

ABSTRACT

Background: Deciding whether or not to have breast reconstruction following breast cancer diagnosis is a complex decision process. This randomized controlled trial assessed the impact of an online decision aid (*BRECONDA* - *Breast RECONstruction Decision Aid*) on breast reconstruction decision-making. **Methods:** Women (N=222) diagnosed with breast cancer or ductal carcinoma in situ (DCIS), and eligible for reconstruction following mastectomy, completed an online Baseline questionnaire. They were then randomly assigned to receive either standard online information about breast reconstruction (control) or standard information plus access to *BRECONDA* (intervention). Participants then completed questionnaires at 1- and 6-months post-randomization. The primary outcome was participants' decisional conflict 1-month after exposure to the intervention. Secondary outcomes included decisional conflict at 6-months, satisfaction with information at 1- and 6-months, and 6-month decisional regret. **Results:** Linear mixed-model analyses revealed that 1-month decisional conflict was significantly lower in the intervention group (27.18) compared with the control (35.5). This difference was also sustained at the 6-month follow-up. Intervention participants reported greater satisfaction with information at 1- and 6-month follow-up, and there was a non-significant trend for lower decisional regret in the Intervention group at 6-month follow-up. Intervention participants' ratings for *BRECONDA* demonstrated high user acceptability and overall satisfaction. **Conclusions:** Women who accessed *BRECONDA* benefited by experiencing significantly less decisional conflict and being more satisfied with information regarding the reconstruction decisional process, than women receiving standard care alone. These findings support the efficacy of *BRECONDA* in helping women to arrive at their breast reconstruction decision.

Approximately 800,000 women in the Western world are diagnosed with breast cancer each year¹⁻⁴, with 30-40% requiring mastectomy, entailing surgical removal of breast tissue⁵. These women face the challenging decision of whether, how, and when to reconstruct their breast following mastectomy. Decisions are complicated by the many available reconstruction options, the need to consider advantages and complications of each option, as well as the potential influence of treatment (i.e., radiation and chemotherapy) on reconstruction outcomes⁶. Decisions regarding immediate reconstruction must often be made within days of diagnosis⁶, although women may opt for delayed reconstruction any time after their mastectomy. The decision about breast reconstruction is influenced by a multitude of factors, including access to breast reconstruction surgery, and understanding of the required surgeries and potential surgical benefits. Personal values play a key role in this decision, and so it is important that patients have access to appropriate information and are supported so that they can carefully weigh up all options and express their true treatment preferences⁷. A key focus for health professionals is to facilitate effective decision making, ensuring that women make informed choices that reflect personal values, rather than specific decisions made for or against having reconstructive surgery.

The responsibility and uncertainty associated with making the reconstruction decision can be overwhelming and burdensome, leading to poor psychosocial outcomes⁶. Decisional conflict is commonly experienced, reflecting indecision characterized by feeling uncertain, delaying decision making, vacillation between choices and questioning of values and beliefs⁸. As breast reconstruction can be performed immediately following mastectomy, or as a delayed procedure, women may experience decisional conflict both prior to initial surgery and at a later date⁸. Moreover, in the longer term women may experience decisional regret regarding the reconstruction decision. Importantly, decisional regret has been documented in both women who have opted for, and against, breast reconstruction, further emphasizing the

importance of the decisional process in arriving at a final decision about reconstructive surgery^{9,10}.

Decision aids are educational resources designed to provide information and facilitate treatment decision-making, taking into account individual values and preferences^{11,12}. Within the breast cancer context generally, tools for assisting women in decisions about mammographic screening, treatment options and genetic risk assessment, have improved knowledge¹³⁻¹⁵, increased satisfaction with information¹¹, clarified personal values and preferences¹⁶, facilitated readiness to make surgical decisions⁷, and reduced decisional conflict and regret^{13,14,17-19}. Computer-based decision aids have similar benefits to paper-based versions, with greater potential reach through web-based applications²⁰.

