	1.23[0.85,1.78]
Kasper 2008	19/134	26/103		4.87%	0.56[0.33,0.96]
Krist 2007	71/196	27/75		7.98%	1.01[0.71,1.43]
Legare 2011	16/81	16/70		3.96%	0.86[0.47,1.6]
Legare 2012	53/163	43/165		8.34%	1.25[0.89,1.75]
Man-Son-Hing 1999	36/137	43/146		7.5%	0.89[0.61,1.3]
Mathers 2012	25/92	28/77		6.16%	0.75[0.48,1.17]
Morgan 2000	42/86	38/94		8.63%	1.21[0.87,1.68]
Murray 2001a	34/57	42/48		11.03%	0.68[0.54,0.87]
Murray 2001b	40/94	36/95		8.12%	1.12[0.79,1.59]
Sawka 2012	15/37	19/37		5.31%	0.79[0.48,1.3]
Smith 2010	17/357	5/173		1.83%	1.65[0.62,4.39]
Vodermaier 2009	35/53	36/54		10.14%	0.99[0.76,1.3]
Subtotal (95% CI)	**1663**	**1310**		**100%**	**0.95[0.83,1.1]**
Total events: 465 (Decision Aid), 413 (Usual Care)					
Heterogeneity: Tau^2=0.03; Chi^2=25.31, df=14(P=0.03); I^2=44.69%					
Test for overall effect: Z=0.64(P=0.52)					



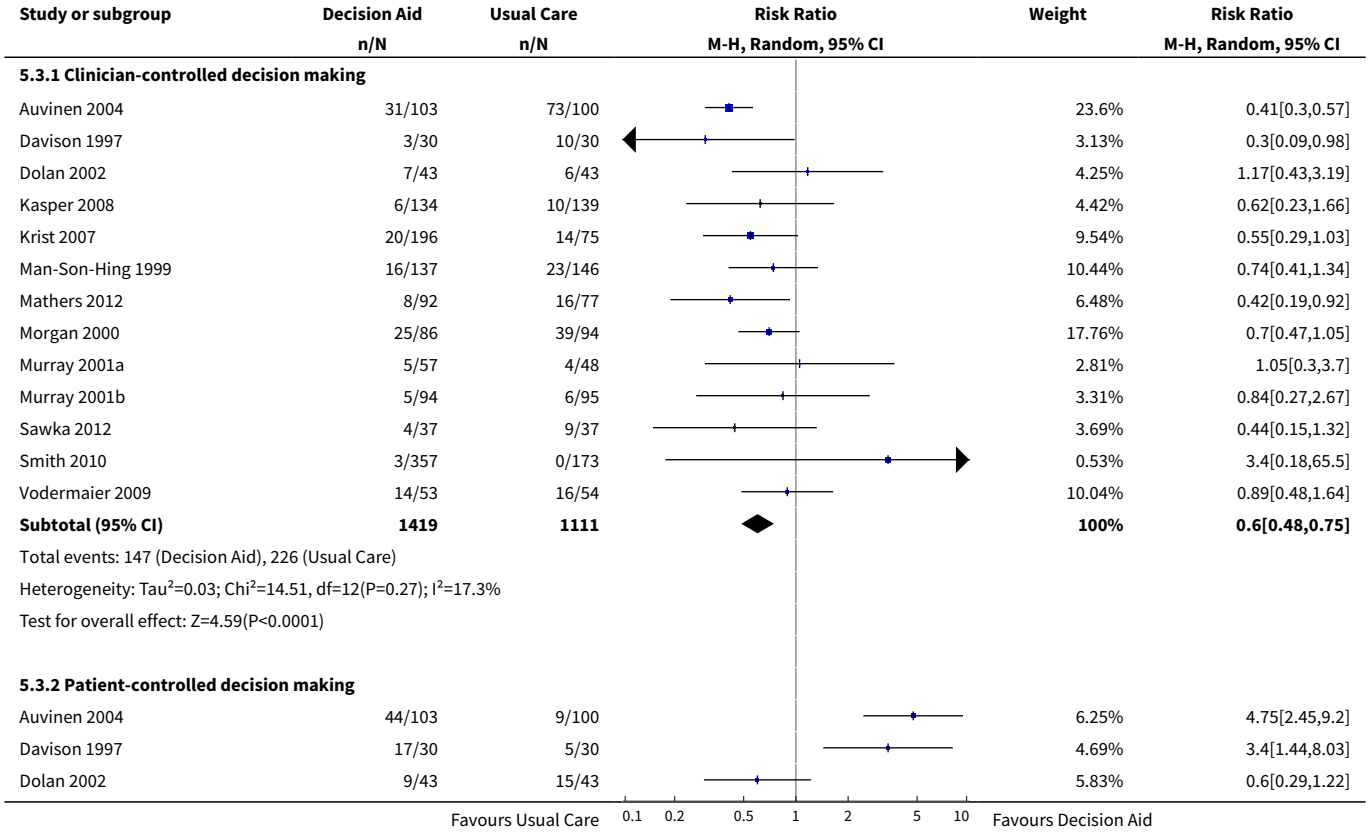
Analysis 5.2. Comparison 5 Participation in decision making, Outcome 2 Participation in decision making - in consultation.

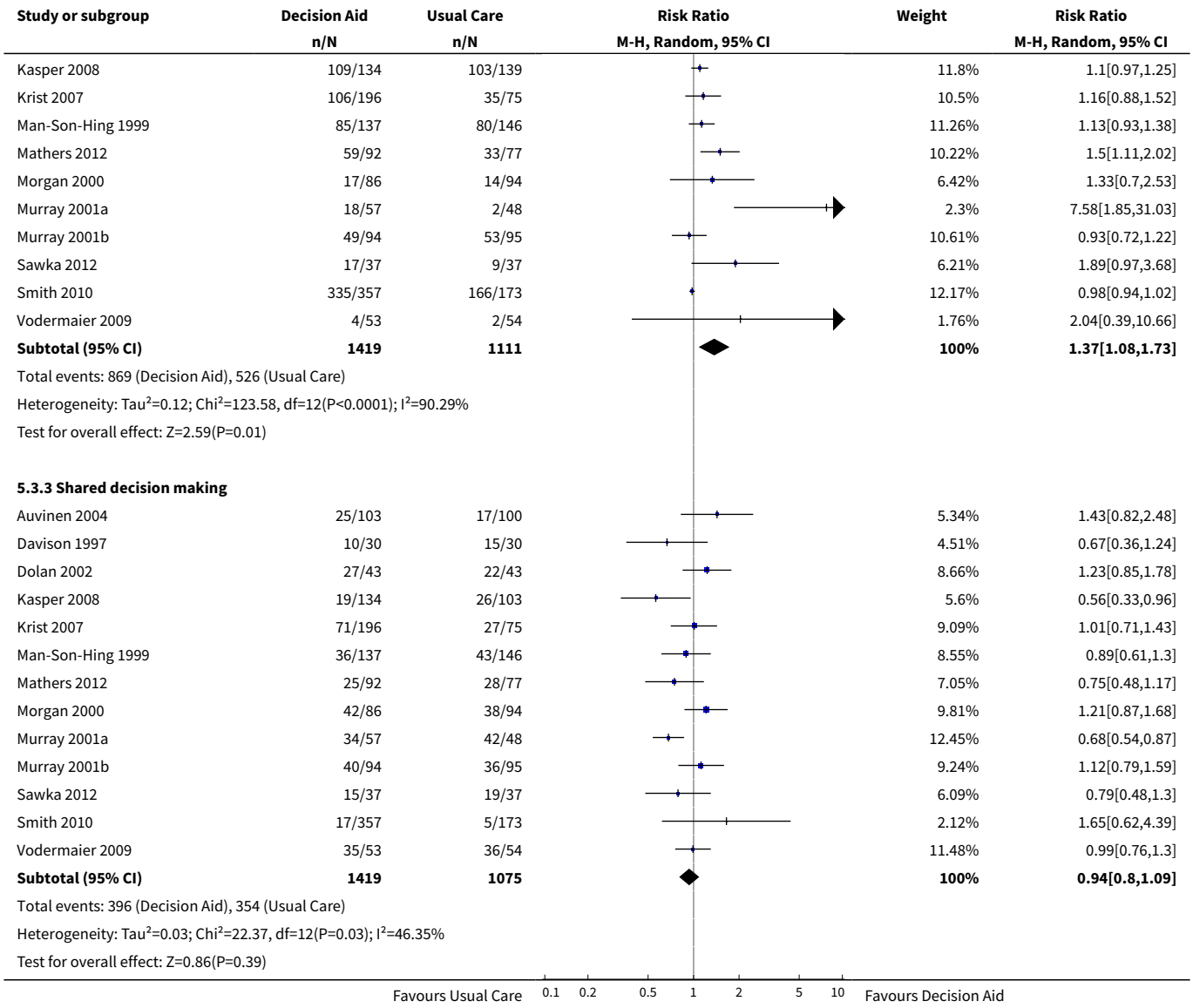
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
5.2.1 Clinician-controlled decision making - in consultation					
Legare 2011	26/81	24/70		25.94%	0.94[0.59,1.47]
Legare 2012	58/163	65/165		67.93%	0.9[0.68,1.2]
Whelan 2003	6/80	12/91		6.13%	0.57[0.22,1.45]
Subtotal (95% CI)	**324**	**326**		**100%**	**0.89[0.7,1.12]**





Analysis 5.3. Comparison 5 Participation in decision making, Outcome 3 Participation in decision making - in preparation for consultation.

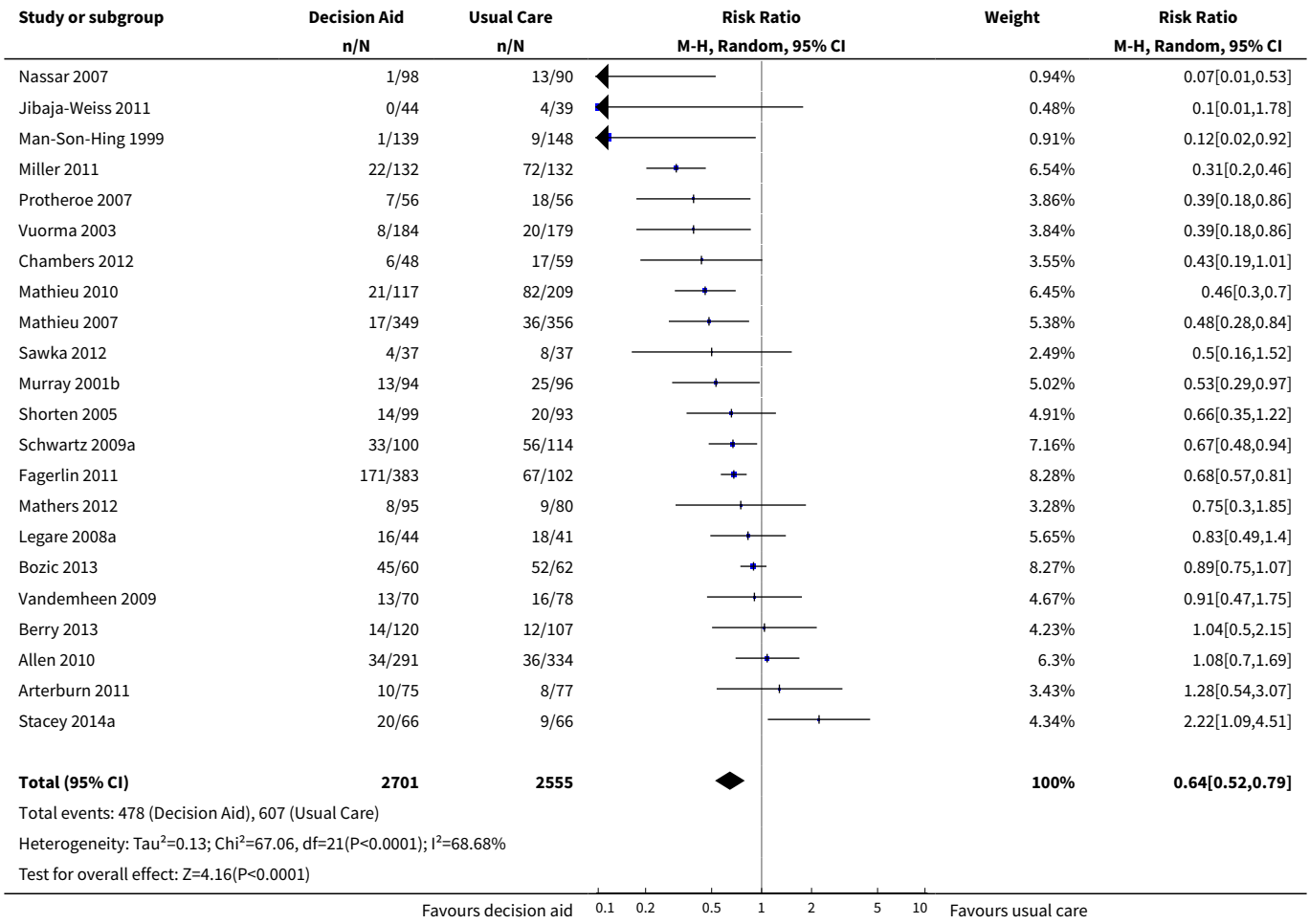




Comparison 6. Proportion undecided

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Proportion undecided - all studies	22	5256	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.52, 0.79]

Analysis 6.1. Comparison 6 Proportion undecided, Outcome 1 Proportion undecided - all studies.



