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Theory based analysis of the effects of decision aids for surgery in early breast cancer: a systematic review

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Abstract

Rationale, aims and objectives: Little is understood about *how* decision aids achieve their reported effects or their impact on the decision-making process. We aimed to evaluate the quality of decision aids for women choosing surgery for early breast cancer and to examine how their reported effects may reflect the contribution of components suggested by an extended Theory of Planned Behaviour (TPB) and the Common Sense Model of Illness Representations (CSM) to be required for good quality decision-making in this domain.
Method: We undertook a systematic review to examine the components of decision aids that influence decision-making processes for women choosing surgery for early breast cancer. The quality and theoretical underpinnings of the decision aids were appraised and reported outcomes meta-analysed.
Results: Ten decision aids were obtained; 4 had been evaluated in randomised trials. The quality of the decision aids was similar, with limited evidence of theoretical base. Data linking decision aid components, design, use and outcomes to judge the effects on the decision-making process were inconsistent. Two trials suggested evidence of a reduction in Decision Conflict scores (SMD = -0.35, 95% CI -0.57 to -0.12, p = 0.002). Improvements in knowledge (4 trials) and trends towards breast conservation surgery (3 trials) were not statistically significant.
Conclusions: A greater understanding of how decision aids impact on the decision-making process is needed if we are to design improved interventions that are effective on the core aspects of decision-making in this domain.

Keywords

Breast cancer, breast surgery, Common Sense Model of Illness Representations, decision aids, decision-making process, decision support interventions, person-centered medicine, systematic review, Theory of Planned Behaviour

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Introduction

Decision aids are interventions that support the health-related decision-making of patients, providing a personalized perspective on the available options and their related outcomes [1,2]. Decision aids are particularly useful in situations where the available options offer no superior clinical benefit over each other and patient preferences can guide decision-making (preference-

sensitive decisions) [3,4]. For example, women newly diagnosed with early invasive breast cancer (Stage I and II) can be offered the choice between mastectomy or breast conservation surgery with radiotherapy (BCS) as their primary surgical treatment [5]. Offering this choice is based on the following: equivalence in survival between the 2 options [5]; lack of definitive evidence of improved overall quality of life associated with either BCS or mastectomy [6]; evidence of superior body image [6], but higher loco-regional recurrence with BCS [7]. Many factors are reported to influence the surgery choices of women in this situation [8,9]. Furthermore, although it is generally assumed that women offered this choice would opt for the less extensive alternative (BCS), there is evidence that some make an informed decision to have a mastectomy [10]. Breast surgery decision aids exist for women facing this choice [2,11]; randomised controlled trials (RCTs) evaluating these decision aids report improvement in knowledge of treatment options, increased satisfaction with decision-making and lower scores on a 'decisional conflict' scale [11]. Women using these decision aids are also reported to be 20% more likely to choose BCS compared with those who do not [2,11]. However, little is understood about *how* the decision aids produce these effects [12,13].

The quality of preference-sensitive decisions cannot be inferred from the choice that is made, therefore other ways of assessing quality are needed [14]. Rather than evaluating the impact of decision aids on patient-based outcomes, it has been proposed that the process of decision-making ought to be considered [13], focusing attention on the "quality of the deliberative process and appraisal of the decision" [14]. Deliberation requires patients to realize and understand the decision to be made, along with the available options and their consequences, before they can consider their preferences [15]. Decision aids can facilitate this process by providing more than information alone [16]. We are not aware of any previous assessment made of the quality of breast cancer decision aids and their components and there is little understanding in general about which components facilitate the decision-making process [12].

A theoretical basis to intervention design would facilitate the evaluation of decision aids and improve our understanding of their effective components [17]. However, a recent review did not find evidence of an explicit theoretical basis to decision aids designed to support women facing surgery for early breast cancer [18]. A theoretical understanding of the factors underpinning women's surgery choices would help inform the design and development of decision aids [17,19]. Social cognition models focus on the determinants of behaviour and individuals' responses to illness and have been extensively applied to understanding health behaviours [20]. These models include the Theory of Planned Behaviour (TPB) [21,22] and the Common Sense Model of Illness Representations (CSM) [23] which are candidate theoretical frameworks for understanding women's surgery choices for breast cancer [19].

The TPB has been extensively used to predict and explain health behaviours, including whether to choose BCS or mastectomy for early invasive breast cancer [24]. The TPB proposes that behaviour (e.g., choosing BCS or mastectomy) is predicted by behavioural intentions, which are themselves predicted by *attitudes* towards the behaviour, *subjective norm* (how significant others expect one to behave) and *perceived control* over that behaviour (how easy or difficult it is to make the decision) [22]. Extended versions of the TPB have been proposed, incorporating additional constructs such as *anticipated regret* (the regret that one experiences after engaging in the behaviour), the inclusion of which has been found to provide better prediction of intentions [25].

The CSM examines the ways in which patients make sense of their condition and their perceptions of the treatments available to them, placing emphasis on emotional and coping responses in accounting for illness-related behaviour [23]. Rather than being a predictive model, the CSM provides a framework for understanding how cognitive representations of breast cancer influence the choice of mastectomy or BCS as part of a coping strategy. The CSM proposes that this occurs in 3 stages until the coping strategies adopted are perceived to have been successful, reaching a state of equilibrium: i) interpretation of the problem; ii) identification and development of action plan/coping strategies; iii) appraisal of coping strategies. According to the CSM, there are 5 key cognitive representations that patients form about their illness: *cause* (perceptions of causal factors of breast cancer); *identity* (symptoms of breast cancer and relation to treatment options); *timeline* (perceptions about the duration of breast cancer and the treatment options); *cure/controllability* (perceptions of treatment) and *consequences* (beliefs concerning the impact of breast cancer and/or treatment on quality of life or on functional capacity) [23]. The extended TPB and the CSM have the potential to contribute to the design of decision support in this context, by providing information about the factors that guide patients' choices [19,26].

We aimed to evaluate the quality of decision aids for women choosing surgery for early breast cancer and to examine how their reported effects may reflect the contribution of components that are suggested by the extended TPB and CSM as factors affecting decision-making in this domain. Our objectives were to: i) identify existing decision aids for women choosing surgery for early breast cancer; ii) appraise the quality of the decision aids and examine the theoretical basis of their development and evaluation; iii) identify the components of decision aids that facilitate decision-making in this context and map them onto the constructs of the extended TPB and CSM & iv) summarise the effects of the decision aids on outcomes related to the decision-making process and determine what effects their quality and components may have.

Methods

Search strategy

A dual approach of literature and Internet searches was undertaken to identify existing decision aids in this field and Randomized Controlled Trials (RCTs) evaluating the decision aids [27].