While some decision tools outline breast reconstruction options^{7,8,21}, they are limited as they do not specifically focus on decisional complexities. Furthermore, while other decision-type tools (e.g., option grids) can be effective²², they do not have the scope to detail all information relevant to reconstruction decision-making, and do not incorporate components unique to decision aids (e.g., values clarification exercises). Thus, existing decision tools are not sufficient to facilitate informed decision making about reconstruction. *BRECONDA* (Breast *RECON*struction Decision Aid; available at www.breconda.org, for access please contact Corresponding Author) is a rigorously-developed, interactive web-based intervention to facilitate decision making regarding breast reconstruction²³. Preliminary testing indicated high user-acceptability and ease-of-use, enabling women to feel secure in their reconstruction decisions and better prepared for surgical consultations.

We conducted a randomized controlled trial (RCT) to evaluate the effectiveness of *BRECONDA* among women who were considering breast reconstruction following mastectomy. The primary outcome was decisional conflict one month following randomization. The decision-making process is multi-faceted²⁴, hence we also assessed

satisfaction with reconstruction-related information and decisional regret as secondary outcomes in this study^{8,25}. We hypothesized that women who accessed *BRECONDA* would report reduced decisional conflict at one-month follow-up, compared with women receiving standard care alone. Secondary hypotheses were that women provided with *BRECONDA* would report reduced decisional conflict and decisional regret at 6-months, and greater satisfaction with information at 1- and 6-months, compared to women receiving standard care. User acceptability of the *BRECONDA* intervention was also assessed at 6-months.

METHODS

Study Design and Procedures

Eligible women were diagnosed with breast cancer or ductal carcinoma in situ (DCIS); recommended to undergo/had already undergone a mastectomy; over 18 years of age; English language competent for reading and writing; had no prior breast surgery (e.g., reconstruction or augmentation); and, had internet access.

Participants (N=222) were recruited between December 2011 and August 2013 from breast centers (n=76) (six metropolitan-based breast clinics - 3 Public, 3 Private; two regional private breast clinics), and nationwide community-based breast cancer consumer organizations (n=146). Figure 1 describes the flow of participants through the study. Clinic staff gave eligible women an invitation containing study information and the web address at which study registration and consent took place, and emailed invitations were sent to consumer organization members with a direct link to the study web address.

After registering and consenting at the study website, participants completed an online baseline questionnaire and were then automatically randomized to the Intervention or Control condition using a computer-generated random number sequence from Statistical Analysis Software (Cary, NC: SAS Institute Inc.). Clinic and surgical staff were blind to condition assignment. Additional online questionnaires were completed at 1- and 6-months post-

baseline. Ethical approval for this trial was granted by the relevant institutional human research ethics committee. This trial was registered with the Australian New Zealand Clinical Trials Registry: ACTRN-12609000363280.

Intervention Condition

Participants allocated to the Intervention condition received access to *BRECONDA* for the 6-month duration of study enrollment, and the standard information provided to Control participants. *BRECONDA* is organized in a menu-driven modular format, with each module addressing an identified area of need for women considering breast reconstruction. It is self-paced and includes core screens providing basic information, plus optional components with more detailed material allowing users to select the extent of information accessed, to match their personal information processing style²⁶. It is estimated that the average user would take 45 minutes to review all sections of the website. *BRECONDA* includes breast reconstruction-related information, strategies for managing emotions related to the reconstruction decision, values clarification components and video segments detailing other patient's experiences. Table 1 details the components of *BRECONDA*, and Figures 2-4 illustrate these components. Other details pertaining to *BRECONDA* are described in detail elsewhere²³.

Control Condition

Participants in the Control group received online access to information from an excerpt of a publicly available booklet "Guide for Women with Early Breast Cancer"²⁷ including basic information about breast surgery and reconstruction, but not components unique to *BRECONDA* (i.e., video interviews with patients/surgeons, values clarification exercises). The booklet was available for all study participants (irrespective of condition) throughout study duration. Participants were not instructed to avoid other information sources.

Study Outcome Measures

The primary outcome for this study was decisional conflict at 1-month post-randomization. Secondary outcomes included decisional conflict (6-months), satisfaction with reconstruction-related information (1- and 6-months), and decisional regret (6-months).