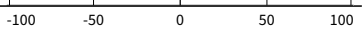
Comparison 7. Satisfaction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Satisfaction with the choice - all studies	11		Mean Difference (IV, Random, 95% CI)	Totals not selected
2 Satisfaction with the choice - in consultation	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Satisfaction with the choice - in preparation for consultation	10		Mean Difference (IV, Random, 95% CI)	Totals not selected
4 Satisfaction with the decision making process - all studies	9		Mean Difference (IV, Random, 95% CI)	Totals not selected
5 Satisfaction with the decision making process - in consultation	1		Mean Difference (IV, Random, 95% CI)	Totals not selected

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Satisfaction with the decision making process - in preparation for consultation	8		Mean Difference (IV, Random, 95% CI)	Totals not selected

Analysis 7.1. Comparison 7 Satisfaction, Outcome 1 Satisfaction with the choice - all studies.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	75.9 (17.2)	117	73.9 (18)		1.99[-2.65,6.63]
Bernstein 1998	61	73.1 (20.9)	48	77.7 (20.5)		-4.6[-12.42,3.22]
Chabrera 2015	61	95.7 (6.9)	61	79.3 (10.3)		16.4[13.29,19.51]
Hanson 2011	126	84.8 (15.2)	127	83.5 (16.2)		1.3[-2.57,5.17]
Jibaja-Weiss 2011	43	93.5 (12)	38	92.5 (15)		1[-4.97,6.97]
Laupacis 2006	54	73 (21.7)	56	61 (25.4)		12[3.18,20.82]
Montgomery 2007	212	85 (15)	209	80 (15)		5[2.13,7.87]
Morgan 2000	86	80 (26)	94	77.5 (26)		2.5[-5.1,10.1]
Nassar 2007	86	87.9 (12.5)	84	84.2 (15)		3.7[-0.46,7.86]
Ozanne 2007	15	82.5 (14.8)	15	80 (12.3)		2.5[-7.2,12.2]
Smith 2010	357	80.3 (11)	173	80.3 (10.8)		0[-1.97,1.97]

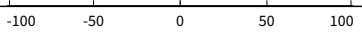


Analysis 7.2. Comparison 7 Satisfaction, Outcome 2 Satisfaction with the choice - in consultation.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Ozanne 2007	15	82.5 (14.8)	15	80 (12.3)		2.5[-7.2,12.2]

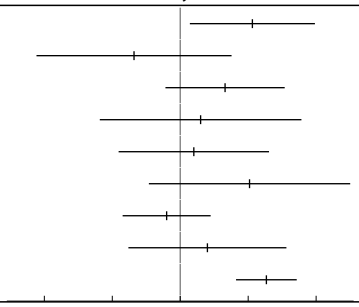
Analysis 7.3. Comparison 7 Satisfaction, Outcome 3 Satisfaction with the choice - in preparation for consultation.

Study or subgroup	Decision aid		Usual care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	75.9 (17.2)	117	73.9 (18)		1.99[-2.65,6.63]
Bernstein 1998	61	73.1 (20.9)	48	77.7 (20.5)		-4.6[-12.42,3.22]
Chabrera 2015	61	95.7 (6.9)	61	79.3 (10.3)		16.4[13.29,19.51]
Hanson 2011	126	15.3 (15.2)	127	16.5 (16.2)		-1.25[-5.12,2.62]
Jibaja-Weiss 2011	43	93.5 (12)	38	92.5 (15)		1[-4.97,6.97]
Laupacis 2006	54	73 (21.7)	56	61 (25.4)		12[3.18,20.82]
Montgomery 2007	212	85 (15)	209	80 (15)		5[2.13,7.87]
Morgan 2000	86	80 (26)	94	77.5 (26)		2.5[-5.1,10.1]
Nassar 2007	86	87.9 (12.5)	84	84.2 (15)		3.7[-0.46,7.86]
Smith 2010	357	80.3 (11)	173	80.3 (10.8)		0[-1.97,1.97]



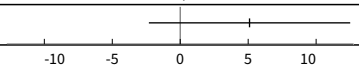
Analysis 7.4. Comparison 7 Satisfaction, Outcome 4 Satisfaction with the decision making process - all studies.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	76.4 (16.5)	117	71.1 (18.4)		5.31[0.71,9.91]
Bernstein 1998	61	73.1 (20.6)	48	76.5 (17.6)		-3.4[-10.58,3.78]
Bozic 2013	60	94.4 (10)	62	91.1 (14.4)		3.3[-1.09,7.69]
Jibaja-Weiss 2011	43	94 (17)	38	92.5 (17)		1.5[-5.92,8.92]
Knops 2014	74	74 (16)	80	73 (19)		1[-4.53,6.53]
Kupke 2013	50	91.4 (12.5)	31	86.3 (18.6)		5.1[-2.31,12.51]
Man-Son-Hing 1999	146	83.8 (14.8)	138	84.8 (13)		-1[-4.24,2.24]
Morgan 2000	86	72 (19.9)	94	70 (19.9)		2[-3.81,7.81]
Schroy 2011	214	84.2 (10.3)	217	77.8 (13.2)		6.34[4.11,8.57]



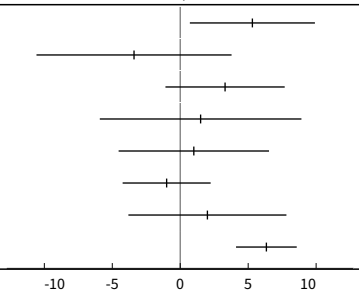
Analysis 7.5. Comparison 7 Satisfaction, Outcome 5 Satisfaction with the decision making process - in consultation.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Kupke 2013	50	91.4 (12.5)	31	86.3 (18.6)		5.1[-2.31,12.51]



Analysis 7.6. Comparison 7 Satisfaction, Outcome 6 Satisfaction with the decision making process - in preparation for consultation.

Study or subgroup	Decision Aid		Usual Care		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Random, 95% CI	Random, 95% CI
Barry 1997	104	76.4 (16.5)	117	71.1 (18.4)		5.31[0.71,9.91]
Bernstein 1998	61	73.1 (20.6)	48	76.5 (17.6)		-3.4[-10.58,3.78]
Bozic 2013	60	94.4 (10)	62	91.1 (14.4)		3.3[-1.09,7.69]
Jibaja-Weiss 2011	43	94 (17)	38	92.5 (17)		1.5[-5.92,8.92]
Knops 2014	74	74 (16)	80	73 (19)		1[-4.53,6.53]
Man-Son-Hing 1999	146	83.8 (14.8)	138	84.8 (13)		-1[-4.24,2.24]
Morgan 2000	86	72 (19.9)	94	70 (19.9)		2[-3.81,7.81]
Schroy 2011	214	84.2 (10.3)	217	77.8 (13.2)		6.34[4.11,8.57]



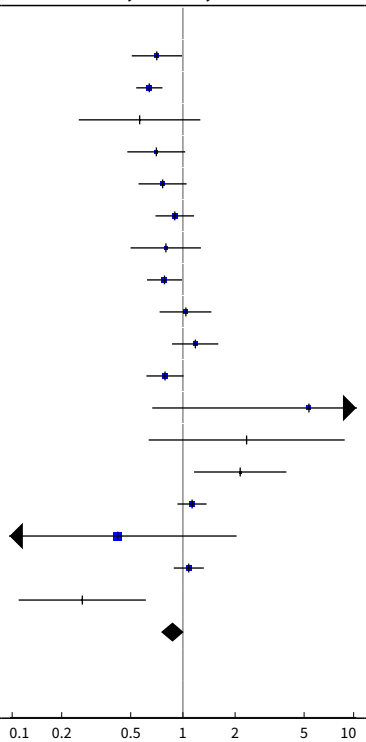
Comparison 8. Choice

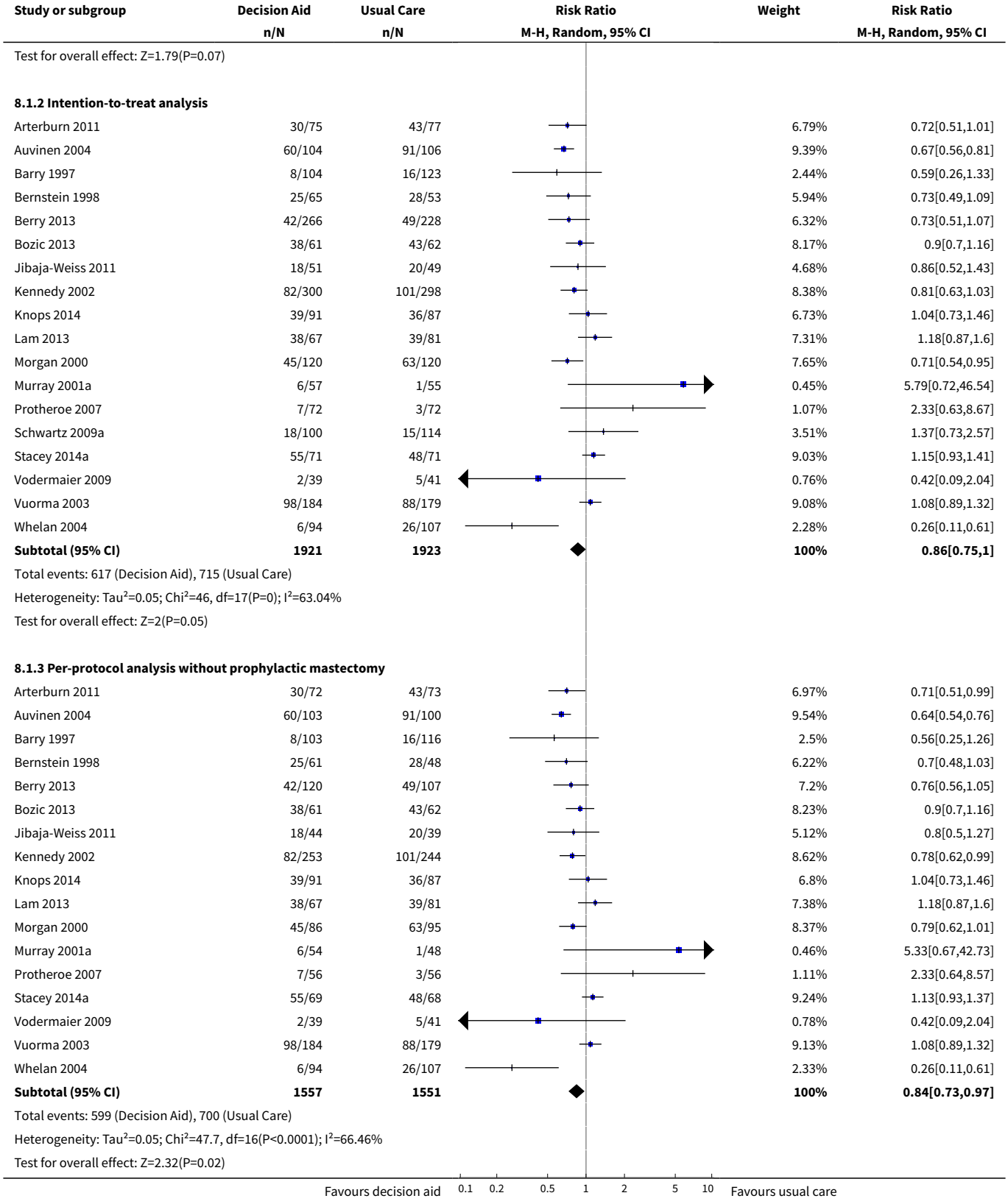
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Choice: surgery over conservative option	18		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Per-protocol analysis	18	3286	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.75, 1.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2 Intention-to-treat analysis	18	3844	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.75, 1.00]
1.3 Per-protocol analysis without prophylactic mastectomy	17	3108	Risk Ratio (M-H, Random, 95% CI)	0.84 [0.73, 0.97]
2 Choice for screening	25		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
2.1 PSA screening	10	3996	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.80, 0.98]
2.2 Colorectal cancer screening	10	4529	Risk Ratio (M-H, Random, 95% CI)	1.12 [0.95, 1.31]
2.3 Breast cancer genetic testing	3	738	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.71, 1.38]
2.4 Prenatal diagnostic testing	2	1100	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.91, 1.09]
3 Choice: diabetes medication (uptake new medication)	4	447	Risk Ratio (M-H, Random, 95% CI)	1.65 [1.06, 2.56]

Analysis 8.1. Comparison 8 Choice, Outcome 1 Choice: surgery over conservative option.

