

Web-based decision aids for postmastectomy breast reconstruction: a systematic review and metaanalysis of randomized controlled trials

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Web-based decision aids for postmastectomy breast reconstruction: a systematic review and meta-analysis of randomized controlled trials

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Abstract

Background: Web-based decision aids (WDAs) have been shown to have a positive effect when used to improve the quality of decision-making for women facing postmastectomy breast reconstruction (PMBR). However, research to determine the effects of WDAs is limited.

Objective: To compare the impact of WDAs on decisions about PMBR.

Methods: This systematic review and meta-analysis followed the PRISMA guidelines. Six databases were searched from starting at the time of establishment of the database to May 2023. The Cochrane Risk of Bias Tool for randomized controlled trials (RCTs) was used to assess the risk of bias. The GRADE system was used to assess the quality of evidence.

Results: Seven RCTs were included in the meta-analysis. The results showed that WDAs used audio and video to present the pros and cons of PMBR versus no PMBR, implants versus flaps, immediate versus delayed PMBR, and the appearance and feel of the PMBR results, and expected recovery time with photographs of actual patients. WDAs may improve in PMBR knowledge, decisional conflict and satisfaction, but have no effect on informed choice, decision regret or anxiety. The overall GRADE quality of the evidence was low.

Conclusions: The results suggest that the WDAs provide a modern, low-cost, and high dissemination rate effective method to promote improved quality of decision-making in women undergoing PMBR. Clinical Trial: The review protocol was registered in the PROSPERO systematic review database (CRD42023450496).

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Original Manuscript

Web-based decision aids for postmastectomy breast reconstruction: a systematic review and metaanalysis of randomized controlled trials

Abstract

Background: Web-based decision aids have been shown to have a positive effect when used to improve the quality of decision-making for women facing postmastectomy breast reconstruction (PMBR). However, the existing findings regarding these interventions are still incongruent, and the overall effect is unclear.

Objective: To assess the content of the web-based decision aids and its impact on decision-related outcomes (decision conflict, decision regret, informed choice, knowledge), psychological-related outcomes (satisfaction, anxiety) and surgical decision-making in women facing PMBR.

Methods: This systematic review and meta-analysis followed the PRISMA guidelines. Six databases: PubMed, Embase, Cochrane Library, CINAHL, PsycINFO, and Web of Science Core Collection were searched from starting at the time of establishment of the database to May 2023, and an updated search took place on 1st April 2024. Medical subject heading (Mesh) terms and text words were used. The Cochrane Risk of Bias Tool for randomized controlled trials (RCTs) was used to assess the risk of bias. The certainty of evidence was assessed using Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach. The review protocol was registered in the PROSPERO systematic review database (CRD42023450496).

Results: Seven studies included 579 women and were published between 2008 and 2023, and the sample size in each study ranged from 26 to 222. The results showed that web-based decision aids used audio and video to present the pros and cons of PMBR versus no PMBR, implants versus flaps, immediate versus delayed PMBR, and the appearance and feel of the PMBR results, and expected recovery time with photographs of actual patients. Web-based decision aids improve in PMBR knowledge, decisional conflict (MD=-5.43, 95% CI: -8.87 to -1.99, Z=3.09, *P*=.002) and satisfaction (SMD=0.48, 95% CI: 0.00 to 0.95, Z=1.97, *P*=.05), but have no effect on informed choice(MD=-2.80, 95% CI -8.54 to 2.94, Z=0.96, *P*=.34), decision regret (MD=-1.55, 95% CI: -6.00 to 2.90,

Z=0.68, P=.49) or anxiety (SMD=0.04, 95% CI: -0.50 to 0.58, Z=0.15, P=.88). The overall GRADE quality of the evidence was low.

Conclusion: The results suggest that the web-based decision aids provide a modern, low-cost, and high dissemination rate effective method to promote improved quality of decision-making in women undergoing PMBR.

Keyword: Decision aids, Internet, Postmastectomy Breast Reconstruction, Decision Conflicts

Introduction

Background

Breast cancer (BC) is a major global health problem. In 2020, more than 2.3 million newly diagnosed cases and 685,000 deaths were associated with BC[1]. There has been a gradual increase in the incidence of BC globally over the past few decades, which has been attributed to lifestyle changes (increase in body mass index and decrease in birth rate), as well as an increase in screening detection as BC becomes more recognized[2-4]. Although BC has the highest incidence rate, its mortality rate declined by 43% between 1989 and 2020, and is concentrated in larger areas[2, 5]. Advances in the early detection and treatment of BC have improved patient survival rates, which in turn has led to an increased focus on improving the quality of life of BC survivors. The surgical approach to BC is complex and usually involves the decision to undergo breast-conserving surgery and mastectomy, For women undergoing mastectomy, the change in appearance of the missing breast can lead to various types of psychological problems including physical imagery discomfort, psychological distress, anxiety and depression[6]. Postmastectomy breast reconstruction (PMBR) is now an option for women to restore their appearance[7].

However, when women face a PMBR decision, they must decide whether to use PMBR, and if they choose to do so, they should further decide on the timing and type of PMBR (i.e., implant, autologous tissue, or combination)[8, 9]. Delayed autologous PMBR results in a (localized) regional recurrence rate similar to immediate PMBR[10]. BC diagnosis can leave patients feeling anxious and

uncertain, which is often exacerbated by presenting multiple, complex treatment options for women to decide in a short period of time[11]. Most BC patients considering PMBR immediately have clinically significant decision conflict[12, 13]. Patients experience postoperative complications leading to decision regret[14]. These above issues can lead to poorer health outcomes, negative perceptions of the healthcare system, and lower quality of life[14, 15]. Therefore, more preoperative patient education about possible complications includes the patient's anatomy, about which PMBR to choose, the associated pros and cons, and previous surgical and medication history. Women should be fully informed of their options and given the tools to weigh the pros and cons of each option, which may reduce the incidence of these adverse effects[16]. At the same time, personalized medicine is increasingly becoming the standard of care for BC patients[17], and based on current evidence, patients should have equal access to all eligible PMBR options[10]. In a sample of 126 patients who underwent mastectomy, a minority of patients made high-quality decisions about PMBR. Specifically, 43.3% of patients were adequately informed and accepted treatment decisions that were consistent with their preferences[11]. Therefore, patients and providers must work together through dialog to optimize treatment options and engage in shared decision-making. However, it is not easy for inexperienced physicians to perform shared decision-making in an orderly and correct manner in a limited amount of time[18]. Decision aids may be helpful before a patient decides to consult a PMBR, and some[19] also suggest that decision aids may be helpful for some women even after consulting a PMBR, as some women exhibit decision conflicts after the consultation. decision aids are powerful tools to support patients in making informed choices based on their own values and are available via the Internet, DVDs, and printed materials [20]. With the increasing popularity of the Internet worldwide, the web has been recognized as one of the most promising of all available formats (e.g., leaflets, brochures, audio, and video) for delivering decision aids to patients via the Internet. Web-based decision aids are characterized by being interactive, dynamic, and customizable[21]. On the one hand, web-based decision aids have a greater advantage in facilitating

patient access than face-to-face interaction with physicians. On the other hand, decision aids on the Internet can store and disseminate information over a longer period of time than traditional static decision aids and can personalize the visit according to the patient's values and preferences[21-23].