Literature Search

Five electronic databases (all EBM Reviews including Cochrane DSR, DARE, ACP Journal Club, CCTR; CINAHL; EMBASE; Ovid MEDLINE R; PsycINFO) were searched from 2006 to January 2012, with no language restrictions. Reference lists of relevant publications were also searched [2,11]. We did not search earlier than 2006 because existing reviews had searched up to 2006 [2,11]. The key search terms included breast cancer, surgery, mastectomy, breast conservation surgery, treatment choice, decision aid, decision support synonyms.

Internet Search

Google (including Google Directory) was searched for websites that reference decision aids or are themselves decision aids. Only Google was searched because other search engines are unlikely to reveal any additional sites [27]. Similar search terms to those used in the literature search (although not MESH terms) were used and saved for repeated searches [27]. We also searched the Ottawa A-Z Inventory of decision aids [28] and contacted known manufacturers/providers directly.

Inclusion Criteria

We used the following definition to distinguish decision aids from interventions concerned only with imparting information: "interventions designed to help people make specific and deliberative choices among options (including the status quo) by providing (at the minimum) information on the options and outcomes relevant to a person's health status" [2].

Only decision aids aiming to support women diagnosed with early invasive breast cancer (Stage I or II) in their choice between mastectomy and BCS were included.

Appraisal of the quality of decision aids

IPDASi evaluation

Decision aids were appraised according to the quality criteria specified by the International Patient Decision Aid Standards instrument (IPDASi) [29,30], which has been validated as a quality assessment tool rating 26 decision aids for a range of clinical contexts [31]. In our study each decision aid was independently evaluated by 2 IPDASi raters (SS and NJ-W). Analyses were based on 9 dimensions, together comprising 38 items: Information (8 items); Probabilities (8 items); Values (4 items); Guidance (2 items); Development (6 items); Evidence (5 items); Disclosure (2 items); Plain Language (1 item) and Evaluation (2 items).

Items were scored from 1 (strongly disagree) to 4 (strongly agree) and discrepancies in scoring were discussed until a consensus was reached. Using SPSS 16.0 [32], items pertaining to each dimension were averaged (where appropriate) and then scaled from 0 to 100 to produce a score for each dimension [29]. Global scores (0 to 100) were calculated as an average of the 9 dimension scores and therefore represent a weighted average of the 38 item scores. Summary statistics for each decision aid were calculated [30].

Theory evaluation

All papers pertaining to the development and evaluation of the decision aids were reviewed to determine the extent to which they had been informed by a specified theory or model. Authors (or developers) were also contacted.

Identification of the components to support decision-making

A new 'Theory Derivation' checklist was developed to identify the components of the decision aids that may support decision-making in this context, with reference to the extended TPB and CSM. The checklist was based on a review of the literature [19] and consists of 20 items addressing decision aid components that map onto the constructs of the extended TPB and CSM. (Supplement 1). Items in the checklist were scored from 1 (strongly disagree) to 4 (strongly agree) and discrepancies in scoring were discussed until a consensus was reached. Scores pertaining to the constructs of the extended TPB (Attitudes, Subjective Norms, Perceived Behavioural Control and Anticipated Regret) and CSM (Cause, Identity, Timeline, Cure/Controllability, Consequences) were derived using the same methods as the IPDASi Evaluation [30]. Global scores from 0 to 100 were calculated for the extended TPB and CSM; this represented a weighted average of 12 items for the extended TPB and 16 items for the CSM. Summary statistics for each decision aid were calculated [30].

Appraisal of RCTs

Two raters (SS, AE) independently assessed the risk of bias of RCTs evaluating the effectiveness of the decision aids [33]; disagreements were discussed until a consensus was reached.

Table 1 Details of evaluation studies of included decision aids

	Goel et al.[73]	Street et al.[74,75]	Whelan et al.[76]	Wilkins et al.[77]
	Making Decisions about the removal of my breast cancer: what do I prefer? [45]	Options for treating breast cancer [51]	Decision Board: Breast Cancer Surgery [52]	Early stage breast cancer: choosing your surgery [53]
Study Design	Cluster Randomized Trial	Randomized Trial	Cluster Randomized Trial	Prospective Controlled Trial
Study Population	Decision aid (n=86) *vs.* trifold pamphlet (n=50)	Interactive multimedia program (n=30) *vs.* 8 page brochure (n=30)	Decision Board (n=94) *vs.* control (n=107)	Educational video & verbal presentation (n=52) *vs.* written materials and verbal presentation (n=49)
Outcomes				
Treatment choice / decision		Majority of patients in both groups chose breast conservation surgery; greater proportion of patients in multimedia group than brochure group chose breast conservation surgery; not statistically significant	Intervention group more likely to choose breast conservation surgery (p=0.03)	25% Intervention *vs.* 14% Controls chose mastectomy (not statistically significant)
Satisfaction with decision	No between group differences			No significant intervention effects
How strongly preferred decision	Those indicating preference for lumpectomy did not benefit from use of the decision aid	Intervention group more likely to strongly prefer the treatment chosen (p=0.05)	Intervention group more likely to strongly prefer the treatment chosen (p=0.05)	
Decisional Regret	No between group differences			
Perceived Choice		Intervention group more likely to perceive that they were offered a clear choice of treatment by their surgeons (p=0.05)	Intervention group more likely to perceive that they were offered a clear choice of treatment by their surgeons (p=0.05)	

Outcome				
Decisional Conflict		Intervention group had less decisional conflict than control group (p=0.02)		No statistically significant differences between groups but a trend for lower decisional conflict in Intervention group
Satisfaction with decision-making		Intervention group were more satisfied with decision-making (p=0.05). No between group differences at 6 and 12 months post surgery		
Knowledge	No significant intervention effects	Intervention group had higher knowledge scores than the control group (p<0.001)	Patients tended to learn more about breast cancer after using the multimedia program than reading the brochure. No between group differences at Time 2	Scores consistent with respondents who make decisions after being informed
Anxiety	No significant intervention effects	No between group differences; anxiety was high just after consultation but decreased 6 and 12 months after surgery	No between group differences; anxiety was high just after consultation but decreased 6 and 12 months after surgery	No between group differences; high levels of anxiety at enrolment and pre-operatively which decreased at 6 months
Depression		No within or between group differences	No within or between group differences	
Perception of involvement in care	No significant intervention effects		Use of multimedia program did not affect patient involvement	
Health-related quality of life			Those who perceived they had greater responsibility for treatment decisions and perceived to have more choice for treatment reported better functional, emotional and physical wellbeing.	Social wellbeing not related to decisional control measures

