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

Stege, J.A. ter

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Chapter 2

The development of a patient decision aid for patients with breast cancer who consider immediate breast reconstruction after mastectomy

ter Stege JA, Raphael DB, Oldenburg HSA, van Huizum MA, van Duijnhoven FH, Hahn DEE, The R, Karssen K, Corten EML, Krabbe-Timmerman IS, Huikeshoven M, Ruhé PQ, Kimmings AN, Maarse W, Sherman KA, Witkamp AJ, Woerdeman LAE, Bleiker EMA.

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ABSTRACT

PURPOSE

The aim of this study was to develop a patient decision aid (pDA) that could support patients with breast cancer (BC) in making an informed decision about breast reconstruction (BR) after mastectomy.

METHODS

The development included four stages: (i) Establishment of a multidisciplinary team; (ii) Needs assessment consisting of semi-structured interviews in patients and a survey among healthcare professionals (HCPs); (iii) Creation of content, design and technical system; and, (iv) Acceptability and usability testing using a think-aloud approach in patients and interviews among HCPs and representatives of the Dutch Breast Cancer Patient Organization.

RESULTS

From the needs assessment, three themes were identified: Challenging period to make a decision, Diverse motivations for a personal decision, and, Information needed to make a decision about BR. Healthcare professionals valued the development of a pDA, especially to prepare patients for consultation. The pDA that was developed contained three parts: first, a consultation sheet for oncological breast surgeons to introduce the choice; second, an online tool including an overview of reconstructive options, the pros and cons of each option, information on the consequences of each option for daily life, exercises to clarify personal values, and patient stories; and third, a summary sheet with patients' values, preferences and questions to help inform and guide the discussion between the patient and her plastic surgeon. The pDA was perceived to be informative, helpful and easy to use by patients and HCPs.

CONCLUSION

Consistent with information needs, a pDA was developed to support patients with BC who consider immediate BR in making an informed decision together with their plastic surgeon.

PATIENT OR PUBLIC PARTICIPATION

Patients participated in the needs assessment and in acceptability and usability testing.

INTRODUCTION

Patients undergoing mastectomy as a treatment for breast cancer (BC) or to reduce their increased risk of BC often have a choice of whether or not to undergo breast reconstruction (BR). Undergoing BR after mastectomy can be beneficial for patients' quality of life and psychosocial functioning (1-5). However, there are also disadvantages of having BR, such as an increased risk for complications (6, 7). Most patients who consider BR also have to make choices regarding the timing (i.e. immediate or delayed) and the type (i.e. implant-based or autologous) of surgery.

The decision for BR largely depends on patients' values and preferences (8, 9). For preference-sensitive decisions such as this, shared decision making is increasingly advocated as the preferred approach (10, 11). Shared decision making is a patient-centered approach in which physicians and patients collaborate and share information about the best available evidence and patient preferences and values to reach a health decision (10, 12, 13). In this approach, physicians are considered experts about the medical evidence and patients are considered experts about what matters most to them (14).

Previous studies have suggested that there remains an unmet need for support in the context of decision making about BR after mastectomy, since both knowledge and decisional preparedness are low among patients deciding about BR (15-17). Moreover, another study found that less than half (43%) of the participants made a high-quality decision regarding BR, defined as having knowledge of important BR facts and undergoing treatment in accordance with one's personal preferences (18). Furthermore, previous studies found that a substantial number of women (37% up to 47%) experienced some level of decisional regret after undergoing BR (19-21). With a median time period between diagnosis and surgery of five weeks patients often have limited time to decide about immediate BR (22). Previous studies have highlighted the importance of high-quality, realistic preoperative information and decisional support to enable patients to make a long-term satisfying decision about BR (19, 20, 23-28). Patient decision aids (pDAs) may be beneficial for patients who are facing the decision regarding BR. PDAs are tools that, as adjuncts to counselling, aim to support shared decision making. PDAs explicitly state the decision, consist of evidence-based information about the options and their pros and cons, and clarify patients' personal values (29). Across a variety of health-related decisions, pDAs have been found to reduce decisional conflict, increase knowledge and increase insight into personal values related to the decision (30, 31).

Worldwide, a limited number of pDAs are available for patients considering BR (32, 33). Whilst studies showed promising results regarding their effectiveness (32, 33), no evidence-based pDA is available for patients considering BR in the Netherlands.

Therefore, the aim of this study was to develop an online pDA that could support patients in making an informed decision about BR after mastectomy together with their plastic surgeon. As part of the development of this pDA, we aimed to assess the information needs of both patients and healthcare professionals (HCPs), and to test the acceptability and usability of the pDA.

METHODS

The development was guided by International Patients Decision Aids Standards (IPDAS) criteria for developing a high-quality pDA (34). The development was performed in partnership with ZorgKeuzeLab, a Dutch company specialized in the development and implementation of pDAs. The development consisted of four stages, briefly described in the protocol of the trial to evaluate the pDA (35), and described in more detail below. For a schematic overview of the four stages and the participants see Figure 1. The development of the pDA started in May 2016 and was completed in March 2017.

STAGE 1: ESTABLISHMENT OF A WORKING GROUP

We assembled a national working group consisting of 16 experts including plastic surgeons, oncological breast surgeons, psychologists, researchers, industrial designers and an expert in the development and implementation of pDAs. In four meetings (one meeting in each development stage), the working group reached consensus on the aim and scope of the pDA, discussed the content of the pDA, and agreed on the final version of the pDA.

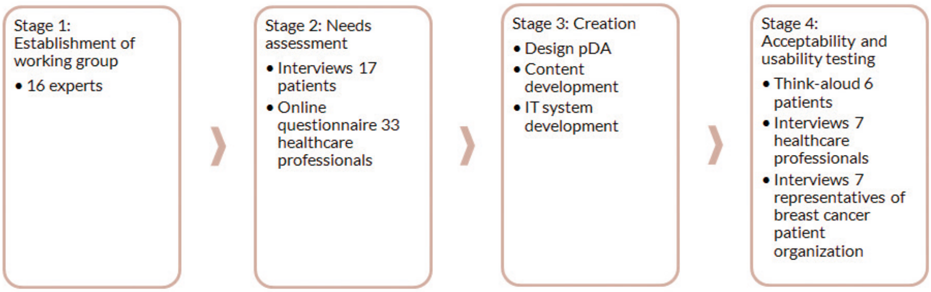

Figure 1. Overview of the four stages of pDA development and participants

STAGE 2: NEEDS ASSESSMENT

We performed a needs assessment among patients and HCPs to assess information and decision support needs regarding BR. The Medical Research Ethics Committee of the Dutch Cancer Institute examined the study protocol and concluded that the obligation to fulfil the specific requirements of the Dutch law for Medical Research Involving Human Subjects was waived (reference: METC16.0840). All patients provided informed consent.

2.1. Patients

Semi-structured interviews were conducted with women who previously faced the decision whether to undergo BR after mastectomy. Participants were recruited through purposive sampling to reach a sample diverse in age, educational level, indication for mastectomy (i.e. BC or prophylaxis), the decision to undergo BR, and treating hospital. Members of the working group identified eligible participants among their patients, and subsequently asked these patients for approval to be contacted for the study. Upon approval, patients received more detailed study information by phone and an information letter and informed consent form by email. Interviews took place face-to-face at the Netherlands Cancer Institute, at ZorgKeuzeLab or, if preferred by the patient, via telephone. A psychologist/researcher (J.A.t.S.) conducted all the interviews, sometimes accompanied by a member of ZorgKeuzeLab (R.T. or K.K.). Interviews lasted approximately 60 minutes (see Supporting information Appendix S1 for the complete interview script). Interviews were audio recorded, transcribed verbatim and coded by two independent researchers (J.A.t.S. and D.R.) using thematic analysis (36). Consensus about the coding scheme was reached in two consecutive meetings. Data were stored and coded in NVivo 10 (QSR International Pty Ltd.).

2.2. Healthcare professionals

Forty HCPs who were involved in the BR decision-making process were invited to complete a brief (15 min) study-specific online questionnaire. HCPs included members of the working group and their colleagues from both within and beyond their hospital. In the questionnaire, HCPs were asked about their experiences and satisfaction with information about BR, their experiences and attitudes towards shared decision making and pDAs, and their preferences for content and implementation of the pDA to be developed. We performed descriptive analyses in IBM SPSS Statistics for Windows, Version 22 (IBM Corp.).

STAGE 3: CREATION

The central question for designing the pDA was as follows: ‘How can the pDA improve the conversation between a patient and a plastic surgeon about the decision for BR?’ (Including, what should a patient know about BR before consultation with a plastic surgeon? What should a plastic surgeon know about a patient regarding the diagnosis, values, preferences, circumstances, and any other aspect relevant for decision making about BR before making a decision together?). Discussion about these questions within the working group guided the design of the pDA. The content was written by a team of physicians based on the guidelines for BR (8), the Stage 2 needs assessment results, and discussion within the working group. Content was reviewed by working group members. A text writer edited texts at B1 language level. Texts written in B1 language level are considered as ‘fairly easy to read’ and are characterized by the use of common words and short, simple, and active sentences (37). It is the recommended language level for public communication by the Dutch government as the vast majority of the population is able to understand it (38). The online infrastructure was built as an extension of an existing platform of pDAs (https://zorgkeuzelab.nl/keuzehulpen).