Prior Work

A systematic review exploring the effectiveness of interventions to assist women in making decisions about PMBR conducted by Paraskeva et al[24] and consisted of six studies with mixed results in terms of knowledge, decision-making, overall satisfaction and quality of life. Berlin et al[25] assessed PMBR decision aids in a systematic review and meta-analysis, concluding that PMBR reduces decision conflict, improves information satisfaction, promotes participation in the decisionmaking process, and enhances awareness of participation in the decision-making process. However, the authors included all types of trials (quantitative and qualitative) and only meta-analyzed decision conflict. This review also did not include the effects of decision aids on outcome indicators such as psychologically relevant outcomes. Yang et al [26]conducted a meta-analysis exploring the effects of decision aids on decision-making in PMBR; however, the authors did not compare whether different forms of decision aids would have different effects. Zhao et al[27]conducted a scoping review with the aim of reviewing, comparing, and discussing the current incorporation of the adverse effects of BC treatments into decision aids, and examined how web-based decision aids personalized BC treatment decision-making tools in patient-healthcare provider communication, clinician decisionmaking processes, and shared decision-making, as yet unassessed patient outcomes (e.g., knowledge, anxiety). In summary, there is a lack of descriptions of the impact of web-based decision aids on the decision-making of women facing PMBR. Overall, there is a lack of descriptions of the impact of web-based decision aids on the decision-making of women facing PMBR. Overall, existing systematic evaluations on related topics regarding the impact of decision aids on the quality of decision-making for women facing PMBR decisions have produced mixed results and, more importantly, many primary trials[28-31], following these reviews, have produced conflicting results,

which may provide new evidence. Therefore, there is a need for a new systematic evaluation to provide a comprehensive overview of the effectiveness of web-based decision aids on the quality of decision-making for women faced with PMBR decision-making, drawn from all available evidence from randomised controlled trials (RCTs) that meet high standards for evidence-based research.

Objectives

The aim of this systematic review and meta-analysis was to assess the content of the web-based decision aids and evaluated the effectiveness on decision-related outcomes (decision conflict, decision regret, informed choice, knowledge), psychological-related outcomes (satisfaction, anxiety), and surgical decision-making in women facing PMBR.

Method

This is a systematic review and meta-analysis is reported in accordance with PRISMA (the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines)[32] (Multimedia Appendix 1). The protocol was registered in PROSPERO (CRD42023450496).

Eligibility and exclusion criteria

An overview of the inclusion and exclusion criteria can be found in Table 1.

Table 1 Eligibility and exclusion criteria

P(Population)	The population included in the study was 18 years of age or older that had
	been diagnosed with BC, considering PMBR, but had not yet had the
	surgery and had Internet access. if the patient at the time of enrollment had
	attempted PMBR, did not have BC (i.e., were considering prophylactic
	mastectomy), and/or had an active psychiatric, cognitive, or visual
	impairment, they were not eligible.
I(Intervention)	Studies focusing on WDAs (including websites and apps).
C(Comparison)	Controls for usual care, counseling, health education pamphlets, non-
:	WDAs.
O(Outcome):	Primary outcome: decision-related outcomes (informed choice, knowledge,
	decision conflict, decision regret), psychological outcomes (satisfaction,

	anxiety), PMBR options and tool usability (women's feedback on use).
S(study)	Randomized controlled trial (RCTs)

Search strategy

A systematic search of studies was carried out using English databases such as PubMed, Embase, Cochrane Library, CINAHL, PsycINFO, and Web of Science Core Collection from the date of inception of each database to May 2023, and an updated search was conducted on 1st April 2024 to cover new research. Medical subject heading (MeSH) terms and text words were used. The keywords used included "Mastectomy" "mammaplasty", "mastectomy", "informed choice*", "shared decision making", "computer", "web based", and "Internet", which are English search terms. These index terms and keywords were explored and modified according to the different grammatical rules of the database. Specific details of the search algorithm are available in Multimedia Appendix 2. The reference lists of the included studies and relevant articles were hand-searched to identify other potentially eligible articles. The search was limited to articles in English and had no limitations on publication year.

Screening

The results were input into EndNote X9, and duplicates were removed automatically. After removing duplicates, two reviewers independently screened the titles and abstracts of identified articles and removed irrelevant citations in accordance with the selection criteria. After the removal of irrelevant studies, the full texts of potentially relevant studies were retrieved. Then, both reviewers independently assessed the full texts. Any disagreements were settled by discussion with a third reviewer.

Data extraction

Characteristics of the included RCTs (e.g. author, year of publication., country, sample size, subject characteristics, form, content, development method and team, theoretical basis, duration of use, reading level, etc., and a brief description of the intervention in the control group, outcome

measurements, follow-up, and results) were extracted into tables. We wrote to the author to obtain more information about the results. Two reviewers compared the findings independently.

Risk of bias assessment

The quality of RCTs was evaluated using the Cochrane Handbook for RCTs[33]. The tool consists of seven items: randomized sequence generation, allocation concealment, participant and personnel blinding, blinding for outcome assessment, incomplete outcome, data selective reporting and other bias. The risk of bias for each domain was judged as low risk of bias, high risk of bias, or unclear risk of bias. The evaluation of study quality was performed independently by two reviewers, and a third reviewer was consulted if necessary.

Statistical analysis

Statistical analysis was performed using Review Manager (RevMan version 5.3). illustrated using a forest plot when at least 2 studies were measured for the same outcomes for a PMBR decision at the longest follow-up timepoint[34, 35]. We used mean differences (MDs) for continuous variables that were measured with the same instrument, standardized mean differences (SMDs) when a similar outcome was assessed with different instruments and relative risks (RRs) for dichotomous variables. We calculated possible missing values such as standard deviation (SD) and 95% confidence interval (95% CI)[33]. In the study, heterogeneity was assessed via the Higgins I^2 statistic with I^2 values of $\leq 25\%$, 50% and $\geq 75\%$ deemed to represent low, medium and high heterogeneity, respectively[33]. When there was no significant heterogeneity, the fixed effects model ($I^2 \leq 50\%$) was used; otherwise, the random effects model is used, resulting in a more conservative summary effect estimate[33]. To identify potential sources of clinical heterogeneity, we also conducted a post hoc sensitivity analysis to determine the stability of the results by omitting each test one by one[36].

Result

Study Selection

Figure 1 shows the research selection process and results based on the PRISMA 2020 guidelines. A

total of 844 studies were identified. A total of 129 of these studies were excluded because they were repetitive. After selecting titles and abstracts, 219 studies were included in the next stage. As a result, seven studies met the inclusion criteria.

