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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Introduction

IN SHORT

Women undergoing mastectomy as a treatment for invasive breast cancer or ductal carcinoma in situ often face the decision of whether or not to have breast reconstruction. This decision can be challenging, particularly given the short and stressful period following a cancer diagnosis. Patient preferences play a crucial role in this decision, and it is essential to provide women with the information and support to make the best decision for their individual circumstances. In this project, we aimed to support breast cancer patients in making an informed decision about immediate breast reconstruction by developing and implementing an online patient decision aid. Additionally, we aimed to evaluate the efficacy of this online patient decision aid in reducing decisional conflict compared to a widely available information leaflet.

BREAST CANCER

Breast cancer is the most common cancer worldwide (1, 2). Incidence rates are still increasing. In the Netherlands, in 2022 over 15.000 women were diagnosed with invasive breast cancer and over 2.300 women were diagnosed with non-invasive breast cancer, known as ductal carcinoma in situ (DCIS) (3). In Western European countries, including the Netherlands, one out of seven women develops breast cancer in her lifetime (2, 3). Thanks to improvements in treatment and national screening, the chances of survival have greatly increased (3). In the Netherlands, the 10-year survival rate of all patients with breast cancer increased from 40% in 1970 to 80% in 2020 (3). This increase in survival has made quality of life issues after cancer and its treatment more important.

SURGICAL TREATMENT OF BREAST CANCER

Approximately 90% of all breast cancer patients undergo surgery (3). Surgical treatment options include breast conserving surgery, in which only the tumor and some of the surrounding tissue is removed, or mastectomy, in which the entire breast tissue including the tumor is removed. Although there is a trend towards more breast conserving treatment, still around 25% - 40% of breast cancer patients undergo a mastectomy (3-6). In the Netherlands, around 40% of patients with invasive breast cancer and 30% of patients with DCIS undergo a mastectomy (7). In addition to surgery, (loco)regional radiotherapy, and/or systemic therapies such as chemotherapy, antihormonal therapy, and targeted therapy may be indicated. A patient's treatment plan largely depends on tumor and clinical characteristics, as well as patient preferences.

BREAST RECONSTRUCTION AFTER MASTECTOMY

Breast reconstruction (BR) after mastectomy is a surgical procedure to recreate a breast. Surgical treatment, and especially mastectomy, can negatively impact psychosocial outcomes such as body image and sexual functioning (8-11). To restore breast contour after mastectomy, and potentially improve psychosocial outcomes, women may opt for BR. Breast reconstruction is oncologically safe and does not increase the risk of recurrence, nor does it affect the ability to detect a recurrence (12-18). Breast reconstruction can be performed in different ways and on different timings (see 'Breast reconstruction choices and options').

Whether or not a patient is eligible for BR after mastectomy depends on multiple factors. There are only few absolute contraindications to BR after mastectomy. According to Dutch guidelines: *"Any request for breast reconstruction should be seriously considered; only metastatic disease with a short life expectancy should be considered a contraindication"* (19). However, contraindications may apply to specific types of reconstruction. Furthermore, certain factors increase the risk of complications or poor outcomes of reconstruction. These factors include smoking, high body mass index, larger cup size, comorbidities such as diabetes and high blood pressure, bilateral surgery, age > 55 years, prior radiotherapy on the breast and adjuvant radiotherapy (20-23).

BREAST RECONSTRUCTION CHOICES AND OPTIONS

Patients who will have mastectomy for invasive breast cancer or DCIS face a choice to have an immediate BR (in the same surgery as the mastectomy) or not. Patients who do not have immediate BR, can consider to have BR later in an extra surgical procedure (delayed BR) or remain without BR (no BR). Breast reconstruction can be performed in different methods. These methods can be divided into implant-based BR and autologous BR or a combination of both techniques. The technique of implant-based BR involves using silicone or saline breast implants, preceded or not by a temporary tissue expander, to restore the breast mound. The technique of autologous BR involves using patient's own fat and skin tissue from another part of the body, such as the abdomen, back, or buttock, to transplant to the thoracic wall and create a new breast. The BR options of an individual patient depend on multiple factors such as a patient's availability of donor tissue, health status, and her oncological treatment (19).

PROS AND CONS OF THE OPTIONS

All BR options after mastectomy have their own pros and cons. These pros and cons are numerous. In the following paragraph, some examples of pros and cons are provided to illustrate the decision. First, BR after mastectomy can benefit patients' quality of life and psychosocial functioning including women's sexual functioning, body image, and feeling of femininity (4, 24-29). However, BR increases the risk of surgical complications and generally leads to higher postoperative pain compared to mastectomy without BR (30-32). *Immediate BR* prevents women from being without a breast for a period of time and, if considered oncologically safe, offers the opportunity to save their own skin envelop and nipple. However, the decision for immediate BR needs to be made in a limited time period before mastectomy and recovery time from the surgery is longer compared to mastectomy alone (12). *Delayed BR* provides women more time to decide for reconstruction. However, it requires at least one extra surgery compared to immediate BR, and may require adding (skin) tissue from other body parts and consequently scarring. *Implant-based BR* is a relatively simple surgery and performable by all plastic surgeons, but looks and feels less natural compared to autologous BR (19). *Autologous BR* leads to a more natural-looking and feeling breast compared to implant-based BR, but requires longer and more complex surgery and entails additional scarring to the donor site (19, 33).

NUMBERS OF BREAST RECONSTRUCTION

Since the first attempt at BR in 1895, significant advancements have been made in breast reconstructive techniques (34). Over the past decades, the number of women choosing BR, particularly *immediate* BR, has been increasing (4, 35-40). In the Netherlands, in 2020, 29% of breast cancer patients and 46% of women with DCIS undergoing mastectomy had *immediate* BR (41). Around 10% of breast cancer patients undergoing mastectomy choose *delayed* BR (42-44). However, there is a substantial variation in immediate BR rates across hospitals and geographical locations, both nationally and internationally (40, 45-48). In Dutch hospitals, immediate BR rates range from 0-75% for invasive breast cancer and 0-86% for DCIS (41). Besides case-mix variation, hospital organizational factors and attitudes of clinicians towards immediate BR, information provision has been identified as possible causes of this hospital variation (45, 49-51). A study among Dutch women who had mastectomy found that being informed about immediate BR increased the odds of receiving immediate BR fourteen-fold (51).

DECISION MAKING ABOUT BREAST RECONSTRUCTION

Decision making about whether to have BR is a preference-sensitive decision that needs to be driven by patients' informed preferences (21). Dutch guidelines recommend discussing the possibility of immediate BR with every patient prior to mastectomy (52).

Decision making regarding BR can be complex and challenging for women. Women often have to consider multiple options, each with numerous advantages and disadvantages. The outcomes of the decision are uncertain and the decision will have a lasting impact on women's lives. Furthermore, women need to make the decision about immediate BR within a limited time period between diagnosis and surgery (47). During this period, it is common for patients to feel distressed and anxious (53-55), which may limit their cognitive functioning and decision-making skills (56, 57).

Women's motives to have BR include the expectation of increased sense of femininity, a strive for symmetry, and prevent limited clothing possibilities (58). Common reasons for women to omit BR are a strive for fast recovery and preventing potential complications (58).

There remains an unmet need for support in the context of decision making about BR, as both knowledge and decisional preparedness are suboptimal among patients deciding about BR after mastectomy (58-61). One study found that less than half (43%) of 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 (62). Women have reported not to be aware of the full range of BR options (58).

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 (63-70). A study investigating women's expectations regarding their wellbeing immediately after BR found that often expectations were unmet, and that women with unmet

expectations were more likely to experience decisional regret (71). Although most women are satisfied with their reconstructed breast, and decision regret is generally low (72), a minority of women experience mild to moderate levels of regret (63, 73).

SHARED DECISION MAKING

For preference-sensitive decisions such as the decision about immediate BR, shared decision making (SDM) is increasingly advocated as the preferred approach (74, 75). 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, values, and circumstances to reach a health decision (74, 76, 77). In this approach, physicians are considered experts about the medical evidence, and patients are considered experts about what matters most to them (78). By engaging patients in the decision-making process, healthcare professionals can help patients make informed decisions that align with their goals and preferences. Studies to objectify the levels of SDM during clinical encounters in oncology, including breast cancer care, suggest that there is room for improvement (79-82). Most patients prefer to be actively involved in decision making, and this has increased over time (83). In women with early-stage breast cancer, only 44-51% of patients achieve the degree of participation they desire (84-87). Practicing SDM is therefore much needed and even demanded by the government, policy makers, patient advocacy and healthcare organizations (78, 88).

PATIENT DECISION AIDS

Patient decision aids (pDAs) are tools developed to support the process of SDM between patients and physicians, as adjuncts to standard counselling (89). They explicitly describe the choice 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 (89). Over the last two decades, there has been an increase in the development and evaluation of pDAs across a range of medical and health contexts (90).

The efficacy of pDAs is most frequently evaluated with decisional conflict as the primary outcome (91). Decisional conflict is defined as a state of uncertainty about the course of action to take (92). Behavioral manifestations of decisional conflict include feeling unsure about what to choose, wanting to delay the decision, questioning what is important, feeling distressed, wavering between the options, and constantly thinking about the options (93).

Patient decision aids for a variety of treatment decisions have shown to reduce decisional conflict and increase knowledge and insight into personal values related to the decision (90, 94). Although there is growing evidence on their efficacy, the implementation of pDAs in clinical practice is only progressing slowly, and remains a challenge (95, 96). Frequently reported barriers include a lack of time perceived by clinicians (95, 97, 98), and a lack of ownership of the pDAs (95). Strategies suggested to support implementation include linking pDAs to hospitals' electronic medical records, reimbursing their use, and making the use of pDAs a

quality of care indicator (99). For more detailed information on the definition, efficacy and current issues regarding pDAs, we refer to our description in **Chapter 1b.**

SHARED DECISION MAKING IN BREAST RECONSTRUCTION

Worldwide, there are few interventions to support patient decision making about BR (100). Most interventions facilitate decision making about BR in general, and only a few specifically focus on the decision about immediate BR. 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 (100). In three out of five studies, the intervention reduced decisional conflict (101-103), in two out of three studies the intervention reduced regret (101, 104), and in one out of three studies the intervention improved knowledge (105). 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 (100, 106). More research is needed to develop and evaluate effective interventions to support patient decision making about BR (100).

AIM OF THIS THESIS

The aim of this thesis was to support breast cancer patients in making an informed decision about immediate BR after mastectomy, by developing and implementing an online pDA. Additionally, we aimed to evaluate the efficacy of the pDA in reducing decisional conflict, and in improving the decision-making process, decision quality, and patient-reported health outcomes. Furthermore, we aimed to get insights into process outcomes and important factors for sustainable implementation of the pDA by evaluating end-users' usage of and satisfaction with the tool.

The research questions addressed in this thesis are:

1. What are the information needs of patients and healthcare professionals regarding the decision about breast reconstruction?
2. Is the pDA acceptable and usable for patients and healthcare professionals?
3. What are the levels of decisional conflict in patients considering immediate breast reconstruction, and what factors are associated with clinically significant decisional conflict?
4. Is the pDA effective as compared to care-as-usual?
    a. What is the effect of the pDA in reducing decisional conflict?
    b. What is the effect of the pDA on the decision-making process, decision quality, and patient-reported health outcomes?
5. What are the experiences of patients and plastic surgeons with the pDA in terms of usage and satisfaction with the tool?

