Supporting women with breast cancer in making an informed decision about immediate breast reconstruction: the development and evaluation of a patient decision aid

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Chapter 5

Efficacy of a decision aid in breast cancer patients considering immediate reconstruction: results of a randomized controlled trial

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ABSTRACT

PURPOSE

Breast cancer patients face complex decisions about immediate breast reconstruction (BR) after mastectomy. We evaluated the efficacy of an online decision aid in improving the decision-making process, decision quality and health outcomes in breast cancer patients considering immediate BR.

METHODS

In a multicenter randomized controlled trial, patients were allocated to either the intervention group receiving care-as-usual (CAU) with access to an online decision aid, or the control group receiving CAU with an information leaflet. The primary outcome was decisional conflict. Secondary outcomes assessed the process of decision making (e.g. preparation for decision making, satisfaction with information), decision quality (decision regret, knowledge) and health outcomes (e.g. satisfaction with BR outcomes, body image). Patients completed questionnaires at baseline (T0), 1 week after consultation with a plastic surgeon (T1), 3 months (T2), and 12 months post-surgery (T3).

RESULTS

We included 250 patients. Decisional conflict decreased over time in both groups, with no between group differences. Intervention participants felt better prepared for decision making than controls ($P = .002$). At T2, 87% of intervention participants were (very) satisfied with the information about BR, compared to 73% of control participants ($P = .011$). No significant between group differences were observed in any other outcome.

CONCLUSION

Our online decision aid was as effective in reducing decisional conflict as an information leaflet about immediate BR after mastectomy. However, the decision aid substantially improved the decision-making process by better preparing breast cancer patients for decisions about immediate BR.

BACKGROUND

In Western European countries, approximately one in seven women develops breast cancer (1). As surgical treatment, approximately 60 - 70% of all breast cancer patients undergo breast-conserving surgery (2-4), whereas 30 - 40% undergo a mastectomy (2-5). Especially mastectomy can have a negative impact on psychosocial outcomes such as body image and sexual functioning (6-9). To restore breast contour, and potentially improve psychosocial outcomes after mastectomy, women may opt for breast reconstruction (BR). Breast reconstructive surgery can be performed immediately after mastectomy (IBR) or BR can be delayed. Additionally, there are several modes of BR (implant-based, autologous, and a combination of both). All BR options have their pros and cons. Personal values and preferences of patients play an important role in the decisions about BR (10, 11).

Dutch guidelines recommend discussing the possibility of IBR with every patient prior to mastectomy (12). The number of women choosing BR, and especially *immediate* BR, is increasing (2, 13-18). In 2021, 29% of patients undergoing a mastectomy opted for *immediate* BR in the Netherlands (19). Around 10% opts for *delayed* BR (20-22). However, both nationally and internationally, immediate BR rates vary substantially across hospitals and geographical locations, ranging from 0-77% among Dutch hospitals (18, 23-25).

Decision making regarding BR is complex, and can be challenging for women, especially so soon after receiving a breast cancer diagnosis (11). Previous studies highlight the importance of providing qualitative and realistic preoperative information and decisional support to enable women to make a long-term satisfying decision about BR (26-33). Although most women are satisfied with their reconstructed breast, and decision regret is generally low (34), a minority of women experience mild to moderate regret (26, 35). Poor knowledge of BR coupled with feelings of being poorly prepared to make a decision are commonly experienced and are linked to poor outcomes, like decision regret (26, 36-38).

Patient decision aids (pDAs) are tools developed to support the process of shared decision making between patients and physicians (39). They explicitly describe the decision that patients face, provide evidence-based information about treatment options including their pros and cons, and support in clarifying personal values relevant to the decision (39). PDAs for a variety of treatment decisions have shown to reduce decisional conflict and increase knowledge and insight into personal values related to the decision (40, 41).

Worldwide, few interventions to support patient decision making about BR are available (42). A systematic review assessing the effectiveness of these interventions found that patient satisfaction and involvement in decision making improved following pDA exposure, yet, results on other outcomes were mixed. However, most studies were methodologically flawed (e.g., small sample size, single-center design), and neglected to control for potential confounding variables such as complications (42, 43).

To support women in making an informed decision regarding IBR following mastectomy, and in the absence of any decision-making supportive interventions for the Dutch population, we developed an online pDA. The primary aim of this study was to evaluate the efficacy of this pDA in reducing decisional conflict, while addressing limitations of prior studies by including a large sample size and using a multicenter randomized controlled design (42, 43). As a secondary aim, we evaluated the impact of the pDA on the decision-making process, decision quality, and patient-reported health outcomes.

METHODS

DESIGN

We conducted a two-arm randomized controlled trial in eight hospitals throughout the Netherlands. A detailed description of the study protocol is published elsewhere (44), and the trial protocol was registered (ClinicalTrials.gov, NCT03791138). Group allocation was via simple randomization (1:1) and stratified by site and by patients' surgical treatment options (i.e. a) patient opted for mastectomy while eligible for both mastectomy and breast conserving surgery, or b) patient opted for mastectomy and was eligible for mastectomy only). The institutional review boards of all participating hospitals approved the study.

ELIGIBILITY CRITERIA

Patients were eligible if they were: (1) females at least 18 years old, (2) diagnosed with breast cancer or ductal carcinoma in situ, (3) scheduled to undergo mastectomy and eligible for IBR, and (4) had been referred to a plastic surgeon. The consultation with the plastic surgeon was scheduled at least three days after study invitation to allow sufficient time for participants to complete informed consent, the baseline questionnaire, and the pDA or the information leaflet prior to their consultation. Additionally, patients were required to have (5) internet access and basic computer skills, and (6) sufficient command of the Dutch language.

PROCEDURE

Patients were invited for study participation by their treating surgeon or nurse during the consultation in which the possibility of BR was discussed. After completing the informed consent form and baseline questionnaire, participants were randomly allocated to the intervention or control group. Intervention group participants received a link to the pDA and control group participants received an information leaflet on BR by email. Participants completed questionnaires at T0 (baseline), T1 (one week after consultation with the plastic surgeon), T2 (three months post-surgery), and T3 (twelve months post-surgery). Intervention group participants had unlimited access to the pDA during the study. See the study protocol for full details (44).

INTERVENTION GROUP

Patients in the intervention group received care-as-usual (CAU) and access to the online interactive pDA (named 'Breast Reconstruction Patient Decision Aid', available at https://

br.keuzehulp.nl (in Dutch)). The pDA aims to prepare patients for consultation with a plastic surgeon. It contains evidence-based information about BR options, the pros and cons of each option, value clarification exercises and patient stories of women who previously faced the decision. It results in a summary sheet including a patient's BR preferences to discuss with their plastic surgeon. The information is tailored to patient's treatment options relevant for decision making about BR (see the development paper (45) for full details of the pDA).