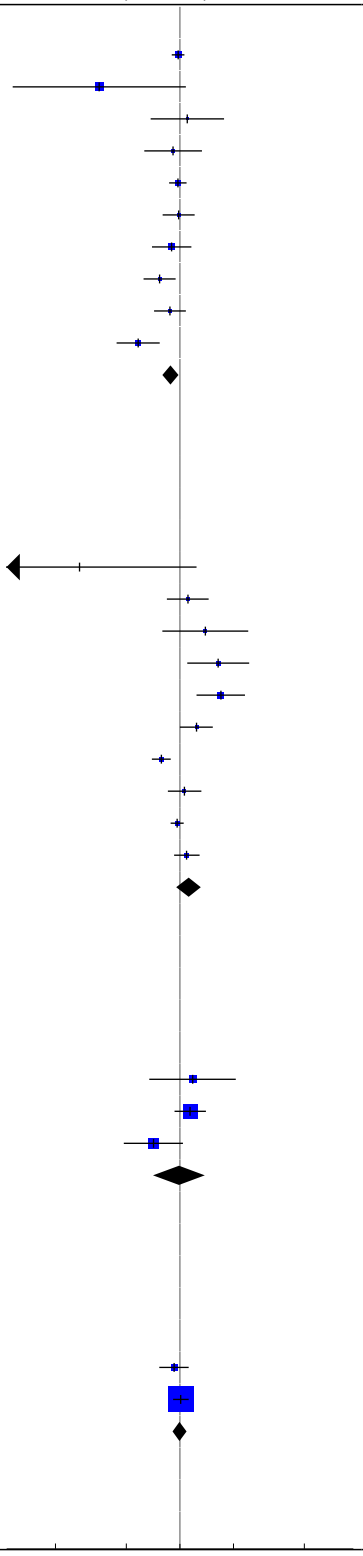
Study or subgroup	Decision Aid n/N	Usual Care n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
8.1.1 Per-protocol analysis					
Arterburn 2011	30/72	43/73		6.76%	0.71[0.51,0.99]
Auvinen 2004	60/103	91/100		8.87%	0.64[0.54,0.76]
Barry 1997	8/103	16/116		2.62%	0.56[0.25,1.26]
Bernstein 1998	25/61	28/48		6.11%	0.7[0.48,1.03]
Berry 2013	42/120	49/107		6.95%	0.76[0.56,1.05]
Bozic 2013	38/61	43/62		7.82%	0.9[0.7,1.16]
Jibaja-Weiss 2011	18/44	20/39		5.13%	0.8[0.5,1.27]
Kennedy 2002	82/253	101/244		8.14%	0.78[0.62,0.99]
Knops 2014	39/91	36/87		6.62%	1.04[0.73,1.46]
Lam 2013	38/67	39/81		7.11%	1.18[0.87,1.6]
Morgan 2000	45/86	63/95		7.93%	0.79[0.62,1.01]
Murray 2001a	6/54	1/48		0.5%	5.33[0.67,42.73]
Protheroe 2007	7/56	3/56		1.2%	2.33[0.64,8.57]
Schwartz 2009a	18/64	15/114		3.8%	2.14[1.16,3.95]
Stacey 2014a	55/69	48/68		8.63%	1.13[0.93,1.37]
Vodermaier 2009	2/39	5/41		0.84%	0.42[0.09,2.04]
Vuorma 2003	98/184	88/179		8.54%	1.08[0.89,1.32]
Whelan 2004	6/94	26/107		2.44%	0.26[0.11,0.61]
Subtotal (95% CI)	**1621**	**1665**		**100%**	**0.87[0.75,1.01]**
Total events: 617 (Decision Aid), 715 (Usual Care)					
Heterogeneity: Tau^2=0.06; Chi^2=55.99, df=17(P<0.0001); I^2=69.63%					



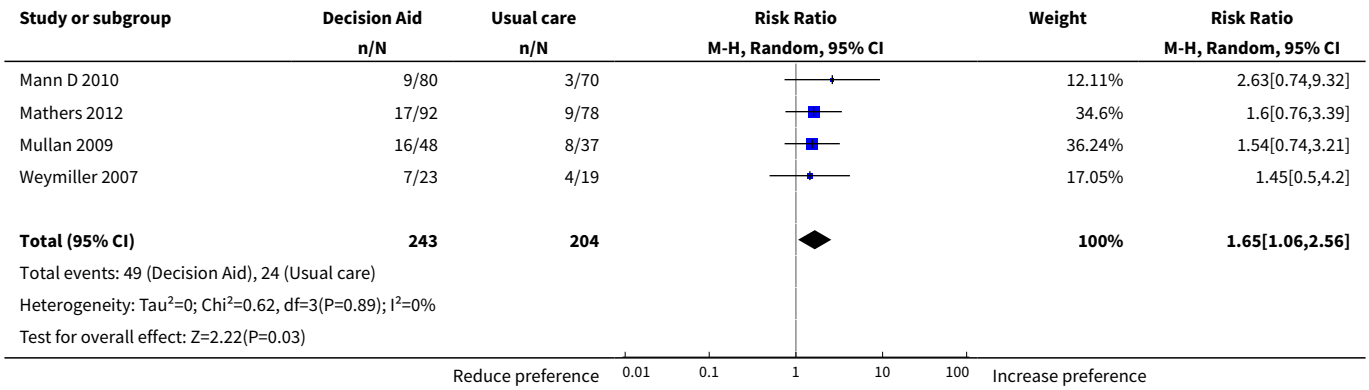


Analysis 8.2. Comparison 8 Choice, Outcome 2 Choice for screening.

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
8.2.1 PSA screening					
Allen 2010	225/291	264/334		19.01%	0.98[0.9,1.06]
Evans 2010	4/127	11/123		0.84%	0.35[0.12,1.08]
Gattellari 2003	27/106	25/108		3.97%	1.1[0.69,1.77]
Gattellari 2005	37/131	42/136		5.79%	0.91[0.63,1.33]
Krist 2007	163/196	64/75		17.25%	0.97[0.87,1.09]
Lepore 2012	97/215	99/216		11.7%	0.98[0.8,1.21]
Partin 2004	83/308	87/290		9.47%	0.9[0.7,1.16]
Volk 1999	48/78	64/80		11.69%	0.77[0.63,0.95]
Watson 2006	119/465	149/512		11.76%	0.88[0.72,1.08]
Wolf 1996	40/103	68/102		8.52%	0.58[0.44,0.77]
Subtotal (95% CI)	**2020**	**1976**		**100%**	**0.88[0.8,0.98]**
Total events: 843 (Experimental), 873 (Control)					
Heterogeneity: Tau^2=0.01; Chi^2=21.43, df=9(P=0.01); I^2=58.01%					
Test for overall effect: Z=2.3(P=0.02)					
8.2.2 Colorectal cancer screening					
Dolan 2002	2/45	7/43		1.02%	0.27[0.06,1.24]
Lewis 2010	71/207	70/226		10.56%	1.11[0.84,1.45]
Miller 2011	25/132	18/132		5.3%	1.39[0.8,2.42]
Pignone 2000	46/124	28/124		7.77%	1.64[1.1,2.45]
Ruffin 2007	56/87	33/87		9.62%	1.7[1.24,2.32]
Schroy 2011	116/269	96/276		12%	1.24[1,1.53]
Smith 2010	211/357	130/173		14.03%	0.79[0.7,0.89]
Steckelberg 2011	141/785	134/792		11.93%	1.06[0.86,1.32]
Trevena 2008	117/134	124/137		14.66%	0.96[0.89,1.05]
Wolf 2000	173/266	79/133		13.1%	1.09[0.93,1.29]
Subtotal (95% CI)	**2406**	**2123**		**100%**	**1.12[0.95,1.31]**
Total events: 958 (Experimental), 719 (Control)					
Heterogeneity: Tau^2=0.04; Chi^2=48.11, df=9(P<0.0001); I^2=81.29%					
Test for overall effect: Z=1.37(P=0.17)					
8.2.3 Breast cancer genetic testing					
Green 2001	13/29	16/42		21.9%	1.18[0.67,2.06]
Lerman 1997	74/122	87/164		46.01%	1.14[0.93,1.4]
Schwartz 2001	35/191	49/190		32.09%	0.71[0.48,1.04]
Subtotal (95% CI)	**342**	**396**		**100%**	**0.99[0.71,1.38]**
Total events: 122 (Experimental), 152 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=5.15, df=2(P=0.08); I^2=61.19%					
Test for overall effect: Z=0.07(P=0.94)					
8.2.4 Prenatal diagnostic testing					
Bjorklund 2012	92/184	111/206		21.75%	0.93[0.77,1.12]
Kuppermann 2014	244/357	238/353		78.25%	1.01[0.92,1.12]
Subtotal (95% CI)	**541**	**559**		**100%**	**0.99[0.91,1.09]**
Total events: 336 (Experimental), 349 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.66, df=1(P=0.42); I^2=0%					
Test for overall effect: Z=0.12(P=0.9)					



Analysis 8.3. Comparison 8 Choice, Outcome 3 Choice: diabetes medication (uptake new medication).



ADDITIONAL TABLES

Table 1. Decision aids evaluated in the trials

Study	Topic	Availability	Source	Contact Information
Allen 2010	Prostate cancer screening	No	Allen, Center for Community-Based Research, Dana-Farber Cancer Institute, Boston, MA, USA, 2010	Requested access
Arterburn 2011	Bariatric surgery	Yes	Informed Medical Decisions Foundation, MA,USA, 2010	informedmedicaldecisions.org/imdf_decision_aid/making-decisions-about-weight-loss-surgery/
Auvinen 2004	Prostate cancer treatment	Yes	Auvinen, Helsinki, Finland, 1993	Included in publication
Barry 1997	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Bekker 2004	Prenatal screening	Yes	Bekker, Leeds, UK, 2003	Included in publication
Bernstein 1998	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA,USA, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Berry 2013	Prostate cancer treatment	No	Berry, Phyllis F. Cantor Center, MA, USA, 2011	donna_berry@dfci.harvard.edu