OUTLINE OF THIS THESIS

Chapter 1b provides general background information on pDAs, including a definition of a pDA and a short summary of evidence on their efficacy and status of implementation. **Chapter 2** describes the development of our pDA, including the information needs of patients and healthcare professionals regarding the decision about BR and the tool's acceptability and usability among its end-users. **Chapter 3** describes the protocol of our randomized controlled trial to study the efficacy of the pDA. **Chapter 4** provides the efficacy of the pDA in reducing decisional conflict and in improving the decision-making process, decision quality and patient-reported health outcomes. **Chapter 5** reports on the experiences of patients and healthcare professionals with the pDA in terms of use and satisfaction. **Chapter 6** describes the general discussion, including strengths and limitations, and future directions for research and practice.

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Chapter 1b

Decision aid

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SYNONYMS

Decision support tool, patient decision aid, patient decision support technology.

DEFINITION

A decision aid is a tool designed to facilitate the process of shared decision making between patients and physicians. Decision aids have typically been developed for preference sensitive health decisions where the patient's preferences and values are critical for identifying how best to proceed. A decision aid aims to clarify the choice that has to be made, and provide understandable information about treatment options, including the likely benefits and harms of each option. Also, it helps to clarify personal values of the patient, often through the use of value clarification exercises, and supports patients to make well-informed decisions, that align with their personal preferences and values. As an adjunct to clinical consultation, decision aids can be used prior to, during ("encounter tools") and/or after the physician consultation. The format of decision aids ranges from paper-based booklets, videos or DVDs, and web-based applications, to face-to-face/live interventions, such as an extra consultation with a social worker. The International Patient Decision Aids Standards (IPDAS) outlines a set of criteria that guide the development of decision aids, including their developmental process, content and function, and that provide a framework by which decision aids can be judged for quality (1, 2). IPDAS quality criteria include among others whether the decision aid provides realistic and accurate expectations of risk, and whether there is evidence that the decision aid improves patients' knowledge and leads to decisions that reflect the values held by the decision aid user (1, 2).

DESCRIPTION

Over the last two decades there has been an increase in the development and evaluation of decision aids across a range of medical and health contexts (3). Decision aids have been developed to assist patients with medical decisions about prevention (e.g. Hepatitis B vaccination), screening and diagnosis (e.g. prostate cancer screening), and treatment (e.g. medication for diabetes, cancer surgery). An overview of some publicly available decision aids can be found at https://decisionaid.ohri.nl.

In general, compared with standard counseling, decision aids have been found to be effective in reducing patient decisional conflict, improving patient knowledge about the treatment options, helping patients feel clearer about personal values, and improving risk perceptions of patients without increasing anxiety (3). Patients that have used a decision aid report feeling more involved in the medical decision-making process, and more able to participate in effective communications with clinicians (3).

Although studies on the effects of decision aids on the decision-making process from the clinicians' perspective are scarce, their results suggest that using decision aids can be mutually beneficial for patients as well as clinicians. Decision aids are likely to improve clinicians' satisfaction with the medical decision-making process and clinicians who used a decision

aid considered the tool to provide patients with more helpful information than usual care (4, 5). Clinicians report added value from the use of a decision aid, for example, by positively challenging patients' preconceived ideas and by facilitating more structured and coherent consultations (4).

The impact of the use of a decision aid on the actual chosen option differs among contexts (3). It has been suggested that the use of a decision aid might decrease the uptake of an option if there is over-use of that option, and might increase the uptake of an option if there is under-use of that option (6). Other studies found no impact of the use of a decision aid on the actual choice made (3).

Moreover, the impact of decision aids on consultation time is yet unknown. A Cochrane review identified ten studies investigating this topic and concluded that the median effect of decision aids on consultation length was 2.6 minutes longer (3). However, only two studies found a significant increase in consultation length in the decision aid group, while eight studies found no difference between the decision aid group and usual care (3).

As an intervention designed for public use in medical contexts it is surprising how little is known about the cost-effectiveness of decision aids (7), although evidence is emerging that decision aids can be beneficial and cost-effective (8, 9).

More research is required about what elements of a decision aid are particularly effective, in what format a decision aid is most effective, and on the optimal timing of provision of a decision aid (3). This could provide insight into unanswered questions like whether or not adding explicit value clarification exercises or patient narratives illustrating other people's experiences with their decision-making process increases a decision aid's effectiveness in improving informed decision making (10-12).

Albeit the evidence on their efficacy is growing, the implementation of decision aids in clinical practice is only progressing slowly (13). Multiple barriers and facilitators for their implementation have been identified, consisting of factors related to clinicians, patients, organizations and the healthcare system (13, 14). Lack of time is often considered as a barrier for using decision aids by clinicians, as is the concern about disruption to established workflows and a lack of training in using the decision aid (13-15). Furthermore, a lack of ownership of the decision aids and a lack of (financial) incentives have also been repeatedly stated as barriers for implementation (13). Strategies suggested to support the implementation include automating decision aid distribution, making decision aids easily available electronically and having them available on hospitals' electronic medical records, reimbursing their use, and making the use of decision aids a quality of care indicator (16).

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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

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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.

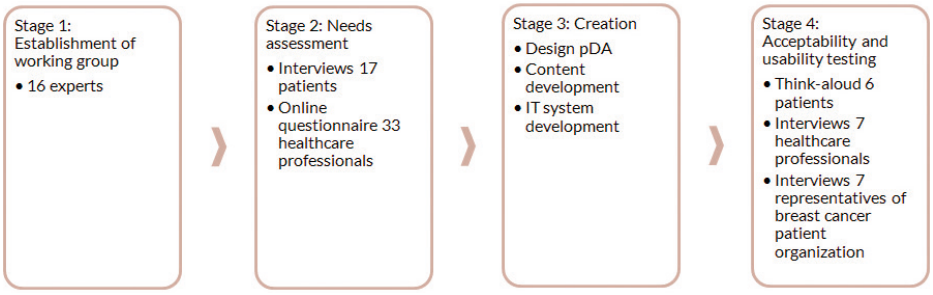

Figure 1. Overview of the four stages of pDA development and participants

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?
  - 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?
  - What information did you receive?
  - What questions did you have during and after this conversation?
  - What information did you miss in the conversations about breast reconstruction?
  - What did you worry about?
- Did you feel that you had a choice about breast reconstruction?
  - If not, could you elaborate on that?
  - 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?)
  - If so, how did your doctor involve you in this decision? How did you experience that? When?
  - 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?
  - What made you chose for breast reconstruction or not?
  - Immediate or delate breast reconstruction?
  - 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

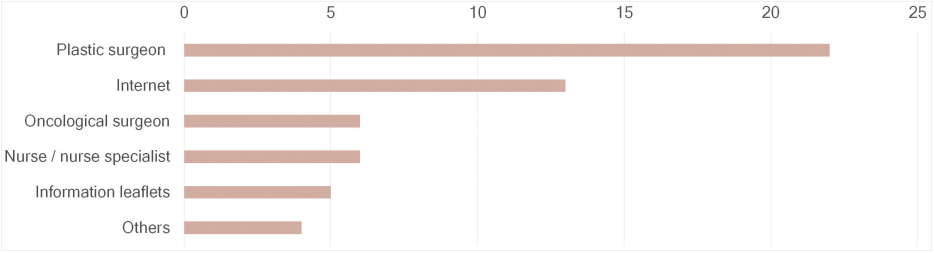


Figure 1. Main information resource about breast reconstruction for patients according to healthcare professionals (N=33)

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

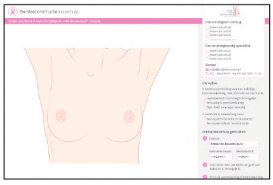
F) Continued

	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

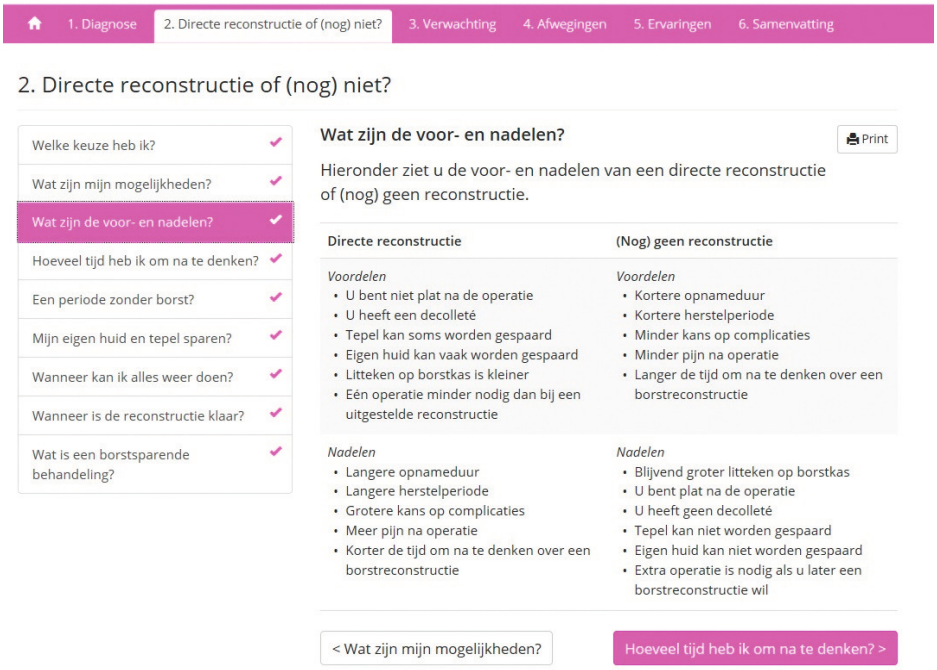


Figure 2. Module 2: Immediate reconstruction or not (yet)?, table with pros and cons of options (in Dutch)

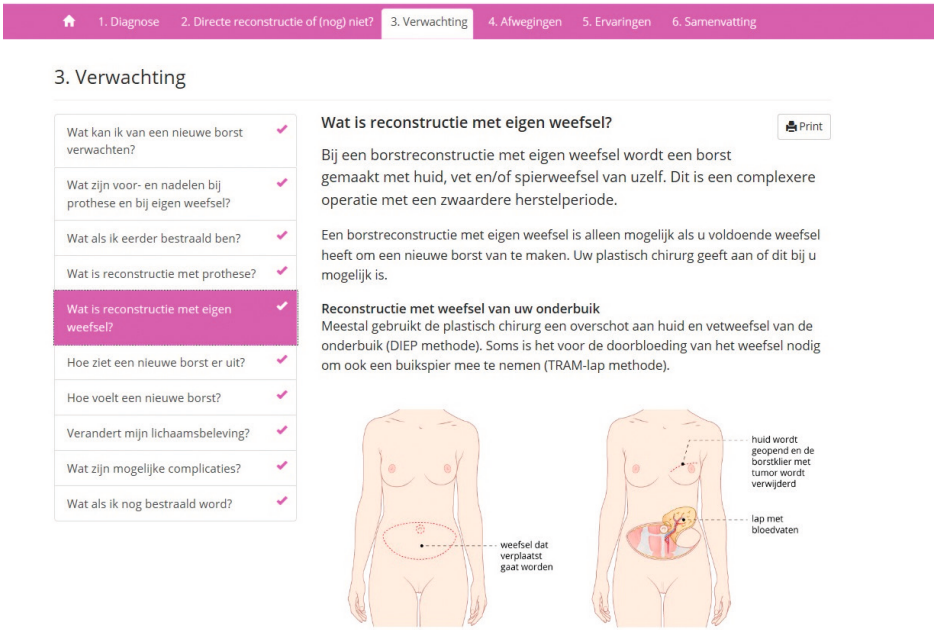


Figure 3. Module 3: Expectations, 'What is autologous breast reconstruction?' (in Dutch)