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	Study 1	Study 2	Study 3
Self-efficacy to communicate with physician/manage disease			No significant intervention or between group differences
Risk of Bias			
Sequence Generation	Low risk of bias	Risk of bias unclear	Low risk of bias
Allocation Concealment	Low risk of bias	Risk of bias unclear	Low risk of bias
Blinding of participants, personnel & outcome assessors	High risk of bias	Risk of bias unclear	Low risk of bias
Incomplete outcome data	High risk of bias	Low risk of bias	Low risk of bias
Selective outcome reporting	Risk of bias unclear	High risk of bias	High risk of bias
Other sources of bias	Low risk of bias	High risk of bias	High risk of bias

Appraisal of the effect of decision aids

Where feasible, meta-analysis was carried out on the outcome data to assess the effects of using the decision aids on various outcome measures, using Review Manager 5 [34]. The timing of follow-up measures varied across studies, so we meta-analysed measures taken *after* use of the decision aid and *before* surgery. For dichotomous outcomes, risk ratios were calculated using an inverse variance with a random effects model [34]. For continuous outcomes, mean differences or standardized mean differences were calculated using inverse-variance, random effects models. Random effects models were used due to heterogeneity in the study settings [34]. Cluster RCTs that had not adequately accounted for the correlated structure of the data were adjusted for clustering [35,36]. Where necessary, standard deviations were calculated using standard errors or confidence intervals (CIs) and 95% CIs were presented for all outcomes. We only meta-analysed the data from the RCTs of the available decision aids.

A narrative synthesis was also undertaken to examine the potential associations between the quality (as assessed by the IPDASi Evaluation) and components of the decision aids (as assessed by the Theory Evaluation) with their reported outcome measures that contribute to the decision-making process. These measures include knowledge, measures to determine personal preferences and measures assessing the degree to which patients are empowered to make a decision based on their personal preferences [14,15]. Knowledge is a vital component of the deliberation process [15]. In order to achieve knowledge, patients need to understand that they have options, what those options are and to have information about their pros and cons and associated outcomes [15]. Decision aids that help patients to determine and consider their personal preferences and improve knowledge through the provision of information are thought to decrease decisional conflict [37]. We hypothesized that decision aids that led to better outcomes would score higher on the IPDASi quality dimensions and components identified through the Theory Derivation checklist.

Results

Search outputs

We identified 14 decision aids of which we obtained copies of 10 [38-47]. (Supplements 2 & 3). We contacted the developers of the 4 decision aids that we were not able to obtain: one developer felt that their decision aid did not meet current standards and stated that it was no longer available; the other 3 developers did not respond despite repeated attempts to contact them by both telephone and email. We appraised the quality and identified the components relating to decision-making of the 10 decision aids we had obtained. Of these 10 decision aids, only four (Goel [39]; Street [45]; Whelan [46]; Wilkins [47]) have been evaluated in RCTs [48-52] (see Table 1); we were therefore only able to appraise the effects of these 4 decision aids.

Appraisal of the quality of decision aids

IPDASi evaluation

Dimension mean scores ranged from 0 [40,42-44,47] to 100 [45,46]. The global mean score ranged from 31.7 [42] to 59.9 [46]. In comparison, the IPDASi validation study of 26 decision aids reported a wider range in global mean scores (23.94 to 80.6) with an overall mean IPDASi score of 53.23 [31].

Theory evaluation

There was limited evidence of *explicit* theoretical underpinnings to the design, development or evaluation of the decision aids. The Goel decision aid [39] is reported to be adapted from a decision aid for post-menopausal women considering long-term hormone therapy that was based on expectancy-value decision theories [53]. The Jibaja-Weiss decision aid [41] uses the soap-opera approach as it "allowed (them) to present role models for the attitudes and behaviours that are desirable for informed decisions" [54] citing Bandura [55] and Singhal and Rogers [56,57], suggesting that this component of the decision aid was based on a social cognitive approach.

Identification of the components to support decision-making

Scores for the extended TPB constructs ranged from 27.8 [40] to 100 [38,41-43,47]. The global mean scores for the extended TPB ranged from 42.4 [40] to 79.9. [41]. Scores for the CSM constructs ranged from 0 [38-40,42-45] to 100 [44,46,47]. The global mean scores ranged from 18.2 [40] to 72.7 [44]. (Supplement 5).

Appraisal of RCTs

Four of the decision aids (Goel [39]; Street [45]; Whelan [46]; Wilkins [47]) have been evaluated in RCTs [48-52] (see Table 1). The Whelan decision aid [46] has been evaluated in 2 separate RCTs [51,58]. In the latter of these RCTs, Vodermaier *et al.* [58] evaluated 3 decision aids (including Whelan [46]) and recruited women with both early and more advanced stages of breast cancer; the data from these 2 groups were not separated and we were therefore not able to include them in our meta-analyses.

Appraisal of the effect of decision aids

Quality of the deliberation: process knowledge

All 4 RCTs [48-52] reported patients' levels of knowledge after using the intervention. Patients using decision aids were likely to have greater knowledge than those receiving standard information (standardized mean difference = 0.19, 95% CI -0.03 to 0.42, p=0.09) (see Figure1).

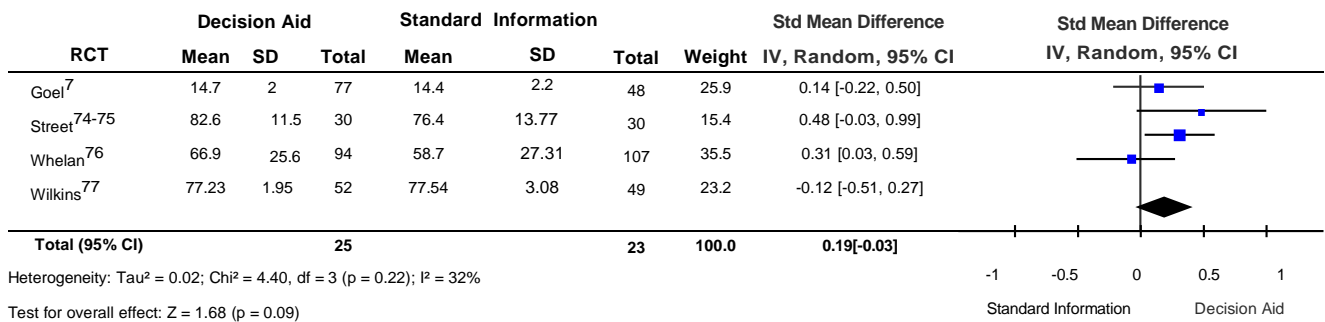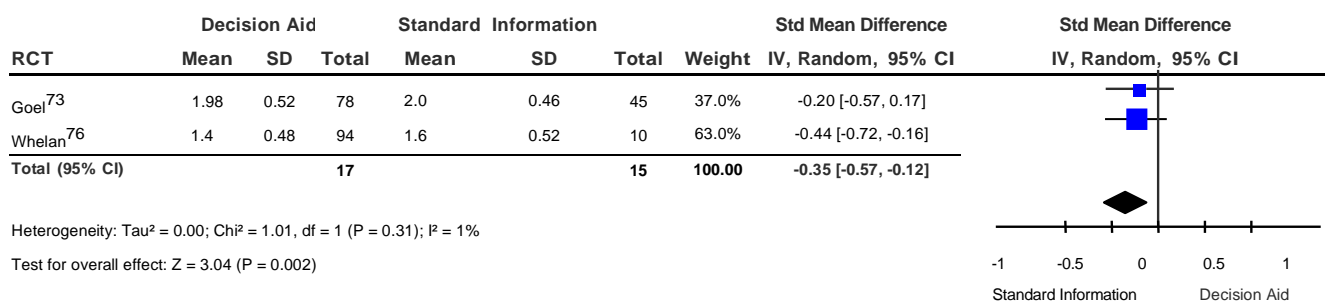**Figure 1 Forest Plot comparing use of decision aid *versus* Standard Information in Knowledge Scores**