STAGE 4: ACCEPTABILITY AND USABILITY TESTING

The acceptability and usability of the developed pDA was assessed in patients who previously considered undergoing BR after mastectomy, HCPs involved in decision making about BR, and representatives of the Dutch Breast Cancer Patient Organization (Borstkankervereniging Nederland). In *patients*, we used a ‘think-aloud approach’, in which they were invited to literally think aloud whilst using the pDA (39). This is a common method for testing ICT tools including pDAs (40-42), and enables to get an impression of how patients perceive and use the pDA. Each session finished with a short interview to evaluate the pDA (see Supporting Information Appendix S2 for the script). A total of eight patients who participated in the needs assessment and agreed to be contacted for acceptability and usability testing were invited. This procedure was performed at either ZorgKeuzeLab, the Netherlands Cancer Institute, or via Skype. *HCPs* and *Representatives of the Dutch Breast Cancer Patient Organization* received access to the tool and were interviewed via telephone about their experiences with the pDA (See Supporting information Appendix S2 for the script). HCPs who participated in the needs assessment and agreed to be contacted for acceptability and usability testing were invited. Representatives of the Dutch Breast Cancer Patient Organization, who had either previously considered BR after mastectomy or had expertise in pDAs, were recruited via the organization's project leader on shared decision making and via a call in a private Facebook group of the organization. The sessions and interviews (between 30 and 60 min each) took place between January and March 2017, and were performed by J.A.t.S. in company of a member of ZorgKeuzeLab (R.T. or K.K.). Major issues that hindered intended use of the pDA were modified directly upon identification. Notes and observations were combined and labelled as either general comments about the pDA or related to a specific section of the pDA. Feedback was presented to the working group, combined with suggestions for change. The working group members collaboratively decided upon the desired adjustments to the pDA.

RESULTS

NEEDS ASSESSMENT

Seventeen patients (85%) and 33 HCPs (83%) participated in the needs assessment. Background characteristics of both groups are provided in Table 1.

Patients

Thematic analysis yielded three themes reflecting patients' most important experiences with, and information needs regarding, their BR decision (see Table 2 for illustrating quotes).

Challenging period to make a decision

Patients with BC experienced the trajectory as a rollercoaster in which they were overwhelmed by emotions after a sudden diagnosis of BC. They had difficulties processing the large amount of information that they received. Some patients felt sick due to neo-adjuvant systemic therapy and did not feel like themselves at the time of making their decision. Other patients highlighted the short period of time between diagnosis and surgery in which they had to made a decision, and the importance of taking adequate time to make a decision. Although many patients perceived having the option of BR as something positive, their highest priority at that time was to be cured from cancer, and aesthetics were less important. In contrast, women who considered undergoing BR after prophylactic mastectomy were not suddenly confronted with a diagnosis, didn't feel sick and perceived sufficient time to get informed about BR and to make a decision. They stressed the importance of planning surgery at a period of time that suited well within their lives, and of taking time to optimally prepare for surgery.

Table 1. Background characteristics of participants in needs assessment

	N (%)
Patients (N=17)	
Age (years), M (SD), range	51.3 (12.3), 31-77
Educational level	
high (higher vocational/university)	10 (59%)
intermediate (secondary school/intermediate vocational)	7 (41%)
low (primary school/lower vocational)	0 (-)
Married or in a relationship	12 (71%)
Indication for mastectomy	
breast cancer	14 (82%)
prophylaxis	3 (18%)
Time since mastectomy (months), M (SD), range	46 (48), 2-173
Time since (last) reconstructive surgery (months), M (SD), range	23 (29), 2-115
Breast reconstruction (yes)	14 (82%)
Timing of breast reconstruction	
immediate	11 (79%)
delayed	3 (21%)
Type of breast reconstruction[1]	
implant	9 (64%)
autologous	6 (43%)
combination	1 (7%)
Hospital[2]	
(breast) cancer specific hospital	9 (53%)
general hospital	3 (18%)
academic medical center	5 (29%)
Healthcare professionals (N=33)	
Sex (female)	23 (70%)
Age (years), M (SD)	45.6 (8.2)
Profession	
oncological breast surgeon	6 (18%)
plastic surgeon	19 (58%)
nurse (specialist/practitioner)	2 (6%)
psychologist	4 (12%)
social worker	2 (6%)
Number of years working in profession, M (SD)	13.8 (8.7)

Table 1. Continued

	N (%)
Average number of new patients with breast cancer treated per month	
> 30 patients	2 (6%)
11-30 patients	10 (30%)
1-10 patients	16 (49%)
none	5 (15%)
Organization[3]	
(breast) cancer specific hospital	8 (24%)
general hospital	14 (42%)
academic medical center	10 (30%)
private practice	1 (3%)
Experience with referring patients to a decision aid (yes)	7 (21%)

Abbreviations. **M** mean; **SD** standard deviation.
[1]Numbers count up above 14 (number of patients with breast reconstruction) due to differences in types of breast reconstruction for left and right breast. [2]Patients were recruited from 5 hospitals. [3]Professionals were recruited from 21 organizations.

Diverse motivations for a personal decision

Patients emphasized the importance of identifying their personal values to make a decision about BR. Although most patients had an immediate preference for or against undergoing BR, some patients had difficulties in making a decision. Patients' reasons for their BR decision were diverse (see Table 3 for an overview of the reasons). The reasons for undergoing immediate BR included the desire to improve body image and appearance, and the reasons against undergoing immediate BR included having no interest in undergoing BR and the desire for faster recovery and avoiding increased risk for complications. The reasons for deciding to undergo implant-based BR included having no option for autologous BR and the desire for a shorter duration of surgery and faster recovery, and the reasons for autologous BR included the desire for more natural outcomes and avoiding the use of foreign materials. Although it was important to feel supported by their partner and relatives in making their decision, most patients emphasized that the decision had been made by themselves.

Information needed to make a decision about breast reconstruction

Patients expressed a need for objective and reliable information about BR, that could be processed at their own pace and in their own time. Information should preferably be tailored to their individual situation, and preferably bundled together in one place. Patients wanted clarity about the reconstructive options that were available to them, and balanced information about the pros and cons of the options. Patients' main questions before surgery were as follows: How will it feel and what will it look like? What will I be able to do in the period after surgery and what kind of restrictions will be imposed? When can I resume my daily activities? And, how will BR affect my daily life? Although most patients avoided emotional stories of other women, they expressed a need to learn about the experiences of other women to gain more insight into the effects of BR on their daily lives. Information about complications and less positive outcomes was also valued by patients to ensure that they have realistic expectations about BR. Although the majority of patients searched for photos to get an impression of how a reconstructed breast would look like, patients acknowledged the limited usefulness of photos in managing their expectations. Patients reported that they had underestimated the duration of the recovery period, and how restricted they would be in their daily activities while recovering from surgery. Patients needed time to get used to their new bodies after surgery. They emphasized that a reconstructed breast was not simply replacing their own breast, as the appearance and sensation changed.

Table 2. Quotes illustrating experiences and information needs of patients deciding about BR (N=17)

Challenging period to make a decision

- *"At that time, you are mainly trying to survive and getting through your chemotherapy etcetera, you are totally not thinking of aesthetics at that time."* (Participant 4, immediate, implant-based BR).
- *"At the moment, that we were inside* [consultation room], *I guess your head is at another place. Because, there was little time in between. Mid-June I was diagnosed, and mid-July I already had surgery. So, in that short period, it had to be explained what was going to happen. But at that time, you are on another planet, so it seems. I did not at all absorb all information."* (Participant 5, immediate, implant-based BR).

Diverse motivations for a personal decision

- *"I think it is a very personal decision. I would suggest, discuss it with others… but well, you can discuss it with other people, but you are you. You have to live with it. You need to be happy with it."* (Participant 6, no BR)
- *"To not be flat. And to avoid the confrontation of a completely flat amputated breast. I knew that it* [reconstructed breast] *would have little of a breast when waking up* [from surgery], *but still, that you are not completely flat, and that you are not wearing a t-shirt and have nothing on one side. That was very nice for me. That was also the reason for having it* [immediate BR]*."* (Participant 9, immediate, implant-based BR)
- *"I have been through this* [breast cancer], *and as soon as I have finished this, I want to be done with it. I don't want any hassle on my body anymore, and I just want to exercise and get on with my life."* (Participant 6, no BR)

Information needed to make a BR decision

- *"Information by women who have had it* [breast reconstruction], *you know, that would matter a lot. I never realized, of course you don't, that a prosthesis is cold. I don't have warm breasts anymore, but cold."* (Participant 4, immediate, implant-based BR)
- *"That you can't walk straight in the first three weeks, but that you will walk like an old lady behind the walker. That are things that I actually only heard of, and experienced, after surgery."* (Participant 16, immediate, autologous BR)
- *"They say that you are allowed to do everything after six weeks* [after surgery], *but at that time, you can't do everything yet. You are still very limited. I could not carry my kids into the bath, or in their crib."* (Participant 14, immediate, implant-based BR)

Abbreviations. **BR** breast reconstruction.

Healthcare professionals

Table 4 summarizes the results among HCPs (a complete overview of results of HCPs is provided in Supporting Information Appendix S3). The majority of HCPs (75%) were satisfied with the current information about BR provided in their hospital. All HCPs agreed that the BR decision requires active patient involvement, and considered the development of a pDA desirable (6% a little bit desirable, 52% desirable, 42% very desirable). The most frequently reported anticipated advantages of a pDA were that patients could read and process information in their own time and at their own pace, and that patients would be better informed and prepared for consultation. The most frequently reported anticipated disadvantages of the pDA were that the pDA might suggest options that are not available for an individual patient, provide patients with too much information, and provide information that is not sufficiently tailored to an individual patient. Regarding the content of the pDA, the majority of HCPs preferred to include all reconstruction options available in the Netherlands, and common risk factors and complications (65%, ≥55%, and ≥76%, respectively). The majority of HCPs (63%) preferred that the pDA be provided to patients during consultation with the oncological breast surgeon when the treatment options are discussed (i.e. before the first consultation with a plastic surgeon).

