Assessing the effectiveness of interventions to support patient decision making about breast reconstruction: A systematic review.

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Abstract

Background: Decision making about breast reconstruction (BR) following a diagnosis of breast cancer, Ductal Carcinoma in Situ (DCIS), or to reduce future breast cancer risk, is difficult and complex. This paper systematically reviews interventions aiming to support patients facing the option of BR, and assesses their effectiveness in improving a range of patient outcomes.

Methods: Ten databases were searched for articles published up to October 2017 that evaluated interventions to support patient decision making about BR within controlled trials**.** All included studies were assessed for methodological quality. Descriptive analyses of patient outcomes within included studies were performed.

Results: The search yielded 3,291 articles. Eight studies met the inclusion criteria resulting in the evaluation of seven distinct interventions (n = 1,212). Six studies were assessed to be of weak methodological quality, with one of moderate and one of strong quality. Three out of five interventions demonstrated a reduction in decisional conflict (ds = 0.26-0.69) and two out of three interventions resulted in reductions in decisional regret (ds = 0.27-3.69) at various time points. Treatment choice was altered in two of five studies. There were no changes in patient-reported anxiety levels, whilst the impact on depression was mixed. In all studies which reported on it, improvements in patient satisfaction and involvement in decision making were found.

Conclusions: Few interventions are currently available. Whilst some findings are encouraging, improvements on patient outcomes are mixed. Further research should focus on the development and evaluation of effective interventions.

Keywords: breast reconstruction; decision making; systematic review; interventions; effectiveness; outcome and process assessment; decision support techniques; patient participation.

INTRODUCTION

Thousands of women undergo breast reconstruction (BR) following mastectomy each year, with the aim of restoring psychosocial and health-related quality of life. Indeed, in England, 5,000 women undergo BR annually, with the numbers offered BR increasing[1]. Making a decision about BR can be difficult and complex[2]; whilst patient choice is fundamental to the delivery of healthcare, and women want to be involved in making treatment decisions [3], for many this can be challenging. Indeed, the choices regarding whether to undergo reconstruction, and the type (e.g., implant-based, autologous) and timing (immediate, delayed) of surgery are considerable, and the best option for each woman will depend on her own individual preferences, goals and needs.[4]. Additionally, these decisions must be made in a relatively short timeframe following diagnosis; which is often a stressful and emotional time [5].

Post-operative regret and dissatisfaction are common among women who have undergone BR [1, 2, 6, 7]. Reasons include unmet expectations [8, 9], and a lack of involvement in the decision making process [2]. Additionally, a recent systematic review found that higher decisional regret is related to a lack of sufficient, understandable information [7]. Interventions designed to support and encourage patient decision making can help involve and inform them, whilst managing their pre-surgical expectations [4, 10]. Such interventions can improve patient satisfaction and involvement in care [11, 12]. Certainly within the wider field of breast cancer treatment, these interventions have been found to improve decision-related self-reported outcomes for a wide range of treatments including radiotherapy, endocrine therapy, and chemotherapy[13].

With regard to support for BR decision making, Preminger and colleagues [14] conducted a systematic review of preoperative patient education aids for BR. They found few interventions, all of which were of limited methodological quality. The review, however,

included studies of retrospective design and student populations (without a diagnosis of breast cancer). Further, studies evaluated interventions designed for women deciding between mastectomy and breast conserving surgery[15, 16], rather than solely BR, thus limiting the conclusions that can be drawn in relation to women who are in the process of making a decision about BR. Most recently, a systematic review of decision aids for patients making a decision about treatment for early breast cancer [13] addressed all treatment decisions including surgery, endocrine therapy, chemotherapy, radiotherapy and fertility-preservation, in addition to BR. The authors identified three papers evaluating decision aids focused on BR decision making, one of which was a conference abstract. Given the extensive scope of the review, there was limited information regarding the content and effectiveness of the interventions developed specifically in relation to decisions concerning BR. It is therefore timely and important to focus solely on interventions to support BR decision making given the growing numbers of women who are being offered an increasing array of surgical BR options. In line with this, the aim of this review was to assess the effectiveness of interventions designed to help women make a decision about breast reconstruction.