RCT	Decision Aid			Standard Information			Weight	Std Mean Difference IV, Random, 95% CI	Std Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Goel[7]	14.7	2	77	14.4	2.2	48	25.9	0.14 [-0.22, 0.50]	
Street[74-75]	82.6	11.5	30	76.4	13.77	30	15.4	0.48 [-0.03, 0.99]	
Whelan[76]	66.9	25.6	94	58.7	27.31	107	35.5	0.31 [0.03, 0.59]	
Wilkins[77]	77.23	1.95	52	77.54	3.08	49	23.2	-0.12 [-0.51, 0.27]	
Total (95% CI)			**25**			**23**	**100.0**	**0.19[-0.03]**	

Heterogeneity: Tau² = 0.02; Chi² = 4.40, df = 3 (p = 0.22); I² = 32%

Test for overall effect: Z = 1.68 (p = 0.09)

Figure 2 Forest Plot comparing use of decision aid *versus* Standard Information in Decisional Conflict Scores

RCT	Decision Aid			Standard Information			Weight	Std Mean Difference IV, Random, 95% CI	Std Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Goel[73]	1.98	0.52	78	2.0	0.46	45	37.0%	-0.20 [-0.57, 0.17]	
Whelan[76]	1.4	0.48	94	1.6	0.52	10	63.0%	-0.44 [-0.72, -0.16]	
Total (95% CI)			**17**			**15**	**100.00**	**-0.35 [-0.57, -0.12]**	

Heterogeneity: Tau² = 0.00; Chi² = 1.01, df = 1 (P = 0.31); I² = 1%

Test for overall effect: Z = 3.04 (P = 0.002)

We examined whether the decision aids with greater (albeit not statistically significant) knowledge improvements scored higher on the IPDASi dimensions and the Theory Derivation checklist relevant to providing information on the available options and their associated outcomes. This was not the case. On the IPDASi Evaluation, the Wilkins [47] and Street [45] decision aids scored the highest on the Information dimension (scoring 81.3 and 79.2, respectively), with the Wilkins decision aid [47] attaining the highest score on the Probabilities dimension (83.3). From the Theory Derivation Checklist, the Goel [39] and Wilkins [47] decision aids scored higher on Cure/Controllability (scoring 83.3 and 66.7, respectively) and Consequences (scoring 77.8 and 72.2, respectively) than did the Street [45] and Whelan [46] decision aids.

Quality of the deliberation process: personal preferences

Two RCTs [48,51] provided an overall mean score using the decisional conflict scale (DCS) [62]; patients using decision aids had lower (i.e., better) scores on the DCS than those receiving standard information (standardized mean difference = -0.35, 95% CI -0.57 to -0.12, p=0.002) (see Figure 2).

The purpose of the IPDASi Values dimension is to assess whether decision aids include methods or components that are designed to help patients to think about what is important to them [29,30]. We would expect decision aids producing lower DCS scores to score highly on the Values dimension; the Goel decision aid [39] did score highly with 83.3, but the Whelan decision aid [46] did not, scoring 50.

Both the Whelan [46] and Goel [39] decision aids scored highly on the IPDASi Guidance dimension (scoring 100 and 66.7, respectively). The Goel decision aid [39] also scored highly on the Perceived Behavioural Control dimension of the Theory Derivation Checklist, obtaining a score of 83.3.

Quality of the deliberation process: decision-making process

Evidence of the impact of decision aids on the extent or nature of the deliberative process is limited (see Table 1). Patients who used the Wilkins decision aid [47] were reported to be significantly more satisfied with the decision-making process than were those using the standard intervention, although no differences were found either 6 months or 12 months later [52]. There is also some evidence that patients who used the Whelan decision aid were more likely to perceive that they had been offered a clear choice of treatment by their physician [51]. Both the Whelan [46] and Wilkins [47] decision aids scored highly on the IPDASi Guidance dimension (scoring 100 and 83.33, respectively). However, the degree to which they help patients to perceive that they have control over the

Figure 3 Forest Plot comparing use of decision aid *versus* Standard Information in Uptake Rates of Breast Conservation Surgery

Plot A – Pragmatic analysis

RCT	Decision Aid		Standard Information		Weight	Risk Ratio IV, Random, 95% CI
	Events	Total	Events	Total		
Street[74,75]	23	30	17	30	24.7%	1.35 [0.93, 1.96]
Whelan[76]	29	31	27	35	37.3%	1.21 [0.99, 1.49]
Wilkins[77]	39	52	42	49	38.0%	0.88 [0.72, 1.06]
Total (95% CI)		113		114	100.0%	1.10 [0.84, 1.43]
Total events	91		86			

Heterogeneity: Tau² = 0.04; Chi² = 7.11, df = 2 (P = 0.03); I² = 72%

Test for overall effect: Z = 0.71 (P = 0.48)

Plot B – Sensitivity analysis

RCT	Decision Aid		Standard Information		Weight	Risk Ratio IV, Random, 95% CI
	Events	Total	Events	Total		
Street [74,75]	23	30	17	30	24.7%	1.35 [0.93,1.96]
Whelan[76]	29	31	27	35	37.3%	1.21 [0.99,1.49]
Total (95% CI) 61 65 100.0% 1.24 [1.04,1.49]						
Total events 52 44						

Heterogeneity: Tau² = 0.00; Chi² = 0.26, df = 1 (P = 0.61); I² = 0%
Test for overall effect Z=2.40 (P = 0.02)

decision-making process may be weaker, given that both decision aids scored 50 on the Perceived Behavioural Control construct.

Perceived involvement in care also reflects the deliberative process; 2 trials assessed this outcome, but did not find statistically significant differences between study groups [49,50,52]. Wilkins [52] also reported there to be no significant effects of this decision aid on patients' self-efficacy to communicate with their physician or manage their disease or on the informational or decisional preferences of patients (see Table 1).