CREATION

The target group of the patient decision aid

Based on the results of the needs assessment and discussion within the working group, we concluded that the information needs regarding BR differed between patient populations considering BR after mastectomy (i.e. patients with BC considering immediate BR, patients with BC considering delayed BR, and healthy women considering BR after prophylactic mastectomy). Therefore, we focussed the pDA's target group on patients with BC considering immediate BR.

The Breast Reconstruction Patient Decision Aid

The Breast Reconstruction Patient Decision Aid ('Borstreconstructie Keuzehulp' in Dutch) contained three parts: a consultation sheet, an online tool, and a summary sheet. The *consultation sheet* was designed for oncological breast surgeons to hand out the pDA to patients during the consultation in which the choice for BR is introduced to patients. Each sheet contained a unique login code for the online tool. The *online tool* (available at https://br.keuzehulp.nl) provided patients with an overview of reconstructive options and the pros and cons of each option, information on the consequences of each option for daily life, value clarification exercises, and patient stories. The online tool consisted of six modules: (1) Diagnosis, (2) Immediate breast reconstruction or not (yet)? (3) Expectations, (4) Considerations, (5) Patient Stories, and (6) Summary (See Table 5 for a detailed description of each module (35) , and Supporting Information Appendix S4 for screenshots of the pDA (in Dutch)). The tool was intended for use by patients at home or at another preferred location before their consultation with a plastic surgeon. Information was presented in a way that did not favour one option over another. Patients could select the information that they want to read. The information was tailored based on the patient's treatment options (i.e. eligibility for skin and nipple-sparing surgery, eligibility for breast conserving surgery, and the indication for adjuvant radiotherapy). The pDA also included illustrations of different BR types. The estimated time to complete the full programme was one hour. Upon completion of the online tool, a *summary sheet* was generated with the patient's personal considerations, preferences and questions to help inform and guide the discussion with a plastic surgeon.

Table 3. Patients' reasons (A) for immediate vs. against immediate breast reconstruction, (B) for implants-based vs. autologous breast reconstruction

A. Reasons for immediate vs. against immediate breast reconstruction			
Immediate breast reconstruction[a]	**N**	**Against immediate breast reconstruction**[b]	**N**
Body image	6	No interest	5
Appearance	4	Faster recovery and avoid increased risk for complications	3
Avoid external prosthesis	3	Avoid scars and harms to other body parts	3
Less confrontation with cancer	2	Avoid foreign materials (implants)	2
Fewer surgeries than delayed reconstruction	2	Avoid surgery to replace implants (implants)	1
More clothing possibilities	1	Immediate breast reconstruction was no option	1
B. Reasons for implant-based vs. autologous breast reconstruction			
Implant-based[c]	**N**	**Autologous**[d]	**N**
Autologous breast reconstruction was no option	6	More natural outcomes	3
Shorter duration of surgery and faster recovery	3	Avoid foreign materials	3
Avoid scars and harms to other body parts	1	Opportunity to get rid of tummy	2
Fear of failure of autologous breast reconstruction	1	Complaint of implants	1
Adviced by plastic surgeon	1		

Note. Patients could give multiple reasons.
[a]11 patients, [b]6 patiens, [c]11 patients (including 2 patients with autologous breast reconstruction who had implants before), [d]6 patients

Table 4. Results of needs assessment in healthcare professionals (N=33)

A. Current information about breast reconstruction and satisfaction with information				
Main resource for information about breast reconstruction for patients*				
Plastic surgeon	67%			
Internet	39%			
Oncological breast surgeon	18%			
Nurse / nurse specialist	18%			
Information leaflets	15%			
Other**	12%			
		Not satisfied / disagree	Neutral	Satisfied / agree
Satisfaction with information about breast reconstruction provided in hospital		10%	16%	74%
Patients are sufficiently informed about the possibilities of breast reconstruction		30%	15%	55%
B. Attitudes towards shared decision making and expectations of patient decision aid		**C. Preferences regarding content of patient decision aid**		
The decision about breast reconstruction should be made by:		Breast reconstruction options		
patient (after seriously considering doctor's opinion)	45%	all options available in the Netherlands		65%
patient and doctor together	55%	Risk factors		
doctor (after seriously considering patient's opinion)	0%	smoking		97%
Desirability of patient decision aid		previous radiotherapy		97%
very desirable	42%	indication adjuvant radiotherapy		97%
desirable	52%	overweight		94%
a little bit desirable	6%	comorbidity		94%
not desirable	0%	large cup size		91%
Top 3 expected advantages of patient decision aid		bilateral surgery		70%
Patient can process information in own time and at own pace	55%	age (> 55 years)		55%
Patient is better informed	46%	Complications		
Patient is better prepared for consultation	27%	infections		100%
Top 3 expected disadvantages of patient decision aid		hematoma		100%
Might suggest options that are not available for patient	33%	necrosis		97%
Too much information for patient	24%	wound healing problems		97%
Information is not sufficiently tailored to patient	21%	implant-related		97%
		abdominal hernia/muscle weakness		76%

Table 4. Continued

	C. Preferences regarding content of patient decision aid	
	Preferred timing to offer patient decision aid	
	consultation with breast surgeon in which treatment options are discussed	63%

*Multiple answers allowed, **Videos, patients, educational meetings, social worker.

Table 5. Overview and summary of the modules of the Breast Reconstruction Patient Decision Aid

Module	**Description of module**
1. Diagnosis	Based on patient's treatment options selected on the consultation sheet by their oncological breast surgeon during the clinical encounter, patients tailor the pDA to their situation (i.e. whether or not the patient is eligible for nipple-sparing surgery, whether or not radiotherapy is or might be necessary following surgery, and whether or not the patient is eligible for BCS). Based on these treatment options, specific information is shown or rephrased.
2. Immediate reconstruction or not (yet)?	Breast reconstruction options and their pros and cons are described. Options include immediate breast reconstruction, delayed breast reconstruction, and no breast reconstruction. Information is structured as answers to the following questions: 'What choices do I have?', 'What are my options?', 'What are the pros and cons?', 'How much time do I have to think?', 'A period without a breast?', 'Sparing my skin and nipple?'[a], 'When can I resume my normal activities?', 'When is breast reconstruction finished?', 'What is breast-conserving asurgery?'[b]
3. Expectations	Information is provided about what patients can expect from breast reconstruction. Also, the different types of breast reconstruction and their pros and cons are described. Options include implant-based breast reconstruction and autologous breast reconstruction. Information is structured as answers to the following questions: 'What can I expect of a new breast?', 'What are the pros and cons of implant-based and autologous breast reconstruction?', 'What if I received breast radiation in the past?', 'What is implant-based breast reconstruction?', 'What is autologous breast reconstruction?', 'How will my breast look like?', 'How will my breast feel like?', 'Will this impact my body image?', 'What are potential complications?', 'What if I need breast radiation after surgery?'[c]
4. Considerations	With value clarification exercises, patients are actively encouraged to weigh the options of immediate breast reconstruction versus no immediate breast reconstruction. Furthermore, patients are invited to indicate their preference for or against immediate breast reconstruction and for the type of breast reconstruction. There is space to note questions for the plastic surgeon.
5. Patient Stories	Six short stories of patients who previously had mastectomy with or without breast reconstruction. The stories illustrate the experiences of these patients with decision making and the impact of their decision on daily life.
6. Summary	A summary sheet (A4 format) including patient's personal considerations, preferences and questions for the plastic surgeon. The sheet can be saved as PDF and printed. Patients are encouraged to discuss the summary sheet with their plastic surgeon.

Abbreviations. **pDA** patient decision aid; **BCS** breast conserving surgery. [a]Information is rephrased dependent on whether or not patient is eligible for nipple-sparing surgery. [b]Section briefly describes reconstruction options after breast conserving surgery. Only shown if patient is eligible for breast conserving surgery. [c]Only shown if adjuvant radiotherapy is indicated.

ACCEPTABILITY AND USABILITY TESTING

Six patients, seven HCPs and seven representatives of the Dutch Breast Cancer Patient Organization participated in acceptability and usability testing. The background characteristics of the participants (N=20) are provided in Table 6.

Table 6. Background characteristics of participants in acceptability and usability testing (N=20)

	Patients (N=6)	**Representatives of Dutch Breast Cancer Patient Organization (N=7)**
	n	**n**
Age (years), M (SD)	54.3 (13.8)	49.9 (6.1)
Level of education		
high (higher vocational/university)	5	7
intermediate (secondary school/ intermediate vocational)	1	0
low (primary school/lower vocational)	0	0
Mastectomy	6	4
Time since mastectomy		
< 1 year	0	0
1 – 3 years	2	0
> 3 years	4	4
Breast reconstruction		
yes	5	3
no	1	1
Timing of breast reconstruction		
immediate	4	2
delayed	1	1
Type of breast reconstruction		
implant-based	3	1
autologous	2	2
combination	0	0
	Healthcare professionals (N=7)	
	n	
Sex		
female	4	
male	3	
Profession		
plastic surgeon	3	
oncological breast surgeon	1	

Table 6. Continued

	Healthcare professionals (N=7)
	n
nurse specialist	1
social worker	1
psychologist	1
Type of hospital	
(breast) cancer specific hospital	3
academic medical center	3
general hospital	1

Abbreviations. **M** mean; **SD** standard deviation.