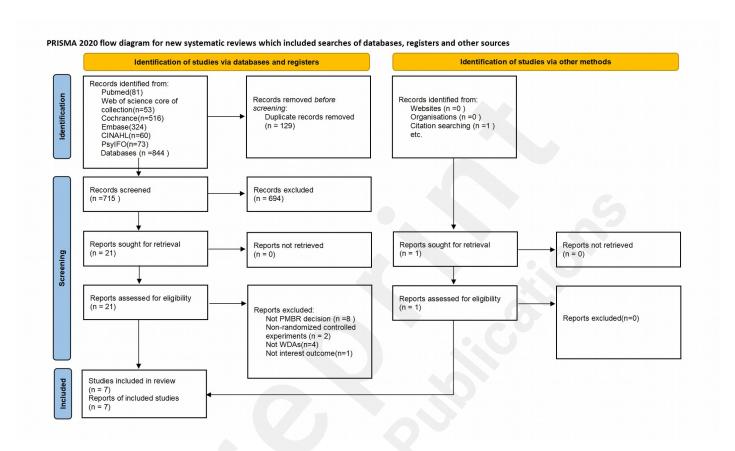


Figure 1 PRISMA flow diagram.

Study characteristics

The seven studies included 579 women and were published between 2008 and 2023, and the sample size in each study ranged from 26 to 222. The age of the women was approximately 50 years old, in the early stages of BC and facing the PMBR decision. The studies were conducted in three countries, six studies were conducted in high-income countries: four in the United States[30, 31, 37, 38], two in Australia[29, 39] and one an upper-middle-income country: China[28]. Detailed characteristics of the included studies are shown in Table 2.

Table 2 The basic characteristics of the included studies

Study,	Dopulation	Sa	Sam	Outcome	Timing	Outcome
year, and	Population	mpl	ple	measures	Tilling	Outcome

		e size	size			
country		Exp eri me ntal	Cont rol	-		
Fang et al, 2020, China	20 years of age or older, newly diagnosed with BC ^a and candidates for mastectomy, able to read and speak Taiwanese or Mandarin.	48	48	bDCS, cBR-DMPS, DRSd, BISe, HADSf.	1week, 1.8mont hs, 12mont hs	Understan ding of medical informatio n, DC ^g , anxiety, depression, DR ^h , body image distress.
Heller et al, 2008, United States	they were unable to read, write, and speak English; (2) they had previously viewed the interactive digital education aid; (3) the initial consultation was for the purpose of obtaining a second opinion.	66	67	Knowledge and satisfaction (self- administered scales) STAI ⁱ .	1 month after surgery	Knowledg e, satisfaction acquiring informatio n about BR, anxiety.
Manne et al, 2015, United States	Female, >18 years, English speaking, diagnosed with ductal carcinoma in situ or stage 1, 2, or 3a breast cancer, considering mastectomy, but had not yet had the surgery, and home Internet access or willingness to use the patient education center computer to access the webbased decision aids, if assigned to this condition.	31	24	Knowledge and satisfaction (self- administered scales), DCS, STAI.	2 weeks	BR knowledge , preparation to make a decision, DC, anxiety and BR intentions.

Mardinger, et al, 2023, Australia	Planning to undergo or having already undergone a therapeutic or prophylactic mastectomy, considering breast reconstruction, aged older than 18 years, proficient in English, with internet access.	30	30	DCS, DRS, The Satisfaction with Decision Scale	6 weeks and 6 months	satisfaction with decision, DC, DR.
Politi et al, 2020, United States	Adult (18+) English-speaking women with stages 0-III breast cancer, who were considering a referral or were referred to 1 of 4 plastic/reconstructiv e surgeons at a single academic medical center to discuss breast reconstruction.	60	60	DQI ⁱ , the 4-item SURE DCS, the BREAST- Q reconstructio n module (preoperative) v1.0; three items from the patient activation measure.	Two months	e, DC, decision process quality, preferences and preference concordanc e, quality of life, patient activation, shared decision- making.
Sherman et al, 2016, Australian	mastectomy, were older than 18 years, were English language competent for reading and writing, had no prior breast surgery (e.g., reconstruction or augmentation), and had Internet access.	116	106	DCS, satisfaction with reconstructio n-related information was assessed by a five- item scale, DRS, DASS-21 ^k , SSQ-6 ^l .	1,6mont hs	DC, satisfaction with informatio n, DR.
al, 2020, United States	adult women >18 years that had been diagnosed with	13	13	knowledge assessment test, STAI,	weeks, 28 weeks,	e, psychologi cal status,

			DC,
		and 36	satisfaction
		weeks	with
breast cancer (stage		of	informatio
I or II only) that had	DCS,	pregnan	n provided
been advised to	BREAST-Q	cy, and	by a
undergo or had	reconstructio	again 6	patient by
already undergone a	n module.	to 8	their
mastectomy.		weeks	surgeon,
		postnata	time of
		lly	consultatio
			n.

^aBC: breast cancer

^bDCS: Decisional Conflict Scale

^cBR-DMPS: Breast Reconstruction-Decision-Making Process scale

^dDRS: Decisional Regret Scale

^eBIS: Body Image Scale

^fHADS: Hospital Anxiety and Depression Scale

^gDC: Decisional Conflict ^hDR: Decisional Regret

ⁱSTAI: State-Trait Anxiety Inventory

^jDQI: The validated Decision Quality Index ^kDASS-21: Depression Anxiety Stress Scales

¹SSQ-6: Social Support Questionnaire

Characteristics of interventions and control

The characteristics of the interventions and control are shown in Multimedia Appendix 3.

Characteristics of intervention

Five of the studies[28-30, 38, 39] explained the web-based decision aids development team includes BC survivors who have undergone mastectomy, plastic/reconstructive surgeons who perform PMBR, and software engineers. The methodology used to develop web-based decision aids includes qualitative research, evidence review and mentoring, and pilot study group meetings. The theoretical basis for Web-based decision aids development is usually the International Patient Decision Aid Standards(IPDAS)[29, 30, 39] or Ottawa decision support framework (ODSF)[28]. Expect for two studies[28, 37] that did not report the time of use, most took between 20 min and 74 min. Two web-based decision aids[29, 30, 39] were developed at a reading level written at a 7th/8th grade reading level. The web-based decision aids content specifically includes the patient population, reconstruction options (including implant reconstruction (tissue expanders and implant types),

autologous flap reconstruction (latissimus dorsi, rectus abdominis, and free flaps, and deep epithelial perforator flaps in the lower abdomen), and skin-sparing and preserving mastectomies (one-phase and two-phase procedures). There are also contraindications and general eligibility criteria. Timing of reconstruction includes immediate versus delayed reconstruction, as well as factors that influence the type and timing of reconstruction. Pros and cons of reconstruction versus no reconstruction, implants versus flaps, and immediate versus delayed reconstruction. Appearance and feel of the PMBR and expected recovery time. The probability of possible implant (e.g., wrinkled breast appearance, periosteal contracture after radiation therapy, and possible need for implant replacement over time) and flap (e.g., muscle weakness and flap failure) are clearly described in a balanced format with quotes from real patients' opinions. The web-based decision aids show photographs, high-quality 3D animated images, pre- and postoperative photographs, audio, and video of actual patients of different skin colors and body types, A list of frequently asked questions from clinicians is also included. Tailored risk assessment, clarification exercises for patient self-assessment of value, tips for managing emotions strategies for communicating with family members regarding reconstructive decisions. Women's stories explain their reasons for choosing particular methods and their impact on their lives. Users enter their questions and the system prompts them to print a summary for use in a consultation with their doctor. This customized printable page also helps patients discuss their concerns and options with their families.