CONTROL GROUP

Patients in the control group received CAU and an information leaflet about BR, typically provided as standard in Dutch hospitals (46). The 39-page leaflet provides information about all types of BR, including drawings and photos of results. In contrast to the pDA, the leaflet is not structured to guide decision making, is not tailored to patient's treatment options, and does not contain value clarification exercises, patient stories or a summary sheet including a patient's BR preferences.

STUDY MEASURES

At baseline, sociodemographic and clinical information were obtained, as well as patients' preference regarding BR, preferred involvement in decision making about BR (47), frequency of and skills regarding internet usage, and information coping style (48). Information about patients' surgical treatment, complications, and adjuvant treatment was obtained via post-surgical questionnaires (T2 and T3). Standardized self-report questionnaires were administered to assess the primary and secondary outcomes (See Table 1 for an overview of study measures). The primary outcome was decisional conflict measured by the Decisional Conflict Scale (49-51), assessing how well-informed patients feel about their decision, the level of uncertainty about the best choice, and the perceived effectiveness of decision making. Secondary outcomes included the *decision-making process* measured by satisfaction with information (52), satisfaction with the plastic surgeon (52), preparedness for decision making (53, 54), patients' perceived levels of shared decision making during consultation with their plastic surgeon (55, 56), and patients' perceived level of involvement in decision making (47). *Decision quality* was measured by knowledge of BR (44), and decision regret (57, 58). *Patient-reported health outcomes* included patients' actual choice regarding BR, patient satisfaction with breast (52), satisfaction with reconstruction outcomes (52), body image (59), sexual functioning (59), breast symptoms (59), and anxiety (60).

Table 1. Overview of primary and secondary outcome measures

Outcome measure	Instrument	Details	T0	T1	T2	T3
Primary outcome						
Decisional conflict	Decisional Conflict Scale (DCS) (49, 51)	The DCS has five subscales (uncertainty, feeling informed, feeling clear about values, feeling supported and effective decision making*) and a total score. Score range: 0 - 100, higher scores indicate more decisional conflict. Scores > 37.5 are associated with decision delay and feeling unsure about implementation (49, 51). The effective decision making subscale was not assessed at T0, as items of this scale were considered inappropriate to assess before patients had a consultation with a plastic surgeon. As an alternative for the total score, the Combined score without Effective Decision Making subscale was calculated by summing items of the other four subscales, dividing by 12, and multiplying with 25 (72, 73).	x	x	x	x
Secondary outcome						
Decision-making process						
Satisfaction with information	2 study-specific questions Satisfaction with Information subscale of BREAST-Q (52)	How satisfied are you with the information about BR? How satisfied are you with the information in the decision aid/information leaflet? Score range: 0 – 100, higher scores indicate higher satisfaction. Subscale is assessed only in women who had BR.			x	x
Satisfaction with plastic surgeon	Satisfaction with the Plastic Surgeon subscale of BREAST-Q (52)	Score range: 0 – 100, higher scores indicate higher satisfaction.		x		
Preparedness for decision making	Preparation for Decision Making Scale (53, 54)	Score range: 0 - 100, higher scores indicate higher perceived level of preparation for decision making.		x		
Shared decision making	Shared Decision Making Questionnaire (SDM-Q-9) (55,56)	Score range: 0 -100, higher scores indicate higher levels of perceived shared decision making.		x		
Patient involvement in decision making	Control Preferences Scale (47)	1 item, 5-point Likert-type scale categorized as Active (A,B), Collaborative (C), or Passive (D,E), with the following answer categories: (A) I made the decision about BR alone, (B) I made the decision about BR after seriously considering my physician's opinion, (C) my physician and I made the decision about BR together, (D) my physician made the decision about BR after seriously considering my opinion, (E) my physician made the decision about BR alone.		x		
Decision quality						
Knowledge of breast reconstruction	Study-specific questionnaire, translated and adapted from a questionnaire used in prior research (74)	10 items answered with true/false/I don't know. The total score is the number of correctly answered items, score range: 0 – 10. Items cover contraindications, risk factors, duration of the recovery period, impact on sensation, number of surgical procedures required, complexity of flap- vs. implant-based BR, risk for complications, impact on breast cancer treatment and survival rates, and the opportunity to spare the nipple.	x	x	x	x

Table 1. Continued

Outcome measure	Instrument	Details	T0	T1	T2	T3
Decision regret	Decision Regret Scale (DRS) (57, 58)	Score range: 0 - 100, higher scores indicate greater regret. A score ≥ 30 means that a participant responded that she was more or less in agreement with at least one of the statements about an experience of regret (75).			x	x
Patient-reported health outcomes						
Actual choice	Study-specific questions	The choice whether or not a patient had immediate BR, and the type of BR (tissue-expander, implant, autologous tissue, or a combination of an implant and autologous tissue).			x	x
Satisfaction with breasts	Satisfaction with Breasts subscale of BREAST-Q (52)	This scale measures body image in terms of a woman's satisfaction with her breast. Items cover breast appearance, and satisfaction with breasts in relation to how a bra fits and how the breasts look when clothed or unclothed. Score range: 0 – 100, higher scores indicate higher satisfaction.			x	x
Satisfaction with reconstruction outcome	Satisfaction with Breast Outcome subscale of BREAST-Q (52)	This scale measures a woman's overall appraisal of the outcome of her breast surgery. Items cover whether woman's expectations were met with respect to the aesthetic outcome and the impact surgery has had upon her life and the satisfaction with the decision to have breast reconstructive surgery. Score range: 0 – 100, higher scores indicate higher satisfaction. Subscale is assessed only in women with BR only.			x	x
Body image	Body Image subscale of EORTC QLQ-BR23 (59)	Score range: 0 – 100, higher scores indicate higher body image.			x	x
Sexual functioning	Sexual Functioning subscale of EORTC QLQ-BR23 (59)	Score range: 0 – 100, higher scores indicate higher sexual functioning.			x	x
Sexual enjoyment	Sexual enjoyment item of EORTC QLQ-BR23 (59)	Score range: 0 – 100, higher scores indicate higher sexual enjoyment.			x	x
Breast symptoms	Breast Symptoms subscale of EORTC QLQ-BR23 (59)	Score range: 0 -100, higher scores indicate higher levels of breast symptoms.			x	x
Anxiety	State scale of the State-Trait Anxiety Inventory (STAI-6) (60)	Score range: 20 - 80, higher scores indicate higher levels of anxiety.	x	x	x	x

Abbrevations: **BR** breast reconstruction**.**
T0 baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery

STATISTICAL ANALYSES

Data were pseudonymized prior to analysis. Missing values were either handled according to published scoring algorithms, or replaced by the mean score of completed items within the (sub)scale for each individual, provided that a minimum of 75% of (sub)scale items were completed. Appropriate tests were used to compare continuous and categorical baseline characteristics between groups.