Surgical choices made

Three RCTs [49-52] reported the actual surgery choices made by patients. The results of our meta-analysis did not show any effect (Risk Ratio = 1.10, 95% CI 0.84 to 1.43, p=0.48); however, there was substantial heterogeneity across the studies, principally arising from the Wilkins RCT (77) (Chi² = 7.11, df = 2 (p=0.03); I2 = 72%) (see Figure 3). After exploring the clinical diversity of the study, population and intervention, there appeared no reason to suspect this was any different to the other RCTs [33]. It is likely that these results are due to including only 3 studies in the meta-analysis. A sensitivity analysis was carried out excluding Wilkins [52], which did suggested evidence of an effect (Risk Ratio = 1.24, 95% CI 1.04 to 1.49, p=0.02). Therefore, it is possible, but remains

unclear, whether patients using decision aids are more likely to choose BCS.

Appraisal of the decision

Evidence of patients' appraisal of their surgery choices following use of the decision aid is limited and mixed (see Table 1). Enabling patients to consider the outcomes of each option and to try to forecast how they would feel may result in a more positive appraisal of their decision. We would therefore hypothesize the Whelan decision aid [46] to score higher on such constructs. However, the Wilkins decision aid [47] attained higher scores than did the Street [45] and Whelan [46] decision aids on Anticipated Regret (100 *vs*. 33.3), Consequences (72.2 *vs*. 66.7 / 38.9) and Cure/Controllability (66.7 *vs*. 50 / 33.3) from the Theory Derivation checklist.

Affective outcomes following use of decision aids

There is limited evidence that patients using the decision aid experienced less anxiety than did those receiving standard information, although this difference was not statistically significant (standardized mean difference = 0.17, 95% CI -0.16 to 0.50, p=0.31). (Supplement 6). The decision aids included in these comparisons scored highly on IPDASi Guidance dimension (Wilkins [47]: 83.3; Whelan [46]: 100), although they only scored 50 on the

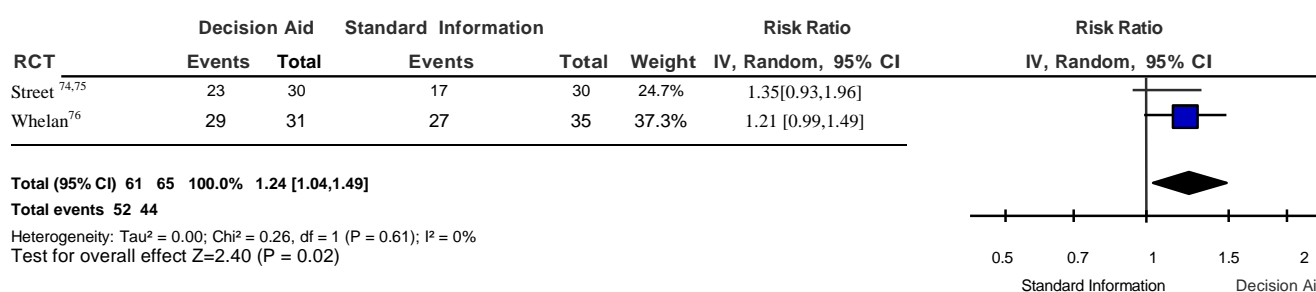Perceived Behavioural Control Construct from the Theory Derivation Checklist.

Summary

Ten decision aids were appraised for their quality and for the components relating to decision-making, of which only 4 decision aids had been evaluated in RCTs. There is limited evidence available to assess the impact of the decision aids on the quality of the deliberation process and patients' appraisal of their decision. We are therefore unable to determine the strength of the relationships between the components, design and use of decision aids and their reported outcomes. It was unclear from the meta-analyses of the 3 trials reporting effects on surgical choices whether using decision aids increases the likelihood of choosing BCS.

Discussion

This examination of the content of decision aids in relation to the decision-making process illustrates the difficulties in drawing firm conclusions regarding components, design, use and outcome. We obtained 10 decision aids for women facing surgery choices for early breast cancer, 4 of which had been evaluated in RCTs. The overall quality of the decision aids, according to IPDASi criteria, was broadly similar; there was limited evidence of an explicit theoretical basis to their development or evaluation. The extent to which components could be mapped onto constructs of the extended TPB and the CSM varied and the evidence available to determine their impact on the decision-making process was also limited.

Little attention has been given to the measurement of the decision process [15]. In contrast to the findings of other reviews [2,11], we are unable to conclude that there are statistically significant effects of decision aids on surgery choices, improvement of knowledge and other outcomes. For the purpose of this review, we only meta-analysed the outcome data from RCTs evaluating the decision aids we were able to obtain and appraise. Other reviews included the data of all published RCTs and therefore had more data available to them [2,11]. Our findings are consistent with the trial by Vodermaier *et al.* [58], which we excluded from our analyses because we could not separate the data of women with early breast cancer from those with more advanced stages of breast cancer. No differences between the intervention and control groups on decisional conflict, satisfaction with decision and treatment and perceived involvement in care were found, although patients in the intervention group reported feeling more informed than those in the control group [58]. The decision aids included in this RCT did not influence treatment uptake [58].

We went further than previous reviews by appraising the quality of each decision aid, exploring the extent to which their component parts affect the quality of the decision-making process – a key strength of this study. A further strength is that the appraisal of decision aids and of the RCTs was undertaken by independent raters and the IPDASi ratings were carried out by experienced IPDASi raters. Other reviews also report limited evidence that decision aids have a theoretical basis [2,18]. However, it is important to consider that the theoretical basis of the decision aids may be implicit; this applies to 2 of the decision aids considered here [39,40]. Nevertheless, the RCTs evaluating these decision aids do not directly base their outcome measurement on theory in order to interpret the impact these decision aids have on their reported outcomes [18].

There are limitations to the present study that need to be considered when interpreting the results. Firstly, our meta-analyses were limited to RCTs where we had access to the relevant decision aid. Also, the instruments used to appraise the quality of the decision aids may not adequately reflect the use of decision aids in practice; they can only evaluate the elements in the decision aid that are known or can be seen rather than the processes and dialogues that might be prompted by them. Methods used to evaluate these decision aids also need to be taken into consideration. Affective outcome measures such as anxiety may require a more long-term follow-up; use of decision aids may lead to greater levels of negative effect in the short-term, but improved outcomes in the long-term [12]. Furthermore, the factors that influenced patients' surgery choices, such as concerns about survival and recurrence rates and the cosmetic outcome, were not reported. Knowing more about these factors would help in understanding how these decision aids work.