Characteristics of control

The control for Politi et al[30]was the enhanced urgent care + American Society of Plastic Surgeons pamphlet on PMBR. Varelas et al[31] used traditional counseling. Control for Fang et al[28] was provider-provided urgent care + pamphlet (describes types of surgery, including mastectomy, implant-based PMBR, and autologous PMBR, as well as the advantages and disadvantages of the different types of surgeries). Manne[38] was the 56-page pamphlet available at no cost from the Cancer Support Community focusing on PMBR. Sherman et al[39] was online access to excerpts of

the public brochure, including basic information on breast surgery and reconstruction, but excluding content unique to the intervention group (i.e., video interviews with patients/surgeons, values clarification exercises). Mardinger et al[29] was decision aids, which is unvalidated that contains six text-based pages that can be accessed in both interactive and noninteractive formats. Heller et al[37] was the group that received the standard patient education included (printed materials in books and pamphlets, as well as personal instruction from the attending physician, physician-in-training, physician assistant, and nurse practitioner).

Outcome measure

Five studies[28, 29, 31, 38, 39] measured decision conflict using the Decision Conflict Scale (DCS), and one study[30] measured decision conflict using the 4-item SURE DCS. Three studies[28, 29, 39] measured decision regret using the Decision Regret Scale (DRS) and two studies[28, 29] measured informed choice using the subdimension of the DCS-feeling informed. Knowledge was measured primarily by the percentage of correct answers to self-administered multiple-choice questions about specific plastic surgery procedures in five studies[28-31, 37, 38]. Satisfaction was measured using the Satisfaction with Decision Scale[29] and some scales adapted from those used in previous studies[28, 37-39]. Anxiety was primarily measured using the Hospital Anxiety and Depression Scale (HADS)[28] and the State-Trait Anxiety Inventory (STAI)[31, 38].

Decision-related outcome

Decision conflict

Six studies[28-31, 38, 39] investigated the impact of decision conflicts in PMBR. Five studies[28, 29, 31, 38, 39] used DCS included in the meta-analysis showed a statistically significant positive impact of web-based decision aids interventions on decision conflict (MD=-5.43, 95% CI: -8.87 to -1.99, Z=3.09, P=.002). Heterogeneity experiments indicated that there was evidence of statistical heterogeneity in the expected summary results(I²=63%) (Figure2). Polite et al[30]used the 4-item SURE DCS and reported that there was no difference between the two groups in terms of decisional

conflict(P>.05).

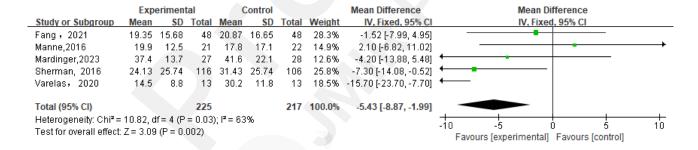
Decision regret

Three studies[28, 29, 39] used DRS to investigate the impact of decision regret in PMBR, the metaanalysis showed that the difference in decision regret after the intervention was not statistically significant compared to the control group (MD=-1.55, 95% CI: -6.00 to 2.90, Z=0.68, P=.49). Heterogeneity experiments indicated that there was evidence of no statistical heterogeneity in the expected summary results (I²=0%) (Figure2).

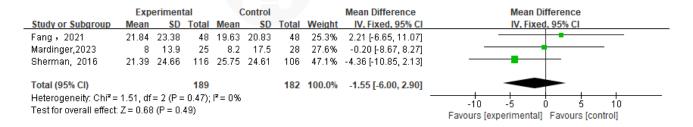
Informed choice

Two studies[28, 29] investigated the impact of informed choice by DCS in PMBR surgery, the metaanalysis showed that the difference in informed choice after the intervention was not statistically significant compared to the control group (MD=-2.80, 95% CI -8.54 to 2.94, Z=0.96, P=.34). Heterogeneity experiments indicate that there was evidence of no statistical heterogeneity in the expected summary results(I²=0%) (Figure 2).

MD for Decision conflict



MD for Decision regret



MD for Informed choice

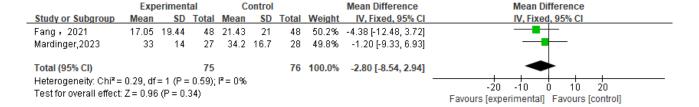


Figure 2 Forest plot comparing decision conflict, decision regret, and informed choice in the webbased decision aids versus control groups.

Knowledge

We did not conduct a meta-analysis of knowledge as an outcome because most of the instruments measuring knowledge were self-administered. The study by Heller et al[37] found significantly higher levels of knowledge in the web-based decision aids group, with a mean increase in correctly answered questions of 14% compared to 8% in the control group (P=.02). Politi et al[30] found that subjects using the web-based decision aids had higher objective knowledge, answering an average of 84.6% of questions correctly compared to 58.2% in the control group (P<.001) Similarly, Varlas et al[31] showed improved knowledge assessment scores in both groups but significantly higher knowledge assessment scores in the intervention group (control = 70.8 ± 15.5%, intervention = 83.1 ± 13.8%, P=.018). However, Manne et al[38] reported similar effects of web-based decision aids on PMBR knowledge, versus the booklet, and Fang et al[28] also reported no difference in the amount of PMBR-related medical information between web-based decision aids and the control group at 1 week post-consultation (P=.13), suggesting that women in both groups had a similar level of comprehension of medical information, whether using the booklet alone or in combination with the web-based decision aids. Mardinger et al also reported that both groups had similar scores on the true or false PMBR knowledge questionnaire over time (P>.05)[29].

Psychological outcomes

Satisfaction

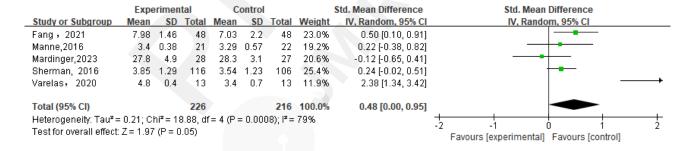
Five studies[28, 29, 31, 38, 39] used different scales to investigate the impact of satisfaction, metaanalyses indicated that web-based decision aids may improve satisfaction compared to controls, but

the results were not statistically significant (SMD=0.48 95% CI: 0.00 to 0.95, Z=1.97, P=.05). Heterogeneity experiments indicated that there was evidence of statistical heterogeneity in the expected summary results(I^2 =79%) (Figure 3). Heller et al[37] similarly reported a higher level of satisfaction with the way in which information about PMBR was obtained in the web-based decision aids group than in the control group(P=.03).

Anxiety

Three studies used to HADS and STAI[28, 31, 38] to investigate the impact of anxiety in PMBR the meta-analysis showed that there was no statistically significant difference in the combination of SMD after intervention (SMD=0.04, 95% CI: -0.50 to 0.58, Z=0.15, P=.88). Heterogeneity experiments indicated that there was evidence of statistical heterogeneity in the expected summary results(I^2 =61%) (Figure3). Heller et al[37] reported that in the web-based decision aids group, there was a trend toward lower levels of anxiety between the preoperative and postoperative visits, but the difference between the groups was not significant as determined by generalized estimating equation modeling.