We used a mixed modelling approach to compare outcomes between groups over time. For outcomes measured at all four time points, we used random intercept and slope models with linear and quadratic time effects to determine whether an initial change in the outcome was maintained during follow-up (time was included as weeks since baseline). For outcomes without a baseline assessment, we used time to follow-up analyses (i.e. the remaining measurement occasions were introduced as a categorical variable). For categorical outcomes, generalized linear models were used.

In all above models, we adjusted for hospital, body mass index (BMI), and potential non-ignorable drop-out on the basis of Akaike's Information Criterion (AIC) and the Bayesian Information Criterion (BIC) (61, 62). In the analyses of outcomes only assessed in participants who had BR (i.e. Breast-Q subscales satisfaction with information and satisfaction with reconstruction outcome), we included history of BC and baseline anxiety in the model selection procedure because of significant baseline differences between the intervention and control groups in this subset.

The difference in mean change scores over time and in mean scores between groups were accompanied by standardized effect sizes (ESs). ESs of 0.20 were considered small, 0.50 moderate, and 0.80 large (63). An ES ≥ .50 was considered clinically relevant (64). To limit Type-I errors due to multiple testing, a *p*-value of .01 was considered statistically significant. Analyses were performed on an intention-to-treat basis.

RESULTS

Patients were recruited between August 2017 and April 2019, and follow-up was completed in November 2020. See Figure 1 for participant flow. In total, 333 patients were informed about the study. Of these patients, 250 patients completed informed consent and baseline questionnaire and were randomly assigned to either the intervention (n=126) or control (n=124) group. Follow-up assessments were completed by 96%, 94%, and 90% of the participants, at T1, T2, and T3, respectively. Completion and inclusion rates of follow-up assessments did not significantly differ between groups.

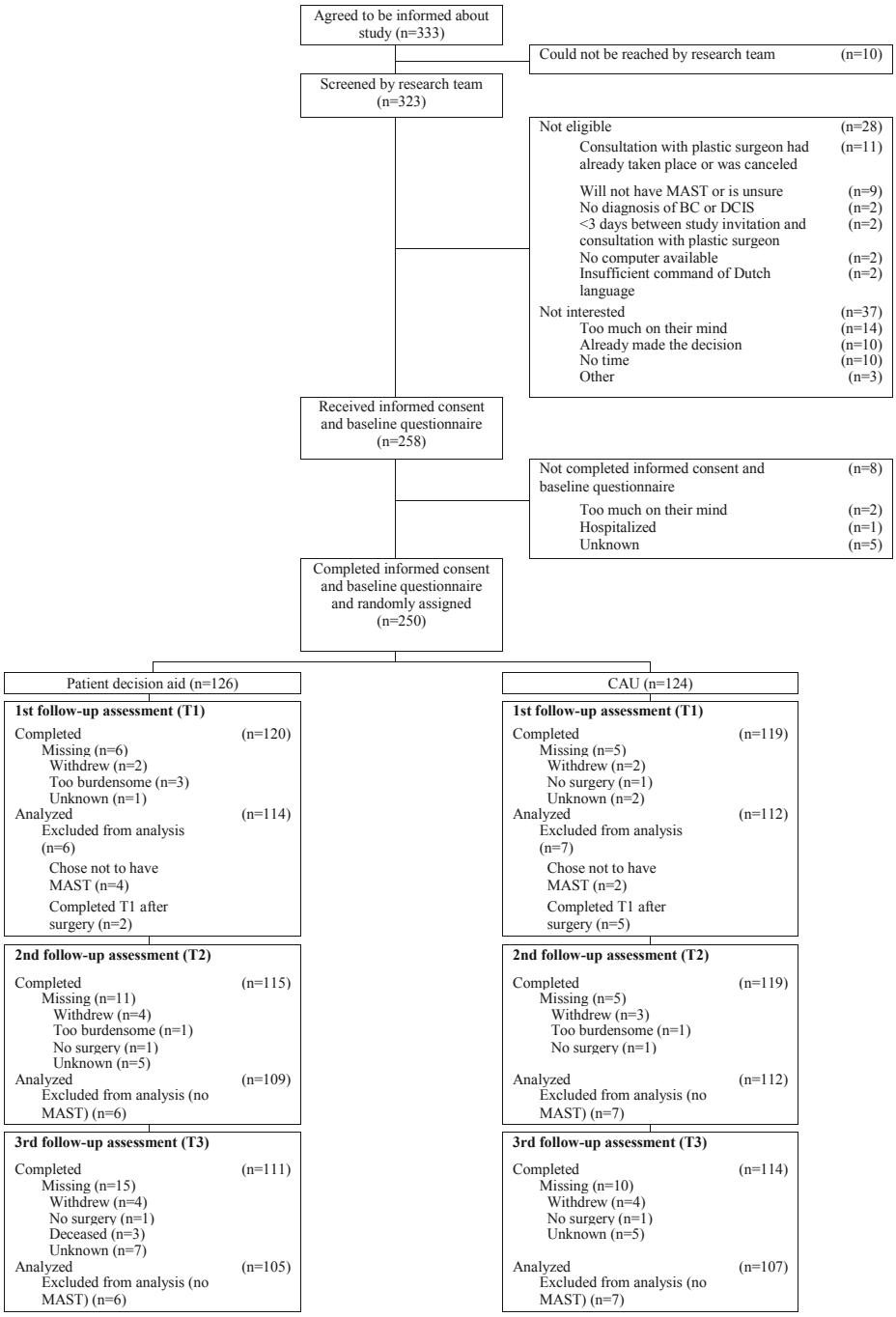

Figure 1. CONSORT diagram.
Abbreviations: **MAST** mastectomy; **BC** breast cancer; **DCIS** ductal carcinoma in situ; **CAU** care-as-usual. **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.

Participants had an average age of 50.1 years. More than half of the participants (51.6%) were highly educated, and most (93.2%) were born in the Netherlands.

All baseline sociodemographic and clinical characteristics were balanced between both groups, except for BMI. Intervention participants were more often obese than control participants (BMI ≥ 30, $p = .01$) (Table 2).

There were no differences between intervention and control groups in the number of participants with adjuvant treatment, surgical complication(s) and loss of BR as a consequence of complication(s) (Supplemental content 1).

Among intervention group participants, 95.6% reported that they used the pDA, of whom 52.8% reported that they discussed the pDA's summary sheet with their plastic surgeon. Among control group participants, 96.4% reported that they used the information leaflet.