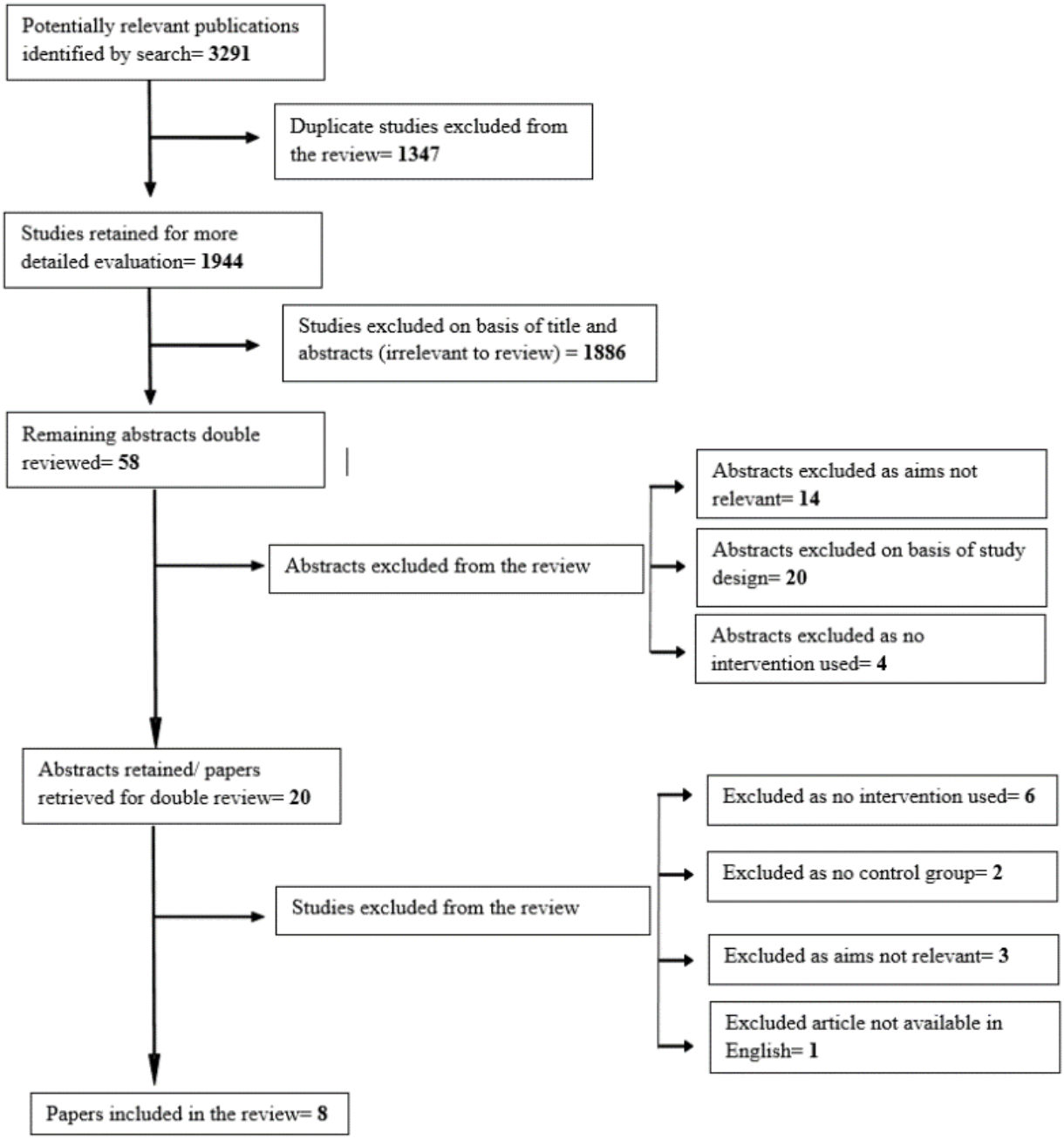
METHOD

This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews [17]. The search was not restricted by date or publication status, in order to reduce the likelihood of publication bias. The following databases were searched up to October 2017; EBSCO (which includes AMED, CINAHL, ERIC, MEDLINE, PsychINFO and PubMed), Cochrane Library, Web of Science and Wiley Online Library. A grey literature search was conducted via Google Scholar. The following search terms with truncations were used:("breast reconstruction" OR "risk reducing mastectomy" OR "mastec* reconstructive breast surgery" OR "prophylactic mastectomy" OR "oncoplastic breast surgery") AND (program*, OR prevent* OR intervention OR evaluat* OR aids OR psychosocial OR self-

help OR online) AND (option OR inform* OR collaboration OR partnership OR shar* OR decision OR shared-decision OR engagement OR proactive OR concordance OR involve* OR support OR "decision-support").