The 16-item Decisional Conflict Scale (DCS)^{28,29} assessed the extent to which an individual experienced conflict regarding the reconstruction decision (α range: .83 - .96). Items were summed, divided by 16 and multiplied by 25. Consistent with the scale's user manual, scores lower than 25 were associated with implementing a breast reconstruction decision; scores exceeding 37.5 were translated to mean greater decision delay and feeling unsure about one's reconstruction decision. Satisfaction with reconstruction-related information was assessed by a 5-item scale adapted from measures used in previous research^{30,31}, with higher scores indicating greater satisfaction ($\alpha = .82$). Regret was assessed by the 5-item Decision Regret Scale ($\alpha = .82$)³². Items were summed and averaged to calculate a final score, with higher scores indicating greater regret. User acceptability of *BRECONDA* was assessed (at 6-month follow-up, by intervention participants) using six statements similar to those used in previous research³³, rated on a 5-point Likert-type scale (0-Not at all to 4-Very much so), with higher scores indicating greater user acceptability ($\alpha = .93$).

Demographics and medical history (age, education, marital status, country of birth, cancer stage, time since diagnosis, and, current treatment-, mastectomy- and reconstruction-status) were measured for sample description and potential use as covariates. Extent of reconstruction information received from a doctor/surgeon prior to study entry, and depressive symptoms DASS-21³⁴ and perceived social support SSQ-6³⁵ at study entry, were measured as these may confound the impact of a decisional support intervention^{36,37}.

Statistical Analysis

Baseline demographic, medical characteristics, and depression and social support, were compared across conditions by conducting *t*-tests and χ^2 tests. Maximum-likelihood linear mixed models tested the effect of the intervention on the outcomes. Confounding effects of several variables were controlled for including age, education, time since diagnosis, mastectomy status at baseline, recent treatment received, reconstruction status at each follow-up, baseline depression and social support, and prior receipt of reconstruction-related information from a breast surgeon or physician. Fixed effects included time, intervention group and their interaction, baseline outcome levels, and identified confounding variables. The parameters of primary interest were the fixed effect interaction terms between conditions and times, describing whether the participants in the two conditions changed differently in decisional conflict across the observation period, as well as the planned contrasts comparing post-randomization group means of all outcomes. Random effects for a participant-specific random intercept accounted for within-participant correlation. Cohen's *d* was used as a measure of effect size for each outcome. All analyses used the standard alpha level of 0.05 and were carried out using SPSS version 21. Sample size was calculated to detect an effect size of 0.3 in decisional conflict (two-sided alpha=.05 and power \geq 80%). The intended final sample was 80 per group. We allowed for an anticipated dropout rate of 30%, which is common in internet-based intervention research^{38,39}. Accordingly, we planned to recruit 226 women into the study.

RESULTS

Forty-five women had undergone bilateral mastectomy for contralateral primaries (no women had bilateral prophylactic mastectomy). At baseline, there were no differences between the two conditions in demographic characteristics (Table 2). There were also no differences in dropout rates between assigned conditions on baseline characteristics ($\chi^2=.045$, $P=.83$). Women who dropped out reported a larger social network than study participants (Social

Support_{Number}: Intervention 6.79 v Control 5.19; $t=2.36$, $P=.03$). There was no difference in reconstruction rate between Intervention and Control groups at 1-month (Intervention 14 v Control 17; $\chi^2=.688$, $P=.701$) with most women (75%) undergoing implant reconstruction. Of all reconstructions, 62% were immediate (80% of which were implants) and 38% were delayed procedures. At 6-months there were also no group differences in reconstruction rate (Intervention 16 v Control 19; $\chi^2=.417$, $P=.451$) with 64% of women undergoing implant, 21% Transverse Rectus Abdominis Myocutaneous flap, 9% Deep Inferior Epigastric Perforator flap, and 6% Latissimus Dorsi flap, surgery. Of all reconstructions, 46% were immediate (85% of which were implants) and 54% were delayed procedures. The median time since mastectomy for women considering delayed reconstruction was 25 months (range 1 week to 29 years). Source of recruitment, mastectomy status at time of recruitment, and reconstruction status at follow-up, had no impact on the effect of the intervention on any of the outcomes assessed.