At present we are not able to relate the content of decision aids to the process of decision-making achieved or apparently 'supported'. Further research is needed to examine the effects of specific components and where, or how, decision-making can be further improved. An explicitly theoretical approach to the design of decision aids would facilitate their evaluation, thereby improving our understanding of which components have an effect and why [19]. This would enhance our ability to support women in making a very difficult decision at a particularly stressful and difficult time, shortly after diagnosis of cancer. Theoretical models such as the extended TPB and the CSM, among others already used to understand and predict health- related behaviour, could be used to guide the development and evaluation of decision aids in this context. Finally, consideration could also be given to assessing the patients' satisfaction with and preferences regarding decision aids, with a view to capturing the perspective of the individual patient.
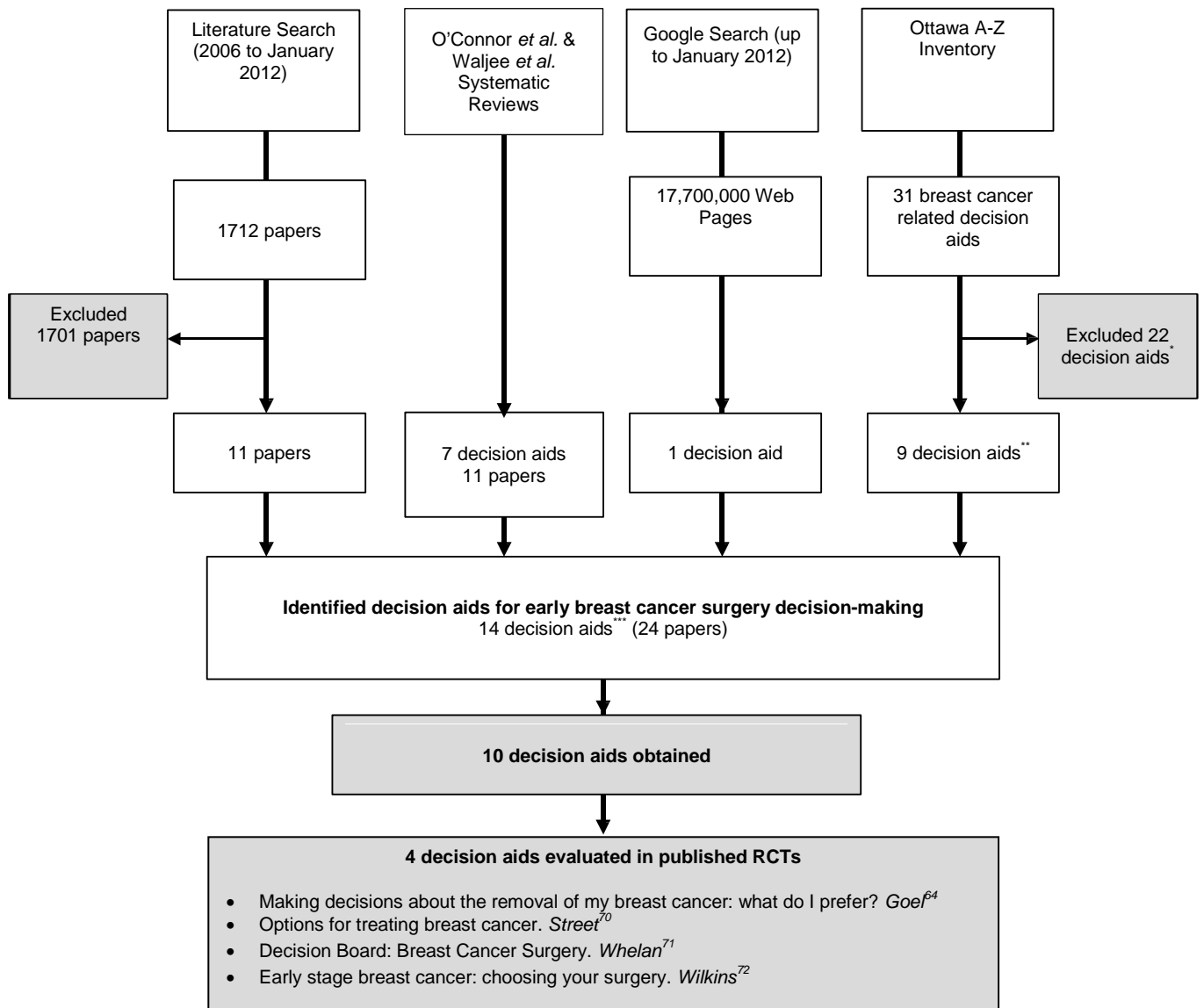
Acknowledgements

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Supplement 1 Theory Derivation Checklist

Items	Theoretical Construst	
	TPB	CSM
Information on Breast Cancer		
1. Different types of breast cancer and their relation to the different options		Identity
2. Risk factors for breast cancer		Cause
3. Causal factors for breast cancer		Cause
Information on Treatment Options		
1. Survival rates for each option	Attitudes	Consequences Cure/Controllability
2. Recurrence rates for each option	Attitudes	Consequences Cure/Controllability
3. Risks & side-effects for each option	Attitudes	Consequences
4. Duration of treatment (& recovery period)		Timeline
5. Possible further treatment (e.g., radiotherapy after breast conservation surgery)	Attitudes	Timeline Consequences
Information on Outcomes		
1. Short-term effects/outcomes of each option		Timeline
2. Effects/outcomes of each option in the medium-term		Timeline
3. Long-term effects / outcomes of each option		Timeline
4. Cosmetic outcome after each option	Attitudes	Consequences
5. Psychosocial outcomes for each option		Consequences
6. Invites patients to imagine how they would feel following surgery and in the future for each option	Anticipated Regret	
Decision-making Support		
1. Allows patient to state treatment intentions	Intention	
2. Structured guidance/support	Perceived Behavioural Control	
3. Allows patient to state decision-making preferences	Perceived Behavioural Control	
4. Encourages patient to think she is free to make a decision that suits her	Perceived Behavioural Control	
5. Invites patients to think about views of significant others (e.g., spouse, family, specialist)	Subjective Norm	
6. Information on what others in the same situation choose to do	Descriptive Norm	