After removing duplicates, the database results were screened for inclusion sequentially by title, abstract and full-text, as illustrated in Figure 1. The reference lists of the remaining articles were also examined manually.

Figure 1: Flow diagram of search strategy and screening



Inclusion Criteria

Articles were included if they met all of the following criteria;

(a) Included women who were making a decision regarding BR following a diagnosis of breast cancer or Ductal Carcinoma in Situ, or were undergoing risk reducing mastectomy.

(b) Used an intervention to aid decision-making about BR. Any method of intervention delivery was included (e.g., online, in person, booklet) and the intervention could be group- or –individual- based. No restrictions were imposed in relation to the setting, duration or the facilitator of the intervention.

(c) Were controlled trials, whereby the intervention group was compared with a group (e.g., treatment as usual). Random allocation was not necessary.

(a) Reported the findings of a primary study or secondary analysis. Data from reviews, qualitative and retrospective designs were excluded.

(b) Included a patient reported outcome measure. There was no restriction on the outcome measure employed, and could include the assessment of decision making (e.g., decisional regret), intervention-specific questions (e.g., knowledge about BR) and psychosocial outcomes (e.g., anxiety). Only measures that compared the outcome of the intervention group with the control group were reported.

(c) Published in English.

Data Extraction

Data was extracted by two reviewers (NP and EG) from the final sample of studies included in the review, in line with the Cochrane Collaboration's double-data collection and extraction methodology [17]. Data extracted included participant characteristics, methodological and design features, and statistical analyses and results.

Methodological Quality Assessment

The methodological quality of each study was assessed independently by NP and EG using the Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project (EPHPP) [18]. This tool provides a standardised method of assessing study quality, resulting in an overall methodological rating of strong, moderate, or weak, in the following eight domains; selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, and intervention. The assessment was based on the information reported in the manuscript. Methodological quality of studies was determined as follows:

- Strong: A study that received no weak ratings.
- Moderate: A study that received one weak rating.
- Weak: A study that received two or more weak ratings.

Synthesis of Results

Due to the heterogeneity between studies in the methodologies and measures employed, a meta-analytic synthesis of the data was not appropriate nor possible. Therefore, a descriptive synthesis of the results across studies was conducted.

RESULTS

The search resulted in the inclusion of 8 studies evaluating 7 distinct interventions (2 papers evaluated the same intervention[19, 20]). A total of 1,212 women (intervention group M*age* = 47.2-56.8 years; control group M*age* = 46.8-54.6 years) participated in the interventions, which were delivered across the USA (n=4),[20-23] China (n=2),[19, 24] Australia (n=1),[25] and Canada (n=1)[26]. All participants included women who were eligible for BR, and were either pre- or post- mastectomy at the time of recruitment. Table 1 displays information concerning participant demographics, study design, outcome and results.

Table 1: Characteristics of included studies

Author/Year/ Location	Type of intervention	Comparison group	Study design	Population	Number of participants allocated	Follow up	Outcomes and results*
Au et al., (2010) China	Booklet	Original booklet	Single arm cohort comparison of original DA with revision	Operable EBC stage 0-11, BCS candidate Intervention M*age* = 51.9 Comparison M*age* = 53.0	Original DA: 95 Revised DA: 38	4-7 days	Acceptability: No difference between groups at 4-7 days post DA Utility. Anxiety/depression: No difference between baseline and 4-7 day visit.
Causarano et al., (2015) Canada	Pre-consultation educational group intervention, in addition to routine education	Routine education booklet with information about BR	RCT	Women who had undergone a mastectomy considering BR M*age* = 51.2	Intervention (DA):21 Control:20	1 week after the intervention and/or surgical consultation	*Decisional conflict*: greater decrease in the intervention group (*d*=0.69, 95% CI=0.02-1.42) *Decision self-efficacy (self-confidence):* no difference *Patient involvement in care: p*atient information was greater in the DA group (*d*=0.91, 95% CI=0.17-1.72) and patient decision making: (d=0.42, 95% CI=-0.23-1.12) *Satisfaction with information*: higher satisfaction in the DA group *(d*=0.11, 95% CI=0.53-0.76)