PRIMARY OUTCOME

There were no significant differences between the intervention group and the control group in decisional conflict over time (Table 3 and Figure 2). In both groups, decisional conflict significantly decreased from baseline to T1, and remained stable thereafter (Table, Supplemental content 2, showing the effects of time on the primary outcome). At T1, 13.4% of participants had clinically significant decisional conflict (score > 37.5) (no between group difference, $\chi^2 = 0.80$, $p = .371$).

Table 2. Background characteristics of participants (N=250)

	No. (%)			
Characteristic	**All Patients**	**Intervention Group (n=126)**	**Control Group (n=124)**	***p***
Age, years				.64
Mean	50.1	50.4	49.8	
SD	11.0	11.0	11.1	
Educational level§				.81
Low	10 (4.0)	5 (4.0)	5 (4.0)	
Intermediate	109 (43.6)	57 (45.2)	52 (41.9)	
High	129 (51.6)	62 (49.2)	67 (54.0)	
Missing	2 (0.8)	2 (1.6)	0 (0.0)	
Born in The Netherlands	233 (93.2)	118 (93.7)	115 (92.7)	.78
Married or in a relationship	214 (85.6)	111 (88.1)	103 (83.1)	.72
Children (yes)	199 (79.6)	101 (80.2)	98 (79.0)	.83
Body mass index				**.01**

Table 2. Continued

	No. (%)			
Characteristic	**All Patients**	**Intervention Group (n=126)**	**Control Group (n=124)**	***p***
<30	219 (87.6)	104 (82.5)	115 (92.7)	
≥30	31 (12.4)	22 (17.5)	9 (7.3)	
Smoker (yes)	14 (5.6)	8 (6.3)	6 (4.8)	.60
Comorbidities				.56
0	128 (51.2)	65 (51.6)	63 (50.8)	
1	79 (31.6)	37 (29.4)	42 (33.9)	
2+	42 (16.8)	24 (19.0)	18 (14.5)	
Missing	1 (0.4)	0 (0.0)	1 (0.8)	
Diagnosis				.18
Invasive BC	151 (60.4)	69 (54.8)	82 (66.1)	
DCIS	62 (24.8)	35 (27.8)	27 (21.8)	
Both	37 (14.8)	22 (17.5)	15 (12.1)	
Bilateral diagnosis	12 (4.8)	5 (4.0)	7 (5.6)	.54
Time since diagnosis, weeks†				.73
Median	3	3	4	
IQR	18	17	18	
Diagnosis in irradiated breast(s)	27 (10.8)	10 (7.9)	17 (13.7)	.14
Genetic predisposition or familial increased risk for BC				.86
No	153 (61.2)	75 (59.5)	78 (62.9)	
Yes	40 (16.0)	21 (16.7)	19 (15.3)	
I don't know	57 (22.8)	30 (23.8)	27 (21.8)	
Neoadjuvant therapy	91 (36.4)	41 (32.5)	50 (40.3)	.20
Chemotherapy	86 (34.4)	39 (31.0)	47 (37.9)	
Endocrine therapy	9 (3.6)	5 (4.0)	4 (3.2)	
Immunotherapy	23 (9.2)	10 (7.9)	13 (10.5)	
Indication for adjuvant radiotherapy				.39
No	71 (28.4)	30 (23.8)	41 (33.1)	
Yes	61 (24.4)	31 (24.6)	30 (24.2)	
Maybe	75 (30.0)	42 (33.3)	33 (26.6)	
I don't know	43 (17.2)	23 (18.3)	20 (16.1)	
Diagnosis BC/DCIS in the past				.46
No	210 (84.0)	108 (85.7)	102 (82.3)	
Yes	40 (16.0)	18 (14.3)	22 (17.7)	

Table 2. Continued

	No. (%)			
Characteristic	**All Patients**	**Intervention Group (n=126)**	**Control Group (n=124)**	***p***
Prior breast surgery for BC/DCIS in the past				
Breast conserving surgery	32 (12.8)	15 (11.9)	17 (13.7)	.67
Mastectomy‡	9 (3.6)	4 (3.2)	5 (4.0)	.72
Mastectomy without BR	4 (1.6)	0 (0.0)	4 (3.2)	
Mastectomy with BR	5 (2.0)	4 (3.2)	1 (0.8)	
BR preference‡				.23
Strong for BR	143 (57.2)	75 (59.5)	68 (54.8)	
Slight for BR	51 (20.4)	21 (16.7)	30 (24.2)	
No preference	33 (13.2)	21 (16.7)	12 (9.7)	
Slight for no BR	9 (3.6)	4 (3.2)	5 (4.0)	
Strong for no BR	14 (5.6)	5 (4.0)	9 (7.3)	
Patients' preferred involvement in decision making about BR				.25
Active	127 (50.8)	69 (54.8)	58 (46.8)	
Collaborative	104 (41.6)	46 (36.5)	58 (46.8)	
Passive	19 (7.6)	11 (8.7)	8 (6.5)	
How often do you use the internet?‡				.60
(Almost) daily	224 (89.6)	114 (90.5)	110 (88.7)	
About once or several times a week	24 (9.6)	12 (9.5)	12 (9.7)	
Less than once a week	2 (0.8)	0 (0.0)	2 (1.6)	
How well can you use the internet?‡				.39
(Very) well	184 (73.6)	90 (71.4)	94 (75.8)	
Average	65 (26.0)	36 (28.6)	29 (23.4)	
(Very) bad	1 (0.0)	0 (0)	1 (0.8)	
Monitoring coping style (TMSI)				.85
Mean	38.2	38.1	38.3	
SD	7.8	7.7	7.9	
Blunting coping style (TMSI)				.76
Mean	34.0	34.1	33.9	
SD	6.3	6.2	6.4	

Abbreviations: **SD** standard deviation; **BC** breast cancer; **IQR** interquartile range; **DCIS** ductal carcinoma in situ; **BR** breast reconstruction; **TMSI** Threatening Medical Situations Inventory.
§Low = primary school, lower vocational; Intermediate = secondary school, intermediate vocational; High = higher vocational, university.
†Based on Mann-Whitney Test. ‡Based on Fisher's Exact Test.