SMD for Satisfaction



SMD for Anxiety

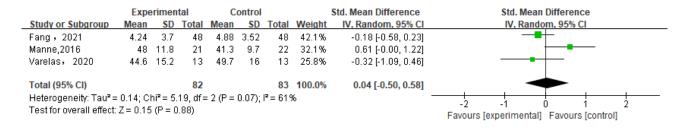


Figure 3 Forest plot comparing satisfaction, anxiety in the web-based decision aids versus control

groups.

Choice of Surgery

The surgical choices differed between the two groups in Fang et al [28], web-based decision aids 56% (27/48) and the control group 46% (22/48), opted for immediate PMBR (P=.05). In addition, the majority of patients chose implantable PMBR, with no difference between groups. Of note, the web-based decision aids group of Mardinger et al[29] was unbalanced in terms of choice of type of PMBR, with 10 women (36%) in the web-based decision aids group refusing PMBR compared with 6 women (21%) in the control group (P=.2).The results of the Politi et al[30] showed that, 95 (79.2%) underwent reconstruction; of these, nearly all (92; 96.8%) underwent immediate PMBR, and there were no differences between groups in median preference scores for reconstruction, type, or time.

Evaluation of the intervention

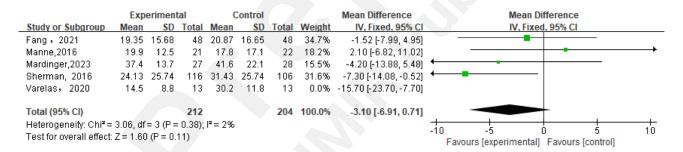
Three studies reported different benefits of web-based decision aids compared to controls. Heller et al[37] reported an upward trend in the number of patients in the web-based decision aids group who reported that they received all the necessary information and improved their ability to choose a PMBR plan. Manne et al[38] reported that 81% of participants in the web-based decision aids found logging in and navigating easy and the length of time was rated as "just right". and the web-based decision aids were more helpful, interesting, and valuable than the brochures. Sherman et al[39] found that women in the intervention group found the web-based decision aids to be 2.94 ± 0.76 informative, very useful, easy to use, contained enough information and helped them to clarify their reconstruction ideas. However, Varelas et al[31] reported that surgeon satisfaction was also significantly higher in the intervention group than in the control group. Meanwhile, consultation time was shorter in the intervention group, but the difference was not statistically significant (P=.46). Similarly, Politi et al[30] reported no difference between the web-based decision aids group and the control group in terms of mean counseling time after the intervention (29.7 min vs. 30.0 min; P>.05)

and Mardinger et al[29] showed that although women used both decision aids with comparable frequency, the total time spent counseling and the time spent per counselling session was significantly greater for women than for the control group (P<.05).Women in Fang et al[28] indicated no difference between the two groups in terms of perceived impact and utility of web-based decision aids on PMBR decisions.

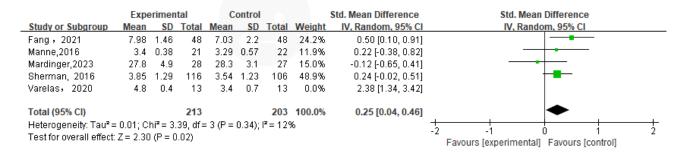
Sensitivity analysis

We conducted sensitivity analyses of decision conflict, satisfaction and anxiety by removing each study. Sensitivity analysis showed that for decision conflict and satisfaction, after removing one study[31], contrary to the previous results, web-based decision aids did improve satisfaction(I^2 range was 79% to 12%) but did not improve decision conflict(I^2 range was 63% to 2%). We found that by removing Manne et al[38], the stability of anxiety did not change, but heterogeneity was reduced from 62% to 0%(Figure 4).

Sensitivity analysis of decision conflict (Varelas, 2020 removed)



Sensitivity analysis of satisfaction (Varelas, 2020 removed)



Sensitivity analysis of anxiety (Manne, 2016 removed)

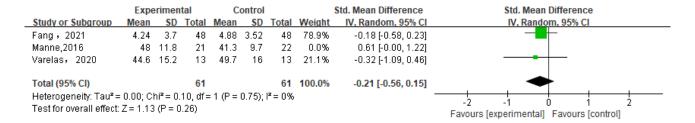
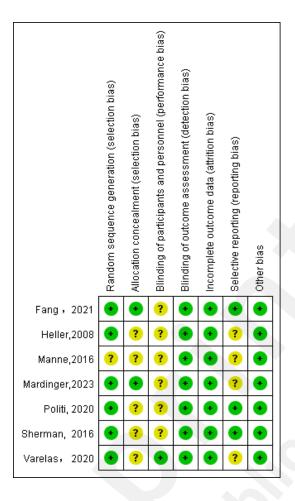


Figure 4 Sensitivity analysis of decision conflict, satisfaction and anxiety.

Risk of bias

Figures 5 present the summary of the risk of deviation for the included studies. In six[28-31, 37, 39] of the seven studies, the description of the method used in random assignment was clearly stated (online automated randomization software, random number generator), and in the remaining study[38] the information obtained about random assignment was insufficient to make a definitive judgment. Of the seven studies, five[30, 31, 37-39] were unable to make definitive judgments in this area because of underreporting, whereas in the remaining two trials[28-30] sufficient information was obtained about allocation concealment (individually sealed envelopes to conceal allocation). Six studies[28-30, 37-39] were judged to be at unclear risk of bias because the effect of unblinding is unknown. One study[31] described blinding of participants. Seven studies[28-31, 37-39] achieved blinding of outcome evaluators (clinic and surgical staff were blinded to condition assignment) or the blinding was unclear, but the outcome was objectively measured and not subjective to interpretation. Incomplete outcome data appeared to be adequately addressed in seven of the studies [28-31, 37-39] (incomplete data were fairly evenly balanced across intervention groups, or intention-to-treat analyses were reported). Three studies[28, 30, 39] underwent clinical registration or reported relevant protocols, showing that outcomes were reported in full, the impact of selective reporting in the remaining four[29, 31, 37, 38] was unclear, and this area was judged to be an unclear risk of bias. Information on other potential sources of bias was sufficient. Therefore, this area was judged to be at low risk of bias for all studies [28-31, 37-39].

A



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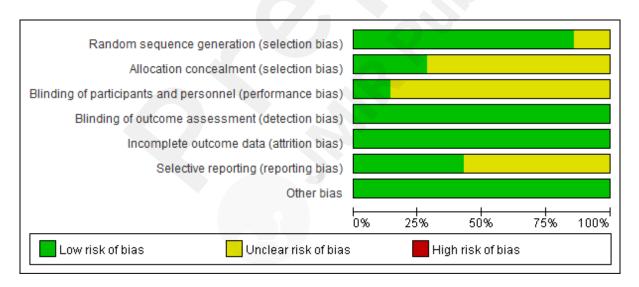


Figure 5 Risk-of-bias assessment of the included studies.