							Treatment decision: higher proportion of patients signed informed consent to undergo BR in the DA group relative to the control *(P* =0.06)
Heller et al., (2008) USA	Interactive digital system	Standard patient education only (printed)	RCT	EBC, candidate for BR. Intervention M*age* = 47.2 Comparison M*age* = 46.8	Intervention (DA): 66 Control: 67	1 month after surgery	*Knowledge about breast reconstruction*: intervention group knowledge increased to a greater extent than control (CI 95% 1.07-11.74, *p* = 0.02). *Satisfaction with means of acquiring information*: intervention group 97% vs control 86% (p = 0.03). *Improved ability to choose reconstruction options*: no difference *Received all necessary information*: no difference *Pleased with choice of treatment*: DA 95% vs control 83%. *Preoperative expectations met*: no difference. *Anxiety:* no difference between groups.

Lam et al., (2013) China	As above	Standard information booklet	RCT	Operable EBC stage 0-11, BCS candidate Intervention M*age* = 56.8 Comparison M*age* = 54.6	Intervention (DA): 138 Control:138	1 week after the consultation. 1, 4 and 10 months after surgery.	*Decisional conflict*: compared to the DA group, the control reported significantly greater conflict 1 week after the consultation (*d*=0.26, *P*= .016). *Decision regret:* No difference between groups 1 month after surgery. Control reported significantly greater decision regret 4 months (*d*= 0.32, P=.026) and 10 months (*d*=0.27, P= .014) after surgery in comparison to the DA group. *Treatment decision-making difficulty*: no difference at 1 week. *Anxiety*: No difference at 1, 4 and 10 months after surgery. *Depression:* No difference at 1 and 4 months after surgery. Control group reported significantly greater depression at 10 months (*d*=0.40, P=.001). *Levels of patient knowledge*: No difference. *Choice of surgery*: No difference.

Lee et al., (2010) USA	Computer-based learning module	Usual care (standard surgical consultation)	Non-randomised comparative cohort	Immediate or delayed BR after mastectomy for EBC Intervention M*age* = 48.4 Comparison M*age* = 48.9	Intervention (DA): 216 Control:120	Minimum of 1 year follow up after surgery	*Patient involvement in decision*: greater in the intervention group ($p < 0.001$). *Surgical choice:* intervention group more likely to choose autologous flap surgery. *Satisfaction with information*: Mostly/very – intervention 91% vs control 85% ($p< 0.001$) *General satisfaction*: no difference
Luan et al., (2016) USA	Printed decision aid (including information and decisional components)	Standard pre-consolation material including an informational video	RCT	Patients undergoing BR for mastectomy indicated for breast cancer. Intervention M*age* = 49.3 Comparison M*age* = 49.0	Intervention (DA):8 Control:8	Immediately preceding the consultation 3-5 months following surgery	*Decisional conflict*: no significant difference immediately preceding the consultation. *Decision regret*: Less regret in the DA condition relative to the control group 3-5 months after surgery (d=3.69, $p < 0.05$). *Quality of life:* no difference 3-5 months after surgery. *Anxiety and depression*: no significant difference 3-5 months after surgery.
Manne et al., (2016) USA	Online intervention (BRAID)	Pamphlet with information about BR	RCT	Breast cancer patients (DCIS or stage 1,2,3 A breast	Intervention (DA):31 Control:24	2 weeks following the intervention	*Decisional conflict*: No difference. *Satisfaction with preparation for BR decision*: No difference.

				cancer) considering mastectomy. No surgery to date. M*age* = 50.2			*BR intentions and decision made*: No difference. *Knowledge about BR*: No difference *Preparation for BR decision*: No difference. *Anxiety*: No difference.
Sherman et al., (2016) Australia	Online interactive DA (BRECONDA)	Widely available standard online information about breast reconstruction	RCT	Women diagnosed with breast cancer or DCIS advised to undergo/had already undergone a mastectomy. Intervention M*age* = 52.0 Comparison M*age* = 51.9	Intervention:116 Control:106	1 and 6 months after the intervention	*Decisional conflict:* this was significantly lower (F = 4.01, p = 0.019) in DA group at 1 (d = 0.35) and 6 (d =0.29) month follow up. *Decision regret*: No significant differences between groups at 6 months. *Satisfaction with information:* this was greater in the DA group at 1 (d=0.31) and 6 (d=0.27) months (F = 7.41, p= 0.007).