Table 3. Group differences in decisional conflict (primary outcome) over time

	T0	T1[a]	T2[a]	T3[a]	Group by Time effect		ES[b]		
	M (SD)	M (SD)	M (SD)	M (SD)	B (SE)	*p*	T0-T1	T0-T2	T0-T3
Decisional conflict (DCS)									
Combined score without Effective Decision Making subscale[c]					-0.00 (0.17)	.978	-.06	.06	-.05
Intervention group[f]	45.50 (15.25)	25.02 (15.01)	28.26 (15.41)	27.16 (15.37)					
Control group	46.88 (15.23)	27.33 (15.51)	28.63 (18.14)	28.93 (17.81)					
Uncertainty subscale					-0.23 (0.21)	.264	-.02	.14	.08
Intervention group[f]	47.69 (28.88)	27.80 (21.58)	32.48 (24.17)	31.73 (22.82)					
Control group	49.13 (26.33)	29.46 (21.49)	29.76 (22.59)	30.14 (23.61)					
Feeling Informed subscale[h]					0.01 (0.22)	.966	.07	.08	-.03
Intervention group[f]	48.08 (22.34)	22.57 (18.59)	25.15 (17.69)	24.12 (18.58)					
Control group	50.54 (22.21)	23.44 (16.72)	26.04 (19.83)	27.26 (21.80)					
Feeling Clear of Values subscale					0.03 (0.20)	.861	-.10	.00	-.01
Intervention group[f]	45.11 (19.16)	27.51 (17.95)	31.79 (18.80)	30.69 (19.51)					
Control group	45.77 (19.67)	30.21 (16.63)	32.29 (21.08)	31.23 (21.26)					
Feeling Supported subscale					0.15 (0.18)	.384	-.21	-.11	-.29

Table 3. Continued

	T0	T1[a]	T2[a]	T3[a]	Group by Time effect			ES[b]		
	M (SD)	M (SD)	M (SD)	M (SD)	B (SE)	*p*		T0-T1	T0-T2	T0-T3
Intervention group[f]	41.14 (14.93)	22.20 (16.16)	23.61 (17.03)	22.12 (17.56)						
Control group	42.07 (14.01)	26.19 (19.31)	26.41 (22.59)	27.10 (20.03)						

					Between-Group effect								
	T0[g]	T1[a,d]	T2[a]	T3[a]	T1			T2			T3		
	M (SD)	M (SD)	M (SD)	M (SD)	B (SE)	*p*	ES[e]	B (SE)	*p*	ES[e]	B (SE)	*p*	ES[e]
Total score					1.55 (1.91)	.417	-.11	0.41 (2.10)	.847	-.03	2.10 (2.23)	.348	-.13
Intervention group[f]	-	22.56 (13.96)	26.71 (14.20)	26.04 (15.38)									
Control group		24.17 (14.00)	27.50 (17.10)	28.08 (17.61)									
Effective Decision Making subscale					-0.27(2.40)	.911	.02	1.59 (2.40)	.506	-.09	2.63 (2.79)	.347	-.13
Intervention group[f]	-	17.79 (17.15)	22.11 (17.03)	22.66 (19.94)									
Control group		17.60 (17.88)	24.11 (18.70)	25.53 (21.22)									

Abbrevations: **M** mean; **SD** standard deviation; **B** beta; **SE** standard error; **ES** effect size
T0 baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.
Raw means and standard deviations are reported.
Scores on all scales range from 0 to 100, with higher scores reflecting more decisional conflict.
[a]1 missing value in the intervention group, N=113, N=108, N=104 for T1, T2, and T3, respectively.
[b]Effect size was calculated by the estimated marginal means and pooled SD (e.g. $mean_{intervention\ group\ T1}$-$mean_{intervention\ group\ T0}$) - ($mean_{control\ group\ T1}$-$mean_{control\ group\ T0}$)/pooled SD_{T0}).
[c]Calculated by summing 12 items (without 4 items of the Effective Decision Making subscale), dividing by 12, and multiplying with 25.
[d]16 missings (7 intervention group, 9 control group) on Total score and Effective Decision Making subscale as patients chose 'Not applicable' for >1 item of Effective Decision Making subscale, such that N=106 in the intervention group and N=103 in the control group.
[e]Effect size was calculated by the estimated marginal means and pooled SD (e.g. $mean_{intervention\ group\ Tx}$- $mean_{control\ group\ Tx}$/pooled SD_{Tx}).
[f]Intervention group is reference group
[g]Items of the Effective Decision Making subscale were not assessed at baseline as these were considered inappropriate to assess before patients had a consultation with a plastic surgeon. Therefore, a Total score (based on all 16 items) was not calculated.
[h]Final model also included potential non-ignorable drop-out.

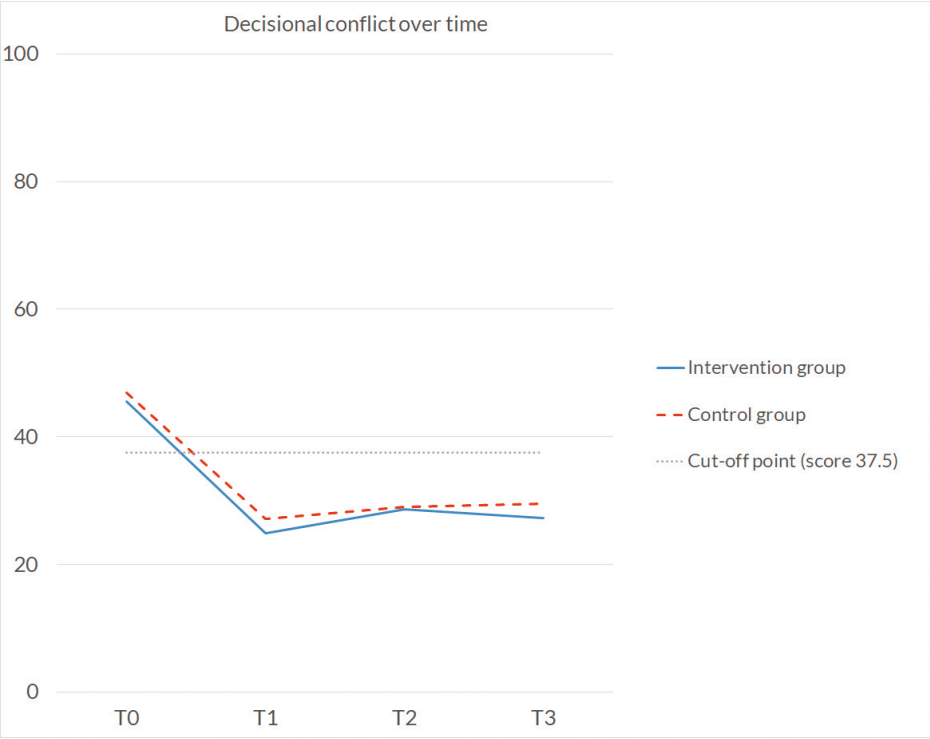

Figure 2. Change over time in decisional conflict (combined score without Effective Decision Making subscale). Cut-off point at score 37.5: scores > 37.5 are associated with decision delay and feeling unsure about implementing decisions. **T0** baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.

SECONDARY OUTCOMES

Results on continuous secondary outcomes are shown in Table 4 (descriptives) and Table 5 (group effects), and categorical secondary outcomes are presented in Table 6 (descriptives) and Table 7 (group effects).