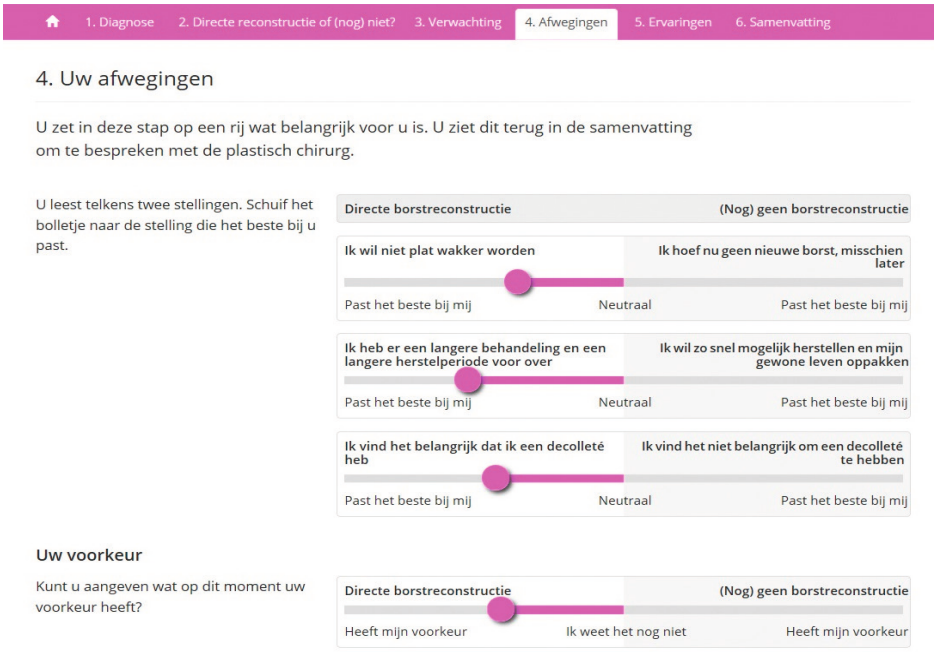


Figure 4. Module 4: Considerations, including value clarification exercises (in Dutch)

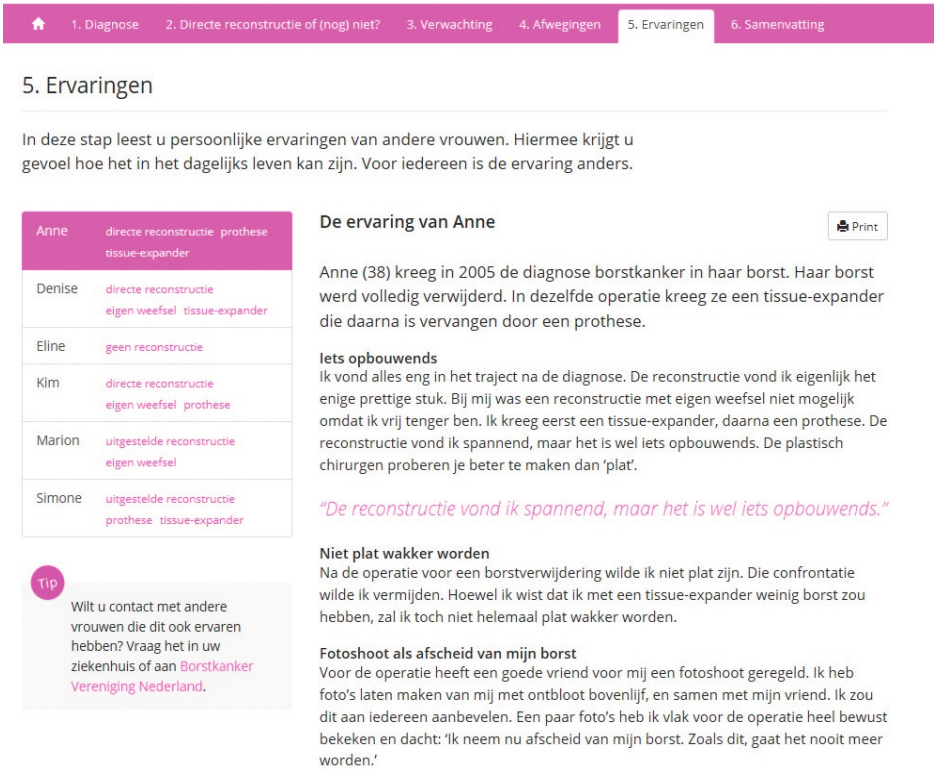


Figure 5. Module 5: Patient Stories (in Dutch)

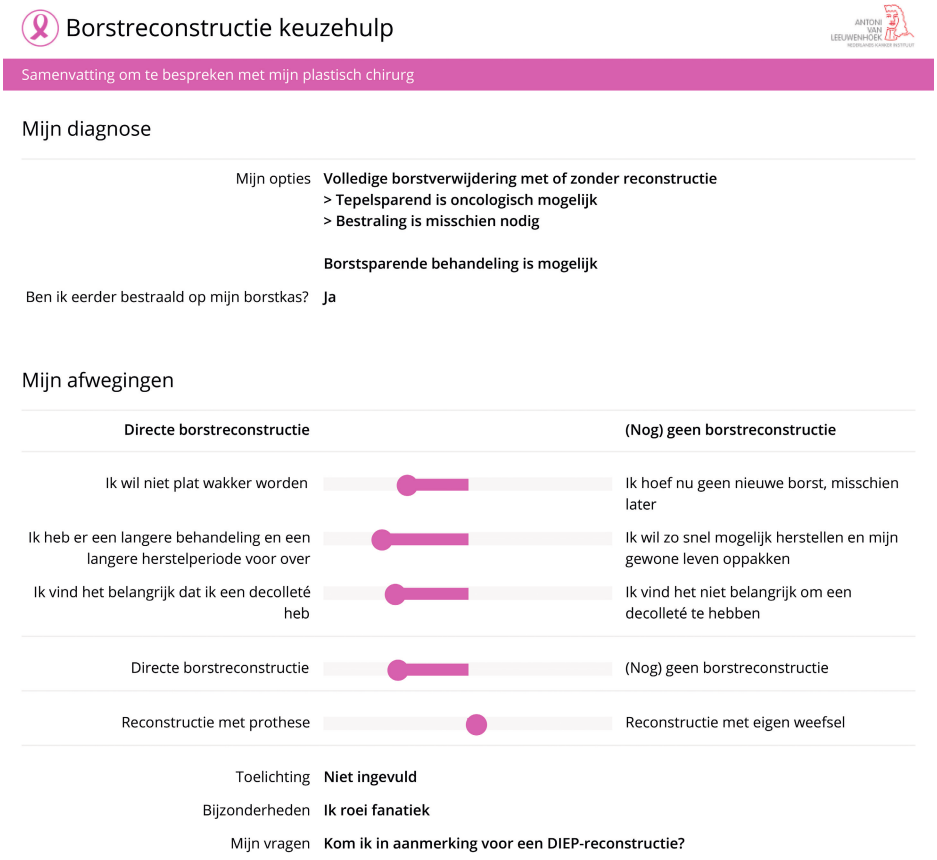


Figure 6. Summary sheet (generated in Module 6) including patient's personal considerations, preferences and questions

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.

Chapter 3

The impact of an online patient decision aid for women with breast cancer considering immediate breast reconstruction: study protocol of a multicenter randomized controlled trial

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ABSTRACT

BACKGROUND

Most breast cancer patients undergoing mastectomy are candidates for breast reconstruction. Deciding about breast reconstruction is complex and the preference-sensitive nature of this decision requires an approach of shared decision making between patient and doctor. Women considering breast reconstruction have expressed a need for decision support. We developed an online patient decision aid (pDA) to support decision- making in women considering immediate breast reconstruction. The primary aim of this study is to assess the impact of the pDA in reducing decisional conflict, and more generally, on the decision making process and the decision quality. Additionally, we will investigate the pDA's impact on health outcomes, explore predictors, and assess its cost-effectiveness.

METHODS

A multicenter, two-armed randomized controlled trial (1:1) will be conducted. Women with breast cancer or ductal carcinoma in situ who will undergo a mastectomy and are eligible for immediate breast reconstruction will be invited to participate. The intervention group will receive access to the online pDA, whereas the control group will receive a widely available free information leaflet on breast reconstruction. Participants will complete online questionnaires at: baseline (T0), one week after consultation with a plastic surgeon (T1), and three (T2) and twelve months (T3) after surgery. The primary outcome is decisional conflict. Secondary outcomes include other measures reflecting the decision-making process and decision quality (e.g., decision regret), patient-reported health outcomes (e.g., satisfaction with the breasts) and costs.

DISCUSSION

This study will provide evidence about the impact of an online pDA for women who will undergo mastectomy and are deciding about breast reconstruction. It will contribute to the knowledge on how to optimally support women in making this difficult decision.

TRIAL REGISTRATION

This study is retrospectively registered at ClinicalTrials.gov (NCT03791138).

BACKGROUND

Breast cancer is the most prevalent type of cancer amongst women (1, 2). In Western European countries, approximately one in eight women will develop breast cancer over the course of her lifetime (1, 3). In The Netherlands alone, more than 14000 women developed breast cancer in 2018 (1). Approximately 60-70% of all breast cancer patients undergo breast-conserving surgery (BCS) in which the tumor and a margin of surrounding breast tissue is removed, conserving breast shape as much as possible (4-6). However, another 30-40% of breast cancer patients undergo a mastectomy, in which all breast tissue is removed and breast contour therefore is lost (4-7). Breast cancer surgery, especially mastectomy, can negatively impact psychosocial outcomes such as body image, sexual functioning and health-related quality of life (8-11). To restore breast contour, and potentially reduce the negative psychosocial impact of mastectomy, women may opt for breast reconstructive surgery.

Breast reconstruction can be performed immediate at the time of mastectomy, or delayed, typically when treatment for breast cancer is completed. Furthermore, there are several types of breast reconstruction (implant-based, autologous, and a combination of both). All options have their pros and cons, and personal values and preferences of women play an important role in this decision (12, 13). In the last decades, the number of women choosing breast reconstruction, and especially immediate breast reconstruction, has increased substantially (14-16).

Decision making regarding breast reconstruction is complex and can be challenging for women. Women often have to consider multiple options within a short and stressful period following breast cancer diagnosis, and make a decision in this timeframe that will have a lasting impact on the rest of their lives. Previous studies have highlighted the importance of the provision of high-quality, realistic preoperative information and decisional support to enable women to make a long-term satisfying decision about breast reconstruction (17-24). Although most women are satisfied with their reconstructed breast, and decision regret is generally low (25), a minority of women experience mild to moderate levels of regret (17, 26). Both knowledge of breast reconstruction and decisional preparedness have been shown to be low among women deciding about breast reconstruction (27-29). A single-centre, cross-sectional study among 126 women undergoing mastectomy demonstrated that less than half of the participants made a high-quality decision regarding breast reconstruction, defined as having knowledge of important breast reconstruction facts and undergoing treatment in accordance with one's personal preferences (30).

Patient decision aids (pDAs) are tools developed to support shared decision making between patients and physicians (31). PDAs explicitly state the treatment decision that patients face, consist of evidence-based information about treatment options including their pros and cons, and clarify personal values relevant for the decision (31). Across a wide variety of treatment decisions, pDAs have been found to reduce decisional conflict, increase knowledge and increase insight into personal values related to the decision, without increasing anxiety (32, 33).

Worldwide, only a limited number of interventions to support patient decision making about breast reconstruction are available (34). In a recent review assessing the effectiveness of these interventions as compared to a control group, eight studies on seven distinct interventions were identified (34). While the intervention improved patient satisfaction and involvement in decision making in all studies that reported on that specific outcome, results on other important outcomes were mixed (34). In three out of five studies the intervention reduced decisional conflict (35-37), in two out of three studies the intervention reduced regret (35, 38) and in one out of three studies the intervention improved knowledge (39). Furthermore, most included studies were rated as of weak methodological quality and none were undertaken in a European country.