Certainty of evidence

We assessed the certainty of evidence for the included RCTs using GRADE (Multimedia

Appendix 4) Except for decision regret, for which the certainty of evidence was "low", the certainty

of evidence was "very low" for the rest, decision conflict, satisfaction, anxiety, and informed choice.

Discussion

Principal Findings

Our systematic review and meta-analysis showed that the modules of web-based decision aids include PMBR basic information, patient stories, risk assessment, value clarification, and emotion management and that patients can be directed to seek information and obtain personalized decision support based on their individual needs. Therefore, these web-based decision aids are helpful and recommended for women. Regarding the effectiveness of web-based decision aids, the results showed that web-based decision aids may improve PMBR knowledge, decision conflict, and satisfaction, but have no effect on informed choice, decision regret, or anxiety. The overall GRADE quality of evidence for decision regret was low, and the overall GRADE quality of evidence for informed choice, decision rconflict, and anxiety was very low.

The content of web-based decision aids

First, regarding the content of web-based decision aids, few of the studies included in our systematic review and meta-analysis reported comprehensive development of their web-based decision aids. The types of decisions on which most web-based decision aids focused primarily were PMBR decision types and reconstruction times. In addition, some of the studies reported that the development of the tool was obtained through a decisional needs assessment. Research suggests that people tend to have decisional needs when confronted with known outcomes with multiple choices, uncertain outcomes, or valuing people differently, and that unmet needs will lead to poor quality decisions, which will adversely affect health outcomes[40]. Research has shown that some patients have difficulty imagining plastic surgery without photos of women of different body types and skin colors when faced with a decision. Therefore, the use of 3D images during the counseling process is an acceptable web-based decision aids, and the results of our review suggest that web-based decision aids on PMBR decision-making show real photographs of patients by incorporating high-quality 3D

animated images, and that viewing 3D images may increase presurgical preparation by giving patients a more realistic understanding of what is actually achievable after PMBR[41]. There are web-based decision aids that are designed with the goal of making patients more comfortable receiving information in a less stressful environment outside of the hospital, and it also allows family members and friends who are members of the patient support group, but who may not necessarily be able to participate in the counseling, to receive specific information about the procedure and participate in the decision-making process. Women and their families are allowed to express their views about breast surgery because family members act as advocates and care coordinators in the decision-making process[42]. In this era of increasing emphasis on evidence-based medicine, the PMBR risk assessment calculator can help individualize and quantify risk to better inform surgical decisions and better manage patient expectations[43]. The purpose of the values clarification exercise is to help women assess, explore, and identify their personal values and to encourage them to think about how their values affect their decision-making, and using the values clarification exercise can help women increase their satisfaction with their appearance. Patient stories are also important to web-based decision aids, and research has shown that women express a need to learn about other women's experiences to gain a deeper understanding of the impact of PMBR on their daily lives. Web-based decision aids have done this by telling the stories of patients who have had previous mastectomies, with or without PMBR. These stories illustrate the decision-making experiences of these patients and the impact of their decisions on their daily lives [44]. Another advantage of webbased decision aids is that they allow patients to absorb the information without being overwhelmed by other information or distracted by other issues. Research has shown that some people feel prepared and emotionally supported for PMBR decision-making, while others feel that elements of supportive care are missing, making the inclusion of an emotion management module in web-based decision aids essential for women's psychosocial support[45]. However, although the Internet has become an easily accessible tool, there is still a persistent digital divide. Therefore, special attention

should be given to the sociodemographic characteristics of the population, building more resources for healthcare infrastructure in underserved communities, and providing free or discounted Wi-Fi connections and mobile devices in low-income areas[46]. These actions, combined with the popularity of smartphone users, are measures that may narrow the digital divide[21].

Effectiveness of web-based decision aids

In line with the results of a previous meta-analysis[26], web-based decision aids reduced decision conflict. Decision conflicts were as high as 45.68(SD=23.40) among women newly diagnosed with early-stage BC in China[47]. Decision conflict was significantly higher among women who chose mastectomy with or without combined reconstruction compared to women who chose conservative breast surgery. Greater decision conflict is associated with less information, higher uncertainty in weighing choices based on personal values, and inadequate social support[40]. Women may second-guess their decisions after the fact, even if those decisions have already been made. Women who face PMBR decision-making need support in making this complex decision, especially those who do not have a strong preference for PMBR. Decision conflict can be reduced by addressing factors of uncertainty, such as providing information about the benefits and risks of each option and helping patients understand their own values[48]. Web-based decision aids can improve the quality of PMBR decisions by enhancing patient knowledge and providing personalized risk assessments, reducing decision conflict[18].

Uncertainty about whether they are making the best decision can trigger emotional turmoil, and decision regret occurs when women compare the unfavorable outcome of a decision with alternative choice they may have[11, 47]. The results of our meta-analysis showed that there was no effect of web-based decision aids on decision regret compared to controls. Those women who choose decisions that result in unexpected clinical outcomes or lower-than-expected outcomes will inevitably experience decision regret, a very common but negative emotion, even though the patient's preferences and needs are honored and taken into account in their treatment[49]. Decision

regret can be used as an indicator of decision-making quality, which can contribute to performance improvement in the healthcare system. Other studies from a psychological perspective have shown that if a decision is regretted, the following "preference reversal" may cause patients to favor another unselected option, which may completely offset their health outcomes, with the degree of decision regret varying widely. However, Becerra et al reported that most studies reported a low mean DRS, resulting in an overall mean score of 16.5 out of 100 across studies[50]. It is important to note that there is no consensus on specific thresholds for clinically important decision regret based on DRS, and authors have rarely justified their choice of thresholds, so minimum and maximum efficiency may limit our ability to perform statistical analyses[51].

Previous research has shown that women with BC who use decision aid receive more information that helps them make informed and values-based decisions[26]. Our results, in contrast, showed no effect of web-based decision aids on informed choice compared to the control group, possibly because, compared to other forms, web-based decision aid requires more effort. Therefore, some women in the web-based decision aids may have been less inclined to seek more information and consider it carefully. This may explain why women in the web-based decision aids group did not feel less uninformed about their decisions[52]. The results of previous meta-analyses[25, 26] suggest that web-based decision aids are promising interventions for improving knowledge related to PMBR decision-making and that web-based decision aids can help patients' knowledge of PMBR and treatment options and can identify patients' PMBR preferences and goals for quality decision-making with their healthcare providers; however, it is important to note that in the present review, the impact of web-based decision aids on PMBR knowledge was mixed, which may be because most of the current instruments on PMBR decision-making knowledge measurement are self-administered scales, and that we found that web-based decision aids improved PMBR knowledge compared to a control group of some conventional education[37], traditional counseling[31], or conventional pamphlets[30]. When the control group was pamphlets [19, 28]or noninteractive decision aids[29]

that contained similar information, web-based decision aids did not have a statistically significant effect on PMBR knowledge. Therefore, to elucidate the impact of web-based decision aids on knowledge, measurement studies using validated and sensitive instruments are needed.