Quality of studies

The majority of included studies (six out of eight)[19-23, 26] were assessed to be of weak quality, primarily due to a lack of reporting and controlling for potential confounding variables (i.e. variables associated with the intervention that causally relate to the outcome, for example, surgical complications). Furthermore, studies typically failed to blind outcome assessors or study participants to the intervention or research question, therefore increasing the chances of detection and reporting bias. Given the nature of the intervention under investigation, the blinding of assessors/facilitators is particularly challenging. Only one study was assessed as being strong,[25] and one of moderate quality [24]. The results of the methodological quality assessment are displayed in Table 2.

Table 2: Methodological quality of included studies assessed using the EPHPP.[17]

	Selection Bias	Study Design	Confounders	Blinding	Data collection method	Withdrawal and dropouts	Global rating
Au et al (2011)	1	2	3	3	1	3	Weak
Causarano et al (2015)	2	1	3	3	1	1	Weak
Heller et al (2007)	2	1	3	2	3	3	Weak
Lam et al (2013)	1	1	1	2	1	3	Moderate
Lee et al (2009)	2	2	3	2	3	2	Weak
Luan et al (2016)	2	1	3	2	1	3	Weak
Manne et al (2016)	2	1	3	2	3	2	Weak
Sherman et al (2016)	1	1	1	2	1	2	Strong

Note: 1= strong; 2= moderate; 3= weak

Intervention format and content

Four interventions were interactive, computer-based programmes [21-23, 25], two were booklets [19, 24], one consisted of an educational group intervention[24] and, finally, one was a printed decision aid [20]. The computer-based interventions were similar in format; they were modular, self-paced, and contained a variety of written information, graphics (e.g. before and after photos) and video clips (e.g. interviews with patients or health professionals). The

programmes varied in duration, ranging between 20 minutes,[22] 45 minutes [25] and 74 minutes [23]. Patients who used the interactive computer program aids reported satisfaction with this method of delivery [21, 25] and satisfaction with the information [22, 23, 25]. The booklet [19, 24] was self-administered for use at home, and contained worksheets and graphics to aid literacy. The educational group intervention[26] was facilitated by a range of health professionals and volunteers lasting approximately 2 hours, whilst the printed decision aid contained worksheets and summaries [20].

The content was similar across the seven interventions. They all provided information on BR and the various options potentially available to women. The benefits, costs/risks, possible outcomes, and patients' values and attitudes, were also frequently included, whilst the mode, timing, and duration of delivery varied. The format and content of each intervention is outlined in Table 3.

Table 3: The format and content of included interventions

Author	Intervention format	Intervention content
Au et al 2016/ Lam et al., 2013	Decision-aid booklet: Based on patient decision aids collaboration criteria Distributed by nurses for home use (self-use decision aid) Post consultation supplement	a) Information about the main differences among the available treatment options (e.g., outcome probabilities, additional surgery) associated with each choice. b) A review of positive (benefits) and negative features (adverse effects and disadvantages) of the available treatment options c) A personal worksheet format facilitating values clarification d) Structured guidance resulting in either current surgical preference or unresolved decision outcomes and next steps.
Causarano et al., 2015	Pre consultation educational group intervention: Consulting plastic surgeon (40 minutes) BR clinical nurse specialist (20 minutes) Social worker (30 minutes) Two volunteer BR peer support patients (30 minutes)	a) Treatment options for reconstruction (e.g. advantages and disadvantages) b) Manage unrealistic expectations c) Clarify personal values d) Knowledge about the complex surgical options e) Risks and benefits f) Probable outcomes g) Alternatives to surgery h) Provide social/peer support.
Heller et al., 2008	Interactive digital education aid (CD:Rom): Menu driven Three dimensional animated graphics Patient testimonials Before and after photographs Video explanations from health professionals. Available to watch outside the hospital setting	a) Answers questions about BR and provides explanations of the various techniques b) The advantages and disadvantages of each method c) A discussion of why women may choose not to have reconstruction d) Includes stories from women who explain their decision and the impact