Patients, HCPs and representatives of the Dutch Breast Cancer Patient Organization were positive about the pDA. Participants could easily navigate through the pDA. They considered the pDA as informative and would recommend it to patients who are considering immediate BR. The patient stories were recognizable to patients, and were perceived as balanced and of added value. Participants were positive about the look and feel of the pDA. Information was perceived as well-structured and understandable. While most participants appreciated the amount of information, some participants felt that it was too much. HCPs considered the pDA valuable for their patients, to prepare for consultation and to increase patient empowerment. Some HCPs expected that the pDA could also be helpful for themselves in supporting patients in decision making.

The most important changes made to the pDA are listed below (a detailed overview of changes is provided in Supporting Information Appendix S5):

- Text was shortened where possible;
- Information about immediate BR and its pros and cons was adjusted to more accurately reflect the situation in which a tissue-expander is used (e.g. “You wake up with a reconstructed breast” was changed to “You will not wake up flat”);
- The burden of recovery from autologous BR was emphasized, and information about recovery from surgery was expanded to include anticipated restrictions in daily life.

DISCUSSION

To support patients with BC in making an informed decision about immediate BR after mastectomy together with their plastic surgeon, an online patient decision aid was developed. The pDA was based on the information needs of patients and HCPs, and in accordance with international criteria for developing a high-quality patient decision aid. The pDA was positively evaluated by patients, HCPs, and representatives of the Dutch Breast Cancer Patient Organization.

Consistent with previous studies (15-18, 27, 43, 44), the results of our needs assessment demonstrated that patients have unresolved information needs regarding their BR decision. Patients' need for a clear overview of the reconstructive options, information about the consequences of each option on patients' daily lives, and the experiences of women who previously faced the decision were consistent with information needs regarding the decision for BR described in previous studies (17, 18, 45). Patients' reasons for having BR, such as the desire for improved body image and appearance, and reasons against BR, such as the desire for faster recovery and avoiding increased risk of complications, were comparable to patients' motivations for or against undergoing BR reported in prior studies (15, 43, 45-50). Furthermore, the challenging period in which the decision about immediate BR needs to be made, has been described as an obstacle for making well-balanced decisions before (51).

Only a limited number of studies investigated the attitudes and preferences regarding shared decision making in BR from the perspective of HCPs (26, 27, 52). The positive attitudes of HCPs towards active patient involvement and usage of the pDA were comparable to findings of these studies (26, 27, 52).

In developing a pDA, it is challenging to determine the appropriate amount of information. In our needs assessment patients reported that they felt overwhelmed by the amount of information that they had to process at the time of decision making about BR. Therefore, we wanted to provide patients with sufficient information, without (further) overwhelming them. Individuals have different preferences in terms of the amount of information they wish to obtain when faced with a cancer-related health threat, as some patients prefer higher levels of details than others (53). This emphasizes the importance of the possibility for patients to tailor the amount of information in tools like a pDA (53). In our pDA, patients were free to select the information they wanted to read, and skip parts they did not want to read. Furthermore, we felt that we reached an appropriate amount of information in our pDA as the majority of the participants in the acceptability and usability study were satisfied with the amount of information in the pDA and members of the working group could not provide suggestions for omissions in the content of the final version of the pDA.

This study had several limitations. First, as a main limitation, selection bias may have occurred. The majority of patients and all representatives of the Dutch Breast Cancer Patient Organization who participated in the development were highly educated. Although the information in the pDA was written at a level (B1) that is understandable to most people, it remains uncertain whether the pDA is consistent with decision support needs of patients with lower educational levels, and whether the pDA is acceptable and usable for this patient group. Second, all patients participating in the acceptability and usability testing had already made their decision about BR in the past. We felt that it was inappropriate to invite recently diagnosed patients to participate in the development of the pDA and to place extra burden on them. Third, all patients participating in the acceptability and usability testing had also participated in the needs assessment.

The strength of this study was the rigorous development process, which included all relevant stakeholders from the beginning. It resulted in a pDA that incorporated information needs of both patients and HCPs and complied with international criteria for a high-quality pDA. According to an independent group of researchers, 81% of all IPDAS criteria were fullfilled in our pDA (54).

To investigate the pDA's impact on the decision-making process and the decision quality, a multicenter randomized controlled trial is currently underway comparing use of the pDA to usual care including a widely available information leaflet (35, 55).

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SUPPORTING INFORMATION APPENDICES

Appendix S1: Interviewguide Needs Assessment Patients

Introduction:

- Goodmorning/good afternoon, I am [name researcher] from the Netherlands Cancer Institute. I am calling you for the interview for which we have previously been in contact. First of all, thank you for participating. This interview is about your experiences with breast reconstruction and the information provision about breast reconstruction. You already received an information letter about it. Do you have any questions about this?
- Before we start, I will first tell you something about the interview and the course of events. The interview will last approximately 45-60 minutes. I will ask you many questions about how you went through the care process and your experiences with it. There are no false answers, everything you say is valuable. To ensure that all topics are discussed, I may sometimes interrupt you. But I might also encourage you to tell more about something, if it is important to know.
- Participation is entirely voluntary and you can stop at any time. You also do not have to answer questions if you do not want to.
- Do you agree with audio recording?
- Do you have any other questions before we start?

Interview:

- Could you introduce yourself/could you tell something about yourself?
    - o age, marital status, children, country of birth, education, occupation, hobbies, diagnosis, date of diagnosis, type of surgery and reconstruction
- Could you tell how you went through the process of breast reconstruction process? (from the beginning to the end)
- What do you remember from the conversations you had with your doctor about breast reconstruction?
    - o What information did you receive?
    - o What questions did you have during and after this conversation?
    - o What information did you miss in the conversations about breast reconstruction?
    - o What did you worry about?
- Did you feel that you had a choice about breast reconstruction?
    - o If not, could you elaborate on that?
    - o If so, how did you experience that choice? (Was it difficult/easy? A quick decision/did you think about it for a long time? Was there any time pressure?)
    - o If so, how did your doctor involve you in this decision? How did you experience that? When?
    - o Who should make the treatment decision. The doctor, you and the doctor, or the both of you?
- What were your most important considerations in making this decision?
    - o What made you chose for breast reconstruction or not?
    - o Immediate or delate breast reconstruction?
    - o Implant-based or flap-based breast reconstruction?

- Could you also tell about your experiences with nipple-reconstruction?
    - Did you make a decision in that? How did you experience that?
- How do you look back on your decision?
    - What went different than you expected?
    - Are you satisfied with the results or did you ever experience regret?
    - Would you recommend it to other women in the same situation?
- What was the role of your partner in decision making? Others?
    - Did you discuss the decision with somebody?
    - Did that influence your decision?
- Did you look for additional information? What information were you mainly looking for?
    - contact with fellow patients, experiences of other patients, photos, chats, blogs, discussion groups, patient association, relaxation exercises
- How did you experience the period after your treatment?
    - Aftercare, recovery(period), home help, what to consider
- What would you advice other patients who just start in the trajectory of making a decision about breast reconstruction?
- We are approaching the end of the interview. Are there any important issues that haven't been discussed so far?

Closing

- We have come to the end of the interview. Thank you very much for participating. How did you feel about doing it yourself? Any suggestions for us?
- When all interviews have been completed, we will write a summary report. We would like to send this to receive your feedback. Are you okay with that?
- We would like to approach you in the future for follow-up research. Are you okay with that?
- To thank you we would like to send you a book receipt. To which address can we send it?

Appendix S2: Interview script acceptability and usability testing

Background (Date, age, profession)
What did you expect of the decision aid (before usage)?
What was your first impression of the decision aid?
What do you consider as positive?
What could be improved?
What do you think of the patient stories?
What do you think about the amount of information? What information can be omitted? What information did you miss?
Patients + Representatives: Would you recommend the decision aid to women with breast cancer deciding about breast reconstruction? *Healthcare professionals* :Would you offer this to your patients? • What barriers do you expect? • What would facilitate using the decision aid?
Do you have any other remarks or considerations that you would like to share?

Appendix S3: Results of needs assessment in healthcare professionals (N=33)

A) Information provision about breast reconstruction

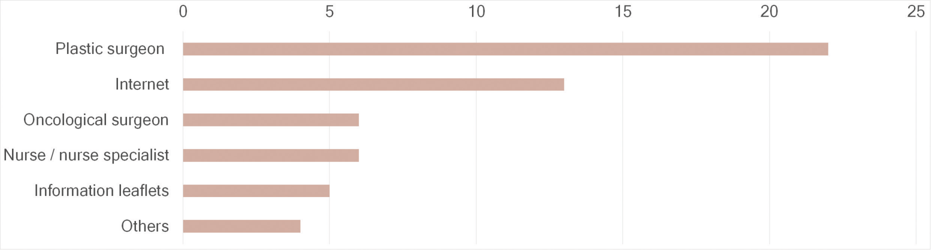


Figure 1. Main information resource about breast reconstruction for patients according to healthcare professionals (N=33)

Note. X-axis= Number of times that information resource was reported. Multiple answers were allowed.