To support women in making an informed decision regarding immediate breast reconstruction following mastectomy, we developed an online pDA for the Dutch population. The aim of this study is threefold. First, we aim to investigate the impact of this pDA on the decision-making process (in terms of decisional conflict, satisfaction with information, satisfaction with plastic surgeon, preparedness for decision making, perceived shared decision making, and involvement in decision making), on decision quality (in terms of knowledge of breast reconstruction and decision regret), and on patient-reported health outcomes (in terms of actual choice, satisfaction with breast, body image, sexual functioning, anxiety, and breast symptoms). Second, we aim to explore factors that are predictive of the effectiveness of the pDA. And third, the cost-effectiveness will be investigated.

METHODS

DESIGN

We will conduct a multicenter, two-armed randomized (1:1) controlled trial. The trial protocol was retrospectively registered at 1st of January 2019 in ClinicalTrials.gov (NCT03791138).

STUDY SETTING

The study will be conducted in eight hospitals (two academic centres, five general hospitals and one cancer-specialized hospital) throughout the Netherlands.

ELIGIBILITY CRITERIA

The study sample will be composed of women (≥18 years of age or older) diagnosed with breast cancer or ductal carcinoma in situ, who will undergo mastectomy, are eligible for immediate breast reconstruction and have been referred to a plastic surgeon. The consultation with a plastic surgeon should be scheduled at least three working days after study invitation, to allow participants for sufficient time to complete informed consent (IC) and the baseline questionnaire and use the pDA or information leaflet prior to their consultation. Additionally, women must have internet access, basic computer skills and sufficient command of the Dutch language.

PROCEDURE

Prior to study commencement, all members of the surgical breast cancer team will receive access to the pDA and attend a meeting to familiarise with the pDA and study procedures. No further training on the delivery or use of the pDA is provided.

Women will be invited for study participation by their treating surgical oncologist, nurse specialist or breast cancer nurse during a regular pre-surgical treatment consultation in which the possibility of breast reconstruction is also discussed. The clinician will provide patients with a study information package consisting of a patient information letter and a sheet outlining patient's treatment options that allows women to tailor the pDA to their situation (see Intervention). Patients will give written approval for sharing their contact information with the research team. A member of the research team will then contact the patient by phone to give detailed study information and to check whether inclusion criteria are met. Eligible women who are interested in participating will receive two emails, one with a link to the online IC form and one with a link to the baseline questionnaire (T0). Following completion of both, participants will be randomly allocated to the intervention or control group. Women in the intervention group will receive access to the online pDA. They will receive an email with a link to the pDA and a personal login code. Women in the control group will receive an email with a digital version of a widely available free information leaflet on breast reconstruction. Two days prior to consultation with their plastic surgeon, participants in the intervention group and the control group will be reminded by email about the possibility of using the pDA or the information leaflet respectively. Study allocation will be noted in patients' medical records, allowing plastic surgeons to discuss the summary sheet of the pDA (see Intervention) with patients in the intervention group. Participants will complete questionnaires at T1 (one week after consultation with the plastic surgeon), T2 (three months after breast surgery) and T3 (twelve months after breast surgery). Questionnaires will be completed online and will be available in paper format upon patient request. To minimize missing data in online questionnaires, we will mark items as obligatory. Participants will receive reminders for completing questionnaires by email up to three times. Participants allocated to the intervention group have unlimited access to the pDA during the study. Participants will not be restrained from using other information sources.

INTERVENTION

The online interactive pDA (named in Dutch '*Borstreconstructie Keuzehulp*', translated in English as 'Breast Reconstruction Decision Aid') aims to support women in making a well-informed decision about breast reconstruction. It is developed to prepare women for consultation with a plastic surgeon. It contains evidence-based information about breast reconstructive options and their pros and cons. Furthermore, the pDA actively encourages women to weigh the options and discuss their preferences with their plastic surgeon during consultation.

The pDA consists of six modules: 1. Diagnosis, 2. Immediate breast reconstruction or not (yet)? 3. Expectations, 4. Considerations, 5. Patient stories, and 6. Summary (See Table 1 for a brief description of each module).

Table 1. Overview and brief summary of the pDA's modules

Module	Description of module
7. Diagnosis	Based on patient's treatment options as provided to them by their clinician 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).
8. Immediate reconstruction or not (yet)?	Breast reconstruction options and their pros and cons are described. Options include undergoing immediate breast reconstruction, undergoing delayed breast reconstruction, and undergoing 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 surgery?'[b]
9. Expectations	Information about what patients can expect from undergoing breast reconstruction is provided. 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 following surgery?'[c]
10. Considerations	With value clarification exercises, women are actively encouraged to weigh the options of undergoing immediate breast reconstruction or not undergoing breast reconstruction (and potentially undergoing delayed breast reconstruction). Furthermore, women are invited to indicate their breast reconstruction preference and note questions they have for their plastic surgeon.
11. Other women's experiences	Short stories of six women who underwent breast surgery with or without breast reconstruction. The stories illustrate the experiences of these women with decision making about breast reconstruction and the impact of their decision on their daily life.
12. 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.

[a]Text of this section is rephrased dependent on whether or not patient is eligible for nipple-sparing surgery. [b]Only shown if the patient is eligible for BCS. [c]Only shown if radiotherapy is or might be needed.

The information is tailored to patient's treatment options relevant for decision making about breast reconstruction (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 text is rephrased (See Table 1 for details). Patients can further tailor the information to their needs by selecting the information that they want to read, in their own preferred speed and order. Information is presented in a balanced way, not favouring any particular outcome. The pDA also includes illustrations of different types of breast reconstruction. It

takes approximately 60 min to complete the full programme. The website is secured (https) and protected by a personal login code.

Development of the intervention

The pDA has been developed by clinicians and researchers of the Netherlands Cancer Institute (NKI), in partnership with ZorgKeuzeLab, a company specialized in the development and implementation of decision aids. The pDA was developed in close collaboration with a multidisciplinary working group consisting of 16 professionals from seven Dutch hospitals. Furthermore, an Australian psycho-oncology researcher and health psychologist (KS), developer of the breast reconstruction decision aid ('BRECONDA') (36, 40, 41), contributed as a consultant.

The pDA development was guided by the criteria of the International Patient Decision Aid Standards (42), and is in line with the Dutch guideline for the development of decision aids (43). Furthermore, it was informed by a needs assessment among patients and healthcare professionals. Content was created by clinicians from the NKI based on most recent guidelines (13, 44), and was critically reviewed by members of the working group. The content was rewritten to B1 language level (45) (characterized by the use of common words and short, simple and active sentences) to be understandable for most people. The technical system was created based on the existing platform of ZorgKeuzeLab.

We tested the usability of the resulting pDA among women who considered breast reconstruction following mastectomy in the past. Furthermore, healthcare professionals and representatives of the Dutch Breast Cancer Patient Organisation, who were not involved in the development, independently reviewed the pDA. Based on received feedback, minor adaptions were made to optimize the pDA. Detailed results of the developmental process will be published.

CONTROL GROUP

Patients in the control group will receive a digital version of a widely available free information leaflet about breast reconstruction developed by the Dutch Cancer Society. This information leaflet is typically included in the standard breast reconstruction information materials in Dutch hospitals. The leaflet consists of 39 pages explaining all types of breast reconstruction including drawings and photos of results. In contrast to the pDA, the leaflet is not tailored to patient's treatment options, does not contain value clarification exercises, patient stories and a summary sheet to discuss with a plastic surgeon, and it is not structured to guide decision making.

STUDY MEASURES

SOCIODEMOGRAPHIC AND CLINICAL DATA

The patient's age, country of birth, primary language, marital status, parity, education level, work status, internet experience, hereditary breast cancer risk, history of malignancy, surgery and/or radiotherapy of the breast, neo-adjuvant treatment, surgical risk factors (i.e. weight and height, smoking status, comorbidities), eligibility for BCS and/or nipple-sparing surgery,

and indication for adjuvant radiotherapy will be obtained via the baseline questionnaire. Via postsurgical follow-up questionnaires (T2 and T3), we will obtain data on surgical treatment (including type and timing of breast reconstruction, if applicable), complications and adjuvant treatment. Surgical treatment and complications will be verified against data in the electronic medical record (EMR). Date of diagnosis, tumour characteristics, second malignancies and patient's cup size will be collected from the EMR.

OUTCOME MEASURES

An overview of outcome measures, corresponding questionnaires and measurement time points is provided in Table 2.

Table 2. Overview of outcome measures, corresponding instruments and measurement time points

Outcome measure	Instrument	Details	T0	T1	T2	T3
Decision-making process and decision quality						
Decisional conflict	Decisional Conflict Scale (DCS) (46, 47)	16 items, 5-point Likert-type scale, score range: 0 - 100, higher scores indicate more decisional conflict. Scores ≤ 25 are associated with follow-through decisions, and scores > 37.5 are associated with decision delay. Cronbach's alpha = >0.78 (47, 48)	x	x	x	x
Satisfaction with information	Three study-specific questions Subscale Satisfaction with Information of the BREAST-Q (49) (slightly adapted), for women with breast reconstruction only	How satisfied are you with the information about breast reconstruction? (5-point Likert-type scale: not at all – very satisfied), Did you miss information? (y/n), Would you have preferred less information? (y/n) Satisfaction with information (Reconstruction module): 15 items, 4-point Likert-type scale, 1=very unsatisfied – 4= very satisfied. Scores range: 0 – 100, with higher scores indicating higher satisfaction. Cronbach's alpha = 0.94 (49)			x	x
Satisfaction with plastic surgeon	Subscale Satisfaction with the Plastic Surgeon of the BREAST-Q (49)	Satisfaction with the Plastic Surgeon (Reconstruction module) (12 items, rated on a 4-point Likert-type scale). Scores range: 0 – 100, with higher scores indicating higher satisfaction. Cronbach's alpha = 0.97 (49)		x		
Preparedness for decision making	Preparation for Decision Making Scale (50, 51)	10 items, 5-point Likert-type scale, score range: 0 - 100, higher scores indicate higher perceived level of preparation for decision making. Cronbach's alpha = 0.92-0.96 (50)		x		
Shared decision making	Shared Decision Making Questionnaire (SDM-Q-9) (52, 53)	9 items, 6-point Likert-type scale, score range: 0 -100, higher scores indicate higher levels of perceived shared decision making. Cronbach's alpha = 0.88 (53)		x		