Lee et al., 2010	Computer based learning module (CD:Rom): Written and visual information Self paced presentation format Approximately 20 minutes to complete the module Could be viewed in the clinic or at home prior to the consultation	a)Information about the various options b)Pertinent operative details c)Recovery d)Associated adverse effects e)Complications Note; During the consultation, options were reviewed with the patient to assess their understanding. Patient's values and preferences were gathered – formulating a treatment plan together.
Luan et al., 2016	Printed decision aid: Bright graphics Worksheets Summaries Questions Distributed 1 week before the initial consultation to review the material before the clinic visit	Informational and decisional components: a) Information regarding BR surgery and most common options (e.g. anticipated pain or length of hospital stay) b) Comparison of BR options (e.g. level of activity after surgery, chance of needing revision surgery) c) Decisional component (e.g., rate importance of various values and/or factors)
Manne et al., 2016	Online intervention (BRAID): Menu driven 10 modules Self-paced Video clips Patient narratives Voice narrated modules Illustrations Approximately 74 minutes to complete	a) Introductory tour of the site b) BR overview (e.g., timing of BR, post-mastectomy options) c) Information specific to implants (including possible complications, pros and cons, outcomes etc.) d) Information specific to abdominal tissue procedures (including possible complications, pros and cons, outcomes etc.) e) Information specific to back tissue procedures (including possible complications, pros and cons, outcomes etc.) f) No reconstruction (reasons, prosthetic options) g) Nipple and areola reconstruction h) Women's stories (include reasons for different types of reconstruction) i) Values and attitudes (towards reconstruction) j) Create a question list (to ask a Health Professional)

Sherman et al., 2016	Online interactive module (BRECONDA) Menu driven Modular Self-paced Videos Basic information plus optional components with more detail 45 minutes on average Participants had access to the website for 6 months	a) Introduction: description of BR and who is eligible for it b) Making decisions; overview of BRECONDA content c) Hints for making a decision d) What reconstructive choices do I have? (e.g., eligibility criteria) e) When can I have reconstruction? (immediate versus delayed) f) What to expect (e.g. recovery time) g) What else to know before making a decision (e.g., advantages and disadvantages) h) What might go wrong (e.g., potential complications) i) Feelings (e.g. strategies for managing emotions related to reconstruction decision j) Family issues (e.g. strategies for communication) k) Others stories (e.g. patient experiences) l) Reconstruction preference/thought about reconstruction (e.g. values clarification) m) Contact information

Intervention effectiveness

An intervention was considered effective if a significant improvement or reduction was found among the intervention group, in comparison to the control group, on any given patient-reported outcome. Where possible, Cohen's *d* effect sizes were calculated by dividing the difference between group means by the pooled standard deviation [27]. The outcomes employed in the studies are examined below.

Decisional conflict

Five studies assessed decisional conflict using the validated 16-item Decisional Conflict Scale [28], defined as 'uncertainty about which course of action to take when choice among competing options involves risk, loss, regret, or challenge to personal life values'[28]. Three out of five interventions using this outcome found a reduction in decisional conflict in the intervention group relative to the control group [24-26]. Specifically, lower levels of decisional conflict were found at 1 week ($d = 0.26$[22]; $d = 0.69$) [26], 1 month ($d = 0.35$)[25] and 6 months ($d = 0.29$)[25] post-intervention. Conversely, two studies found no difference in decisional conflict between the intervention and control groups at 2 weeks or 3-5 months [20, 23].

Decisional regret

Decisional regret is typically described as 'remorse or distress after a (health care) decision'[29]. Three studies examined this outcome using the validated 5-item Decision Regret Scale [29]. Whilst Sherman and colleagues[25] found no group differences in self-reported regret at 6 months, Lam et al (2013) and Luan et al (2016) found significantly reduced decisional regret in the intervention group compared to the control group at 4 months ($d = 0.32$) [24], 10 months ($d = 0.27$)[24] and 3-5 months ($d = 3.69$)[20] respectively.

Treatment choice and decision making

Two of the five studies that used treatment choice as an outcome measure reported changes in the intervention group including: an increased use of flap-based reconstruction surgery [22] and fewer women opting to undergo breast reconstruction [26]. Conversely, two studies found no difference in the numbers of women deciding to have breast reconstruction.[23, 24]. Similarly, no difference in reconstruction rate between groups at 1 or 6 months was found [25].

No differences were found between groups regarding treatment decision making difficulty [24] or decision self-efficacy [26]. Furthermore, no differences were found between the groups when examining women's ability to choose reconstruction[21] their satisfaction with the preparation for BR and for the BR decision [23].