Because the initial anxiety experienced by women may be related to the new diagnosis and anticipated surgery, this anxiety lessened once the surgery was over. There was no difference in the level of anxiety experienced after surgery between the two groups given the severity of a BC diagnosis, it is very reassuring that web-based decision aids did not exacerbate anxiety while providing benefits in terms of patient satisfaction and knowledge as well as surgeon satisfaction. Several studies have shown that patient satisfaction is higher when receiving PMBR information digitally[53]. Our study also suggests that web-based decision aid improves patient satisfaction with decision-making. Although most of the studies included in our systematic review reported that the use of web-based decision aids increased women's satisfaction with PMBR, most of the measurement tools used to assess outcomes used self-administered scales. Therefore, more high-quality evidence, including studies using validated and sensitive instruments, is needed to elucidate the impact of web-based decision aids on satisfaction[26].

Sensitivity analysis

Some of the outcome indicators in this review (decision conflict, satisfaction and anxiety) showed significant heterogeneity, which may be related to factors such as the fact that the measurement tools were also different and the web-based decision aids were delivered in an inconsistent form and content. We conducted sensitivity analyses for decision conflict, satisfaction and anxiety, and the adjusted total estimates of anxiety did not significantly change these results when studies were progressively omitted, excluding Manne et al[38]. With respect to decision conflict and satisfaction, the adjusted total estimates changed significantly, a result that excludes the Varelas et al study[31]. Contrary to the original results, the effect of web-based decision aid on improving satisfaction was statistically significant, the effect of web-based decision aid on improving decision conflict was

similar to the control group effect, therefore, the effect of web-based decision aid on decision conflict and satisfaction should be carefully interpreted. Regarding the heterogeneity of this meta-analysis, sensitivity analyses showed that the heterogeneity of all outcomes was also reduced by excluding one study.

Limitations

Some limitations of this review must be recognized. First, we did not perform an assessment of publication bias because only seven studies were ultimately included in the analysis, which may cause publication bias. In addition, the included studies had no follow-up surveys and lacked evidence of the long-term impact of the interventions. Our findings serve as a reminder that even when statistical information is effectively communicated, participants may not make estimates of the same order of magnitude after a period of time. Third, the number of included studies was small. Some studies had inconsistent outcome indicators and were therefore not included. Finally, many of the included studies were conducted in developed countries, which may limit the generalizability of the results.

Conclusion

This review shows that web-based decision aids can increase knowledge and satisfaction, and reduce levels of decision conflict among women facing PMBR; however, there is no effect on informed choice, decision regret, or anxiety. Currently, web-based decision aids for women's PMBR decision-making are relatively easy to implement in terms of content and form. Based on our meta-analysis, due to limitations in the number of included studies, well-designed studies, including multicenter RCTs through the use of high-quality decision aids, are necessary in the future to further validate our conclusion that web-based decision aids play a role in the quality of decision-making for women facing PMBR.

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Author contributions

Criteria	Author Initials
Made substantial contributions to conception and	Lin Yu, Lei Liu,
design, or acquisition of data, or analysis and	Shengmiao Yu Jianmei
interpretation of data;	Gong, Xiaoting Sun, Min
	Zang
Involved in drafting the manuscript or revising it	Lin Yu, Lei Liu,
critically for important intellectual content;	Shengmiao Yu Jianmei
	Gong, Xiaoting Sun, Min
	Zang
Given final approval of the version to be published.	Lin Yu, Lei Liu,
Each author should have participated sufficiently in	Shengmiao Yu Jianmei
the work to take public responsibility for appropriate	Gong, Xiaoting Sun, Min
portions of the content;	Zang
Agreed to be accountable for all aspects of the work	Lin Yu, Lei Liu,
in ensuring that questions related to the accuracy or	Shengmiao Yu Jianmei
integrity of any part of the work are appropriately	Gong, Xiaoting Sun, Min
investigated and resolved.	Zang

Conflicts of Interest

None declared.

Multimedia Appendix 1: [PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-

Analyses) statement]

Multimedia Appendix 2: [Search strategy]

Multimedia Appendix 3: [Characteristics of interventions and control]

Multimedia Appendix 4: [Certainty of evidence]