	No.	**%**
How are patients informed about breast reconstruction in your hospital?		
oral information by plastic surgeon	32	100
oral information by oncological surgeon	25	78
information leaflet of hospital	24	75
oral information by breast cancer nurse	23	72
information leaflet of Dutch Cancer Society	17	53
oral information by nurse specialist	13	41
website of hospital	11	33
website Dutch Breast Cancer Patient Organization	7	22
website of Dutch Society for Plastic Surgeons	6	19
others	6	19
B-Bewust website	5	16
website keuzehulp.info	2	6
website kanker.nl	1	3
information center in hospital	1	3
website of other hospital	1	3
Average number of consultations with plastic surgeon for decision making about (immediate) breast reconstruction following breast cancer diagnosis		
one consultation	9	28
two consultations	17	53
three or more consultations	1	3
I don't know	5	16

N=32 as questions were inappropriate for 1 healthcare professional who did not work in a hospital

B) Satisfaction with current information about BR according to healthcare professionals

			No. (%)				
	N	**M (SD)**	**1**	**2**	**3**	**4**	**5**
Satisfaction with information about breast reconstruction	32	3.3 (0.8)	0 (0)	7 (22)	11 (34)	13 (41)	1 (3)
Satisfaction with information about breast reconstruction provided in your hospital*	31*	3.7 (0.8)	0 (0)	3 (10)	5 (16)	20 (65)	3 (10)
Patients are sufficiently informed about the possibilities of breast reconstruction	33	3.4 (1.1)	0 (0)	10 (30)	5 (15)	13 (39)	5 (15)
The information about breast reconstruction is reliable[1]	33	3.4 (0.9)	0 (0)	5 (15)	13 (39)	12 (36)	3 (9)

1 = 'not satisfied at all' or 'completely disagree', 3 = 'neutral', 5 = 'very satisfied' or 'completely agree'
*2 missing; 1 not applicable, 1 missing
[1]Due to a data storage issue, the number of healthcare professionals in categories 2 (disagree) and 4 (agree) might have been 6 and 11, respectively, resulting in a mean score of 3.5.

C) Attitudes of healthcare professionals on patient involvement in decision making about breast reconstruction (N=33)

			No. (%)				
	N	**M (SD)**	**1**	**2**	**3**	**4**	**5**
Better informed patients facilitate the decision-making process[1]	33	4.3 (0.7)	0 (0)	1 (3)	2 (6)	15 (45)	15 (45)
Better-informed patients complicate the decision-making process[2]	33	2.2 (1.2)	13 (39)	9 (27)	6 (18)	3 (9)	2 (6)
If a patient does not want to be involved in decision making, the doctor must still try to involve the patient	33	4.0 (0.7)	0 (0)	1 (3)	5 (15)	19 (58)	8 (24)
Every patient must be informed about the reconstructive options that apply to her, also if she has to be referred to another hospital for this option	33	4.9 (0.4)	0 (0)	0 (0)	0 (0)	5 (15)	28 (85)

1 = 'completely disagree', 3 = 'neutral', 5 = 'completely agree'
[1]Due to a data storage issue, the number of healthcare professionals in categories 2 (disagree) and 4 (agree) might have been 0 and 16, respectively, resulting in a mean score of 4.4.
[2]Due to a data storage issue, the number of healthcare professionals in categories 2 (disagree) and 4 (agree) might have been 10 and 2, respectively, resulting in a mean score of 2.1.

	N	**%**
The decision about breast reconstruction should be made by..		
patient	2	6
patient after seriously considering the doctor's opinion	13	39
patient and doctor together	18	55
doctor after seriously considering the patient's opinion	0	0
doctor	0	0

Facilitators and barriers for patient involvement in decision making about breast reconstruction according to healthcare professionals (N=33)

	Facilitators	Barriers
Patient-related	Well-informed (5)	Insufficiently or erroneously informed (4)
	Active/asks questions (2)	Emotional state (3)
	Aware of preference-sensitive nature of decision (1)	Limited understanding and/or language barrier (3)
	Trust in doctor (1)	No headspace to think about breast reconstruction (2)
	High educational level (1)	Demanding (1)
	Feeling of social support (1)	Subassertive (1)
		Unrealistic expectations (1)
		Difficulties to foresee consequences (1)
Physician-related	Informs about options and pros and cons (3)	Provides personal opinion (instead of options) (1)
	Knowledge of and attitude towards breast reconstruction of oncological surgeon (3)	
	Emphasizes personal nature of decision / importance shared decision making (2)	
	Is involved (1)	
Organization of care	Easy access to (supportive) care (3)	Limited time to decide / for consultation (2)
	More than one consultation (2)	
	Time to think after consultation (1)	
Information	Provision of visual materials (2)	Large amount of information (1)
	Experiences of other patients (1)	
Relatives	Presence/involvement of relatives in consultation (2)	Dominant partner (2)
Decision		Large number of options (2)

D) Attitudes of healthcare professionals towards development of breast reconstruction decision aid (N=33)

	n	%
Desirability of the development of decision aid		
not at all desirable	0	0
not desirable	0	0
a little bit desirable	2	6
desirable	17	52
very desirable	14	42

Expected advantages and disadvantages of breast reconstruction decision aid according to healthcare professionals (N=33)

Expected advantages (n)	Expected disadvantages (n)
Patient can process information in own time and at own pace (18)	Might suggest options that are not available for patient (11)
Patient is better informed (15)	Too much information for patient (8)
Patient is better prepared for consultation (9)	Information is not sufficiently tailored to patient (7)
Provides objective information (5)	Not accessible for all patients (6)
Higher patient satisfaction and less regret (4)	Patients might feel conflicted about decision or 'left alone' to make the decision (5)
	No possibility to provide immediate feedback (4)
Enables well-informed decision (4)	Patient might rely too much on outcome of decision aid (3)
Supports doctor in discussing pros and cons and clarifying patients' values (3)	Too little attention for emotional aspects in decision making (3)
Provides standardized information (3)	Some patients do not want to make / be involved in the decision (2)
Saves time during consultation (3)	Increases consultation time (2)
	Might confuse patients (2)
Provides reliable information (2)	Leads to unrealistic expectations (2)
Provides tailored information (2)	No substitute for consultation (2)
Patient has realistic expectations (2)	Extra burden for patient (2)
Fastens decision-making process (2)	Information must constantly be kept up-to-date (2)
Increases patient involvement (2)	Partner might be involved to little (1)
Increases choice awareness (1)	Might provide subjective information (1)
Reduces stress (1)	Negative impact on patient communication if plastic surgeon is not aware of or does not support content of decision aid (1)
Pictures and examples (1)	

E) Preferences for content and timing of the patient decision aid according to healthcare professionals (N=33)

	n	%
Which breast reconstruction options should be included in the patient decision aid?		
all breast reconstructive options offered worldwide	5	15
all breast reconstructive options offered in The Netherlands	20	61
all breast reconstructive options discussed in guideline	5	15
all breast reconstructive options offered in hospital	0	0
other	3	9
Which risk factors should be included in the patient decision aid?		
smoking	32	97
previous radiotherapy	32	97
indication adjuvant radiotherapy	32	97
overweight	31	94
comorbidity (e.g. diabetes, high blood pressure)	31	94
large cup size	30	91
bilateral surgery	23	70
age (>55 years)	18	55
other*	5	-
Which complications should be included in the patient decision aid?		
infections	33	100
hematoma	33	100
necrosis	32	97
wound healing problems	32	97
implant-related (including capsular contracture)	32	97
abdominal hernia/muscle weakness (DIEP-flap)	25	76
other**	28	-
Preference regarding visual material in patient decision aid		
no photos or illustrations	2	6
photos	0	0
illustrations	7	21
photos and illustrations	24	73
Preferred timing to offer the patient decision aid to patient		
consultation in which diagnosis is communicated	4	13
consultation with oncological breast surgeon in which treatment options are discussed	20	63
consultation with plastic surgeon	4	13
other***	4	13
missing	1	3

E) Continued

*Other risk factors (all reported once): quality of skin and tissue and scars, surgeries of abdomen or back in the past, surgeries of breast in the past, mental state, history of thromboembolism.
**Other complications (number of times reported): failure (7), reoperations (3), pulmonary embolism (3), spasm of pectoralis major (2), asymmetry (2), abnormal scarring (2), regret (1), thrombosis leg (1), pain (1), malpositioning of prosthesis (1), prosthetic rupture (1), seroma (1), dogears (1), impact of complications on adjuvant treatment (1), functional problem (1).
***other = prior to consultation with plastic surgeon

F) Healthcare professional's (N=33) beliefs about patients' most important motivations to decide for a specific breast reconstruction option

	No.
Breast reconstruction (versus no breast reconstruction)	
retain/restore femininity	12
avoid to be 'flat'	8
retain/restore identity and self-image	4
more clothing possibilities	4
cosmetics	3
symmetry	3
self-confidence	2
avoid use of external breast prosthesis	2
keep/restore breast shape	2
feel 'whole'	2
repair of mutilation	2
keep cleavage	1
attractiveness	1
prevent stigma	1
No breast reconstruction	
too much hassle	8
avoid additional operations	7
avoid additional risks for complications	6
avoid foreign materials and/or silicones	4
no need for breast reconstruction / reconstruction is considered unnecessary	3
breasts do not determine patients' femininity or well-being	2
indication for adjuvant radiotherapy	2
faster recovery	2
age	2
recover from breast cancer first	2
avoid additional scars	2
experiences from relatives	1