Supplement 2 Search Outputs

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┌──────────────────┐  ┌──────────────────┐  ┌──────────────────┐  ┌──────────────────┐
│ Literature Search│  │ O'Connor et al. &│  │ Google Search (up│  │ Ottawa A-Z       │
│ (2006 to January │  │ Waljee et al.    │  │ to January 2012) │  │ Inventory        │
│ 2012)            │  │ Systematic       │  │                  │  │                  │
│                  │  │ Reviews          │  │                  │  │                  │
└──────────────────┘  └──────────────────┘  └──────────────────┘  └──────────────────┘
         │                     │                     │                     │
         ▼                     │                     ▼                     ▼
┌──────────────────┐           │           ┌──────────────────┐  ┌──────────────────┐
│ 1712 papers      │           │           │ 17,700,000 Web   │  │ 31 breast cancer │
│                  │           │           │ Pages            │  │ related decision │
│                  │           │           │                  │  │ aids             │
└──────────────────┘           │           └──────────────────┘  └──────────────────┘
    │     │                    │                     │                 │      │
    ▼     │                    │                     │                 │      ▼
┌─────────┐ │                  │                     │                 │  ┌──────────────┐
│Excluded │◀│                  │                     │                 │  │ Excluded 22  │
│1701     │ │                  │                     │                 └─▶│ decision aids*│
│papers   │ │                  │                     │                    └──────────────┘
└─────────┘ ▼                  ▼                     ▼                 ▼
   ┌──────────────┐  ┌──────────────────┐  ┌──────────────┐  ┌──────────────────┐
   │ 11 papers    │  │ 7 decision aids  │  │ 1 decision   │  │ 9 decision aids**│
   │              │  │ 11 papers        │  │ aid          │  │                  │
   └──────────────┘  └──────────────────┘  └──────────────┘  └──────────────────┘
```

Identified decision aids for early breast cancer surgery decision-making
14 decision aids[***] (24 papers)

10 decision aids obtained

4 decision aids evaluated in published RCTs

- Making decisions about the removal of my breast cancer: what do I prefer? *Goel*[64]
- Options for treating breast cancer. *Street*[70]
- Decision Board: Breast Cancer Surgery. *Whelan*[71]
- Early stage breast cancer: choosing your surgery. *Wilkins*[72]

*Decision aids not specifically designed for women choosing surgery for early breast cancer were excluded.
**We searched the Ottawa A-Z Inventory a second time after it had been updated. Fewer decision aids relating to early stage breast cancer were listed on the database the second time, one of which we had not identified previously; we have included the numbers for each separate decision aid identified from both searches.
***Total number of separate decision aids identified from all searches; some decision aids were identified in more than one search.

Supplement 3 Overview of decision aids

Author (Location)	Title	Developed By	Delivery Format	Purpose	Content
Collaborative Care[63] (USA)	Early Stage Breast Cancer: Surgery Choices		Internet, paper	Public Use	Background information on breast cancer Information on available surgical options Values clarification exercise Includes some medical illustrations Encourage patient to speak to their physician, with possible questions they may wish to ask/consider when making their decision
Goel[64] (Toronto/Ottawa Canada)	Making Decisions about the removal of my breast cancer: what do I prefer?	Developed in collaboration with women living with breast cancer and based on the Ontario Practice Guidelines Initiative Guideline on Breast Cancer Surgery The web based version was a collaboration of Evidence Applications Linkages Network (HEALNet), the University of Western Ontario, The Canadian Cancer Society, Ontario Division	Audiotape, print & Internet	Current status unknown	Background information on breast cancer Information on available surgical options
Healthwise[65] (USA)	Healthwise Breast Cancer (Should I have breast-conserving surgery or a mastectomy to treat early-stage breast cancer?) (30)	Health information team (professional medical researchers, writers and editors with extensive experience in scientific research and medical writing), Medical team (chief medical officer, the medical director, 8 associate medical directors) and Medical Review Board	Internet & PDF	Public Use	Background information on breast cancer Information on available surgical options Patient experiences (written quotations) Includes medical illustrations Provides a worksheet to determine preferences. User is encouraged to discuss the worksheet with her physician

Jibaja-Weiss[66] (Houston, Texas, USA)	A Patchwork of Life: One woman's story for women making breast cancer treatment decisions	Research Team and expert content panel from medical institutions who are experts in breast cancer treatment and medical decision-making	Internet	Public Use	'Soap-opera' episodes to structure the decision aid and to facilitate understanding of low-literacy users; Background information on breast cancer; Information on available surgical options; Values clarification exercise; Includes medical illustrations and animations; Statistical information presented using illustrations (e.g., faces grid)
Mayo Clinic[67] (USA)	Mastectomy vs. Lumpectomy	Not stated	Internet	Public Use	Background information on breast cancer; Information on available surgical options; Patient experiences (written quotations); Includes some medical illustrations; Encourage patient to speak to their physician, with possible questions they may wish to ask/consider when making their decision; Suggests that patient may wish to consider how much she will worry at the end of her treatment, how she would feel about losing a breast, how her choice will affect her partner, family and work, and how her lifestyle will accommodate her radiation therapy
NCI[68] (USA)	Surgery choices for women with early stage breast cancer	National Cancer Institute in partnership with the National Research Center for Women & Families	Internet & PDF	Public Use	Background information on breast cancer; Information on available surgical options; No graphics; Encourage patient to speak to their physician, with possible questions they may wish to ask/consider when making their decision