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Abbreviations

BC: Breast cancer

DCS: Decision Conflict Scale

DRS: Decision Regret Scale

GRADE: The Grading Assessment, Development and Evaluation of Recommendations

HADS: Hospital Anxiety and Depression Scale

IPDAS: International Patient Decision Aid Standards

MDs: Mean differences

ODSF: Ottawa decision support framework

PMBR: Postmastectomy breast reconstruction

PRISMA: Preferred Reporting Items for Systematic Evaluation and Meta-Analysis

RCT: Randomized controlled trials

RRs: Relative risks

SD: Standard deviation

SMDs: Standardized mean differences

STAI: State-Trait Anxiety Inventory

95%CI:95%confidence interval

SD: Standard deviation

SMDs: Standardized mean differences

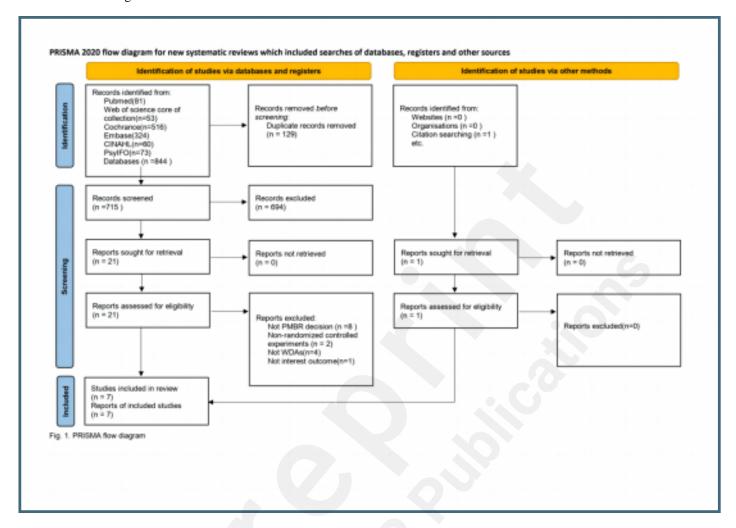
STAI: State-Trait Anxiety Inventory

95%CI:95% confidence interval

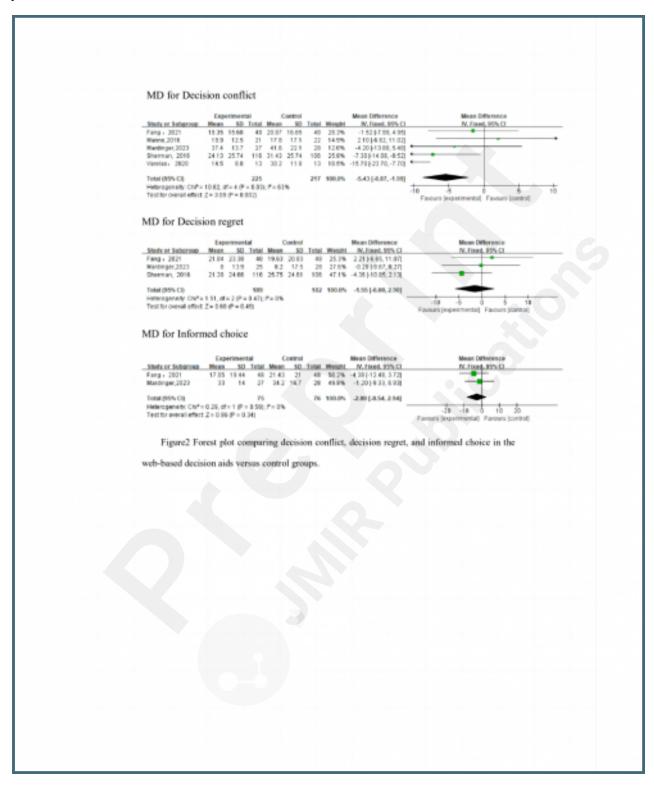
Supplementary Files

Figures

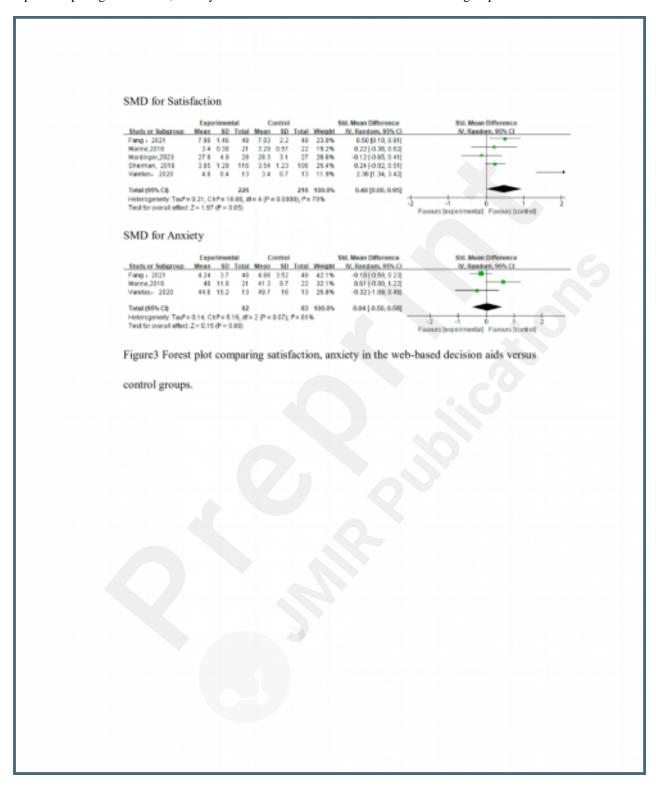
PRISMA flow diagram.



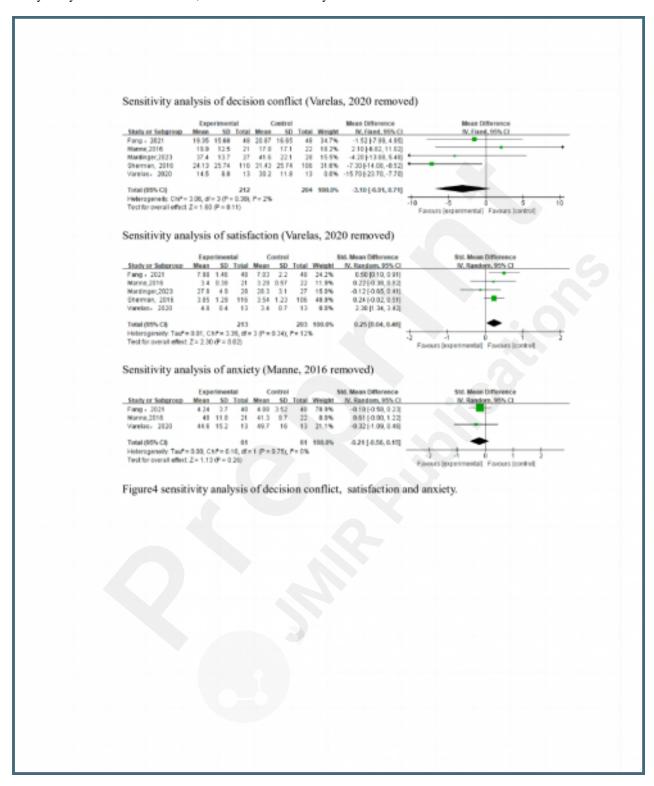
Forest plot comparing decision conflict, decision regret, and informed choice in the web-based decision aids versus control groups.



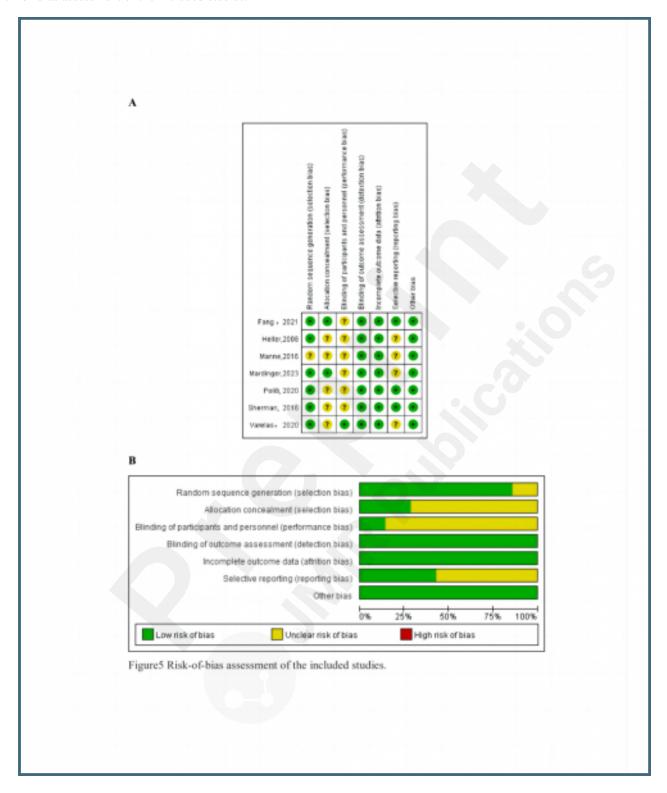
Forest plot comparing satisfaction, anxiety in the web-based decision aids versus control groups.



Sensitivity analysis of decision conflict, satisfaction and anxiety.



Risk-of-bias assessment of the included studies.



Multimedia Appendixes

Author related information.

URL: http://asset.jmir.pub/assets/6a54ff7938170ac4d290c2bcef71d279.docx

PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement.

URL: http://asset.jmir.pub/assets/26bf2d25efd8c61d6b43d26b9c2be715.docx

Search strategy.

URL: http://asset.jmir.pub/assets/f9c612f8619a3ad71468c05377a13b94.docx

Characteristics of interventions and control.

URL: http://asset.jmir.pub/assets/9424cdbeb211fb0459da17664963cc7e.docx

Certainty of evidence.

URL: http://asset.jmir.pub/assets/4321fcc56503895eb992f1ce4d34efd5.docx