Decision-making process

Intervention group participants reported feeling better prepared for decision making than those in the control group (Preparedness for decision making: ES_{T1}=0.42, p = .002, Table 5). There were no significant differences between the intervention and control groups in terms of their satisfaction with the plastic surgeon, perceived levels of shared decision making during consultation with their plastic surgeon, satisfaction with information about BR, satisfaction with information in the pDA or the information leaflet at T1, and the perceived levels of involvement in decision making. In women who received BR, satisfaction with information (measured with the BREAST-Q) did not differ between the intervention and control groups, and remained stable over time (Table, Supplemental content 3, showing the effects of time on secondary outcomes).

Decision quality

In both groups knowledge of BR significantly increased from baseline to T1 (Linear time effect: B (SE) = 0.07 (0.01), $p < .001$, Supplemental content 3), and remained stable during T2 and T3 (Table 4 and 5 and Supplemental content 3). There were no between-group differences in knowledge of BR over time or in decision regret at T2 and T3 (Table 4 and 5). At T3, 34.0% of all participants experienced clincally relevant levels of decision regret (score ≥ 30) (no between-group difference, $\chi^2 = 1.16$, $p = .561$).

Patient-reported health outcomes

At T2 and T3, no differences were found between the intervention and control groups in terms of satisfaction with breasts, satisfaction with reconstruction outcome (in women who received BR), body image, sexual functioning, sexual enjoyment, and breast symptoms. There were no significant differences between groups in anxiety over time; in both groups anxiety significantly decreased over time (Linear time effect: B (SE) = -0.45 (0.06), $p = .000$, Supplemental content 3). In both groups, breast symptoms significantly decreased from T2 to T3 ($p = .005$, Supplemental content 3). There were no significant time effects from T2 to T3 in any other patient-reported health outcome. The actual choice whether or not to have IBR and regarding the type of BR did not differ between groups (Table 6 and 7). The majority had IBR (70.3% and 72.3% for intervention and control group, respectively).

Table 4. Descriptives of secondary outcomes over time

	T0		T1		T2		T3	
	n	M (SD)	n	M (SD)	n	M (SD)	n	M (SD)
Decision-making process								
Satisfaction with information (BREAST-Q)[a]								
Intervention group					80	65.75 (13.84)	85	64.84 (14.12)
Control group					80	63.11 (15.91)	81	63.48 (17.41)
Satisfaction with plastic surgeon (BREAST-Q)								
Intervention group			114	83.39 (18.13)				
Control group[b]			108	83.44 (17.86)				
Preparedness for decision making[c]								
Intervention group			107	63.11 (26.45)				
Control group			106	52.51 (23.67)				
Perceived shared decision making (SDM-Q-9)								
Intervention group			114	67.39 (20.97)				
Control group[b]			108	63.74 (19.07)				
Decision quality								
Knowledge								
Intervention group	126	7.06 (2.19)	114	8.92 (1.40)	109	8.80 (1.59)	105	8.54 (1.80)
Control group	124	6.88 (2.01)	112	8.60 (1.59)	111	8.68 (1.45)	107	8.08 (1.80)
Decision regret (DRS)								
Intervention group[d]					108	17.45 (17.19)	105	20.19 (17.32)
Control group					112	19.02 (18.60)	107	23.22 (19.89)
Patient-reported health outcomes								
Satisfaction with breasts (BREAST-Q)								
Intervention group[d,e]					108	51.72 (18.32)	104	55.70 (18.28)
Control group					112	52.83 (17.95)	107	57.23 (18.46)

Table 4. Continued

	T0		T1		T2		T3	
	n	M (SD)	n	M (SD)	n	M (SD)	n	M (SD)
Satisfaction with reconstruction outcomes (BREAST-Q)[a]								
Intervention group					80	62.88 (19.18)	86	64.84 (14.12)
Control group					81	57.93 (18.67)	82	63.48 (24.04)
Body image (QLQ-BR23)								
Intervention group					109	66.51 (27.68)	105	68.81 (28.12)
Control group					111	66.22 (28.97)	107	70.48 (28.67)
Sexual functioning (QLQ-BR23)								
Intervention group					109	25.69 (24.48)	105	26.35 (23.66)
Control group					111	26.58 (23.82)	107	29.75 (23.24)
Sexual enjoyment (QLQ-BR23)[f]								
Intervention group[g]					57	58.48 (26.93)	61	66.12 (23.95)
Control group[h]					64	58.85 (27.69)	70	62.38 (27.17)
Breast symptoms (QLQ-BR23)								
Intervention group					109	23.32 (17.85)	105	17.94 (18.84)
Control group					111	26.65 (20.62)	107	21.42 (21.14)
Anxiety (STAI-6)[i]								
Intervention group	126	47.88 (12.90)	114	45.58 (13.31)	109	40.86 (11.24)	105	39.30 (11.47)
Control group	124	44.87 (12.79)	112	43.87 (13.10)	111	38.89 (11.36)	107	37.51 (12.46)

Abbrevations: **M** mean; **SD** standard deviation; **SDM-Q-9** shared decision making questionnaire 9 items; **DRS** decision regret scale; **QLQ-BR23** european organisation of research and treatment of cancer breast cancer specific quality of life questionnaire; **STAI-6** six-item short-form of the state scale of the spielberger State-Trait Anxiety Inventory. **T0** baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.
[a]Only assessed in participants who had breast reconstruction.
[b]4 missings (patients cancelled their consultation with a plastic surgeon).
[c]13 missings (7 intervention group, 6 control group) (reasons: participant did not use pDA/information leaflet (n=5), administrative mistake (n=1), >2 items were answered with 'Not Applicable' (n=7)).
[d]1 missing at T2.
[e]1 missing at T3.
[f]Only assessed in participants who reported to have had some level of sexual activity in past 4 weeks (T2 n=128, T3 n=135).
[g]3 and 2 patients chose 'Not Applicable' at T2 and T3, respectively and were considered missing.
[h]4 and 2 patients chose 'Not Applicable' at T2 and T3, respectively and were considered missing.
[i]Final model also included random slope.