Table 2. Continued

Outcome measure	Instrument	Details	T0	T1	T2	T3
Patient involvement in decision making	Control Preferences Scale (54)	1 item, 5-point Likert-type scale		x	x	
Knowledge of breast reconstruction	Study-specific questionnaire, translated and adapted from a questionnaire used in prior research (55)	10 items that can be answered with true/false/I don't know. Items are about contraindications, risk factors, duration of the recovery period, impact of BR on sensation, number of surgical procedures, flap vs. implant, complications, impact of breast reconstruction on breast cancer treatment and survival rates and the opportunity to spare the nipple. Total score is the number of correctly answered items, ranging from 0 – 10.	x	x	x	x
Decision regret	Decision Regret Scale (DRS) (56, 57)	5 items, 5-point Likert-type scale. Score range: 0 - 100, with higher scores indicating greater regret. Cronbach's alpha = 0.81-0.92 (56)			x	x
Health outcomes						
Choice regarding breast reconstruction	Patient-reported questions and data from EMR				x	x
Satisfaction with breasts	Subscale Satisfaction with Breasts of the BREAST-Q Subscale Satisfaction with Breast Outcome of the BREAST-Q (women with breast reconstruction only)	Satisfaction with Breasts (Reconstruction or Mastectomy Module, as appropriate): 16 items (women with breast reconstruction)/4 items (women without breast reconstruction)). Cronbach's alpha = 0.96 (Reconstruction) (49). Satisfaction with Breast Outcome (Reconstruction Module): 7 items, recall period: past 2 weeks. Higher scores indicate higher satisfaction. Cronbach's alpha = 0.88 (49)			x	x
Body image	Subscale Body Image of the EORTC QLQ-BR23 (58)	4 items, 4 point Likert-type scale Cronbach's alpha = 0.69-0.91 (58)			x	x
Sexual functioning	Subscale Sexual Functioning of the EORTC QLQ-BR23 (58)	2 items + 1 items sexual enjoyment (if applicable), 4 point Likert-type scale Cronbach's alpha =0.87-0.94 (58)			x	x
Breast symptoms	Subscale Breast Symptoms of the EORTC QLQ-BR23 (58)	4 items, 4 point Likert-type scale Cronbach's alpha =0.46-0.85 (58)			x	x
Anxiety	STAI-6 (State scale of the State-Trait Anxiety Inventory) (59)	6 items, 4-point Likert-type scale. Score range: 20 - 80, higher scores indicate higher levels of anxiety. Cronbach's alpha = 0.82 (59)	x	x	x	x

Table 2. Continued

Outcome measure	Instrument	Details	T0	T1	T2	T3
Cost-effectiveness						
Use of health care services	A selection of questions of the Medical Consumption Questionnaire (see www.imta.nl), and data from EMR	Selection of questions on the number of consultations related to breast surgery with a (plastic) surgeon, nurse practitioner/ nurse specialist, social worker, psychologist, general practitioner and a physiotherapist, and the amount of received home care during the last three months.			x	x
Health-Related Quality of life	EuroQoL-5D-5L (60)	EuroQoL-5D-5L descriptive system: 5 items, 5-point Likert-type scale, and the EQ Visual Analogue Scale (EQ VAS): patients' self-rated health.	x		x	x

MAIN OUTCOME

The primary outcome is decisional conflict, measured by the Decisional Conflict Scale (DCS) (46). Decisional conflict is defined as a state of uncertainty about the course of action to take (61). The DCS measures how well-informed patients feel about their decision, the level of uncertainty about the best choice, and the perceived effectiveness of decision making. It has a total scale and five subscales (uncertainty, feeling informed, feeling clear about values, feeling supported and effective decision making). Items belonging to the subscale effective decision making will not be assessed at baseline, since these items were considered inappropriate to assess before patients had a consultation with a plastic surgeon. The DCS is reliable and valid (46-48), and is the most commonly used instrument to evaluate effectiveness of pDAs (62).

SECONDARY OUTCOMES

Decision-making process and decision quality

The *decision-making process* is further measured in terms of I) satisfaction with information (49), II) satisfaction with the plastic surgeon (49), III) preparedness for decision making (50, 51), IV) patients' perceived levels of shared decision making during consultation with their plastic surgeon (52, 53), and V) patients' perceived level of involvement in decision making (54). *Decision quality* is measured by I) knowledge of breast reconstruction (36, 55) and II) decision regret (56, 57).

Patient-reported health outcomes

Patients' actual choice regarding breast reconstruction will be measured by patient-report at postsurgical follow-up (T2, T3), and will be verified against patients' EMR. Patient satisfaction with the breast (49), body image (58), sexual functioning (58), and breast symptoms (58) will be obtained at postsurgical follow-up. Anxiety will be measured at all four time points (59).

MODERATING MEASURES

At baseline, we will measure patients' preferred level of involvement in decision making regarding breast reconstruction (Control Preferences Scale (54)), preference for breast reconstruction (1 item, 5 point Likert-type Scale, with 1 = "I have a strong preference for undergoing breast reconstruction", and 5 ="I have a strong preference for not undergoing breast reconstruction") and information coping style (Threatening Medical Situations Inventory (63)). At all assessments, patients will be asked to report on the information sources they used regarding breast reconstruction.

PROCESS MEASURES

Among women in the intervention group, the actual usage of the pDA (i.e. whether and when they logged in, whether the summary sheet was discussed with a plastic surgeon) will be obtained via self-report at T1. Usage data will be supplemented with log data collected in the pDA (e.g., number of logins, number of completed modules). Additionally, at T1, all participants will report on how satisfied they are with the received information (i.e., pDA or information leaflet) and how useful it was for them in making a decision about breast reconstruction.

COST-EFFECTIVENESS

For the cost-effectiveness analysis we will determine incremental costs, incremental effects (in terms of quality adjusted life years (QALYs), reduction in decisional conflict, reduction of regret), and the incremental cost-effectiveness ratio.

Utilities

QALYs are calculated by multiplying the life years with the utilities. An utility is a score that is derived from the generic five-level EuroQol five-dimensional questionnaire (EQ-5D-5L) (60). This preference based instrument consists of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (60, 64).

Costs

Unit costs will be estimated based on the trial data and published sources in the Netherlands (65). Fixed costs of the development of the pDA will be based on the R&D of the pDA, including expected maintenance costs. For the control group, costs of a leaflet will be taken into account. Direct medical costs will include (1) treatment costs: type and number of (reconstructive) breast surgeries during study participation (data collected from the EMR), number of nights hospitalized (EMR)/inpatient days in hospital (for any reason) (EMR), and (2) resource use: participants are asked for professional care resources they used related to their breast (reconstructive) surgery. This consists of the number of consultations (live or by phone) with plastic surgeons and other medical and paramedical professionals pre- and post-operatively. For medical consumption, patients are asked to report on the received amount of home care (selection of items of the iMTA Medical Consumption Questionnaire on T2 (3 months after surgery) and T3 (12 months after surgery); see www.imta.nl). Production losses are measured by means of work status at T2 and T3, controlled for work status at baseline, and the number of hours in sick leave.

RANDOMIZATION

Simple randomization stratified by site and patients' surgical treatment options (e.g., whether the patient is eligible for both mastectomy and BCS or for mastectomy only) will be used to assign participants to the intervention group or the control group. Randomization ratio is 1:1. Randomization will be performed with ALEA software. This study is non-blinded, since blinding was not considered feasible due to the nature of the trial.

STATISTICAL ANALYSES

Data will be pseudonymized prior to data analysis and will not be traceable to any individuals. Depending on the level of measurement, analysis of variance or appropriate non-parametric statistics will be used to evaluate the comparability of baseline sociodemographic and clinical characteristics between the intervention and the control group. If differences in background characteristics are found, these will be taken into account in the subsequent analyses. Scores on the questionnaires will be calculated according to published scoring algorithms.

We will look at group differences in decisional conflict for the entire study duration (T0 to T3) using a mixed effect growth model with random intercept and slope and site as a cluster variable. This approach takes into account the within and between person variability, and deals adequately with missing data (66). A comparable mixed effect model approach will also be used to determine the effects of the pDA on other patient reported outcomes. Differences in mean change scores over time between the intervention and control group will be accompanied by effect sizes (ES). An ES of 0.2 is considered small, 0.5 moderate and 0.8 large (67).

Analyses will be done on an intention-to-treat basis. As a secondary analysis, per-protocol analyses will be carried out on data from patients who meet the criteria for minimal compliance (to be determined). Appropriate statistical measures will be taken to adjust for multiple comparisons.

To evaluate between-group differences over time in categorical variables such as the actual choice in breast reconstruction, generalized estimating equations for longitudinal data will be used. This approach accounts for correlated within subject responses, allows for not normally distributed variables and deals adequately with missing data (68, 69).

We will explore which variables are predictive for the efficacy of the pDA on the primary outcome (decisional conflict) within the intervention group. A mixed effect model for longitudinal data will be used with decisional conflict as dependent variable and the following independent (baseline) variables: knowledge of breast reconstruction, patients' preferred level of involvement in decision making, information coping style, and sociodemographic variables. The *p*-values for each model will be adjusted for multiple comparisons.

COST-EFFECTIVENESS ANALYSIS

We will perform a cost-effectiveness analysis comparing the pDA with usual care expressed as: (1) cost per clinically relevant reduction in decision regret (as measured by the Decision

Regret Scale (DRS) (57)), (2) cost per clinically relevant reduction in decisional conflict (as measured by the DCS (47)), and (3) cost per QALY gained.

For decision regret, measured with the DRS, we will use a score of 30 out of 100 as a cut-off point (70). A score of 30 or higher 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 (70). For decisional conflict, measured with the DCS, we will use a score of 37.5 out of 100 as a cut-off point (47, 71-73). Scores exceeding 37.5 are associated with decision delay and feeling unsure about implementation (46, 47).

A Markov model will be constructed with four mutually exclusive health states: "no regret", "regret","recurrence" and "death" (or "no decisional conflict", "decisional conflict", "recurrence" and "death"). A healthcare and societal perspective from the Netherlands, plus a five year time horizon (25), and a cycle length of three months will be adopted. Production losses will be analysed by means of the Friction cost method (74). The friction cost method calculates the costs over the friction period; the period in which the patient has not yet been replaced at work by another employee. Future costs and effects will be discounted at 4 and 1.5%, respectively, in line with Dutch guidelines (65). The incremental costs-effectiveness ratio is calculated by dividing the difference in total costs of pDA and usual care by the difference in (1) reduction of regret/decisional conflict and (2) QALYs, which indicates the additional costs of pDA per QALY gained. The deterministic mean together with the degree of uncertainty, represented by the relevant distributions around the input parameters, will be estimated. Sensitivity analyses will be carried out to test the robustness of the model. Probabilistic sensitivity analyses will be performed to estimate the probability of cost-effectiveness. Visualization of data will be realized by means of a cost-effectiveness plane and cost-effectiveness acceptability curve (75, 76). A ceiling ratio of €20.000/QALY, corresponding with the Dutch threshold for willingness to pay, will be used in this analysis (77).

POWER CALCULATION

Power calculations for estimating sample size requirements were based on the following criteria: (1) power of 0.80, (2) alpha of 0.05, and (3) an ES d of 0.4. With these criteria a total sample size of 198 cases (99 per group) is needed. To allow for an anticipated attrition rate of approximately 20%, we will recruit 250 participants.

DISCUSSION

Decision making about breast reconstruction is challenging and the preference-sensitive nature of this decision requires an approach of shared decision making between patient and physician. To support women with breast cancer in making a well-informed decision about immediate breast reconstruction and optimize the decision-making process, we developed an online pDA. We hypothesize that the pDA will improve the decision-making process, the decision quality and health outcomes. This study will provide valuable insights into the impact

of an online decision support tool for an increasing group of women facing the choice for immediate breast reconstruction after mastectomy.

Our study has several strengths. First, in evidence-based research, randomized controlled trials are considered to produce the highest level of evidence when evaluating the effectiveness of interventions (78, 79) . Second, assessments are at clinical relevant time points and include longer follow-up than in previous studies (34, 37-39). Since the process of breast reconstruction can take up to one year or longer and outcomes only become evident after a while (25, 80), our study will give a more accurate account of this process and the different issues surrounding it. Finally, a cost-effectiveness analysis will provide new insights into the added value of the pDA in terms of cost-effectiveness (32, 81).