Table 1. Decision aids evaluated in the trials *(Continued)*

Bjorklund 2012	Antenatal Down syndrome screening	Yes	Södersjukhuset, Department of Obstetrics and Gynecology, Stockholm, Sweden	vimeo.com/34600615/
Bozic 2013	Osteoarthritis of the knee or hip	No	Informed Medical Decisions Foundation and Health Dialog; USA	www.healthdialog.com
Brazell 2014	Pelvic Organ Prolapse	Yes	Healthwise, USA	decisionaid.ohri.ca
Chabrera 2015	Prostate cancer treatment	No	C Chabrera. School of Health Sciences, Department of Nursing. Mataro, Spain	cchabrera@tecnocampus.cat
Chambers 2012	Healthcare personnel's influenza immunization	Yes	A McCarthy. Ottawa Influenza Decision Aid Planning Group, CA, 2008	decisionaid.ohri.ca/decaids.html#oida
Clancy 1988	Hepatitis B Vaccine	No	Clancy, Richmond VA, USA, 1983	—
Davison 1997	Prostate cancer treatment	No	Davison, Manitoba CA, 1992-1996	—
De Achaval 2012	Total knee arthroplasty treatment	Yes	Informed Medical Decisions Foundation, MA,USA	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-knee-osteoarthritis/
Dolan 2002	Colon cancer screening	No	Dolan, Rochester NY, USA, 1999	—
Evans 2010	Prostate cancer screening	Yes	Elwyn, Cardiff, UK	www.prosdex.com
Fagerlin 2011	Breast cancer prevention	Yes	Fagerlin, Ann Arbor, MI, USA	—
Fraenkel 2007	Osteoarthritis knee treatment	No	Fraenkel, New Haven CT, USA	Author said DA never fully developed, all info in paper
Fraenkel 2012	Atrial fibrillation	No	Veterans Affairs Connecticut Healthcare System, USA	Obtained from author terri.fried@yale.edu
Frosch 2008a	Prostate cancer screening	No	Frosch, Los Angeles, USA	Screenshots from author
Gattellari 2003	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication
Gattellari 2005	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	Included in publication
Green 2001	Breast cancer genetic testing	Yes	Green, Hershey PA, USA, 2000	1-800-757-4868 dwc@mavc.com
Hamann 2006	Schizophrenia treatment	Yes	Hamann, Munich, GER	Emailed by author (in German)

Table 1. Decision aids evaluated in the trials *(Continued)*

Hanson 2011	Feeding options in advanced dementia	Yes	Mitchell, Tetroe, O'Connor; 2001 (updated 2008)	decisionaid.ohri.ca/decaids.html#feedingtube
Heller 2008	Breast reconstruction	Yes	University of Texas MD Anderson Cancer Center, Houston TX, USA, 2003	Disc mailed
Hess 2012	Stress testing for chest pain	Yes	Hess, Rochester, MN, USA, 2012	Included in publication
Jibaja-Weiss 2011	Breast cancer treatment	Yes	Jibaja-Weiss, Baylor College of Medicine, 2010	www.bcm.edu/patchworkoflife
Johnson 2006	Endodontic treatment	Yes	Johnson, Chicago, USA, 2004	Included in publication
Kasper 2008	Multiple sclerosis	No	Jürgen Kasper	—
Kennedy 2002	Abnormal uterine bleeding treatment	No	Kennedy/Coulter, London UK, 1996	—
Knops 2014	Asymptomatic Abdominal Aortic Aneurysm treatment	Yes	Amsterdam, The Netherlands	www.keuzehulp.info/amc/AAA/landing-page
Krist 2007	Prostate cancer screening	Yes	Krist, Fairfax VA, USA	www.familymedicine.vcu.edu/research/misc/psa/index.html
Kupke 2013	Dental - posterior tooth decay	Yes	University of Cologne, Cologne, Germany	jana.kupke@uk-koeln.de
Kuppermann 2014	Prenatal screening	No	Kuppermann, San Francisco CA, USA	Interactive web-based decision aid
Lam 2013	Breast cancer treatment	Yes	Kwong Wah Hospital, Hong Kong, China	Obtained from author. wwtlam@hku.hk
Langston 2010	Contraceptive method choice	Yes	World Health Organization, 2005	www.who.int/reproductive-health/publications/family_planning/9241593229index/en/index.html
Laupacis 2006	Pre-operative autologous blood donation	No	Laupacis, Ottawa, CA, 2001	Decisionaid.ohri.ca/decaids-archive.html
LeBlanc 2015	Treatment for osteoporosis	Yes	Mayo Clinic	—
Legare 2008a	Natural health products	No	Legare, Quebec City, CA, 2006	—
Legare 2011	Use of antibiotics for acute respiratory infections	Yes	Legare, Quebec City, CA, 2007	www.decision.chaire.fmed.ulaval.ca/index.php?id=192&L=2

Table 1. Decision aids evaluated in the trials *(Continued)*

Legare 2012	Antibiotics for acute respiratory infections	Yes	Legare, Quebec City, CA	www.decision.chaire.fmed.ulaval.ca/index.php?
Leighl 2011	Advanced colorectal cancer chemotherapy	Yes	Princess Margaret Hospital, Toronto, 2011	Natasha.Leighl@uhn.on.ca
Lepore 2012	Prostate cancer screening	Yes	Sally Weinrich University of Louisville, USA	Obtained from author slepore@temple.edu
Lerman 1997	Breast cancer genetic testing	No	Lerman/Schwartz, Washington DC, USA, 1997	—
Lewis 2010	Colorectal cancer screening	Yes	Lewis, University of North Carolina, Chapel Hill, NC, USA, 2010	decisionsupport.unc.edu/CHOICE6/
Loh 2007	Depression treatment	Yes	Loh, Freiburg, GER	Emailed to us by author - in German
Man-Son-Hing 1999	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CA, 2000	decisionaid.ohri.ca/decaids-archive.html
Mann D 2010	Diabetes treatment - statins	Yes	Montori, Rochester MN, USA	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm
Mann E 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Additional file 2 of publication
Marteau 2010	Diabetes screening	Yes	Marteau, King's College London, London, England, 2010	Provided by author, same DA as Mann E 2010
Mathieu 2007	Mammography	Yes	Mathieu, Sydney, AU	DA emailed by author
Mathers 2012	Diabetes treatment	Yes	The University of Sheffield, Sheffield, UK, 2008	Obtained from author C.Ng@sheffield.ac.uk
Mathieu 2010	Mammography	Yes	Mathieu, University of Sydney, AUS, 2010	www.psych.usyd.edu.au/cemped/com_decision_aids.shtml
McAlister 2005	Atrial fibrillation treatment	No	McAlister/Laupacis, Ottawa CAN, 2000	decisionaid.ohri.ca/decaids-archive.html
McBride 2002	Hormone replacement therapy	Yes, update in progress	Sigler/Bastien, Durham NC, USA, 1998	basti001@mc.duke.edu
McCaffery 2010	Screening after mildly abnormal pap smear	Yes	Screening & test evaluation program, School of public health, University of Sydney 2007	kirstenm@health.usyd.edu.au
Miller 2005	BRCA1/BRCA2 gene testing	No	Miller, Fox Chase PA, USA	—

Table 1. Decision aids evaluated in the trials *(Continued)*

Miller 2011	Colorectal cancer screening	Yes	University of North Carolina, Chapel Hill, NC, USA, 2007	intmedweb.wakehealth.edu/choice/choice.html (no longer available)
Montgomery 2003	Hypertension treatment	No	Montgomery, UK, 2000	—
Montgomery 2007	Birthing options after caesarean	Yes	Montgomery, Bristol, UK, last update 2004	www.computing.dundee.ac.uk/acstaff/cjones/diamond/Information.html
Montori 2011	Osteoporosis treatment	Yes	Montori, Mayo Foundation for Medical Education and Research, 2007	shareddecisions.mayoclinic.org/decision-aids-for-diabetes/other-decision-aids/
Morgan 2000	Ischaemic heart disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2002	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-carotid-artery-disease/
Mott 2014	PTSD treatment	Yes	Michael E DeBakey Veterans Affairs Medical Center, Houston, USA	Obtained from author juliette.mott@va.gov
Mullan 2009	Diabetes treatment	Yes	Montori or Mayo Foundation(?) Rochester MN, USA,	Included in publication
Murray 2001a	Benign prostate disease treatment	Yes	Informed Medical Decisions Foundation, MA, USA, 2001	informedmedicaldecisions.org/imdf_decision_aid/treatment-options-for-benign-prostatic-hyperplasia/
Murray 2001b	Hormone replacement therapy	No, update in progress	Informed Medical Decisions Foundation, MA, USA	informedmedicaldecisions.org/imdf_decision_aid/treatment-choices-for-managing-menopause/
Nagle 2008	Prenatal screening	Yes	Nagle, Victoria, AU	www.mcri.edu.au/Downloads/PrenatalTestingDecisionAid.pdf
Nassar 2007	Birth breech presentation	Yes	Nassar, West Perth WA, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
Oakley 2006	Osteoporosis treatment	No	Cranney, Ottawa CA, 2002	decisionaid.ohri.ca/decaids-archive.html
Ozanne 2007	Breast cancer prevention	No	Ozanne, Boston MA, USA	—
Partin 2004	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA,USA, 2001	informedmedicaldecisions.org/imdf_deci-

Table 1. Decision aids evaluated in the trials *(Continued)*

				sion_aid/deciding-if-the-psa-test-is-right-for-you/
Pignone 2000	Colon cancer screening	Yes	Pignone, Chapel Hill NC, USA, 1999	www.med.unc.edu/medicine/edusrc/colon.htm
Protheroe 2007	Menorrhagia treatment	No	Protheroe, Manchester, UK	Computerized decision aid, Clinical Guidance Tree - no longer in existence, author sent chapter in thesis
Rubel 2010	Prostate cancer screening	No	Centers for Disease Control and Prevention (CDC), USA, 2010	No longer available
Ruffin 2007	Colorectal cancer screening	Yes	Regents of the University of Michigan (copyright info), Ann Arbor MI, USA, 2006	colorectalweb.org
Sawka 2012	Adjuvant radioactive iodine treatment for patients with early-stage papillary thyroid cancer	No	University Health Network, Toronto, Canada, 2009	—
Schroy 2011	Colorectal cancer screening	Yes	Schroy III, Boston, USA	Paul.schroy@bmc.org
Schwalm 2012	Coronary angiogram access site	Yes	Schwalm, Hamilton, ON, Canada, 2009	www.phri.ca/workfiles/studies/presentations/PtDA%20Vascular%20Access%2023-May–2012.pdf
Schwartz 2001	Breast cancer genetic testing	No	Schwartz/Lerman, Washington DC, USA, 1997	—
Schwartz 2009a	BRCA mutation prophylactic surgery	No	Schwartz, Washington DC, USA	—
Sheridan 2006	Cardiovascular prevention	Yes	Sheridan, Chapel Hill, NC, USA	www.med-decisions.com/cvtool/
Sheridan 2011	Coronary heart disease prevention	Yes	Sheridan, University of North Carolina at Chapel Hill, Division of General Internal Medicine, North Carolina, USA, 2011	www.med-decisions.com/h2hv3/
Shorten 2005	Birthing options after previous caesarean	Yes (updated 2006)	Shorten, Wollongong, AU, 2000	ashorten@uow.edu.au or www.capersbookstore.com.au/product.asp?id=301
Shourie 2013	Measles mumps and rubella vaccination	Yes	University of Leeds, UK & NSIRS Australia	www.leedsmmr.co.uk
Smith 2010	Bowel cancer screening	Yes	Smith, Sydney, AU 2008	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php

Table 1. Decision aids evaluated in the trials *(Continued)*

Stacey 2014a	Osteoarthritis of the hip and knee	No	Informed Medical Decisions Foundation and Health Dialog; USA	www.healthdialog.com
Steckelberg 2011	Colorectal cancer screening	Yes	Steckelberg, Hamburg, Germany	—
Taylor 2006	Prostate cancer screening	Yes	Georgetown University Medical Center, Washington DC, USA, 2000	Obtained from author taylorkl@georgetown.edu
Thomson 2007	Atrial fibrillation treatment	Yes	Thomson, Newcastle Upon Thyne, UK	Disc sent by mail
Trevena 2008	Colorectal cancer screen	Yes	Trevena, Sydney, AU	sydney.edu.au/medicine/public-health/shdg/resources/decision_aids.php
Van Peperstraten 2010	Embryos transplant	Yes	Radboud University Nijmegen Medical Centre; 2006	www.umcn.nl/ivfda-en
Vandemheen 2009	Cystic Fibrosis referral transplant	Yes	Aaron, Ottawa ON, CA, 2009 (last update 2011)	decisionaid.ohri.ca/decaids.html#cfda
Vodermaier 2009	Breast cancer surgery	Yes	Vodermaier, Vancouver BC, CA	Received by email (in German)
Volk 1999	Prostate cancer screening	Yes	Informed Medical Decisions Foundation, MA, USA, 1999	informedmedicaldecisions.org/imdf_decision_aid/deciding-if-the-psa-test-is-right-for-you/
Vuorma 2003	Menorrhagia treatment	No	Vuorma, Helsinki Finland, 1996	—
Watson 2006	Prostate cancer screening	Yes	Oxford, UK	Included in publication
Weymiller 2007	Diabetes mellitus type 2 treatment	Yes	Montori, Rochester MN, USA	mayoresearch.mayo.edu/mayo/research/ker_unit/form.cfm
Williams 2013	Prostate cancer screening	Yes	Georgetown University, Washington, DC, USA	Obtained from author taylorkl@georgetown.edu
Whelan 2003	Breast cancer chemotherapy	Yes	Whelan, Hamilton CA, 1995	Included in publication
Whelan 2004	Breast cancer surgery	Yes	Whelan, Hamilton CA, 1997	Included in publication
Wolf 1996	Prostate cancer screening	Yes	Wolf, Charlottesville VA, USA, 1996	Script in publication
Wolf 2000	Colon cancer screening	Yes	Wolf, Charlottesville VA, USA, 2000	Script in publication
Wong 2006	Pregnancy termination	No	Bekker, Leeds, UK, 2002	—