Table 5. Group effects in decision-making process, decision quality, and patient-reported health outcomes (secondary outcomes)

	Between-Group effect T1			Between-Group effect T2			Between-Group effect T3			Group by Time effect		ES[a]		
	B (SE)	*p*	ES[b]	B (SE)	*p*	ES[b]	B (SE)	*p*	ES[b]	B (SE)	*p*	T0-T1	T0-T2	T0-T3
Decision-making process														
Satisfaction with information (BREAST-Q)[c,d]				-3.88 (2.27)	.090	.26	-2.87 (2.35)	.223	.18					
Satisfaction with plastic surgeon (BREAST-Q)[e]	0.01 (2.31)	.996	.00											
Preparedness for decision making	-10.59 (3.42)	**.002**	.42											
Perceived shared decision making (SDM-Q-9)[e]	-3.88 (2.27)	.090	.18											
Decision quality														
Knowledge										0.00 (0.02)	.954	.05	-.04	.13
Decision regret (DRS)				1.52 (2.40)	.527	-.08	2.98 (2.52)	.239	-.16					
Patient-reported health outcomes														
Satisfaction with breasts (BREAST-Q)[e]				1.44 (2.31)	.534	-.08	1.36 (2.48)	.585	-.07					
Satisfaction with reconstruction outcomes (BREAST-Q)[c,d,f]				-6.87 (2.92)	.020	.36	-6.49 (3.29)	.050	.33					
Body image (QLQ-BR23)				-0.33 (3.79)	.930	.01	1.51 (3.84)	.694	-.05					
Sexual functioning (QLQ-BR23)				1.19 (3.24)	.714	-.05	3.11 (3.17)	.328	-.13					
Sexual enjoyment (QLQ-BR23)[g]				0.30 (4.84)	.950	-.01	-3.09 (4.43)	.486	.12					
Breast symptoms (QLQ-BR23)				3.31 (2.59)	.202	-.17	3.12 (2.73)	.254	-.16					
Anxiety (STAI-6)										0.11 (0.09)	.204	-.12	-.11	-.13

Abbrevations: **B** beta; **SE** standard error; **ES** effect size; **SDM-Q-9** shared decision making questionnaire 9 items; **DRS** decision regret scale; **QLQ-BR23** European organisation of research and treatment of cancer breast cancer specific quality of life questionnaire; **STAI-6** six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory. **T0** baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.

[a]Effect size was calculated by the estimated marginal means and pooled SD (e.g. $mean_{intervention\ group\ T1}$-$mean_{intervention\ group\ T0}$) - ($mean_{control\ group\ T1}$-$mean_{control\ group\ T0}$)/pooled SD_{T0}).

[b]Effect size was calculated by the estimated marginal means and pooled SD (e.g. $mean_{intervention\ group\ Tx}$- $mean_{control\ group\ Tx}$/pooled SD_{Tx}).

[c]Only assessed in participants who had breast reconstruction.

[d]Final model also included baseline anxiety.

[e]Final model also included hospital.

[f]Final model also included BMI.

[g]Only assessed in participants who reported to have had some level of sexual activity in past 4 weeks (T2 n=128, T3 n=135).

The intervention group is the reference group.

Bold font indicates significant effects.

Table 6. Descriptives of categorical secondary outcomes over time

	T1		T2		T3	
	Intervention group	**Control group**	**Intervention group**	**Control group**	**Intervention group**	**Control group**
	N (%)	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**
Decision-making process						
Satisfaction with information in pDA or information leaflet						
Not at all satisfied / not satisfied	5 (4.4)	14 (12.5)				
Neutral	19 (16.7)	16 (14.3)				
Satisfied/very satisfied	86 (75.4)	80 (71.4)				
Missing	4 (3.5)	2 (1.8)				
Satisfaction with information about breast reconstruction						
Not at all satisfied / not satisfied			3 (2.8)	6 (5.4)	3 (2.9)	10 (9.4)
Neutral			11 (10.1)	24 (21.4)	16 (15.2)	17 (15.9)
Satisfied / very satisfied			95 (87.2)	82 (73.2)	86 (81.9)	80 (74.8)
Perceived levels of involvement in decision making						
Active	78 (68.4)	67 (59.8)				
Collaborative	15 (13.2)	24 (21.4)				
Passive	6 (5.3)	9 (8.0)				
Missing	15 (13.2)	12 (10.7)				

Table 6. Continued

	T1		T2		T3	
	Intervention group	**Control group**	**Intervention group**	**Control group**	**Intervention group**	**Control group**
	N (%)	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**
Patient-reported health outcomes						
Actual choice						
Immediate breast reconstruction[a]						
No			33 (29.7)	31 (27.7)		
Yes			78 (70.3)	81 (72.3)		
Type of immediate breast reconstruction[a]						
Tissue-expander			16 (20.5)	19 (23.5)		
Implant			57 (73.1)	51 (63.0)		
Autologous			3 (3.8)	8 (9.9)		
Combination implant and autologous			2 (2.6)	3 (3.7)		

Abbreviations: **pDA** patient decision aid.
T0 baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.
[a]Patient-reported on T2. For 2 patients with missing data on T2, patient-reported data on T3 were used, such that n = 223.

Table 7. Group differences in secondary categorical outcomes

	T1			T2			T3		
	B (SE)	**χ^2**	***p***	**B (SE)**	**χ^2**	***p***	**B (SE)**	**χ^2**	***p***
Decision-making process									
Satisfaction with information in pDA or information leaflet	-0.37 (0.31)	1.42	.233						
Satisfaction with information about breast reconstruction				-0.90 (0.36)	6.40	.011	-0.48 (0.34)	2.01	.157
Perceived levels of involvement in decision making	-0.59 (0.32)	3.34	.068						
Patient-reported health outcomes									
Actual choice									
Immediate breast reconstruction (no/yes)[a]				-0.10 (0.30)	0.12	.735			
Type of immediate breast reconstruction (alloplastic/autologous)[a,b]				1.01 (0.70)	2.09	.148			

Abbreviations: **B** beta; **SE** standard error; **χ2** Chi-squared; **pDA** patient decision aid.
T0 baseline; **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.
Wald Chi-squared are reported.
[a]Patient-reported on T2 (for 2 patients with missing data on T2, patient-reported data on T3 were used).
[b]Alloplastic reconstruction includes reconstruction with tissue-expander, implant, and a combination of an implant and autologous tissue.

CONCLUSION

This study aimed to evaluate the efficacy of an online pDA in reducing decisional conflict in women considering IBR. Both the pDA and the information leaflet were effective in reducing decisional conflict. The pDA however, provided additional improvement over CAU in the decision-making process, by enabling patients to feel better prepared for making a decision. No added value of the pDA over CAU was found on other outcomes related to the decision-making process, decision quality and health outcomes.

The benefit of the pDA in improving patients' preparedness for decision making is in line with healthcare professionals' expectations that a BR pDA would help patients to prepare for consultation (45), and the qualitative experiences of both patients and healthcare professionals with using a BR pDA (65, 66). Our finding that the pDA did not affect patients' anxiety is in line with existing literature (40, 42), and is important given the concern that shared decision making can unintentionally increase anxiety in patients (67, 68).

The lack of any beneficial effect of our pDA over CAU on other outcomes related to the decision-making process and decision quality seems in stark contrast with the body of evidence showing the beneficial effects of pDAs in all kinds of healthcare decisions, including decisions about BR (40, 42, 43, 69, 70).