Nexcura[69] (Seattle, USA)	NexProfiler: Newly diagnosed breast cancer	Medical editorial board	Internet	Public Use	Scientific evidence tailored to provide patient with more personalized information; Background information on breast cancer

	Title	Developers	Format	When used	Content features
					Information on available surgical options
					No graphics
Street[70] College Station, Tx, USA	Options for treating breast cancer		Interactive multimedia program driven by an Apple computer with a touch screen monitor - authors unaware of the status of the program	When developed used in 2 clinics – first for research purposes and second for clinical work	Background information on breast cancer
					Information on available surgical options
					Patient experiences (video clips)
					Encourage patient to speak to their physician, with possible questions they may wish to ask/consider when making their decision
Whelan[71] Hamilton, Canada	Decision Board: Breast Cancer Surgery	Multi-disciplinary group of investigators including oncologists, psychologists, medical sociologists, decision analysts	Decision Board	For use in the surgeon-patient consultation (and to take home afterwards)	Background information on breast cancer
					Information on available surgical options
					Includes line drawings of women following BCS and mastectomy
Wilkins[72] Boston USA	Early stage breast cancer: choosing your surgery	Senior medical director, clinical advisors, decision support editors, consultants	DVD/VHS & booklet	Public Use	Background information on breast cancer
					Information on available surgical options
					Patient experiences (video clips)
					Information on the differences between the two types of surgery in terms of appearance and, time and energy.
					Includes some medical illustrations
					Encourages patient to speak to their physician, with possible questions they may wish to ask/consider when making their decision

Supplement 4 Mean Theory Construct and Global Theory Scores*

Decision Aid	TPB					CSM					
	Attitudes Mean (SD)	Subjective Norms Mean (SD)	Perceived Behavioural Control Mean (SD)	Anticipated Regreat Mean (SD)	Global Score (weighted) Mean (SD)	Cause Mean (SD)	Identity Mean (SD)	Timeline Mean (SD)	Cure/ Controllablity Mean (SD)	Consequences Mean (SD)	Global Score (weighted) Mean (SD)
Collaborative Care[63]	72.22 (0.00)	66.67 (0.00)	66.67 (0.00)	100.00 (0.00)	**76.39 (0.00)**	0.00 (0.00)	33.33 (0.00)	60.00 (0.00)	66.67 (0.00)	72.22 (0.00)	**46.44 (0.00)**
Goel[64]	77.78 (0.00)	66.67 (0.00)	83.33 (0.00)	66.67 (0.00)	**73.61 (0.00)**	0.00 (0.00)	33.33 (0.00)	73.33 (0.00)	83.33 (0.00)	77.78 (0.00)	**53.56 (0.00)**
Healthwise[65]	27.78 (0.00)	33.33 (0.00)	75.00 (0.00)	33.33 (0.00)	**42.36 (0.00)**	0.00 (0.00)	33.33 (0.00)	13.33 (0.00)	16.67 (0.00)	27.78 (0.00)	**18.22 (0.00)**
Jibaja-Weiss[66]	77.78 (0.00)	66.67 (0.00)	75.00 (0.00)	100.00 (0.00)	**79.86 (0.00)**	33.33 (0.00)	66.67 (0.00)	73.33 (0.00)	66.67 (0.00)	66.67 (0.00)	**61.33 (0.00)**
Mayo Clinic[67]	38.89 (0.00)	100.00 (0.00)	41.67 (0.00)	100.00 (0.00)	**70.14 (0.00)**	0.00 (0.00)	66.67 (0.00)	66.67 (0.00)	66.67 (0.00)	55.56 (0.00)	**41.11 (0.00)**
NCI[68]	55.56 (0.00)	100.00 (0.00)	66.67 (0.00)	33.33 (0.00)	**63.89 (0.00)**	0.00 (0.00)	33.33 (0.00)	66.67 (0.00)	66.67 (0.00)	66.67 (0.00)	**50.00 (0.00)**
Nexcura[69]	72.22 (0.00)	33.33 (0.00)	33.33 (0.00)	33.33 (0.00)	**43.06 (0.00)**	0.00 (0.00)	100.00 (0.00)	80.00 (0.00)	80.00 (0.00)	83.33 (0.00)	**72.67 (0.00)**
Street[70]	66.67 (0.00)	66.67 (0.00)	33.33 (0.00)	33.33 (0.00)	**50.00 (0.00)**	0.00 (0.00)	66.67 (0.00)	46.67 (0.00)	46.67 (0.00)	66.67 (0.00)	**46.00 (0.00)**
Whelan[71]	44.44 (0.00)	66.67 (0.00)	50.00 (0.00)	33.33 (0.00)	**56.94 (0.00)**	100.00 (0.00)	100.00 (0.00)	40.00 (0.00)	40.00 (0.00)	38.89 (0.00)	**62.44 (0.00)**
Wilkins[72]	72.22 (0.00)	66.67 (0.00)	50.00 (0.00)	100.00 (0.00)	**72.22 (0.00)**	0.00 (0.00)	66.67 (0.00)	60.00 (0.00)	66.67 (0.00)	72.22 (0.00)	**53.11 (0.00)**

*All scores scaled from 0-100%

Supplement 5 Mean Dimension and Global IPDASi scores*

Decision Aid	Information Mean (SD)	Probability Mean (SD)	Values Mean (SD)	Guidance Mean (SD)	Development Mean (SD)	Evidence Mean (SD)	Disclosure Mean (SD)	Language Mean (SD)	Evaluation Mean (SD)	Global Score (weighted) Mean (SD)
Collaborative Care[63]	66.67 (5.89)	68.75 (2.95)	70.83 (5.89)	66.67 (23.57)	52.56 (0.00)	50.00 (4.71)	41.67 (11.79)	0.00 (0.00)	0.00 (0.00)	**46.68 (0.10)**
Goel[64]	68.75 (8.83)	60.42 (38.66)	83.33 (0.00)	66.67 (0.00)	69.44 (11.79)	36.67 (4.71)	66.67 (0.00)	66.67 (0.00)	8.33 (11.79)	**58.55 (0.79)**
Healthwise[65]	60.42 (2.95)	0.00 (0.00)	54.17 (5.89)	83.33 (0.00)	5.56 (0.00)	73.33 (0.00)	91.67 (11.79)	0.00 (0.00)	0.00 (0.00)	**40.94 (2.29)**
Jibaja-Weiss[66]	79.17 (0.00)	18.75 (8.84)	70.83 (5.89)	100.00 (0.00)	16.67 (0.00)	46.67 (9.43)	91.67 (11.79)	33.33 (0.00)	50.00 (23.57)	**56.34 (0.07)**
Mayo Clinic[67]	77.08 (2.95)	0.00 (0.00)	87.50 (17.68)	83.33 (23.57)	2.78 (3.93)	26.67 (9.43)	8.33 (11.79)	0.00 (0.00)	0.00 (0.00)	**31.74 (6.83)**
NCI[68]	68.75 (2.95)	52.08 (8.84)	54.17 (5.89)	91.67 (11.79)	0.00 (0.00)	16.67 (4.71)	16.67 (0.00)	0.00 (0.00)	0.00 (0.00)	**33.33 (2.49)**
Nexcura[69]	89.58 (2.95)	50.00 (0.00)	50.00 (0.00)	83.33 (0.00)	8.33 (3.93)	66.67 (0.00)	50.00 (0.00)	0.00 (0.00)	0.00 (0.00)	**44.21 (1.41)**
Street[70]	81.25 (8.84)	29.17 (11.79)	79.17 (5.89)	50.00 (0.00)	27.78 (23.57)	46.67 (0.00)	100.00 (0.00)	66.67 (0.00)	58.33 (11.79)	**59.89 (4.26)**
Whelan[71]	68.75 (8.83)	37.50 (5.89)	50.00 (0.00)	100.00 (0.00)	66.67 (0.00)	50.00 (4.71)	50.00 (0.00)	66.67 (0.00)	50.00 (0.00)	**59.95 (2.16)**
Wilkins[72]	79.17 (0.00)	83.33 (11.79)	83.33 (0.00)	83.33 (0.00)	22.22 (15.71)	53.33 (0.00)	83.33 (0.00)	0.00 (0.00)	8.33 (11.79)	**55.15 (1.75)**

*All scores scaled from 0-100%

Supplement 6 Forest Plot comparing use of decision aid *versus* Standard Information in Anxiety Scores

RCT	Decision Aid			Standard Information			Weight	Std Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total		
Whelan[57]	42.3	12.6	94	41.9	13.45	107	58.7%	0.03 [-0.25,0.31]
Wilkins[58]	12.12	0.86	52	11.28	3.08	49	41.3%	0.37 [-0.02,0.77]
Total (95% CI)			**146**			**156**	**100%**	**0.17[-0.16,0.50]**

Heterogeneity: Tau² = 0.03; Chi² = 1.95, df = 1 (P = 0.16); I² = 49%

Test for overall effect: Z = 1.02 (P = 0.31)