F) Continued

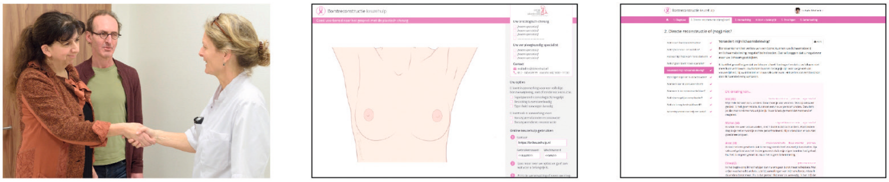
	No.
insufficient information about possibilities	1
too much information	1
accepts impact of disease	1
considers ‘flat’ as beautiful	1
stress overload	1
Immediate breast reconstruction (versus delayed breast reconstruction)	
fewer surgeries	16
avoid being ‘flat’ after surgery	10
sparing breast skin	3
superior cosmetic result	2
medically superior	1
feeling less mutilated	1
superior for psychological functioning	1
less confrontation with loss of breast	1
prevent stigma	1
feeling feminine immediately after surgery	1
return to normal as fast as possible	1
Delayed breast reconstruction (versus immediate breast reconstruction)	
complete oncological treatment first	12
no headspace to think about breast reconstruction after diagnosis	8
need more time to decide	2
wait to see how life is experienced without breast	2
adjuvant radiotherapy	2
fear for adjuvant therapy	1
fear for silicone implants	1
way to reach preferred results	1
doctor’s advice	1
letting the wound heal first	1
avoid additional risks and complications	1
belief of superior cosmetic results	1
presence of surgical risk factors	1
Implant-based breast reconstruction (versus autologous breast reconstruction)	
relative simple operation	18
no scarring of other body parts	13
shorter surgery	9

F) Continued

	No.
faster recovery	5
not eligible for autologous breast reconstruction	4
opportunity to increase cup size	3
keep the possibility of autologous breast reconstruction in case of complications	1
can be performed in all hospitals	1
most patients are satisfied with implant-based breast reconstruction	1
If this option is better for medical reasons	1
Autologous breast reconstruction (versus implant-based breast reconstruction)	
more natural outcomes (e.g. temperature, look, feel, aging of breast)	19
avoid foreign materials/silicones in body	19
no more surgeries required once completed/sustainability	6
superior cosmetic results	6
opportunity to get rid of redundant body tissue	3

Note. Multiple answers were allowed

Appendix S4: Screenshots of the Breast Reconstruction Patient Decision Aid



1. The surgeon discusses the options and indicates that the patient has a choice

2. The surgeon invites the patient to participate in the decision-making process and offers the decision aid for support

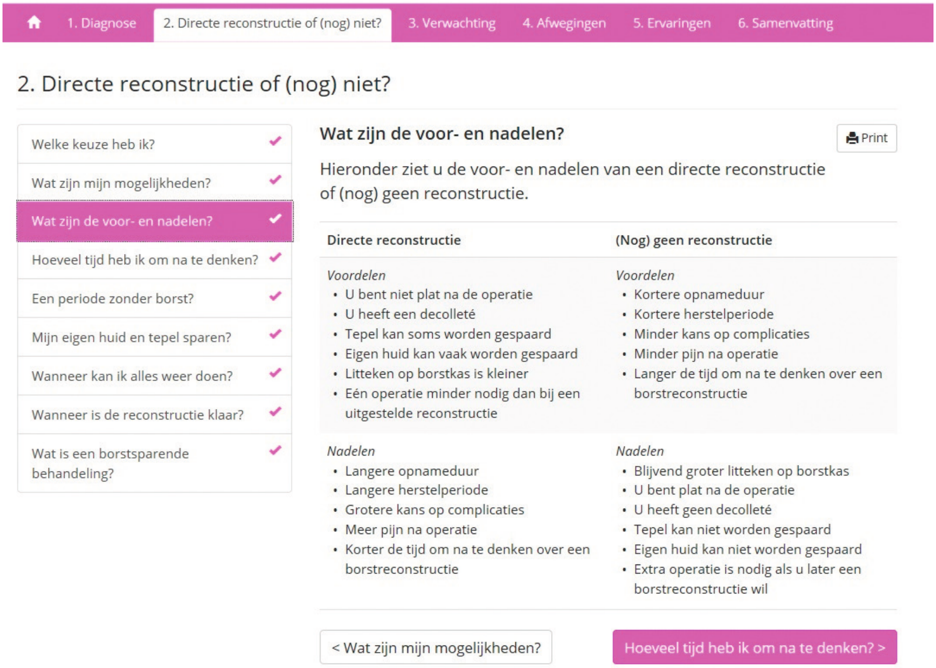
3. The patient accesses the online decision aid

4. The patient learns more about the options and experiences of other women

5. The patient is supported in clarifying her personal values and preferences

6. The plastic surgeon and patient can discuss important considerations and choose the most appropriate option

Figure 1. Roadmap illustrating how the breast reconstruction decision aid is used



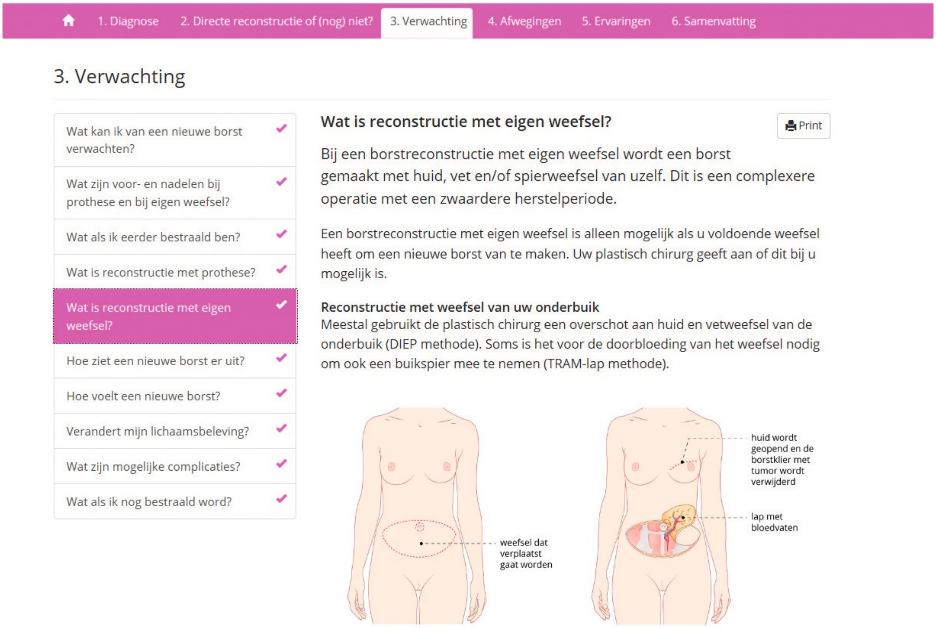
2. Directe reconstructie of (nog) niet?

Wat zijn de voor- en nadelen?

Hieronder ziet u de voor- en nadelen van een directe reconstructie of (nog) geen reconstructie.

Directe reconstructie	(Nog) geen reconstructie
Voordelen • U bent niet plat na de operatie • U heeft een decolleté • Tepel kan soms worden gespaard • Eigen huid kan vaak worden gespaard • Litteken op borstkas is kleiner • Eén operatie minder nodig dan bij een uitgestelde reconstructie	*Voordelen* • Kortere opnameduur • Kortere herstelperiode • Minder kans op complicaties • Minder pijn na operatie • Langer de tijd om na te denken over een borstreconstructie
Nadelen • Langere opnameduur • Langere herstelperiode • Grotere kans op complicaties • Meer pijn na operatie • Korter de tijd om na te denken over een borstreconstructie	*Nadelen* • Blijvend groter litteken op borstkas • U bent plat na de operatie • U heeft geen decolleté • Tepel kan niet worden gespaard • Eigen huid kan niet worden gespaard • Extra operatie is nodig als u later een borstreconstructie wil

Figure 2. Module 2: Immediate reconstruction or not (yet)?, table with pros and cons of options (in Dutch)



3. Verwachting

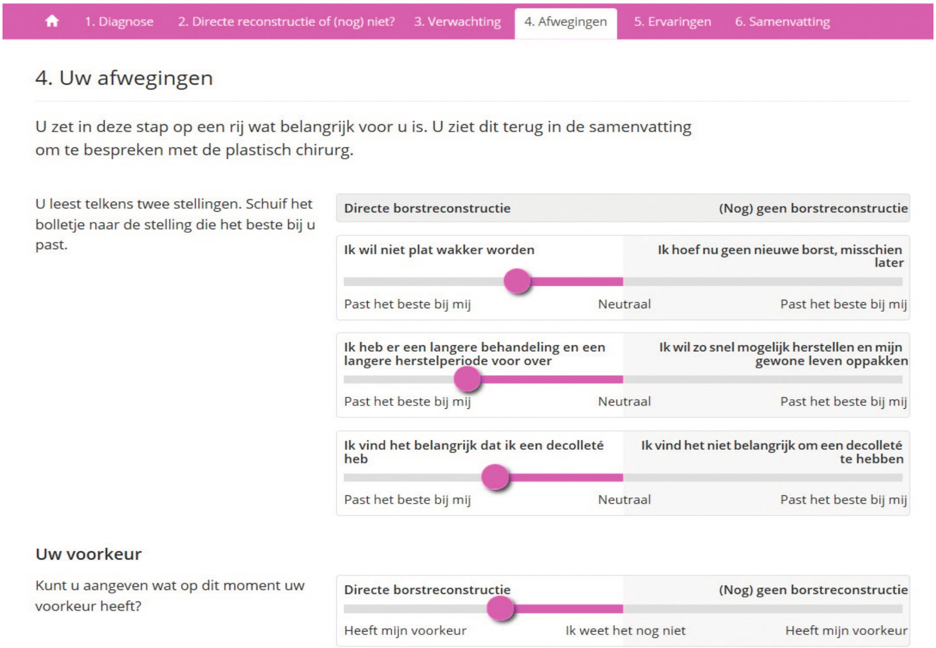
Wat is reconstructie met eigen weefsel?