Table 2. Knowledge

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Bozic 2013	Decision quality instrument, 19 items re knowledge (> 50%)	After 1st consultation with surgeon	60	58.3%	60	33.3%	P = 0.01
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	Postintervention	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	Postintervention	53	49%	46	37%	OR 1.9 (95%CI: 0.9 to 4.0; P = 0.07)
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
LeBlanc 2015 (in consultation)	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
	9-items knowledge based on decision aid	Immediately post	32	6 (3.5 to 6.5)	45	4 (2.0 to 8.0)	P = 0.01
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)

Table 2. Knowledge *(Continued)*

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 postintervention	95	51.6%	80	28.8%	P < 0.001
	Correctly answers question about best option to lower complications	6 months postintervention	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 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) pamphlet group. OR 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
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)
Trevena 2008	Adequate knowledge (positive score: understanding benefits/harms)	1 month	134	28/134	137	8/137	P = 0.0001

Table 2. Knowledge *(Continued)*

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 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 prior to the consultation)

CI: confidence interval; **DA**: decision aid; **OR**: odds ratio; **SD**: standard deviation.

Table 3. Accurate risk perceptions

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
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)	Postintervention	69	9.1 (SD 13.3)	66	14.2 (SD 13)	P = 0.002
	Accuracy of bleeding risk (reported same as above)	Postintervention	69	8.7 (SD 12.5)	66	13.1 (SD 12.2)	P = 0.004
Hanson 2011	Expectation of benefit index 11 items score from 1 to 4 with lower score indicating better knowledge	Post (after reviewing DA)	127	2.3	129	2.6	P = 0.001
Kuppermann 2014	Correct estimate of amniocentesis miscarriage risk	3-6 months postintervention	357	263 (73.8%)	353	208 (59.0%)	P < 0.001
	Correct estimate of Down syndrome risk	3-6 months postintervention	357	210 (58.7%)	353	163 (46.1%)	P = 0.001

Table 3. Accurate risk perceptions *(Continued)*

Mann E 2010	3 of 8 multiple choice items in the knowledge test (question 4, 5, 7)	2 weeks post	—	—	—	—	Total knowledge reported only
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
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 group 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.

Table 4. Values congruent with chosen option

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
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.	Postintervention	75	—	77	—	The intervention group experienced a more rapid early improvement in value concordance immediately after the intervention compared to control

Table 4. Values congruent with chosen option *(Continued)*

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 postintervention	239	—	209	—	No difference OR = 0.82; 95% CI 0.56 to 1.2
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 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 valuing of non-chemical aspect 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
Vandemheen 2009	Congruence between personal values and decision	3 weeks	70	—	70	—	Patient choices were consistent with their values across both randomized groups

DA: decision aid; **SD**: standard deviation.

Table 5. Decisional Conflict Score

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes

Table 5. Decisional Conflict Score *(Continued)*

Arterburn 2011	Total decisional conflict- change from baseline (standardised values)	Immediately post	75	Mean −20 SD 19.44	77	Mean −11.8 SD 22.83	P = 0.03
Berry 2013	Decisional conflict scale	Uncertainty	—	−3.61 units	—	—	P = 0.04
		Uninformed	—	—	—	—	No significant difference
		Unclear values	—	−3.57 units	—	—	P = 0.002
		Unsupported	—	—	—	—	No significant difference
		Ineffective decision	—	—	—	—	No significant difference
		Total	—	−1.75 units	—	—	P = 0.07
Fagerlin 2011	Decisional conflict scale	Immediately post	—	—	—	—	DCS was higher in the intervention group compared to control, 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
		Feeling supported	155	30.51	151	35.21	P < 0.05
		Feeling uncertain	155	—	151	—	No difference
		Effective decisions	155	—	151	—	No difference
Knops 2014	Decisional conflict (total score)	4 months	73	19 SD 14	81	22 SD 17	No difference
		10 months	73	21 SD 17	81	18 SD 17	No difference
Krist 2007	Decisional conflict	Immediately after office visit	196	1.54	75	1.58	No difference

Table 5. Decisional Conflict Score *(Continued)*

LeBlanc 2015 (in consult)	Decision conflict (overall) median, IQR	Immediately post	28	10.9 (95% CI 1.6 to 26.6)	36	22.7 (95% CI 7.8 to 28.5)	P = 0.18
	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
	Support subscale	Immediately post	28	8.3 (95% CI 0 to 25)	36	16.7 (95% CI 0 to 25)	P = 0.35
	Certainty subscale	Immediately post	28	8.3 (95% CI 0 to 25)	36	25 (95% CI 0 to 25)	P = 0.3
	Effectiveness sub-scale	Immediately post	28	12.5 (95% CI 0 to 25)	36	18.8 (95% CI 0 to 25)	P = 0.15
Legare 2012 (in consult)	Decisional conflict - proportion who had a value of 2.5 or more on the 1−5 DCS. (n,%)	Immediately post	163	4.6% (95% CI 2.6 to 7.4)	165	6.3% (95% CI 0 to 12.8)	Absolute difference 1.7; RR 0.8 (95% CI 0.2 to 2.4)
Leighl 2011	Decisional conflict scale median (range)	1-2 weeks postin-tervention	107	26 (range 0-79)	100	26 (range 0-67)	No difference
Mathieu 2010	Based on approach-es suggested by Marteau et al. (in-formed choice)	Immediately after intervention	91	71%	110	64%	P = 0.24
Ozanne 2007 (in consult)	Decisional conflict	Postconsultation	15	—	15	—	Both groups showed lower decision-al conflict postconsultation (P < 0.001) but no difference between groups
Rubel 2010	Decisional conflict	Immediately post	—	—	—	—	The total mean score was 24.5 with a SD of 15.25 (N = 200)
Schwartz 2009a	Decisional conflict	12 of 16 items of the original scale	—	—	—	—	Significant longitudinal impact of the decision aid was moderated by base-line decision status; decision aid led

Table 5. Decisional Conflict Score *(Continued)*

							to significant decreases in decisional conflict for those who were undecided at the time of randomisation
Thomson 2007 (in consult)	Decisional conflict	Postconsultation	53	—	56	—	Difference between decision aid and control group were −0.18 (95% CI −0.34 to −0.01). P = 0.036
		3-months post	51	—	55	—	Difference between decision aid and control group were −0.15 (95% CI −0.37 to 0.06), no significant difference
Van Peperstraten 2010	15 item questionnaire (1-5) - satisfaction-uncertainty	Postintervention, pre IVF	124	72.5	128	75	P = 0.76
	15 item questionnaire (1-5) - informed (includes some items from DCS)	Postintervention, pre IVF	124	77.5	128	87.5	P = 0.001
Weymiller 2007 (in consult)	Decisional conflict	Immediately post	52	—	46	—	Mean difference indicates statistically significantly lower decisional conflict for decision aid compared to usual care. Total DCS −10.6 (95% CI −15.4 to −5.9) Uncertain −12.8 (95% CI −18.4 to −7.3) Informed −17.3 (95% CI −22.6 to −12.0) if administered during consult −6.6 (95% CI −14.3 to −1.1) if administered prior to consult Values clarity −8.5 (95% CI−15.7 to −1.3) Support −9.4 (95% CI −14.8 to −3.9) Effective decision −10.0 (95% CI −15.0 to −5.0)

CI: confidence interval; **DA**: decision aid; **DCS**: decisional conflict scale; **IVF**: in vitro fertilisation; **SD**: standard deviation.

Table 6. Decisional Conflict Score - low literacy version

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Fraenkel 2012	Informed	Immediately post	69	13.0	66	24.8	P = 0.01
	Values	Immediately post	69	6.4	66	21.0	P <.001
Smith 2010	Total DCS	2 week follow-up	357	13.63 (SD 20.55)	173	14.91 (SD 18.34)	P = 0.02
Taylor 2006	Total DCS	Used 8 of 10 items only 1 month post	80	24.1% high	74	41.9% high	Results were dichotomized (items removed choosing without pressure from others; know what options are available to you)
Williams 2013	Total DCS	2 months post	153	27.5%	136	38.2%	Significant decrease for DA group compared to usual care in the home condition site
		13 months post	153	38.6%	136	31.6%	No difference

DA: decision aid; **DCS**: decisional conflict scale; **SD**: standard deviation.

Table 7. Decisional Conflict Score - SURE test

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Stacey 2014a	SURE tool Item: 'Feels sure about the best choice'	Postintervention; prior to surgical consult	65	72.3%	66	80.3%	No difference
	'Knows the benefits and harms . . .'	Postintervention; prior to surgical consult	65	92.3%	66	66.7%	No difference
	'Clear about which benefits and harms . . .'	Postintervention; prior to surgical consult	65	87.7%	66	74.2%	No difference
	'Has enough support and advice . . .'	Postintervention; prior to surgical consult	65	76.9%	66	77.3%	No difference

Table 7. Decisional Conflict Score - SURE test *(Continued)*

	Total SURE score	Postintervention; prior to surgical consult	65	69.2%	66	57.6%	No difference

Table 8. Patient-clinician communication

Study	Scale used	Timing	N decision aid	Decision aid - mean	N comparison	Comparison - mean	Notes
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
Hess 2012 (in consult)	OPTION scale	Analysis of the consultation using video-recordings	101	Mean 26.6% (95% CI 24.9 to 8.2)	103	Mean 7% (95% CI 5.9 to 8.1)	Significantly greater in the intervention arm
LeBlanc 2015 (in consult)	OPTION scale	Analysis of the consultation using video-recordings	25	Mean 57% (95% CI 50 to 64)	13	Mean 43% (95% CI 37 to 48)	P = 0.001
Lepore 2012	Discussed PSA testing with physician postintervention	8 months postintervention	215	15.8%	216	8.3%	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
Mullan 2009 (in consult)	OPTION scale	Analysis of the consultation using video-recorded consultations	48 used decision aid within consultation	Mean 49.7% (SD 17.74)	37 usual care	Mean 27.7% (SD 11.75)	MD 21.8 (95% CI 13.0 to 30.5) for decision aid vs usual care. All but 2 of the 12 items significant-

Table 8. Patient-clinician communication *(Continued)*

							ly favoured the decision aid
Sheridan 2006	Discussed CHD with doctor	Patient reported Immediately post	16/41 decision aid pre-consult with summary report to bring to consult	—	8/34 usual care	—	Absolute difference 16% (95% CI −4 to 37)
	Plan to reduce CHD risk and discussed with doctor	Patient reported Immediately post	15/41 decision aid pre-consult with summary report to bring to consult	—	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-consult with summary report to bring to consult	—	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)

Table 8. Patient-clinician communication *(Continued)*

	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)
	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)
Weymiller 2007 (in consult)	OPTION Scale	Analysis of the consultation using video-recorded consultations	1/2 used decision aid prior to consult and 1/2 used it during consult	—	Usual care	—	Greater patient participation MD 4.4 (95% CI 2.9 to 6.0) in decision aid compared to usual care

CHD: coronary heart disease;**CI**: confidence interval; **DA**: decision aid; **DCS**: decisional conflict scale; **ICC**: intraclass correlation coefficient;**MD**: mean difference; **OPTION scale**: observing patient involvement scale; **RR**: risk ratio; **SD**: standard deviation

Table 9. Participation in decision making

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Allen 2010	Control preferences - patients choosing active/collaborative decision making	Postintervention	291	95%	334	92%	No difference
	Control preferences did not change	Postintervention	291	92%	334	87%	No difference

Table 9. Participation in decision making *(Continued)*

	Control preferences changed to passive	Postintervention	291	3%	334	5%	No difference
	Control preferences changed to active/ collaborative	Postintervention	291	3%	334	7%	No difference
Hamann 2006	COMRADE used to measure patients' perceived involvement in decisions	Postconsultation	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 postintervention 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	Postintervention	—	83%	—	77%	P = 0.18
Leighl 2011	Achieved decision involvement	Postintervention	—	32%	—	35%	No difference
Loh 2007 (in consult)	Patients' perceived involvement in decision making	Postconsultation	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
Rubel 2010	Adapted from the Control Preferences Scale	Postintervention	—	—	—	—	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
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)
Van Peperstraten 2010	Decision Evaluation scale (15 item questionnaire) Decision control subscale	Postconsultation	124	85	128	87.5	P = 0.33

DA: decision aid; **SD**: standard deviation.