It might be that in our study the effects of the pDA are underestimated as the CAU control group received an information leaflet. Although this information leaflet is widely available in Dutch hospitals and on internet, the active provision of the leaflet to the control group before their consultation with a plastic surgeon might have led to higher uptake and possibly more profound processing of the information in the leaflet. This could have positively benefitted the decision making process in that the information led to decreased decisional conflict, increased knowledge about BR, and higher perceived levels of involvement in decision making, more than in a true CAU setting. However, given the substantial time and effort that was required of all participants in this trial, including the control group, we provided the information leaflet to the control group for ethical reasons. In addition, most women in both groups used the internet (almost) daily. This may also have had an impact on decision making, and may partly explain the minimal differences between the two groups. Also, study participation itself might have increased awareness for the importance of information provision and shared decision making about IBR among patients and healthcare professionals, leading to contamination bias.

This study had some limitations. First, our sample was relatively young and highly educated, limiting the generalizability of our findings. Secondly, although we assume that randomization successfully led to two comparable groups, the lack of baseline assessment of some outcomes (i.e. satisfaction with information, body image, sexual functioning, breast symptoms) limits our conclusions. While some outcomes were not considered appropriate at baseline (such as decision regret, and preparedness for decision making), others were omitted to limit burden

for participants. Furthermore, our study lacks observations of the interaction that took place between patients and their physicians during consultation (e.g. by audio-recordings of consultations). Adding such observations could provide more detailed insights into the effect of the pDA on the shared decision making process (71).

Strengths of this study include the randomized controlled trial design of our study, the long follow-up, the high participation rate and our low attrition rates.

For future studies, an even longer-term follow-up assessment (> 12 months) could provide more insights into the effect of the pDA on outcomes such as decision regret, satisfaction with breasts and satisfaction with reconstruction outcome, given the lengthy recovery process of BR and additional procedures that are often required after BR. Also, an extra assessment *before* consultation with a plastic surgeon (and after pDA usage) would allow to better distinguish effects of the pDA from the effects of the consultation itself. This time point seems especially interesting, as our results show that patients felt better prepared for consultation by the pDA.

In conclusion, our finding indicate that both the online pDA and the information leaflet are helpful for breast cancer patient having to make a decision about IBR. The online pDA better prepares patients for consultation with their plastic surgeon and decision making than an information leaflet. Also, the online format of the pDA more easily allows for adaptions required by future developments in BR options and scientific evidence, and for the further tailoring of information to patients' personal situation and information needs. Potential benefits in cost-effectiveness of the pDA including decreased health care usage, and the preferences among health care providers should be further investigated. All together, we recommend the pDA for use in clinical practice.

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SUPPLEMENTAL CONTENT

Supplemental content 1. Table showing group differences in adjuvant treatment, complications of breast surgery, and nipple reconstruction.

	All Patients (N=212)*		Intervention Group (N=105)		Control Group (N=107)		
	N	%	N	%	N	%	*p*
Adjuvant treatment**							
Radiotherapy (yes)	71	33.5	33	31.4	38	35.5	.529
Chemotherapy (yes)	43	20.3	23	21.9	20	18.7	.561
Endocrine therapy (yes)	110	51.9	54	51.4	56	52.3	.895
Immunotherapy (yes)	22	10.4	14	13.3	8	7.5	.162
Complication(s) of breast surgery (yes)**	59	27.8	31	29.5	28	26.2	.586
Lost BR due to complication(s) (yes)**/***	19	9.0	8	7.6	11	10.3	.498
Nipple reconstruction**/****							
No, nipple was spared	65	38.7	30	34.9	35	42.7	.275
No, nipple was removed	92	54.8	52	60.5	40	48.8	
Yes	11	6.5	4	4.7	7	8.5	

Abbreviations. **BR** breast reconstruction.
*Selection of participants who completed T3.
**Patient-reported at 12 months after surgery (T3).
***12 patients who lost their BR due to complication(s) reported to have BR (again) at time of completing T3.
****Only assessed in participants who had breast reconstruction (n=168, 86 in the intervention group, 82 in the control group).

Supplemental content 2. Table showing the effects of time on decisional conflict (primary outcome).

	Linear Time effect			Quadratic Time effect		
	B	SE	*p*	B	SE	*p*
Combined score without Effective Decision Making subscale[c]	-0.52	0.12	**.000**	0.01	0.00	**.002**
Uncertainty subscale	-0.37	0.15	.016	0.00	0.00	.090
Feeling Informed subscale	-0.77	0.17	**.000**	0.01	0.00	**.001**
Feeling Clear of Values subscale	-0.35	0.15	.015	0.00	0.00	.094
Feeling Supported subscale	-0.58	0.13	**.000**	0.01	0.00	**.002**
	T1-T2			T1-T3		
	B	SE	*p*	B	SE	*p*
Total score	4.36	1.49	**.004**	3.42	1.65	.040
Effective Decision Making subscale	4.44	2.01	.028	4.89	2.28	.033

Abbrevations: **B** beta; **SE** standard error.
T1 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.
[a]1 missing value in the intervention group
[c]Calculated by summing 12 items (without 4 items of the Effective Decision Making subscale), dividing by 12, and multiplying with 25.
Intervention group is reference group.

Supplemental content 3. Table showing the effects of time on secondary outcomes.

	Linear Time effect			**Quadratic Time effect**			**T2-T3**		
	B	**SE**	***p***	**B**	**SE**	***p***	**B**	**SE**	***p***
Decision-making process									
Satisfaction with information (BREAST-Q)[d]							-0.45	1.53	.770
Decision quality									
Knowledge	0.07	0.01	**.000**	-0.00	0.00	**.000**			
Decision regret (DRS)							2.75	1.69	.106
Patient-reported health outcomes									
Satisfaction with breasts (BREAST-Q)							4.35	1.83	.018
Satisfaction with outcomes (BREAST-Q)[d]							-0.79	2.20	.720
Body image (QLQ-BR23)							1.79	1.95	.361
Sexual functioning (QLQ-BR23)							1.04	2.08	.619
Sexual enjoyment (QLQ-BR23)[e]							7.68	3.61	.035
Breast symptoms (QLQ-BR23)							-5.17	1.82	**.005**
Anxiety (STAI-6)	-0.45	0.06	**.000**	0.01	0.00	**.000**			

Abbrevations: **B** beta; **SE** standard error; **DRS** decision regret scale; **QLQ-BR23** european organisation of research and treatment of cancer breast cancer specific quality of life questionaire; **STAI-6** six-item short-form of the state scale of the spielberger state-trait anxiety inventory.
T2 3 months after surgery; **T3** 12 months after surgery.
[d]Only assessed in participants who had breast reconstruction
[e]Only assessed in participants who reported to have had some level of sexual activity in past 4 weeks (T2 n=128, T3 n=135)
Intervention group is the reference group.
Bold font indicates significant effects.