Intervention Effects on Decisional Conflict, Satisfaction with Information and Decisional Regret

Overall, the interaction of condition by time was significant $F=4.01$, $P=.019$ for decisional conflict, which decreased over time for both conditions, but at a greater rate for Intervention participants. Decisional conflict planned contrasts results are displayed in Table 3, Figure 2 and Figure 3 (adjusted means). After adjusting for baseline decisional conflict, and covariates, mean decisional conflict was significantly lower in the *BRECONDA* group at 1-month follow-up. Secondary analyses indicated that this difference in decisional conflict between conditions was sustained at the 6-month follow-up.

Analysis of secondary outcomes also indicated a significant difference in satisfaction with information between groups at 1- and 6-months $F=7.41$, $P=.007$ (after adjusting for covariates), with satisfaction greater in the *BRECONDA* group at both timepoints (Table 3,

Figure 2 and Figure 3). At 6-months, *BRECONDA* participants demonstrated lower regret (non-significant trend) compared with Control participants $F=3.46$, $P=.065$ (Table 3).

User Satisfaction

Intervention participants' ratings of *BRECONDA* demonstrated high user acceptability with overall high satisfaction ($M = 2.89$, $SD=.68$). They reported that the website provided a balanced view ($M = 2.94$, $SD=.76$), was useful ($M=2.79$ $SD=.92$) and easy to use ($M=3.05$, $SD=.88$), contained sufficient information ($M=2.88$, $SD=.80$), and helped them to clarify their thoughts about reconstruction ($M=2.50$, $SD=.81$).

DISCUSSION

This study assessed the impact of *BRECONDA* in women with breast cancer who were eligible for breast reconstruction. Of primary interest was the effect on decisional conflict at 1-month post-randomization. As predicted, participants who received *BRECONDA* experienced significantly less decisional conflict, compared with control participants. At baseline, both participant groups experienced moderate levels of decisional conflict. Following provision of *BRECONDA*, decisional conflict at 1-month decreased for intervention participants to levels consistent with having implemented, or made, the decision, whereas controls reported levels of decisional conflict reflecting indecision and decisional delay²⁹. Even by 6-months the control group still experienced decisional conflict scores reflecting indecision (>31), whereas the intervention participants retained the benefits of low decisional conflict that were evident at 1-month. This finding is important, given that higher levels of decisional conflict have been associated with greater depressive symptomatology in the long-term⁴⁰. Thus, the changes in decisional conflict reported are both statistically and clinically significant. For *BRECONDA* participants, their reduction in decisional conflict was both greater, and at a faster rate, than for individuals assigned to the Control group. This suggests that *BRECONDA* helped women to feel informed, have clarity about their

reconstruction-related values, feel supported in the decision-making process, and feel certain and satisfied about their decision. The reduction in decisional conflict represents a statistically and clinically meaningful reduction, having gone from a state of indecision to decision completion or implementation²⁹. These findings are consistent with previous research, which demonstrated reductions in decisional conflict in patients who accessed general breast surgery-related decision aids^{13,14,17-19,41}, and indicate the potential for *BRECONDA* to diminish feelings of decisional conflict amongst women faced with the option of breast reconstruction. As such, these results suggest that the *BRECONDA* intervention is a valuable adjunct to medical consultations, and can be used by surgeons according to their unique surgical expertise and preferences.

Our results also demonstrated that, compared with control participants, those who accessed *BRECONDA* reported greater satisfaction with breast reconstruction information. This is consistent with previous research, where decision aids in the breast cancer context increase satisfaction with information received¹¹. It is possible that women allocated to *BRECONDA* believed that the information was more comprehensive than what is typically offered, given the limited time available to decide on immediate reconstruction, and the preferences of some surgeons for specific reconstruction options. Furthermore, the only difference between women who dropped out and those remaining in the study was their baseline reported social support, suggesting that *BRECONDA* is more appreciated by those lacking an adequate support network. Given the benefits of *BRECONDA*, it is reassuring that women found the website useful and user-friendly, and believed it represented a balanced view of the options available. This suggests that women will be inclined to utilize the website once it is made widely available. While decisional regret did not differ between groups at 6-months, there was a non-significant trend indicating that individuals receiving *BRECONDA* experienced