Table 10. Proportion undecided

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Kasper 2008	Single item - ranging from '0 = completely undecided' to '100 = made my decision'	—	—	—	—	—	No difference
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 11. Satisfaction with the choice

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Heller 2008	1-item; pleased with treatment choice	1 month post-surgery	62/66	—	55/67	—	P = 0.03
Legare 2012 (in consult)	Single question Likert scale to assess the quality of the decision made (0 = very low quality; 10 = very high quality)	Immediately post	162	8.54 (SD 1.56)	159	8.53 (SD 1.51)	No difference; MD 0.0 (95% CI −0.4 to 0.4)
Leighl 2011	Satisfaction with decision scale: median (range)	1 month postintervention	107	22 (13-25)	100	21(15-25)	No difference

Table 11. Satisfaction with the choice *(Continued)*

Marteau 2010	Scale: ranging from 1−7 and standardized out 100	4 weeks	—	91.17 (SD 14)	—	91.33 (SD 14.50)	No difference
Schwartz 2009b	6-item	1, 6, 12 months	100	—	114	—	Overall, no difference between groups; decision aid led to significantly increased satisfaction compared to usual care among those who were undecided at randomization but not among those who had made a decision before randomization; (only graph in paper with no raw data)
Taylor 2006	Single item - "Are you satisfied with your decision about prostate cancer testing?	1 month	80	79.7%	74	75.7%	—
Trevena 2008	Satisfaction with the decision	Immediately post	134	—	137	—	No difference (P = 0.56)
Williams 2013	6-item Satisfaction with Decision Scale	Baseline	—	> 95%	—	> 95%	—

DA: decision aid.

Table 12. Satisfaction with the decision-making process

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Satisfaction with the decision-making process							
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)
Vodermaier 2009	Satisfied with process	1 week follow-up	53	42	56	50	High satisfaction with no difference by group

Table 12. 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							
LeBlanc 2015 (in consult)	Amount of information was just right	Postconsultation	29	25 (86%)	37	34 (92%)	P = 0.69
	Information received was clear	Postconsultation	27	17 (63%)	36	26 (72%)	P = 0.43
	Information received was helpful	Postconsultation	28	21 (75%)	34	23 (68%)	P = 0.53
	Would recommend method to others	Postconsultation	28	24 (86%)	35	27 (77%)	P = 0.52
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
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	Postintervention	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	Postintervention	39	5.8 6.1	33	5.2 4.9	P = 0.006 P < 0.001

Table 12. Satisfaction with the decision-making process *(Continued)*

	• Would want other decisions • Recommend to others			5.9		4.8	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
Satisfaction with the clinician							
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
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

DA: decision aid; **SD**: standard deviation.

Table 13. Preparation for decision making

Study	Scale used	Timing	N decisionaid	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
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'	Postintervention; pre-consultation	66	4.12 (SD 1.21)	64	3.78 (SD 1.25)	No difference
	Preparation for Decision Making Scale item	Postintervention; pre-consultation	66	4.48 (SD 0.85)	64	4.14 (SD 1.10)	No difference

Table 13. Preparation for decision making *(Continued)*

	'Help know decision depends on what matters most'						
	Preparation for Decision Making Scale item 'Help think about how involved you want to be in decision'	Postintervention; pre-consultation	66	4.48 (SD 0.81)	64	4.25 (SD 1.05)	No difference
	Preparation for Decision Making Scale item 'Prepare you to talk to your doctor about what matters most'	Postintervention; pre-consultation	66	4.36 (SD 0.91)	64	4.23 (SD 1.04)	No difference
Vandemheen 2009	Preparation for Decision Making Scale	3 weeks	70	65.1 (SD 24.9)	79	53.9 (SD 27.1)	P = 0.009

DA: decision aid; **SD:** standard deviation.

Table 14. Choice

Study	Type of comparison	N decision-aid	Decision aid - mean	N comparison	Comparison - mean	Notes
Surgery - elective more minor surgery						
Hanson 2011	Actual choice (feeding tube)	127	1	129	3	No difference
Wong 2006	Actual choice (abortion)	—	—	—	—	No difference
Screening - breast cancer genetic testing						
Miller 2005	Preference	—	—	—	—	Intervention decreased intention for genetic testing in women at average risk; increased in women at high risk
Screening - breast screening						
Mathieu 2007	Actual choice	—	—	—	—	No difference in women who participated in screening within 1 month
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 - diabetes						
Marteau 2010	Actual choice	633	353	639	368	P = 0.51
Mann E 2010	Preference	273	—	134	—	No difference
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).
Lepore 2012	Actual choice 2 years postintervention	215	62.7%	216	66.7%	No difference Exp (B) = 0.829

Table 14. Choice *(Continued)*

						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 - 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
Thomson 2007 (in consult)	Actual choice	—	93.8%	—	25%	RR 0.27 (95% CI 0.11 to 0.63)
Medication - breast cancer prevention						
Fagerlin 2011	Actual choice	383	0.5%	102	0%	No difference
Medication - cardiovascular disease prevention						
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

Table 14. Choice *(Continued)*

	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
Whelan 2003 (in consult)	For early breast cancer	—	—	—	—	No difference
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	29	12 (41%)	38	11 (29%)	P = 0.57
	Prescription during encounter	29	13 (41%)	38	12 (27%)	P = 0.2
Montori 2011 (in consult)	Uptake	52	44%	48	40%	No difference
Mental health treatment						
Hamann 2006	Uptake prescribed medication	—	—	—	—	No difference
Hamann 2006	Uptake psychoeducation	—	—	—	—	Higher uptake in DA group (P = 0.003)

Table 14. Choice *(Continued)*

Mott 2014	Uptake of 9 psychoeducation sessions	9	44%	11	9%	All 4 decision aid participants received 9 or more sessions. 1 of 5 usual care received 9 or more sessions.
Obstetrics - birth control method						
Langston 2010	Preference	114	—	108	—	No difference in the methods chosen between groups, participants in the intervention group were not more likely to initiate the requested method immediately compared to those in the usual care group (OR 0.65, 95% CI 0.31 to 1.34)
Obstetric - childbirth procedure						
Montgomery 2007	Uptake	—	—	—	—	No difference
Nassar 2007	Uptake	—	—	—	—	No difference
Shorten 2005	preference	—	—	—	—	No difference
Obstetric - embryo transplant						
Van Peperstraten 2010 - single embryo transfer	Uptake	152	43%	156	32%	P = 0.05
Other- lung transplant referral						
Vandemheen 2009		—	—	—	—	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						

Table 14. Choice *(Continued)*

Chambers 2012	Uptake flu shot	48	46%	59	27%	No difference
Clancy 1988	Uptake hepatitis B	—	—	—	—	Significant increase of 76% in the DA group
Shourie 2013	Measles, mumps, rubella in infant	48	48 (100%)	71	70 (99%)	No difference

CHD: congenital heart disease;**DA**: decision aid; **OR**: odds ratio; **RR**: risk ratio.

Table 15. Adherence with chosen option

Reference	Scale used	N decision aid	Mean (SD) Decision aid	N comparison	Mean (SD) Comparison	Notes
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
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

Table 15. Adherence with chosen option *(Continued)*

						choice. 95% CI 0.69 to 1.42
Loh 2007 (in consult)	6-8 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
	6-8 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 (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviours 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 (7 yes/no items and 1 item with 5-point Likert scale to elicit behaviours 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 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%	PtDA higher aderence to baseline choice P = 0.041
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 to 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%	No difference in adherence to baseline choice P = 0.009

Table 15. Adherence with chosen option *(Continued)*

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)
Oakley 2006	4 months - extent to which the participants' behaviour 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
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

Table 15. Adherence with chosen option *(Continued)*

Trevena 2008	1 month - faecal 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 On adherence to statin use: missed 1 dose or more within the last week	33	93.94%	29	79.31%	No difference in adherence to baseline choice or treatment when analysis adjusted by sex, cardiovascular disease, and number of medications

AMD: absolute mean difference; DA: decision aid; OR: odds ratio

Table 16. General quality of life

Reference	Timing	N decision aid	Mean Decision aid (SD)	Change from baseline	N comparison	Mean comparison (SD)	Change from Baseline	Notes
General health								
Barry 1997 (SF-36)	Baseline	104	67.2 (19.0)	—	123	71.1 (17.6)	—	P = 0.02
	3 months	—	—	−0.96 (1.41)	—	—	−3.59 (1.57)	
	6 months	—	—	−1.46 (1.41)	—	—	−4.93 (1.45)	
	12 months	—	—	0.61 (1.58)	—	—	−4.99 (1.44)	
Legare 2011 (percentage of people who felt they had a stable and better health, (SF-12))	2 weeks post	Not reported	94	+7	Not reported	85	−6	P = 0.08
Morgan 2000 (SF-36)	6 months post	72	62 (23)	+ 4.0	88	65 (20)	+ 7.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	2.2	159	—	2.8	No difference
Physical function								
Barry 1997 (SF-36)	Baseline	104	81.9 (20.0)	—	123	83.0 (18.9)	—	P = 0.02
	3 months	—	—	−0.34 (1.61)	—	—	−1.81 (1.07)	
	6 months	—	—	0.10 (1.28)	—	—	−3.26 (1.37)	
	12 months	—	—	0.15 (1.40)	—	—	−3.74 (1.18)	
Knops 2014 (SF-12)	Baseline	91	45	—	87	44	—	—
	1 month	80	44	—	84	43	—	—
	4 months	80	43	—	84	43	—	—
	10 months	80	44	—	84	42	—	—

Table 16. General quality of life *(Continued)*

Legare 2012 (SF-12)	2 weeks post	160	49.4 (SD 7.5)	+ 0.08	162	48.16 (7.80)	+ 0.43	Absolute difference 1.2; MD 0.4 (95% CI −2.6 to 3.3)
Morgan 2000 (SF-36)	6 months post	72	67 (29)	+ 7.0	88	71 (24)	+ 10.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	2.4	159	—	2.2	No difference
Bernstein 1998 (SF-12)	3 months post	61	38 (12.1)	+ 0.6	48	37.6 (10.6)	+ 3.8	No difference
Social function								
Barry 1997 (SF-36)	Baseline	104	90.6 (15.5)		123	91.7 (15.7)		P = 0.17
	3 months	—	—	0.34 (1.58)	—	—	−2.26 (1.36)	
	6 months	—	—	−0.05 (1.92)	—	—	−2.46 (1.45)	
	12 months	—	—	−1.46 (1.85)	—	—	−3.52 (1.71)	
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	84.7	—	71	82.1	—	P = 0.39
Vuorma 2003 (RAND-36)	1 year	156	—	5.2	159	—	7.1	No difference
Mental function								
Legare 2012 (SF-12)	2 weeks post	160	50.79 (SD 9.28)	−0.38	162	51.21 (8.36)	+ 2.7	Absolute difference 0.4; MD −1.9 (95% CI −4.9 to 1.1)
McCaffery 2010 (SF-36)	2 weeks	77	71.3	—	71	71.6	—	P = 0.46
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
Vuorma 2003 (RAND-36)	1 year	156	—	4.7	159	—	5.3	No difference
Bernstein 1998 (SF-12)	3 months post	61	49.1 (11.4)	0.0	48	48.9 (10.8)	+ 0.9	No difference