There are also some limitations to our current study. First, its design may lead to an underestimation of the pDA's impact. By providing the information leaflet to women in the control group, the control group can partially be considered as an active control group, and the effects of the pDA on outcomes such as knowledge might be reduced. However, we provided the information leaflet to the control group for ethical reasons and we expect that it will stimulate recruitment and decrease drop-out rates in the control group, as was suggested in a study in which 27% of enrolled participants dropped out because they refused to participate when they were randomized to the control group without any additional information (39). Secondly, there is a potential risk of contamination caused by the individual randomisation. Although there is little empirical evidence that contamination is a real problem for trials on educational interventions (82), it seems plausible that plastic surgeons adjust the style, structure and/or content of their consultations based on their experiences with women in the intervention group, after reviewing the pDA itself, or simply by participating in the trial. Cluster randomization to minimize contamination was however considered less favourable due to problems with selection bias and the need for larger samples (83).

Because of an increasing number of women who are offered immediate breast reconstruction and the clearly expressed need for decision support by women facing this complex decision, our pDA is expected to fill a gap in current clinical practice. This study contributes to the knowledge of the impact of a pDA on the decision-making process and decision quality. If the pDA positively contributes to the decision-making process and the decision quality, the pDA can be implemented nationwide.

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Chapter 4

Decisional conflict in breast cancer patients considering immediate breast reconstruction

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ABSTRACT

BACKGROUND

Breast cancer (BC) patients who are treated with mastectomy are frequently offered immediate breast reconstruction. This study aimed to assess decisional conflict in patients considering immediate breast reconstruction, and to identify factors associated with clinically significant decisional conflict (CSDC).

METHODS

Baseline data of a multicenter randomized controlled trial evaluating the impact of an online decision aid for BC patients considering immediate breast reconstruction after mastectomy were analyzed. Participants completed questionnaires assessing sociodemographic and clinical characteristics, decisional conflict and other patient-reported outcomes related to decision making such as breast reconstruction preference, knowledge, information resources used, preferred involvement in decision making, information coping style, and anxiety. Multivariable logistic regression analysis was performed to identify factors associated with CSDC (score > 37.5 on decisional conflict).

RESULTS

Of the 250 participants, 68% experienced CSDC. Patients with a *slight* preference *for* breast reconstruction (odds ratio (OR) = 6.19, $p < .01$), *no* preference for or against breast reconstruction (OR = 11.84, $p < .01$), and a *strong* preference for *no* breast reconstruction (OR = 5.20, $p < .05$) were more likely to experience CSDC than patients with a *strong* preference *for* breast reconstruction. Furthermore, patients with more anxiety were more likely to experience CSDC (OR = 1.03, $p = .01$).

CONCLUSION

A majority of BC patients who consider immediate breast reconstruction after mastectomy experience clinically significant decisional conflict. The findings emphasize the need for decision support, especially for patients who do not have a strong preference for breast reconstruction.

HIGHLIGHTS

- A majority of patients considering immediate breast reconstruction experience decisional conflict
- Patients without a strong preference for breast reconstruction are more likely to experience decisional conflict
- Patients with more anxiety are more likely to experience decisional conflict

INTRODUCTION

Immediate breast reconstruction (BR) after mastectomy is increasingly performed (1-3). The choice for immediate BR after mastectomy largely depends on the values and preferences of the patient (4). A breast cancer (BC) patient treated with mastectomy has to decide whether or not to have immediate BR, and, if immediate BR is chosen, make a decision among the types of BR (i.e. with an implant, autologous tissue or a combination) that are available to her.

Decision making on immediate BR is complex as outcomes are uncertain and there are multiple reconstructive options with numerous advantages and disadvantages associated with each option (5). For example, BR may have a positive impact on patients' body image, self-esteem and quality of life after mastectomy, but it also increases the risk of surgical complications compared to mastectomy without BR (6-15). BR with autologous tissue often leads to a more natural looking and feeling breast, but it also entails additional scarring to the donor site (5). Patients undergoing mastectomy have to weigh these pros and cons to make a personal choice about which option is best for them (4, 16). Decision making is further complicated by the fact that patients often need to make this decision in a short period of time, between diagnosis and mastectomy. During this period it is common for patients to feel distressed and anxious (17-19), which may limit their cognitive functioning and decision making skills (20, 21).

The complexity of this decision might increase feelings of decisional conflict in patients considering immediate BR. Decisional conflict is defined as a state of uncertainty about the course of action to take (22). Behavioral manifestations of decisional conflict include feeling unsure about what to choose, wanting to delay the decision, questioning what is important, feeling distressed, wavering between the options, and constantly thinking about the options (23). Although a certain level of decisional conflict might be inherent when deliberately making a complex decision, high levels of decisional conflict are associated with delayed decision making, indecisiveness, and feelings of depression and regret (24-26). These outcomes should be prevented, especially in the context of BR, as the primary goal of BR is to improve psychosocial outcomes and patient satisfaction.

Literature is sparse on decisional conflict about immediate BR, and the factors associated with it. Therefore, in this study we aimed to assess the levels of decisional conflict in BC patients who consider immediate BR after mastectomy, and to identify factors associated with clinically significant decisional conflict (CSDC).

METHODS

STUDY SAMPLE & PROCEDURE

For this study we used baseline data from a multicenter randomized controlled trial evaluating the impact of an online patient decision aid (pDA) for BC patients who are considering immediate BR after mastectomy. For a detailed description of the trial see ter Stege et al. (27, 28). In short, patients were invited for trial participation by their surgical oncologist, nurse specialist or BC nurse during a routine treatment consultation in which the possibility of immediate BR was discussed. After written approval to share contact information with the researchers, patients were provided more study details and screened for eligibility via a telephone call by a member of the research team. Patients were eligible for participation if they were ≥18 years of age, diagnosed with BC or ductal carcinoma in situ, undergoing mastectomy, eligible for immediate BR and referred to a plastic surgeon. The consultation with a plastic surgeon had to be scheduled at least three working days after the study invitation to allow patients to have sufficient time to complete the informed consent form and baseline questionnaire, and to use the pDA before consultation. Participants were required to have internet access, basic computer skills and sufficient command of the Dutch language. Eligible patients who were interested in participating completed the informed consent form and baseline questionnaire via an online platform (29). They were subsequently randomized to either the intervention group, in which they received access to the pDA, or to the usual care group, in which they received a standard BR information leaflet from the Dutch Cancer Society. Participants were invited to complete follow-up questionnaires one week after consultation with their plastic surgeon, and three and 12 months after mastectomy.

MEASURES

Sociodemographic and clinical characteristics

We collected data on patient's age, country of birth, educational level, marital status, parity, body mass index (BMI), current smoking status, comorbidities, diagnosis, date of diagnosis, laterality, history of BC, prior BC treatment, hereditary or familial increased risk for BC, neoadjuvant therapy, and indication for adjuvant radiotherapy.

Decisional conflict

Decisional conflict was measured by the 16 item Decisional Conflict Scale (DCS) for which there is demonstrated reliability and validity (24, 25, 30, 31). Items are rated on a 5-point response scale (0=strongly disagree, 4=strongly agree), with positive statements having reversed scoring such that a higher score indicates higher decisional conflict. A total score is calculated, as well as five subscale scores (uncertainty (3 items), feeling informed (3 items), feeling clear about values (3 items), feeling supported (3 items) and effective decision making (4 items). Since consultation with a plastic surgeon had not yet taken place at the time of administration, the effective decision making subscale was omitted from baseline assessment. The total score was based on 12 items (DCS Total–12). According to the published scoring

algorithm, total and subscale scores were calculated by averaging the sum of the individual item scores, multiplied by 25 (25). Scores ranged from 0 (no decisional conflict) to 100 (extremely high decisional conflict). According to the published manual (25), scores of 25 or below are associated with implementing decisions, and scores exceeding 37.5 are associated with delaying decision making and feeling unsure about implementation. These cut-offs are derived from data in women considering preventive hormone therapy, whereby those who delayed their decision had average scores above 37.5 (unpublished data referred to in O'Connor et al. (1998) (32)). The cut-off (>37.5) served as a gold standard by which a checklist to screen on CSDC in clinical practice was validated (33).

Patient-reported outcomes related to decision making

Breast reconstruction preference (BR preference) was assessed by a study-specific item asking patients to indicate which of the following five statements suits them best: (a) 'I have a strong preference for BR', (b) 'I have a slight preference for BR', (c) 'I do not (yet) have a preference for or against BR', (d) 'I have a slight preference for no BR', or (e) 'I have a strong preference for no BR'.

Knowledge was measured with ten statements about BR that participants indicated as being "true/false/I don't know". These statements were translated and adapted from statements used in prior research evaluating knowledge in women with increased risk for BC deciding about risk-reducing mastectomy and BR (34). Statements concerned topics such as risk factors, recovery time, and the impact of BR on sensation in the breast (See Appendix A for full instrument). The total score is the number of correctly answered items, ranging from 0 to 10.

Information resources used were assessed with an item, asking participants to select all types of BR information resources they used from a set of predefined answers (i.e. surgical oncologist, plastic surgeon, nurse/nurse specialist, information leaflet(s), book(s), website(s), relative(s), scientific article(s), article(s) from magazines or newspapers, other).

Preferred involvement in decision making was measured by the Control Preferences Scale (CPS) (35). Patients were asked to select one of five statements that best reflected their preferred role in BR decision making: I prefer (a) to make the decision alone, (b) to make the decision alone, after considering the clinician's opinion, (c) to make the decision together with the clinician, (d) the clinician to make the decision after considering my opinion, (e) the clinician to make the decision alone.

Information coping style was assessed with the Threatening Medical Situations Inventory (TMSI) (36). This 24-item questionnaire measures cognitive confrontation [i.e., the tendency to actively search for information in case of a medical threat ('monitoring')], and cognitive avoidance [i.e., the tendency to avoid information/look for distraction in case of a medical threat ('blunting')] within the domain of a medical threat. It consists of four scenarios of threatening medical situations followed by three monitoring and three blunting alternatives [e.g., 'I plan to ask the specialist as many questions as possible' (monitoring) and 'I think things will turn out to

be alright' (blunting)]. Participants were asked to rate the extent to which the alternative is applicable to them on a 5-point scale (1 = not at all applicable to me, to 5 = strongly applicable to me). Total monitoring and blunting scores are obtained by summing the relevant items. Scores on both scales range between 12 and 60 (36).

Anxiety was measured by the 6-item state scale of the Spielberger State-Trait Anxiety Inventory (STAI-6) (37, 38). Participants were asked to indicate on a 4-point scale to what extent a state applies to them at that moment (1 = not at all, 4 = very much). A total score is calculated by taking the mean of the items multiplied by 20 and ranges from 20 to 80, with higher scores indicating more anxiety.

STATISTICAL ANALYSES

Descriptive statistics were used to characterize the sample and to evaluate the levels of decisional conflict. Decisional conflict was dichotomized into CSDC (score >37.5 on DCS) and no CSDC (score ≤ 37.5 on DCS) (25, 32). Based on literature (32, 39-42), and expert opinions, we evaluated possible explanatory variables for CSDC using logistic regression analysis. The following variables were considered for selection in the regression model: (1) Sociodemographic characteristics (age, country of birth, educational level [low (primary school, lower vocational education), intermediate (secondary school, intermediate vocational education), or high (higher vocational education, university)], marital status, BMI [underweight (BMI <18.5), normal (BMI 18.5-<25), overweight (BMI 25-<30), obese (BMI 30+)], current smoking status, number of comorbidities, type of hospital); (2) Clinical characteristics (time since diagnosis, laterality, prior BC diagnosis, diagnosis in irradiated breast(s), hereditary or familial increased risk for BC, indication for adjuvant radiotherapy); and, (3) Patient-reported outcomes (BR preference, knowledge, information resources used, preferred involvement in decision making, information coping style, anxiety). Explanatory variables were included in the multivariable model if the association with the outcome was significant at $p < .10$. Furthermore, if potential explanatory variables were strongly correlated with each other ($r > .80$), we selected one of the predictors to represent the whole set. Results of the multivariable model were considered statistically significant at a P value < .05. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 25 (IBM corp.).