The subsequent section describes the range of items used to assess outcomes specific to the intervention. For example, knowledge about BR, satisfaction with information, and involvement in decision making. The outcomes examined and measures used varied between studies, with minimal standardisation:

Patient satisfaction with information provision

Three studies assessed patients' satisfaction with information provision using a measure adapted from previous research [25], a measure developed by the authors [22], and Causarano and colleagues [26] used the BREAST-Q [30]. All 3 studies [22, 25, 26] found greater satisfaction with information provision in the intervention groups. Specifically, satisfaction with the information was greater in the BRECONDA group at 1 month (d=0.31)

[25] and 6 month (d=0.27) [25] follow-up, the educational group at 1 week post-intervention (*d* = 0.91)[26], and the computer based learning module[22] at follow up of less than a year.

Patient-perceived involvement in decision making

The two studies [22, 26] that examined patients' perceived involvement in decision making reported greater involvement in the intervention groups, assessed using a measure developed by the authors[22] and Causarano and colleagues[26] used the Modified-Patient perceived Involvement in Care Scale (M-PICS) [30].

BR knowledge

Regarding knowledge concerning BR, one study[21] found that self-reported knowledge increased in the intervention group using a 12-item measure (developed by the authors), whereas two studies[23, 24] reported no differences in knowledge between the groups.

Finally, no difference in general satisfaction[22], quality of life [20] or meeting pre-operative expectations[21] were found between intervention and control groups.

Anxiety and Depression

Across the five studies which examined anxiety, four [19, 20, 23, 24] employed the Hospital Anxiety and Depression Scale [31], whilst one [21] used the Spielberger State and Trait Anxiety Inventory for Adults short form [32]. There were no significant differences [19-21, 23, 24]. This holds true across a range of time points, including 4-7 days[20] and 10 months after surgery [24]. Fewer studies examined postoperative levels of depression (as measured by the HADS)[31], and the findings were mixed. One study[20] found no difference between

groups whereas another[24] found that depression scores were significantly lower among women in the intervention versus the control group 10 months following surgery (d = 0.40).

DISCUSSION

A systematic review of interventions designed to support women making a decision about BR was conducted, with the purpose of assessing their effectiveness in improving patient outcomes. Overall, the impact of the evaluated interventions were mixed. Three out of five interventions demonstrated a reduction in decisional conflict,[24-26] and two of three showed reductions in decisional regret [20, 24]; these attained small to large effects. Treatment choice had changed in two [22, 26] of the five studies that reported this outcome. Whilst participation in the decision making appeared to have no effect on anxiety levels [19, 20, 23, 24], the impact on self-reported levels of depression were mixed [20, 24]. In all studies which reported on it, improvements in patient satisfaction and involvement in decision making were found [22, 25, 26]. However, there were mixed results for improvements in knowledge, decision making, and general satisfaction/quality of life [20-24].

The identified improvements in decisional conflict are promising, given that high levels of decisional conflict are related to poorer outcomes among women in the long term [33]. The three interventions which found a reduction in decisional conflict varied in terms of format, implying that no one single format is indicated for recommendation. Interestingly, the content of those interventions that were found to be effective in reducing decisional conflict and those that were not, were very similar (e.g., they all included clarifying patients' values). However, the studies which found no differences in decisional conflict were of weak methodology and had small sample sizes, potentially limiting the power necessary to detect effects.

Previous research has identified considerably high levels of decisional regret among women who have undergone BR [6]. It is therefore encouraging that two interventions [20, 24] successfully reduced decisional regret with medium to large effects. It is, however, likely that levels of decisional regret change over time. Indeed, the final results (e.g. the aesthetic outcome) of BR are unlikely to be evident for some time following surgery and women may still be recovering or undergoing additional reconstructive or further procedures at the point of follow-up data collection [25].

Consequently, the relatively short (i.e., <12 months) follow up times across the studies could help to explain the mixed findings in relation to decisional regret, but also those relating to quality of life and general satisfaction. It is therefore crucial that future studies measure both short and longer term follow up given the lengthy recovery process [24].

The findings pertaining to BR knowledge and decision making were generally mixed. A possible reason for this is the considerable variety in the measures used. The majority of authors developed their own measure or adapted questions from previous research, limiting the ability to identify group differences (i.e. a lack of sensitivity) or to compare outcomes across studies. Indeed, the lack of consistent and validated measures coupled with different follow up points across the included studies could, in part, explain the mixed findings. Further, unlike other decisions concerning breast cancer treatment, decisions about BR are often distinct, because women may have more time to consider their options and seek information [13]. Women may already possess high levels of knowledge concerning BR and a desired treatment choice prior to the intervention.