Table 16. General quality of life *(Continued)*

Role function								
Morgan 2000 (SF-36)	6 months post	72	62 (44)	+ 20.0	88	58 (43)	+ 15.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	P = 0.04
Vuorma 2003 (RAND-36)	1 year		—	9.2	—	—	6.3	No difference
Bodily pain								
Morgan 2000 (SF-36)	6 months post	72	81 (22)	+ 6.0	88	77 (24)	+ 5.0	No difference
Kennedy 2002 (SF-36)	2 years	176	—		157	—		No difference
Vuorma 2003 (RAND-36)	1 year	156	—	6.5	159	—	6.2	No difference
Role emotional								
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	80.3	—	71	77.4	—	P = 0.61
Vuorma 2003 (RAND-36)	1 year	156	—	12.6	159	—	1.9	P = 0.01
Energy/vitality								
Kennedy 2002 (SF-36)	2 years	176	—	—	157	—	—	No difference
McCaffery 2010 (SF-36)	2 weeks	77	55.2	—	71	54.1	—	P = 0.09
Vuorma 2003 (RAND-36)	1 year	156	—	8.9	159	—	8.8	No difference
SF-3***6 all dimensions***								
McCaffery 2010 (SF-36)	2 weeks	77	47	—	71	46.3	—	P = 0.35
Murray 2001b (SF-36)	9 months	93	—	—	94	—	—	No difference
Murray 2001a (SP−36)	9 months	54	—	—	48	—	—	No difference
Health utilities								

Table 16. General quality of life *(Continued)*

Murray 2001a (Euroqol EQ-5D)	—	—	—	—	—	—	—	No difference
Murray 2001b (Euroqol EQ-5D)	—	—	—	—	—	—	—	No difference
Euroqol 5D - Health Thermometer (scale of 0 to 100)								
LeBlanc 2015	Postconsultation	29	85 (IQR 80, 95)	—	85 (IQR 73, 90)	—	—	P = 0.19

DA: decision aid; SF-36: Medical Outcomes Study 36-item Short-Form Health Survey; SF-12: 12-item Short-Form Health Survey; RAND-36: the 36-item short form survey from the RAND Medical Outcomes Study

Table 17. Condition-specific quality of life

Study	Outcome	Scale used	Timing	N decision aid	Decision aid mean change (SD)	N comparison	Comparison mean change (SD)	Notes
Barry 1997	Urinary symptoms	AUA Symptom Index (0 to 100)	3 months	104	−4.80% (1.74)	117	−1.40% (1.37)	No difference; trend toward DA
	Urinary symptoms	AUA	6 months	104	−3.66% (2.06)	117	−3.17% (1.77)	No difference
	Urinary symptoms	AUA	12 months	104	−2.51% (2.11)	117	−4.14% (1.66)	No difference; trend toward control
	Impact of symptoms	BPH Impact Index (0 to 100)	3 months	104	−6.58% (1.10)	117	−3.00% (1.05)	No difference; trend toward DA
	Impact of symptoms	BPH	6 months	104	−4.37% (1.32)	117	−3.89% (1.16)	No difference; trend toward DA
	Impact of symptoms	BPH	12 months	104	−5.53% (1.32)	117	−2.63% (1.32)	No difference; trend toward DA
Bernstein 1998	Satisfaction	SAQ (0 to 100)	3 months	61	+ 6.2%	48	+ 10.5%	Control significantly more satisfied

Table 17. Condition-specific quality of life *(Continued)*

	Angina stability	SAQ	3 months	61	+ 17.2%	48	+ 28.3%	No difference
	Angina frequency	SAQ	3 months	61	+ 5.5%	48	+ 15.3%	No difference
	Disease Perception	SAQ	3 months	61	+ 14.1%	48	+ 18.8%	No difference
	Physical Capacity	SAQ	3 months	61	−0.5%	48	+ 7.1%	No difference
Leighl 2011 (FACT-G) median (range)	Functional status at 1 month post	74	17 (6-28)	—	68	17.5 (7-28)	—	P = 0.02
	Physical function at 1 month post	74	21 (0-28)	—	68	20 (4-28)	—	No difference
	Role emotional at 1 month post	74	17 (0-20)	—	68	17(7-20)	—	No difference
Murray 2001a	Urinary symptoms	AUA symptom Index (0 to100)	—	—	—	—	—	No difference
Murray 2001b	Menopausal symptoms	MenQol	—	—	—	—	—	No difference
Protheroe 2007	Menorrhagia specific utility scale	(0 to 100)	6 months	60	59.3 (30.0)	56	50.9 (25.1)	P = 0.03 higher menorrhagia quality of life favouring DA group
Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference

AUA: American Urological Association; **BPH**: benign prostatic hyperplasia; **DA**: decision aid; **SAQ**: Seattle Angina Questionnaire; **FACT-G**: Functional Assessment of Cancer Therapy-General.

Table 18. Other condition-specific health outcomes

Study	Outcome	Scale used	Timing	N decision aid	Decision aid outcome	N comparison	Comparison outcome	Notes

Table 18. Other condition-specific health outcomes *(Continued)*

Auvinen 2004	Death	—	5 years	104	41 (39%)	106	33 (31%)	No difference
	Disease-free survival	—	10 years	104	74 (70.8%)	106	66 (62.5%)	P = 0.14
	Biochemical failure (rising serum PSA)	—	5 years	100	42 (42%)	96	34 (35%)	P = 0.57
	Disease progression	—	5 years	97	31 (32%)	92	28 (30%)	P = 0.94
Knops 2014	Postoperative mortality	—	10 months	91	0 (0%)	87	0 (0%)	
	Postoperative major morbidity	—	10 months	91	0 (0%)	87	2 (6%)	P = .23
	Aneurysm rupture during watchful waiting	—	10 months	91	0 (0%)	87	3 (8%)	P = 0.12
Mathers 2012	HbA1c (change from baseline)	—	6 months	95	−0.37%	80	−0.24%	P = 0.12
Morgan 2000	No angina	CCVA	6 months	72	+ 49%	88	+ 48%	No difference
	Class I angina	CCVA	6 months	72	−1%	88	+ 6%	No difference
	Class II angina	CCVA	6 months	72	−23%	88	−26%	No difference
	Class III angina	CCVA	6 months	72	−26%	88	−28%	No difference
	Class IV angina	CCVA	6 months	72	0%	88	0%	No difference
Thomson 2007	Strokes or bleeds requiring admission	—	3 months	51	—	55	—	No strokes and no bleeds requiring admission. 1 bleed and 1 transient stroke both in control group that required GP consultation
Van Peperstraten 2010	Ongoing pregnancies (> 12 weeks gestation)	—	After 1st IVF cycle	152	—	156	—	32% of participants in the intervention group and 38% of participants in the control group had ongoing pregnancies, P = 0.25

Table 18. Other condition-specific health outcomes *(Continued)*

	Twin pregnancies (> 12 weeks gestation)	—	After 1st IVF cycle	152	—	156	—	4% of participants in intervention group and 6% of participants in control group had twin pregnancies, P = 0.33
Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference

AUA: American Urological Association; **CCVA**: Canadian Cardiovascular Angina; **BPH**: benign prostatic hyperplasia; **DA**: decision aid; **SAQ**: Seattle Angina Questionnaire.

Table 19. Anxiety

Study	Timing	N decision aid	Mean decision aid (SD)	Change from baseline	N comparison	Mean comparison(SD)	Change from baseline	Notes
State Anxiety Inventory: < 30 days postintervention (standardized scores)								
Bekker 2004; prenatal screening	Immediately post	50	58.9 (16.6)	—	56	61.2 (13.7)	—	No difference
Evans 2010; PSA screening	Immediately post-DA	89	4.98	—	103	4.88	—	No difference P = 0.98
Fraenkel 2012; atrial fibrillation	Immediately post-DA	69	13.0	—	66	13.4	—	No difference P =0.48
Leighl 2011	Post consult, 1-2 weeks and 4 weeks post	—	—	—	—	—	—	No difference
Mathieu 2007; mammography screening	Immediately after	321	29.61	—	315	29.34	—	No difference
McCaffery 2010; HPV screening (state trait anxiety inventory)	2 weeks	77	10.5	—	71	10.6	—	No difference P = 0.25

Table 19. Anxiety *(Continued)*

Montgomery 2003; hypertension	Immediately post-DA	44	35.45 (10.52)	—	50	37.67 (13.92)	—	No difference
Montgomery 2007; previous cesarean section	37 weeks gestation	196	38.7 (12.2)	—	195	42.1 (12.2)	—	P = 0.016
Nassar 2007; breech presentation	1 week	98	41.4 (12.5)	—	90	44.4 (13.9)	—	No difference
Protheroe 2007; menorrhagia	2 weeks	59	11.6 (3.7)	—	61	12.2 (3.7)	—	P = 0.016
Rubel 2010; PSA screening	Immediately after 20 items adapted from state portion of State-Trait Anxiety Inventory Scale STAI - Form Y;	—	—	—	—	—	—	No difference Mean score = 1.66 (SD 0.59) (N = 200) for both groups
Smith 2010; bowel cancer screening	2-week follow-up	357	13.67	—	173	14.05	—	No difference P = 0.80
Thomson 2007; anti-thrombotic treatment for atrial fibrillation	Immediately after	53	—	—	56	—	—	Significant fall in anxiety (−4.57) but no difference between groups (P = 0.98)
Trevena 2008 colorectal cancer screening	Immediately after	134	—	—	137	—	—	No difference (P = 0.59)
Van Peperstraten 2010; number of embryos transferred	Immediately after	152	27.33%	—	156	24.5%	—	No difference P = 0.14
Whelan 2004; breast cancer surgery	7 days post-DA	94	42.3 (1.3)	—	107	41.9 (1.3)	—	No difference
Whelan 2003; breast chemotherapy	7 days post-DA	82	45.6	+ 2.2	93	47.4	+ 0.8	No difference

Table 19. Anxiety *(Continued)*

Wong 2006; pregnancy termination	Immediately post	154	54 (15.8)	—	159	54 (16.1)	—	No difference
State Anxiety Inventory: 1 month postintervention (standardized scores)								
Bekker 2004; prenatal screening	1 month post-DA	29	35.3 (12.5)	—	39	34.7 (14.8)	—	No difference
Davison 1997; prostate cancer treatment	5-6 weeks post-DA	30	35.5	−9.0	30	34.5	−2.5	No difference
State Anxiety Inventory: 3 months postintervention (standardized scores)								
Murray 2001a; benign prostatic hypertrophy	3 months post-DA	55	36.36 (14.99)	+2.4	48	32.08 (9.836)	+0.7	No difference
Murray 2001b; hormone replacement therapy	3 months post-DA	93	38.42 (10.83)	−0.5	95	40.53 (12.96)	+1.8	No difference
Nagle 2008; prenatal screening	˜1 to 12 weeks post-DA	167	37.2 (12.1)	—	171	37.36 (12.6)	—	No difference
Nassar 2007; breech presentation	3 months post-DA	86	29.2 (9.9)	—	84	30.8 (10.5)	—	No difference
Vuorma 2003; menorrhagia treatment	3 months post-DA	184	37.1	+1.0	179	35.9	−1.0	No difference
Whelan 2003; breast chemotherapy	3 months post-DA	82	36.0	—	93	37.8	—	No difference
State Anxiety Inventory: 6 months postintervention (standardized scores)								
Lepore 2012; prostate screening	8 months post-DA	215	9.6 (10.3)	—	216	10.3 (10.2)	—	No difference No condition by time interaction on anxiety. Low in both groups.
Protheroe 2007; menorrhagia	6 months post-DA	47	11.2 (4.2)	—	52	13.3 (4.9)	—	No difference P = 0.067