RESULTS

PARTICIPANTS

Figure 1 shows the flowchart of the study. In total, 333 patients agreed to be informed about the study. Of these patients, 323 were reached by the research staff. Twenty-eight patients were ineligible. Of the remaining 295 patients, 37 were not interested in participating. The informed consent form and baseline questionnaire were sent to 258 patients. In total, 250 patients returned both and were included for analyses. This resulted in a participation rate of 85% (250/295).

BACKGROUND CHARACTERISTICS

Sociodemographic and clinical background characteristics are provided in Table 1. Patients had an average age of 50.12 years (SD = 11.03), and more than half (52%) were highly educated. The median time since diagnosis was three weeks (interquartile range (ICR) = 18), and 60% of the patients were recruited in a cancer-specific hospital.

DECISIONAL CONFLICT

The mean total and subscale scores are summarized in Table 2. Sixty-eight percent of the patients experienced CSDC. Statements with which most patients agreed, reflecting more conflict, were: 'I want more advice and information about the options', 'I am not sure what to decide', and 'this decision is difficult for me to make' (82%, 40%, and 39% (strongly) agreed, respectively). Statements with which the least patients agreed (or if appropriate disagreed), reflecting less conflict, were: 'I feel pressured by others in making this decision', and, 'I have enough support from others to make a choice' (4% (strongly) agreed and 7% (strongly) disagreed, respectively) (See Appendix B for results on all items).

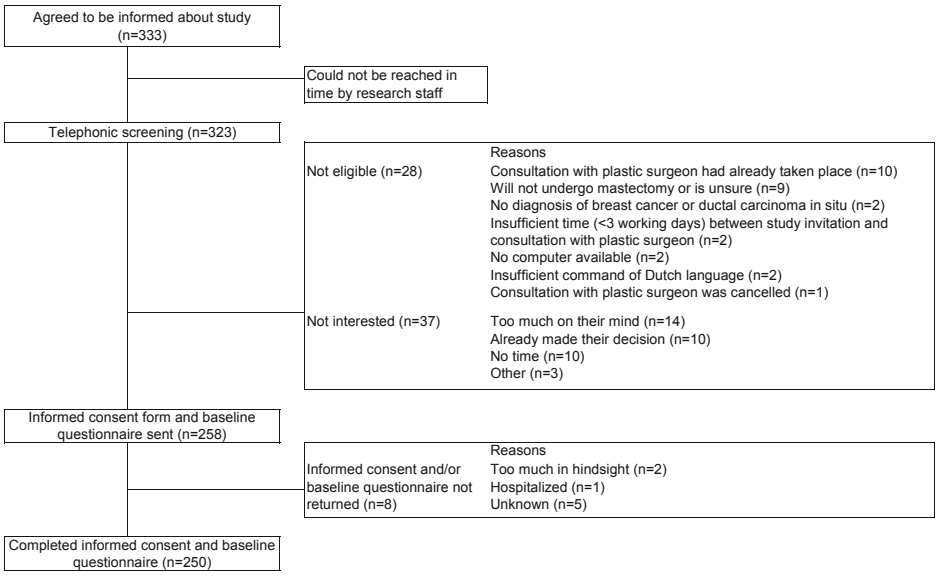

Figure 1. Flowchart of study participants

Table 1. Background characteristics (N=250)

	N	%
Age (years), M (SD)	50.12 (11.03)	
Born in NL	233	93
Highest level of education		
high	129	52
intermediate	109	44
low	10	4
missing	2	1
Married or in a relationship	214	86
Having children	199	80
BMI		
underweight (<18.5)	5	2
normal (18.5 - <25)	139	56
overweight (25 - <30)	75	30
obese (30+)	31	12
Current smoking status (yes)	14	6
Comorbidities		
none	128	51
1	79	32
2 or more	42	17
missing	1	0
Diagnosis		
invasive BC	151	60
invasive BC and DCIS	37	15
DCIS	61	24
other	1	0
Time since diagnosis (weeks), median (ICR)		3 (18)
Bilateral diagnosis	12	5
Diagnosis in irradiated breast(s)	27	11
Prior diagnosis of BC and/or DCIS	40	16
Surgical treatment for BC and/or DCIS in the past		
breast conserving surgery	32	13
mastectomy	4	2
mastectomy with BR	5	2
Genetic predisposition or familial increased risk of BC	40	16
Neoadjuvant therapy	91	36

chemotherapy	86	34
hormone therapy	9	4
immunotherapy	23	9
Indication for adjuvant radiotherapy		
no	71	28
yes	61	24
maybe	75	30
I don't know	43	17
Type of hospital		
cancer-specific center	150	60
academic center	27	11
general hospital	73	29

Abbreviations. **M** mean; **SD** standard deviation; **NL** Netherlands; **BMI** body mass index; **BC** breast cancer; **DCIS** ductal carcinoma in situ; **ICR** interquartile range; **BR** breast reconstruction.

Table 2. Decisional conflict in breast cancer patients considering immediate breast reconstruction (N=250)

	M (SD)
DCS Total-12	46.18 (15.22)
CSDC, n (%)	169 (68%)
DCS subscales	
Uncertainty	48.40 (27.60)
Feeling informed	49.30 (22.26)
Feeling clear about values	45.43 (19.37)
Feeling supported	41.60 (14.46)

Abbreviations. **DCS** Decisional Conflict Scale; **CSDC** clinically significant decisional conflict; **M** mean; **SD** standard deviation.

FACTORS ASSOCIATED WITH CLINICALLY SIGNIFICANT DECISIONAL CONFLICT

Based on the univariable analyses ($p < .10$) and correlations among the potential explanatory variables ($r > .80$), the following variables were included in the multivariable logistic regression analysis: educational level, BR preference, being informed by scientific article(s), blunting coping style, and anxiety (see Appendix C for results of the univariable analyses).

The results of multivariable analyses are shown in Table 3. We found a significant effect for BR preference and anxiety. Specifically, patients with a *slight* preference *for* BR were 6.19 times more likely (95% Confidence Interval (CI) = 2.47-15.54), and patients with *no preference* for or against BR were 11.84 times more likely to experience CSDC (95% CI = 2.68 – 52.28) than patients with a *strong* preference *for* BR. Additionally, patients with a *strong* preference for *no* BR were 5.20 times more likely to experience CSDC (95% CI = 1.04-25.86) than patients

with a *strong* preference *for* BR. Patients with more anxiety were 1.03 times more likely to experience CSDC (95% CI = 1.01-1.06). No significant effects were found for educational level, blunting information coping style, and being informed by scientific article(s).

Based on the above results, we performed an explorative analysis into the association between anxiety and BR preference using Analysis of Variance. Group differences were accompanied by effect sizes (ES) (ES of 0.2 = small, 0.5 = moderate and clinically relevant, 0.8 = large) (43). Patients with a *strong* preference *for* BR were significantly less anxious (M (SD) = 44.15 (12.65)) than patients with a *slight* preference *for* BR (M (SD) = 48.30 (12.53), $p < .05$, ES = 0.33), and patients with *no preference* for or against BR (M (SD) = 50.20 (12.36), $p = .01$, ES = 0.48). And, although not significant, effect sizes show (almost) clinically relevant differences in anxiety between patients with a *strong* preference *for* BR and patients with a *slight* preference or a *strong* preference for *no* BR (M (SD) = 51.85 (11.32), $p = .08$, ES= 0.61, and M (SD) = 49.76 (15.66), $p = .12$, ES = 0.43, respectively).

Table 3. Multivariable logistic regression predicting clinically significant decisional conflict (N=248*)

	n	CSDC	B (SE)	*p*	OR	95% CI for OR
constant			-0.85 (1.24)	0.49	0.43	
Educational level						
low	10	40%	-1.37 (0.77)	0.08	0.26	0.06 - 1.16
intermediate	109	68%	-0.23 (0.32)	0.48	0.80	0.42 - 1.50
high	129	69%	ref			
BR preference						
strong preference for BR	142	52%	ref			
slight preference for BR	51	86%	1.82 (0.47)	**0.00**	6.19	2.47 - 15.54
no preference for or against BR	32	94%	2.47 (0.76)	**0.00**	11.84	2.68 - 52.28
slight preference for no BR	9	89%	1.63 (1.09)	0.13	5.10	0.60 - 43.21
strong preference for no BR	14	86%	1.65 (0.82)	**0.04**	5.20	1.04 - 25.86
Informed by scientific article(s)	21	48%	-1.08 (0.55)	0.05	0.34	0.12 - 1.01
Blunting coping style (TMSI)[A]			-0.01 (0.03)	0.70	0.99	0.94 - 1.04
Anxiety (STAI-6)[B]			0.03 (0.01)	**0.01**	1.03	1.01 - 1.06

Abbreviations. **CSDC** clinically significant decisional conflict; **B** beta; **SE** standard error; **OR** odds ratio; **CI** confidence interval; **BR** breast reconstruction; **TMSI** Threatening Medical Situations Inventory; **STAI-6** State scale of the State-Trait Anxiety Inventory.
Note. $R^2 = .30$ (Nagelkerke). Model $\chi^2(9) = 59.10$, $p<.001$. Significant values (at $p < .05$) are shown in bold.
*N=248 due to 2 missings on variable educational level.
[A]Mean = 34.02, Standard Deviation = 6.33
[B]Mean = 46.39, Standard Deviation = 12.91

DISCUSSION

Our results show that more than two thirds of BC patients considering immediate BR after mastectomy experienced clinically significant decisional conflict, and that this was associated with BR preference and anxiety. Patients with a *slight* preference for BR, patients with *no preference* for or against BR and patients with a *strong* preference for *no* BR were more likely to experience CSDC than patients with a *strong* preference *for* BR. In addition, patients with higher levels of anxiety were more likely to experience CSDC than patients with lower levels of anxiety.

To our knowledge, this is the first study in which decisional conflict regarding immediate BR was assessed in a large sample of BC patients. The levels of decisional conflict in our sample are comparable to the levels of decisional conflict in two prior studies in BC patients who considered delayed BR (44, 45), and relatively high compared to levels in a sample of BC patients who considered immediate BR (M = 33, SD = 24) (39), and to average decisional conflict regarding a variety of health-related decisions (31). The specific population, complexity of the decision, and the timing of our assessment might all have contributed in evoking higher decisional conflict (31). Highest baseline (before decision making) decisional conflict has been found among individuals who were ill and were making decisions for themselves (31), which is the case for our population. Furthermore, as the majority of participants in our study had only recently been diagnosed with BC and introduced to the possibility of BR, and all were waiting to be informed by a plastic surgeon, this will likely have contributed to the high levels in our sample.

Although we found a significant positive association between anxiety and CSDC, the association was weak. This is in line with the study of Manne et al. (2016) (39), in which they did not find any association between anxiety and decisional conflict regarding immediate BR. However, we do think it is a factor worth considering in future research, as we did find anxiety levels to differ between BR preference groups. Thus, the weak association could be attributed to effect modification in which the degree of association between anxiety and CSDC differs among different BR preference groups. Additionally, the association between anxiety and decisional conflict has been reported in other populations (46-48), and is in line with the conceptual framework of decisional conflict (22,24).