Bij een borstreconstructie met eigen weefsel wordt een borst gemaakt met huid, vet en/of spierweefsel van uzelf. Dit is een complexere operatie met een zwaardere herstelperiode.

Een borstreconstructie met eigen weefsel is alleen mogelijk als u voldoende weefsel heeft om een nieuwe borst van te maken. Uw plastisch chirurg geeft aan of dit bij u mogelijk is.

Reconstructie met weefsel van uw onderbuik
Meestal gebruikt de plastisch chirurg een overschot aan huid en vetweefsel van de onderbuik (DIEP methode). Soms is het voor de doorbloeding van het weefsel nodig om ook een buikspier mee te nemen (TRAM-lap methode).

Figure 3. Module 3: Expectations, ‘What is autologous breast reconstruction?’ (in Dutch)



4. Uw afwegingen

U zet in deze stap op een rij wat belangrijk voor u is. U ziet dit terug in de samenvatting om te bespreken met de plastisch chirurg.

U leest telkens twee stellingen. Schuif het bolletje naar de stelling die het beste bij u past.

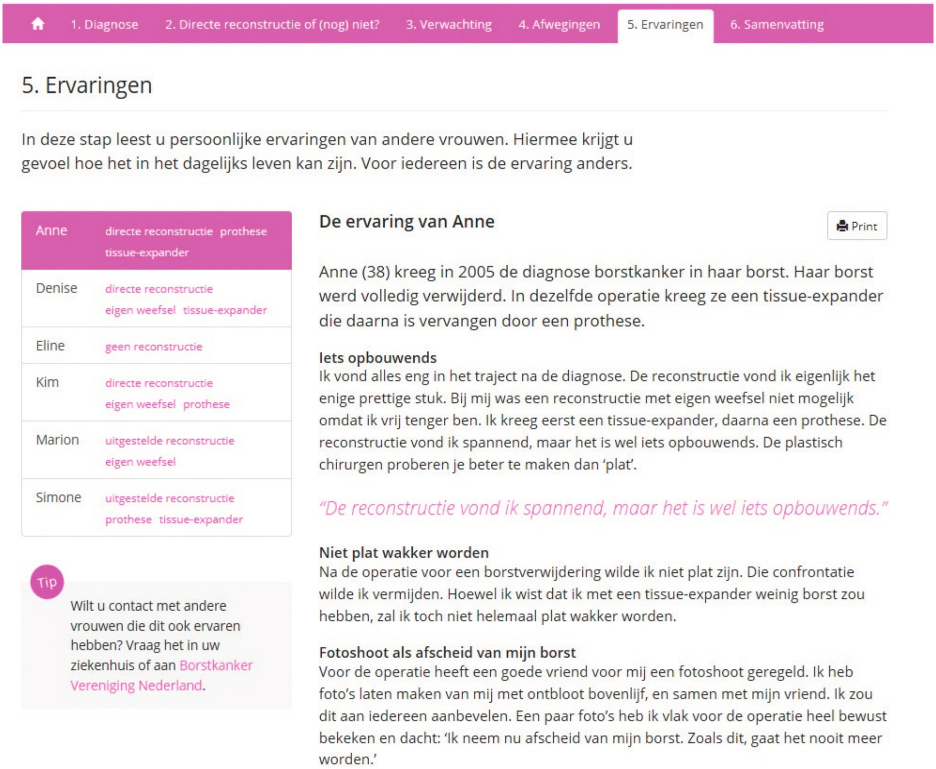
Directe borstreconstructie		(Nog) geen borstreconstructie
Ik wil niet plat wakker worden		Ik hoef nu geen nieuwe borst, misschien later
Past het beste bij mij	Neutraal	Past het beste bij mij
Ik heb er een langere behandeling en een langere herstelperiode voor over		Ik wil zo snel mogelijk herstellen en mijn gewone leven oppakken
Past het beste bij mij	Neutraal	Past het beste bij mij
Ik vind het belangrijk dat ik een decolleté heb		Ik vind het niet belangrijk om een decolleté te hebben
Past het beste bij mij	Neutraal	Past het beste bij mij

Uw voorkeur

Kunt u aangeven wat op dit moment uw voorkeur heeft?

Directe borstreconstructie		(Nog) geen borstreconstructie
Heeft mijn voorkeur	Ik weet het nog niet	Heeft mijn voorkeur

Figure 4. Module 4: Considerations, including value clarification exercises (in Dutch)



5. Ervaringen

In deze stap leest u persoonlijke ervaringen van andere vrouwen. Hiermee krijgt u gevoel hoe het in het dagelijks leven kan zijn. Voor iedereen is de ervaring anders.

Anne	directe reconstructie prothese tissue-expander
Denise	directe reconstructie eigen weefsel tissue-expander
Eline	geen reconstructie
Kim	directe reconstructie eigen weefsel prothese
Marion	uitgestelde reconstructie eigen weefsel
Simone	uitgestelde reconstructie prothese tissue-expander

Wilt u contact met andere vrouwen die dit ook ervaren hebben? Vraag het in uw ziekenhuis of aan Borstkanker Vereniging Nederland.

De ervaring van Anne

Anne (38) kreeg in 2005 de diagnose borstkanker in haar borst. Haar borst werd volledig verwijderd. In dezelfde operatie kreeg ze een tissue-expander die daarna is vervangen door een prothese.

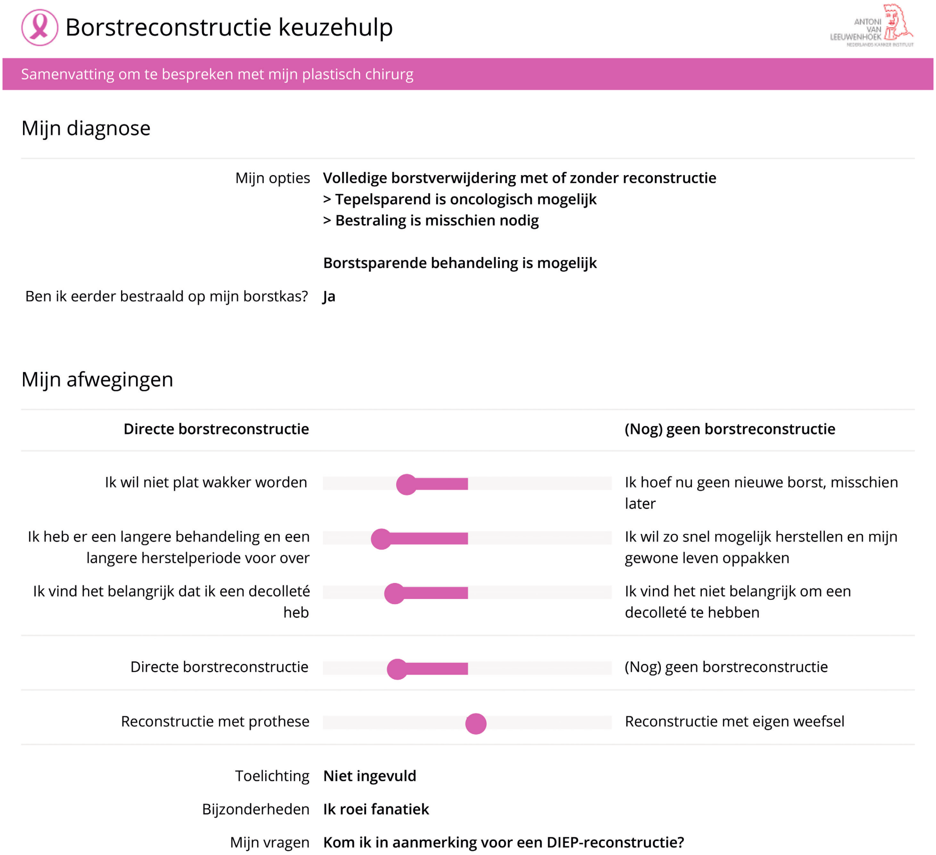
Iets opbouwends
Ik vond alles eng in het traject na de diagnose. De reconstructie vond ik eigenlijk het enige prettige stuk. Bij mij was een reconstructie met eigen weefsel niet mogelijk omdat ik vrij tenger ben. Ik kreeg eerst een tissue-expander, daarna een prothese. De reconstructie vond ik spannend, maar het is wel iets opbouwends. De plastisch chirurgen proberen je beter te maken dan 'plat'.

"De reconstructie vond ik spannend, maar het is wel iets opbouwends."

Niet plat wakker worden
Na de operatie voor een borstverwijdering wilde ik niet plat zijn. Die confrontatie wilde ik vermijden. Hoewel ik wist dat ik met een tissue-expander weinig borst zou hebben, zal ik toch niet helemaal plat wakker worden.

Fotoshoot als afscheid van mijn borst
Voor de operatie heeft een goede vriend voor mij een fotoshoot geregeld. Ik heb foto's laten maken van mij met ontbloot bovenlijf, en samen met mijn vriend. Ik zou dit aan iedereen aanbevelen. Een paar foto's heb ik vlak voor de operatie heel bewust bekeken en dacht: 'Ik neem nu afscheid van mijn borst. Zoals dit, gaat het nooit meer worden.'