In line with previous studies examining the impact of decision aids on breast cancer surgery more widely [16, 34], this review found that the interventions did not influence post-surgical anxiety. This is important, given the concern that shared decision making can inadvertently increase anxiety [35]. Further, these findings show that interventions designed

to help women make a decision about BR do not remove the anxiety experienced at such a difficult time. There were however mixed results for depression which warrants further exploration.

In addition to the points addressed above (i.e., the need for longer follow up times and use of validated measures), there are several other methodological issues worth noting. First, the vast majority of interventions outlined in this review were developed for, and tested with, women from resource-rich countries (i.e., USA), which restricts the ability to generalise the utility of these interventions to women from resource-poor countries or backgrounds. Further, women's preferences for, and decisions about, breast cancer treatment and BR, in addition to their ability to engage with decision aids, may be impacted by cultural and personal values [24]. Whilst decision aids have been developed for patients with low literacy or from particular ethnic groups [36], to date, these interventions do not focus on the decision regarding BR. Further research must consider women's literacy levels (for example, those with limited proficiency in English), culture, socio-economic and ethnic backgrounds.

Second, a woman's outcome is likely to depend on numerous factors including those related to the surgery (e.g., complications), the patient (e.g., coping skills), in addition to the pre-surgical intervention designed to support decision making. Future research could benefit from measuring potential confounding or moderating factors that may play a powerful role in the decision making process and beyond, for example, partner and family involvement and support.

Third, although information concerning the format and content of the included interventions was provided, information regarding adherence to the intervention was largely omitted. Au and colleagues[19] reported that one in three women did not want to spend time completing the worksheet (clarifying values) or ignored it; this information is crucial in

providing insight in to how the interventions are being used in 'real life' settings. Further, this information may help to identify what components within the intervention drive any potential benefits.

Another consideration is that the interventions included within this systematic review are generally focussed on information specific to the procedure and treatment options available to patients. However, they largely neglect the psychosocial aspects of breast reconstruction, and the impact it can have on the lives of individual patients. For this reason, future interventions should enable health professionals to tailor the information they give to the needs of each woman [37], incorporating clinical features which are specific to each patient, and giving attention to their personal motivations and preferences [5]. This may enhance the shared decision-making process, by enabling health professionals to manage their patients' expectations and better meet their individual needs [38].

Finally, future research would benefit from including a cost utility analysis to compare the cost of implementing the intervention in comparison to treatment as usual. In this review, the booklet developed by Lam and colleagues[24] was distributed as a post consultation supplement, therefore not prolonging consultations or increasing workloads with encouraging benefits to women whereas the educational group intervention was resource-intensive, with multiple stakeholders (e.g., nurses, surgeons) facilitating the intervention with similar benefits. Given the limited resources (i.e., time and cost) within the health service, it is important to consider the cost of implementing such interventions and to weigh the benefits with any additional costs.

On a positive note, ongoing developments in this field mean that preliminary evaluations of new interventions to support patient decision about breast reconstruction have been published since our review was conducted. For example PEGASUS [38] (Patients' Expectations and Goals: Assisting Shared Understanding of Surgery) is a patient-centred intervention that aims

to support shared decision-making by helping patients to clarify their motivations for surgery and to share these with their surgical team in discussions that are centred around physical and psychosocial goals, expectations and possible outcomes of immediate or delayed breast reconstruction of any sort. This intervention is currently being evaluated in a multi-centre controlled trial [38]. Furthermore, Metcalfe et al. (2018) [39] have developed a decision aid for women contemplating delayed breast reconstruction. Studies have found their decision aid to be both acceptable and feasible, and a small (n = 26) uncontrolled pre-test post-test evaluation showed reduced decisional conflict and increased knowledge about the procedure [39].

Conclusion

To date, there are few interventions available to women making a decision about BR. Whilst the impact of these interventions on patient outcomes are generally mixed, a handful have shown encouraging effects, whereby reductions in decisional conflict and regret have been found. However, research developing and evaluating interventions designed to help women make a choice about BR is in its infancy. Consequently, it is too premature to recommend certain interventions over others. Further evaluation is required. Going forward, more research is needed to focus on the rigorous development and evaluation of effective interventions which aim to support patients facing the option of BR.

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Conflict of interest

None

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