less regret, with this group now experiencing mild regret¹⁰. This finding is congruent with the concept of decisional regret^{32,42}, which typically manifests over the longer term, suggesting that as time passes, women who accessed *BRECONDA* may experience less remorse following their reconstruction decision¹¹. This finding is important, given that higher levels of decisional regret are associated with greater distress and poorer functional quality of life^{40,43}.

While these findings highlight the efficacy of *BRECONDA* in facilitating reconstruction decisions, certain limitations warrant consideration. Although, the multicentered nature of this study meant that the breast reconstruction information provided to patients was not standardised, the fact that both private and public hospitals were utilised for participant recruitment represented a wide range of patients and surgeons. The relatively small sample of women recruited from clinics precluded analyses to examine whether the intervention effects differed for women eligible for both immediate *and* delayed reconstruction versus delayed reconstruction alone. Future research should address this, to ascertain the most suitable timing for this tool to be provided. The dropout rate (approximately 27%) in this study was relatively high, although comparable or less than other studies assessing the impact of web-based interventions⁴⁴. As women dropping out had a greater perceived social support network at baseline, there may have been a self-selection bias whereby women perceiving a need for this decisional support participated and remained in this study. While participants were recruited nation-wide, the generalizability of these findings to non-Australian participants should be addressed in future research. Further, as participants were treated at many hospitals, the variability in surgical expertise could not be controlled for in analyses. Breast reconstruction rate was relatively low (<20%), although this is greater than the national rate (approximately 9-12%)⁴⁵. It was beyond the scope of the

current study to assess a number of potential confounding variables, including type and timing of reconstruction and radiation therapy. Future research is warranted to investigate this. Finally, the follow-up in this study was relatively short; additional research must assess the longer-term impact of *BRECONDA*. This is especially relevant to decisional regret, as the aesthetic results of reconstruction are typically not evident for some time after surgery⁴⁶, and some may not have completed their final reconstruction surgical procedures at the 6-month follow-up. Nonetheless, the finding that women who accessed *BRECONDA* felt less conflicted and more satisfied with the information on which they were making a reconstruction decision, and were tending to be less regretful over time, lends support for the intervention in facilitating decision-making among women considering reconstruction. The next steps are to determine the longer term effects of *BRECONDA* on a range of medical and social outcomes, and to investigate the most efficient and effective means by which to translate these findings to the broader clinic setting by making *BRECONDA* available in breast clinics throughout Australia, to ascertain whether these benefits are sustained in the longer term.

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Table 1. *BRECONDA* Website Content.

Module	Content Description
Introduction	Description of breast reconstruction and who can undergo this procedure.
Making decisions	Overview of the <i>BRECONDA</i> content and the general purpose of the website.
Hints for making a decision	Questions women can ask themselves to aid decision-making.
What reconstruction choices do I have?	Provides reconstruction options, contraindications and eligibility criteria.
When can I have reconstruction?	Immediate versus delayed reconstruction, and factors influencing the type and timing of reconstruction offered.
What to expect	How the reconstructed breast will look and feel, reconstruction results, and expected recovery time.
What else should I know before making a decision?	Advantages and disadvantages of reconstruction versus no reconstruction and comparison of reconstruction options.
What might go wrong?	Potential complications for reconstruction options.
My feelings about the reconstruction decision/ Tips for managing my feelings	Emotions that may arise during the decision process and strategies for recognising and reducing stress.
Family issues	Strategies for communicating with family members about reconstruction decisions.
Other people's stories	Video segments of other women's experiences of deciding whether or not to undergo reconstruction.
What do I think about	Requires the user to indicate the importance of specific values.

reconstruction?/What type of reconstruction do I prefer?	Presents a tabular summary, colour coded to reflect the personal importance of each value.
Who to contact for more information	Contact information for healthcare professionals and support services. Provides additional websites for further information.
Conclusion	Reminder to make decisions about reconstruction in consultation with a doctor/ healthcare professional.