Table 19. Anxiety *(Continued)*

Whelan 2004; breast cancer surgery	6 months post-DA	94	39.3 (1.3)	—	107	38.9 (1.6)	—	No difference
Whelan 2003; breast chemotherapy	6 months post-DA	82	38.2	—	93	38.2	—	No difference
State Anxiety Inventory: 12 months postintervention (standardized scores)								
Whelan 2004; breast cancer surgery	12 months post-DA	94	37.5 (1.4)	—	107	36.6 (1.5)	—	No difference
Whelan 2003; breast chemotherapy	12 months post-DA	82	39.2	—	93	40.2	—	No difference
Anxiety subscale of the Hospital Anxiety and Depression Scale (HADS)								
Knops 2014; asymptomatic abdominal aortic aneurysm	1 month post-DA - (HADS standardized)	81	21.0 (17.1)	—	85	23.8 (19.1)	—	No difference P = 0.73
	4 months post-DA (HADS)	81	20.0 (19.1)	—	85	21.9 (17.6)	—	—
	10 months post-DA (HADS)	81	20.5 (20.0)	—	85	21.4 (20.5)	—	—
Lam 2013; breast cancer surgery	1 week post-DA Hospital Anxiety and Depression Scale (HADS standardized	101	25.2 (22.4)	—	97	24.8 (23.3)	—	No difference P = 0.655
	1 month postsurgery	101	11.9 (15.2)	—	97	12.4 (15.7)	—	No difference P = 0.859
	4 months postsurgery	91	10.5 (15.2)	—	88	10.0 (14.8)	—	No difference P = 0.908
	10 months postsurgery	88	12.9 (16.8)	—	90	13.3 (17.1)	—	No difference P = 0.553
Other measures indicating anxiety								
Chabrera 2015; prostate cancer	Seeking and using social support	61	22.3 (5.20)	+ 7.8	61	16.2 (5.44)	+ 1.8	P < 0.001

Table 19. Anxiety *(Continued)*

	Focusing on the positive	61	15.1 (6.93)	+ 0.3	61	16.2 (9.47)	+ 0.9	P < 0.001
	Behavioural escape-avoidance	61	23.7 (5.53)	+ 4.5	61	22.0 (4.22)	+ 1.2	P < 0.001
	Cognitive escape avoidance	61	11.7 (5.37)	+ 4.47	61	10.5 (4.65)	+ 1.84	P < 0.001
	Distancing	61	8.75 (3.90)	+ 1.85	61	8.54 (4.28)	+ 0.47	P < 0.001
Fraenkel 2012; atrial fibrillation	Worry about having a stroke over next 5 years (10 point scale - lower scores=less worry)	69	1.8 (SD 1.7)	—	66	1.6 (SD 1.6)	—	P = 0.47
	Worry about having a bleed over next 5 years (10 point scale - lower scores = less worry)	69	1.5 (SD 3.3)	—	66	1.9 (SD 3.2)	—	P = 0.24
Johnson 2006; endodontic treatment	Immediately post - single question 7-point Likert scale	32	3.2 (1.7)	—	35	3.8 (2.1)	—	P = 0.27
Lewis 2010; colorectal cancer screening	Intrusive thoughts - 3 items; 4 point scale - not at all	139	66.2%	—	157	68.0%	—	P = 0.92
	Intrusive thoughts - 3 items; 4 point scale - sometimes	66	31.4%	—	69	29.9%	—	
	intrusive thoughts - 3 items; 4 point scale - often	5	2.4%	—	5	2.2%	—	
McCaffery 2010	Intrusive thoughts - measured using 1 item from the impact of events scale	77	43%	—	71	32%	—	No difference
Smith 2010	Worry about developing bowel cancer - quite or very	357	6%	—	173	8%	—	P = 0.78

Table 19. Anxiety *(Continued)*

	Worry about developing bowel cancer - none or a bit	357	94%	—	173	92%	—

DA: decision aid; **HPV**: human papilloma virus; **PSA**: prostate-specific antigen.

Table 20. Depression

Study	Timing	N decision aid	Mean decision aid (SD)	Change from baseline	N comparison	Mean comparison (SD)	Change from Baseline	Notes
Davison 1997 (20-item CES-D)	5-6 weeks	30	29.8	−0.6	30	29.5	+ 1.3	No difference
Lam 2013 (Hospital and Anxiety Depression Scale)	1 week post-DA	101	16.7 (17.1)	—	97	16.7 (19.5)	—	No difference P = 0.849
	1 month postsurgery	101	11.0 (12.9)	—	97	11.0 (12.9)	—	No difference P = 0.649
	4 months post-surgery	91	10.0 (15.7)	—	88	9.0 (11.4)	—	No difference P = 0.637
	10 months post-surgery	88	6.7 (9.0)	—	90	11.9 (16.2)	—	P = 0.001
Loh 2007 (Brief Patient Health Questionnaire-D)	6 to 8 weeks	191	29.8 (2.7)	—	96	27.0 (3.6)	—	No difference P = 0.236
Nagle 2008 (Edinburgh Postnatal Depression Scale)	˜1-12 weeks post-DA	167	19 (11.6)	—	171	19 (11.2)	—	No difference
Van Peperstraten 2010 (Beck Depression Inventory)	After multifaceted intervention/ before IVF	126	16 (13%)	—	136	5 (4%)	—	P = 0.01
	At uptake of IVF	147	16 (11%)	—	151	113 (9%)	—	No difference

Table 20. Depression *(Continued)*

Whelan 2004 (20-item CES-D)	1 week post-DA	94	13.8 (1.0)	—	107	13.4 (1.1)	—	No difference
	6 months post-DA	94	15.1 (1.1)	—	107	14.2 (1.2)	—	No difference
	12 months post-DA	94	13.2 (1.3)	—	107	12.8 (1.2)	—	No difference

CES-D: Centre for Epidemiology Studies Depresion Scale; **DA**: decision aid; **IVF**: in vitro fertilization.

Table 21. Decisional regret

Author	Item	N decision aid	Proportion or mean (SD)	N control	Proportion or mean (SD)	Notes
Brazell 2014	Decision Regret Scale at 3 months postchoice	28	12.1 (18.5)	26	10 (20.1)	No difference P = 0.969
Hanson 2011	5-item Decisional Regret Index	126	11.9	127	14.3	No difference P = 0.14
Kupper-mann 2014	Decision Regret Scale (out of 100) at 3-6 months postintervention	357	8.29 (12.5)	353	6.83(10.8)	No difference P = 0.12; 95% CI 1.46 (−0.36 to 3.29)
Lam 2013	Decision Regret Scale at 1 month postsurgery	101	21.4 (17.2)	97	23.1 (18.3)	No difference Adjusted P = 1.0
	Decision Regret Scale at 4 months postsurgery	91	18.8 (15.8)	88	24.4 (18.9)	P = 0.026
	Decision Regret Scale at 10 months postsurgery	88	20.1 (14.5)	90	24.6 (18.8)	P = 0.014
Legare 2011	Proportion of patients with decisional regret	—	7%	—	9%	No difference P = 0.91
Legare 2012	Decision Regret Scale 2 weeks postconsultation	162	12.38(19.08)	164	7.59 (13.67)	No clinically significant difference; Absolute difference 4.8; MD 4.8 (95% CI 0.9 to 8.7)
Mathers 2012	Decision Regret Scale at 6 months postintervention	95	44.63	80	44.57	No difference P = 0.872

DA: decision aid.

Table 22. Confidence

Study	Scale used	Timing	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Notes
Allen 2010	11-item self-efficacy scale	Postintervention	291	83% (SD 40.26)	334	79% (SD 33.08)	No difference
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
Chambers 2012	Mean confidence with decision: scale from 1 (low confidence) to 5 (high confidence)	Postintervention	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
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
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
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

CI: confidence interval; **DA**: decision aid; **SD**: standard deviation.

Table 23. Healthcare system effects

Study	Scale used	N decisionaid	Decision aid - mean	N comparison	Comparison - mean	Difference between groups	Notes
Consultation length							
Bekker 2004 (in consultation)	Consultation length using DA 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)
Bozic 2013	Consultation length with practitioner post-DA (minutes)	61	20.9 (SD 6.8)	62	21.0 (SD 7.2)	−0.1 minutes	No difference; P = 0.91
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)	—
Loh 2007 (in consultation)	Consultation length using DA in consultation (minutes)	191	29.2 (10.7)	96	26.7 (12.5)	+2.5 minutes	P = 0.681
Ozanne 2007 (in consultation)	Consultation length using DA in consultation (minutes)	15	24	15	21	+3 minutes	P = 0.42
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 23. 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 and resource use							
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 23. 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
Van Peperstraten 2010	Mean total savings per couple in the Netherlands for decision about embryo transfer for invitro fertilization	—	—	—	—	—	Mean total saving per couple in the intervention group were EUR 169.75 (USD 219.12)
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
Resource use							
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)
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
Wait time from screening of eligibility to decision							
Stacey 2014a	Wait time in weeks	69	33.4 weeks	71	33 weeks	—	No difference

CI: confidence interval; **DA**: decision aid; **RR**: risk ratio; **SD**: standard deviation.

Table 24. Subanalysis using higher quality trials

Outcome	Overall mean effect (95% CI), 105 total studies	Without trials having high risk of bias on at least 1 of 7 criteria (N = 16)
Knowledge	13.27 (95% CI 11.32 to 15.25) 52 studies	13.43 (95% CI 11.37 to 15.49) 47 studies
Accurate risk perceptions - with probabilities versus no probabilities	2.10 (95% CI 1.66 to 2.66) 17 studies	2.02 (95% CI 1.57 to 2.59) 15 studies
Values congruent with chosen option	2.06 (95% CI 1.46 to 2.91) 10 studies	2.06 (95% CI 1.46 to 2.91) 10 studies
Uninformed subscale of Decisional Conflict Scale	−9.28 (95% CI −12.20 to −6.36) 27 studies	−9.96 (95% CI −13.13 to −6.78) 25 studies
Unclear values subscale of Decisional Conflict Scale	-8.81 (95% Ci −11.99 to −5.63) 23 studies	−9.55 (95% CI −13.08 to −6.02) 21 studies

CI: confidence interval.

Table 25. 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 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
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

(Continued)

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 2. 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
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-congruence choices and the sub-analysis indicated improved knowledge and accurate risk perceptions when decision aids are used either within or in preparation for the consultation.

HISTORY

Protocol first published: Issue 1, 1999
Review first published: Issue 3, 2001

Date	Event	Description
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 compared 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 coordinate this update.

Date	Event	Description
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 on 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 on 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 mislabelled 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 on 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 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 7 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 ex-

Date	Event	Description
		tent 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 measure 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 1 large scale trial that evaluated a suite of 8 decision aids in a number of health services. • There are an additional 6 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. • There continues 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 coordinated 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 coordinated 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 coordinated 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, DR, contributed to the interpretation of results, and the revision and final approval of the paper.
AO led the team and CB coordinated the update.
CB, SK, DS, AO, 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 coordinated 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 coordinating 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.

2016 (current) Review:

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 coordinating 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.

DECLARATIONS OF INTEREST

Several of the investigators have developed patient decision aids (DS, FL, HL, MHR, MB, KE, RT, LT, KL), but none reviewed their own studies.

Within the last five years, two investigators (HL, MB) have received financial support from the not-for-profit Informed Medical Decisions Foundation (IMDF). MB serves on the Board of and received salary and grant support as President of the Foundation. In 2014, the Foundation merged with another not-for-profit, Healthwise. MB continues to receive salary and grant support as Chief Science Officer at Healthwise. Healthwise develops, licenses, and distributes patient decision aids. Several investigators (DS, FL, HL, MHR, MB, KE, RT, LT) who were involved in a special issue in *BMC Medical Informatics and Decision Making* that included a series of 14 papers focused on the theoretical and empirical evidence underlying the International Patient Decision Aid Standards (IPDAS), received partial funding from the Foundation to cover publishing costs.

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Internal sources

- University of Ottawa, Canada.

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- Ottawa Hospital Research Institute, Canada.

Scientific Director, Patient Decision Aids Research Group

External sources

- No sources of support supplied

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' assessment (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 for the main comparison.

For the 2016 (current) update, we removed 28 studies that compared detailed versus simple decision aids. This update is limited to comparisons of patient decision aids versus usual care to provide a more focused review. This change resulted in removal of these comparisons for pooled results including knowledge scores, decisional conflict, perceived participation in decision making, proportion undecided, choice, and satisfaction. For other outcomes including congruence between chosen option-values and accurate risk perception, the new pooled comparisons only focus on patient decision aid versus usual care, rather than previous comparisons that reported on patient decision aids with explicit values clarification and probabilities of outcomes versus any comparisons without these features.

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Support Techniques; *Health Knowledge, Attitudes, Practice; *Patient Participation; Communication; Conservative Treatment; Elective Surgical Procedures; Patient Education as Topic [*methods]; Physician-Patient Relations; Publication Bias; Randomized Controlled Trials as Topic

MeSH check words

Humans