Figure 5. Module 5: Patient Stories (in Dutch)



Borstreconstructie keuzehulp

Samenvatting om te bespreken met mijn plastisch chirurg

Mijn diagnose

Mijn opties	**Volledige borstverwijdering met of zonder reconstructie** **> Tepelsparend is oncologisch mogelijk** **> Bestraling is misschien nodig** **Borstsparende behandeling is mogelijk**
Ben ik eerder bestraald op mijn borstkas?	**Ja**

Mijn afwegingen

Directe borstreconstructie	**(Nog) geen borstreconstructie**
Ik wil niet plat wakker worden	Ik hoef nu geen nieuwe borst, misschien later
Ik heb er een langere behandeling en een langere herstelperiode voor over	Ik wil zo snel mogelijk herstellen en mijn gewone leven oppakken
Ik vind het belangrijk dat ik een decolleté heb	Ik vind het niet belangrijk om een decolleté te hebben
Directe borstreconstructie	(Nog) geen borstreconstructie
Reconstructie met prothese	Reconstructie met eigen weefsel

Toelichting	**Niet ingevuld**
Bijzonderheden	**Ik roei fanatiek**
Mijn vragen	**Kom ik in aanmerking voor een DIEP-reconstructie?**

Figure 6. Summary sheet (generated in Module 6) including patient's personal considerations, preferences and questions

Appendix S5: Overview of issues raised in acceptability and usability testing and changes made to the patient decision aid

No.	Module	FAQ	Topic	Issue	Change
1	NA	NA	Language/ comprehension	The term oncological may be difficult to understand for patients	The word oncological was avoided
2	NA	NA	Language/ comprehension	The amount of information was considered as too large by some	Texts were restructured with subheadings, divided into separate sections, and shortened where possible
3	1	NA	Content	The treatment option 'breast conserving surgery with or without BR is possible' is confusing, as BR refers to BR after mastectomy throughout the tool	Changed to 'Breast conserving surgery is possible'
4	1	NA	Content	The question to fill in particularities that should be taken into account is difficult to complete at this point	Question was moved to module 4
5	2	What choices do I have?	Content	An exemplar reason to have immediate BR (i.e. I want to wake up with a reconstructed breast) does not hold for patients with BR with TE	Exemplar reason for immediate BR changed to: I don't want to wake up flat
6	2	What are my options?	Content	The information about immediate BR does not accurately correspond to the situation in which a TE is placed prior to the final implant	The option of immediate BR with a TE is introduced earlier in the pDA, and Information was adjusted to better reflect this situation
7	2	What are the pros and cons?	Content	It is unclear how much longer the hospital stay is in case of an immediate BR	No change made because of variability between hospitals
8	2	What are the pros and cons?	Content	The pro of immediate BR 'wider choice of clothing' can be perceived normative	This pro was removed
9	2	How much time do I have to think?	Content	Suggestion to add the advice to take sufficient time for decision making	Advice was added
10	2	How much time do I have to think?	Content	Suggestion to add that patients need to wait at least 6 months after mastectomy for delayed BR	Not added as working group disagreed
11	2	A period without a breast?	Content	Suggestion to add the advice to ask for special information days about external prosthesis in hospital	Not added to not further increase the amount of information in this section
12	2	A period without a breast?	Content	Suggestion to add common inconveniences of wearing an external prosthesis	Common inconveniences were added (i.e. It may feel heavy, fall out of the bra, sometimes still be visible and you may sweat more)
13	2	Sparing my skin and nipple?	Content	Information is provided about lost/reduced sensation of the beast and breast skin in case of immediate BR. However, it is unclear what happens in case of mastectomy without immediate BR	Text was changed to clarify ("After mastectomy, sensation is lost or reduced. Also after breast reconstruction, you will not or barely have sensation in your skin if it is touched")
14	2	Sparing my skin and nipple?	Content	Suggestion to add that scars are red and big shortly after surgery, but that this disappears after a while	No information added

Appendix S5: Continued

No.	Module	FAQ	Topic	Issue	Change
15	2	When can I resume my normal activities?	Content	Information does not reflect the true burden of the recovery period after surgery	We added: You may need help at home with getting dressed and with your household.
16	2	When can I resume my normal activities?	Language/ comprehension	A fragment of patient story dealing about a scar on patient's belly is unclear, as A-BR has not yet been explained	The fragment was left out from patient story at that section
17	2	When can I resume my normal activities?	Content	Duration of complaints following surgery in patient story (mastectomy without BR) was not considered representative	The duration of the period was left out from patient story
18	2	When is breast reconstruction finished	Content	Suggestion to specify possible adjustments to the breast in the phrase 'sometimes the healthy breast is adjusted' (i.e. reduced, lifted, etcetera)	No change made
19	3	'What can I expect of a new breast?	Content	Suggestion to leave out the information that A-BR can also be performed after I-BR, because of doubts whether this is covered by health insurance	No change made
20	3	What are the pros and cons of implant-based and autologous BR?	Content	Suggestion to add 'does not require replacements in the future' as pro for A-BR	Pro was added. 'Real chance for needing a replacement in the future' was added as a con for I-BR
21	3	What are the pros and cons of implant-based and autologous BR?	Content	Information about differences in the recovery period between A-BR and I-BR is lacking	Information was added, emphasizing the burden of recovery after A-BR
22	3	What are the pros and cons of implant-based and autologous BR?	Content	Suggestion to specify duration of surgery and recovery period	Not specified because of variability
23	3	What are the pros and cons of implant-based and autologous BR?	Content	Suggestion to add con of immediate I-BR: Prosthesis can move if not preceded by a TE	Information was not added as it is rare and we refer to an additional information resource containing this information
24	3	What are the pros and cons of implant-based and autologous BR?	Content	Suggestion to add 'tummy tuck' as pro of A-BR	Not added, as this was not considered most important pro of A-BR, only applicable for specific type of A-BR, and this aspect is highlighted in a patient story

Appendix S5: Continued

No.	Module	FAQ	Topic	Issue	Change
25	3	What are the pros and cons of implant-based and autologous BR?	Content	Change con of A-BR to 'Can't be performed in every hospital' instead of 'Complex surgery'	Not changed
26	3	What are the pros and cons of implant-based and autologous BR?	Content	Suggestion to add that immediate BR is not offered in every hospital and that you might have to change from hospital.	Not changed
27	3	What is implant-based breast reconstruction?	Content	Specify the impact of having a TE on traveling	'This means that you will have to come to the hospital multiple times' was added
28	3	What is implant-based breast reconstruction?	Content	Suggestion to add that filling a TE might cause pain	Not added (to be as concise as possible, and was not perceived of high importance for the decision for a TE)
29	3	What is implant-based breast reconstruction?	Lay-out	Reference to surgical package insert seemed to be in the wrong place	Reference was replaced
30	3	What is autologous breast reconstruction?	Content	Suggestion to place greater emphasis on the burden of recovery after A-BR	Burden of recovery period was emphasized, and patient story illustrating recovery period was added
31	3	Will this impact my body image?'	Content	Text was phrased in a negative way	Text was rephrased in a more positive way
32	3	Will this impact my body image?'	Content	The text about impact of BC diagnosis 'you may feel that your body has failed you and that you can no longer trust your body' was considered irrelevant for the decision about BR	Information was left out
33	3	What are potential complications?	Content	Pulmonary embolism is missed as complication	Not added, as this is very rare and a complication of surgery in general
34	3	What are potential complications?	Content	Information raises questions about the probabilities of complications	We added the suggestion to ask your plastic surgeon for individual risk estimates. Probabilities of complications were not added, because there was no consensus on the numbers (i.e. risk for complications differs per patient, very broad range, and differences per hospital)

Appendix S5: Continued

No.	Module	FAQ	Topic	Issue	Change
35	3	What if I need breast radiation following surgery?	Content	Suggestion to add information about the risks of radiotherapy after immediate I-BR	Text was rewritten to: Radiation treatment after reconstruction is more likely to cause scarring. As a result, there is a good chance that after a few years you will need surgery in your reconstructed breast
36	3	What if I need breast radiation following surgery?	Content	Text 'If it is clear before surgery that you will need radiotherapy after surgery, a delayed breast reconstruction is often advised' is not in line with current practice	Text changed to: 'If it is clear that you will need radiotherapy after surgery, delayed breast reconstruction can be advised'
37	4	Considerations	Content	Value statements "I can think about breast reconstruction at this time" vs. "I can't think about it yet" (leaning towards immediate BR vs. not, respectively) can be perceived normative, and are not correct	Statements were left out
38	4	Considerations	Content	Value statement "I don't mind waking up without a breast" (leaning towards not having immediate BR) was considered inappropriate	Statement was changed to "I don't need a new breast now, maybe later"
39	4	Considerations	Content	Value statement 'It is important to me, that I am able to wear all types of clothing, including swimwear' (leaning towards immediate BR) was considered normative	Value statement was changed into "It is important for me to have a cleavage"
40	4	Considerations	Content	Suggestion to refer to existing resource (Question Prompt Lists) of Dutch breast cancer patient organization	Linkage was added
41	5	NA	Content	There is no story of a patient with complications among the patient stories	Listed as a wish for further development of pDA
42	5	NA	Content	Suggestion to add reference to peer contact team of Dutch breast cancer patient organization	Reference was added

Abbreviations. **A-BR** Autologous breast reconstruction; **BR** Breast reconstruction; **I-BR** Implant-based breast reconstruction; **pDA** patient decision aid; **TE** Tissue-expander.