Table 2. Participant Demographic and Clinical Characteristics at Baseline

Characteristic	Control arm		<i>BRECONDA</i> arm		<i>P</i> -value
	(n=106)		(n=116)		
	No.	%	No.	%	
Age (years)					.18
Mean	51.88		51.99		
SD	9.12		9.95		
Country of birth					.12
Australia/NZ	92	86.8	90	77.6	
Western Europe	9	8.5	16	13.8	
Other	5	4.7	10	8.6	
Marital status					.37
Single, never married	7	6.6	14	12.1	
Married/living with partner	77	72.6	81	69.8	
Separated/divorced/widowed	22	20.8	21	18.1	
Education					.04
Year 10 or less	14	13.2	14	12.1	
High School Certificate	14	13.2	11	9.5	
Vocational/TAFE	13	12.3	30	25.9	
Undergraduate	43	40.6	36	31.0	
Postgraduate	22	20.7	25	21.5	
Household income					.49
Less than \$50, 000	29	28.2	33	28.9	
\$50, 001 to \$90, 000	30	29.1	32	28.1	
More than \$90, 000	44	42.7	49	43.0	

Grade of breast cancer					.81
DCIS	18	17.0	15	12.9	
Stage 1	10	9.4	12	10.4	
Stage 2	34	32.1	37	31.9	
Stage 3	30	28.3	31	26.7	
Don't know	14	13.2	21	18.1	
Time Since Diagnosis (years)					.31
Mean	3.10		2.67		
SD	4.34		3.28		
About to have a mastectomy					.41
No	84	80.8	84	76.4	
Yes	20	19.2	26	23.6	
Mastectomy type					
Single	84	79.3	89	78.1	.34
Double	22	20.7	25	21.9	
Radiation (last month)					.40
No	101	95.3	113	97.4	
Yes	5	4.7	3	2.6	
Chemotherapy (last month)					.91
No	100	94.3	109	94.0	
Yes	6	5.7	7	6.0	
Info. from breast/plastic surgeon					.54
Neither	50	46.3	55	47.9	
Breast or plastic surgeon	36	33.3	45	38.7	
Breast and plastic surgeon	20	20.4	16	13.4	

Social Support Satisfaction			.28
Mean	5.04	5.01	
SD	.93	.82	
Social Support Number			.51
Mean	5.72	5.49	
SD	3.50	3.96	

Abbreviation: Radiation (last month) = Radiation treatment in last month; Chemotherapy (last month) = Chemotherapy treatment in last month; Info from breast/plastic surgeon = Received information from breast and/or plastic surgeon.

Table 3. Summary Results of Follow-Up Planned Contrasts

Primary Outcome	<i>BRECONDA</i> (<i>n</i> = 116)		Control (<i>n</i> = 106)		Adjusted <i>P</i>	Cohen's <i>d</i>	Possible range
	Mean	SE	Mean	SE			
Decisional conflict							
1-month	27.18	2.31	35.50	2.46	.005	.35	0-100
Secondary Outcome	<i>BRECONDA</i> (<i>n</i> = 116)		Control (<i>n</i> = 106)		<i>P</i>	Cohen's <i>d</i>	Possible range
	Mean	SE	Mean	SE			
Decisional Conflict							
6-month	24.13	2.39	31.43	2.50	.016	.29	0-100
Satisfaction with							
Information							
1-month	3.71	.11	3.39	.12	.016	.31	1-5

6-month	3.85	.12	3.54	.12	.028	.27	1-5
Decision Regret							
6-month	21.39	2.29	25.75	2.39	.065	.21	0-164

Figure Legends

Figure 1. CONSORT Diagram

Figure 2. *BRECONDA* Main Menu

Figure 3. “My Feelings about Reconstruction” section of *BRECONDA*

Figure 4. “Other People’s Stories” section of *BRECONDA*

Figure 5. Change over time for Decisional Conflict by Condition

Figure 6. Change over time for Satisfaction with Information by Condition