Intuitively, one would expect that patients with a *strong* preference for a certain option would experience less decisional conflict than patients with either a *slight* preference for - or with *no* preference for a certain option. However, this was only partially true in our results. Surprisingly, patients with a *strong* preference for *no* BR more frequently experienced CSDC than patients with a strong preference *for* BR. Although additional exploratory analyses comparing both groups demonstrated that patients with a *strong* preference for *no* BR were older (M (SD)= 56.9 (11.9), M (SD) = 48.1 (11.0), p = .005, data not shown), we did not find any between group differences that could explain these findings. However, consistent with our finding, Manne et al. (2016) found that BC patients who reported a greater number of reasons *not* to choose BR had higher decisional conflict (39), suggesting that patients who may tend to decline BR feel

more conflicted about their decision. Although speculative, based on clinical experience and interviews with patients about their experiences with decision making about BR (manuscript submitted), the possibility of BR is often communicated as something positive. Thus, patients who prefer not to have BR might perceive information provision as 'favoring BR over *no* BR', which may have contributed to increased decisional conflict.

Besides anxiety and BR preference, no factors were associated with CSDC. It is difficult to compare our results with prior findings, as literature on predictors of decisional conflict is scarce and heterogeneous in studied predictors and populations (e.g. individuals with diabetes (40), prostate cancer (41, 46), or tested for hereditary cancer (47)). However, the absence of associations with sociodemographic and clinical characteristics is largely consistent with a prior study in a comparable population (39), with the exception that we did not find an association with time since diagnosis. Furthermore, the absence of any association of decisional conflict with knowledge is in contrast to the conceptual model of decisional conflict (22,24). Possibly, decisional conflict might be more strongly related to a patients' perceived knowledge than their actual knowledge (24).

This study has several limitations. Our sample consisted of highly educated patients limiting the generalizability of our findings. Furthermore, since data were collected as part of a trial evaluating the impact of a patient decision aid, we might have included patients with relatively higher decision support needs, potentially leading to an overestimation of the levels of decisional conflict. Another limitation is that data on the psychometric properties of the total score of the Decisional Conflict Scale without the assessment of the Effective Decision Making subscale is lacking. Although the developers of the instrument indicated that this subscale should only be assessed in circumstances where a decision has already been made (24), and other studies also omitted it (48, 49), the reliability and validity of the instrument without the Effective Decision Making subscale needs to be confirmed. Finally, although the cutoff (>37.5) for CSDC has been used in prior research (24, 31, 50, 51), and a review that examined decisional conflict over time including 253 studies found support for it (31), more evidence on its validity in the context of BR decision making seems warranted.

The large sample size is considered a major strength of this study. Additionally, the timing of our assessment, namely during the short period between diagnosis and mastectomy, is highly relevant and rarely studied. While immediate BR after mastectomy is increasingly performed (1-3), previous studies have mainly focused on decisional conflict in patients who had already undergone mastectomy and were considering BR after completion of their oncological treatment (44, 45, 52).

Our results emphasize the need for support for BC patients in making this complex decision, especially for those patients without a strong preference for BR. Decisional conflict may be reduced by addressing contributors to uncertainty, such as providing information about benefits and risks for each option and helping patients understand their own values (32). The

use of decision aids as an addition to standard clinical counseling has been found to reduce decisional conflict, also in patients deciding about BR (52-55).

We conclude that the majority of BC patients who consider immediate BR after mastectomy experienced CSDC. Our results emphasize the need for support for BC patients in making this complex decision, especially in patients without a strong preference for BR.

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SUPPORTING INFORMATION APPENDICES

Appendix A. study-specific instrument to measure breast reconstruction knowledge

The following statements describe ideas that women can have about breast reconstruction. Some statements are correct, others are incorrect.

Indicate for all statements whether you think it is correct or incorrect. If you are unsure, you can select the answer 'I don't know'.

1. Breast reconstruction is only possible for younger women
2. Smoking increases the risk of complications of breast reconstruction
3. The recovery time from breast surgery with breast reconstruction will likely be longer than the recovery time from breast surgery without breast reconstruction
4. The sensation in a reconstructed breast is the same as in your own breast
5. Breast reconstruction is always done in one operation
6. Reconstruction with a breast implant is a more complex surgical procedure than reconstruction with tissue from your body
7. Complete removal of the breast with an immediate breast reconstruction increases the risk of complications as compared to complete removal of the breast without breast reconstruction
8. Breast reconstruction has no influence on the treatment of my breast cancer
9. Breast reconstruction has no influence my chances of survival
10. With breast reconstruction, it is always possible to preserve the nipple.

Scoring

The correct answers:

1. incorrect
2. correct
3. correct
4. incorrect
5. incorrect
6. incorrect
7. correct
8. correct
9. correct
10. incorrect

Appendix B. Results on items of the Decisional Conflict Scale

	M (SD)**	**(strongly) disagree, n (%)**	**neither agree or disagree, n (%)**	**(strongly) agree, n (%)**
This decision is difficult for me to make	1.86 (1.34)	113 (45%)	39 (16%)	98 (39%)
I am clear about the best choice for me*	2.02 (1.21)	91 (36%)	69 (28%)	90 (36%)
I am not sure what to decide	1.93 (1.31)	104 (42%)	46 (18%)	100 (40%)
I know which options are available to me*	1.84 (1.10)	74 (30%)	63 (25%)	113 (45%)
I know the benefits of breast reconstruction*	1.91 (1.06)	80 (32%)	61 (24%)	109 (44%)
I know the disadvantages of breast reconstruction*	2.16 (0.98)	97 (39%)	80 (32%)	73 (29%)
I want more advice and information about the options	3.22 (0.93)	14 (6%)	32 (13%)	204 (82%)
I am clear how much the benefits of breast reconstruction matter to me*	1.56 (1.08)	49 (20%)	68 (27%)	133 (53%)
I am clear how much the disadvantages of breast reconstruction matter to me*	1.80 (1.04)	57 (23%)	95 (38%)	98 (39%)
It is difficult to decide which (the benefits or the disadvantages) are most important to me	2.10 (1.10)	63 (25%)	104 (42%)	83 (33%)
I feel pressured by others in making this decision	0.64 (0.85)	211 (84%)	30 (12%)	9 (4%)
I have enough support from others to make a choice*	1.14 (0.94)	18 (7%)	63 (25%)	169 (68%)

Abbreviations. **M** mean; **SD** standard deviation.
*Positively stated items for which the answer '(strongly) disagree' reflects higher decisional conflict.
**A higher score (range 0-4) reflects higher decisional conflict.

Appendix C. Univariable logistic regression for clinically significant decisional conflict (N=250)

	B	SE	Wald	df	*p*	OR	95% CI of OR	
							Lower	Upper
Sociodemographic variables								
Age	-0.01	0.01	0.30	1	0.59	0.99	0.97	1.02
Country of birth (NL vs. elsewhere)	-0.47	0.59	0.65	1	0.42	0.62	0.20	1.98
Educational level*								
low	-1.21	0.67	3.21	1	0.07	0.30	0.08	1.12
intermediate	-0.05	0.28	0.03	1	0.86	0.95	0.55	1.65
high	-	-	3.24	2	0.20	ref	-	-
Marital status (married or in a relationship vs. not)	-0.42	0.41	1.04	1	0.31	0.66	0.29	1.47
BMI								
normal	-	-	0.87	3	0.83	ref	-	-
underweight	-0.40	0.93	0.18	1	0.67	0.67	0.11	4.17
overweight	-0.23	0.30	0.57	1	0.45	0.80	0.44	1.44
obese	0.09	0.44	0.04	1	0.84	1.09	0.47	2.57
Number of comorbidities**								
none	-	-	3.46	2	0.18	ref	-	-
1	0.51	0.31	2.60	1	0.11	1.66	0.90	3.06
2+	0.53	0.40	1.76	1	0.18	1.69	0.78	3.67
Current smoking status (yes vs. no)	-0.78	0.55	2.01	1	0.16	0.46	0.16	1.35
Type of hospital								
cancer-specific hospital	-	-	1.42	2	0.49	ref	-	-
academic hospital	0.56	0.49	1.28	1	0.26	1.75	0.66	4.61
general hospital	-0.04	0.30	0.02	1	0.89	0.96	0.53	1.73
Clinical variables								
Time since diagnosis (weeks)	0.01	0.01	0.24	1	0.63	1.01	0.98	1.03
Laterality (bilateral vs. unilateral)	-0.42	0.60	0.49	1	0.49	0.66	0.20	2.14
Prior BC diagnosis (yes vs. no)	0.13	0.38	0.13	1	0.72	1.14	0.55	2.38
Diagnosis in irradiated breast(s) (yes vs. no)	0.35	0.46	0.58	1	0.45	1.42	0.57	3.51
Hereditary or familial increased risk for BC								
no	-	-	0.26	2	0.88	ref	-	-
yes	-0.05	0.38	0.02	1	0.89	0.95	0.45	2.00
I don't know	-0.17	0.33	0.26	1	0.61	0.85	0.45	1.61
Indication for adjuvant radiotherapy								
no	-	-	1.09	3	0.78	ref	-	-
yes	0.34	0.38	0.81	1	0.37	1.41	0.67	2.95

Appendix C. Continued

	B	SE	Wald	df	*p*	OR	95% CI of OR	
							Lower	Upper
maybe	0.02	0.35	0.01	1	0.95	1.02	0.52	2.02
I don't know	0.23	0.42	0.30	1	0.59	1.25	0.56	2.83
Patient-reported outcomes								
BR preference								
strong preference for BR	-	-	31.93	4	0.00	ref	-	-
slight preference for BR	1.77	0.44	16.15	1	0.00	5.86	2.47	13.88
no preference for or against BR	2.67	0.75	12.73	1	0.00	14.45	3.33	62.67
slight preference for no BR	2.01	1.07	3.50	1	0.06	7.46	0.91	61.19
strong preference for no BR	1.72	0.78	4.85	1	0.03	5.60	1.21	25.90
Knowledge	-0.08	0.07	1.54	1	0.22	0.92	0.81	1.05
Informed by surgical oncologist (yes vs. no)	0.15	0.29	0.25	1	0.61	1.16	0.66	2.04
Informed by plastic surgeon (yes vs. no)	-0.58	0.41	1.97	1	0.16	0.56	0.25	1.26
Informed by nurse or nurse specialist (yes vs. no)	0.09	0.27	0.12	1	0.73	1.10	0.64	1.87
Informed by leaflet(s) (yes vs. no)	-0.43	0.27	2.49	1	0.12	0.65	0.38	1.11
Informed by book(s) (yes vs. no)	0.80	0.79	1.01	1	0.32	2.22	0.47	10.53
Informed by website(s) (yes vs. no)	-0.20	0.27	0.51	1	0.47	0.82	0.48	1.41
Informed by relative(s) (yes vs. no)	0.17	0.28	0.36	1	0.55	1.18	0.68	2.06
Informed by scientific article(s) (yes vs. no)	-0.92	0.46	3.97	1	0.05	0.40	0.16	0.99
Informed by newspaper or magazine(s) (yes vs. no)	-0.21	0.50	0.19	1	0.67	0.81	0.31	2.14
Total number of information resources used	-0.09	0.08	1.14	1	0.29	0.92	0.78	1.08
Preferred involvement in decision making (CPS)	0.17	0.19	0.88	1	0.35	1.19	0.83	1.71
Monitoring coping style (TMSI)	0.01	0.02	0.50	1	0.48	1.01	0.98	1.05
Blunting coping style (TMSI)	-0.04	0.02	3.84	1	0.05	0.96	0.92	1.00
Anxiety (STAI-6)	0.04	0.01	14.07	1	0.00	1.05	1.02	1.07

Abbreviations: **B** beta; **SE** standard error; **df** degrees of freedom; **OR** odds ratio; **CI** confidence interval; **NL** Netherlands; **BMI** body mass index; **BC** breast cancer; **BR** breast reconstruction; **CPS** Control Preferences Scale; **TMSI** Threatening Medical Situations Inventory; **STAI-6** State scale of the State-Trait Anxiety Inventory; **Ref** reference category.
*N=248. **N=249.

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.

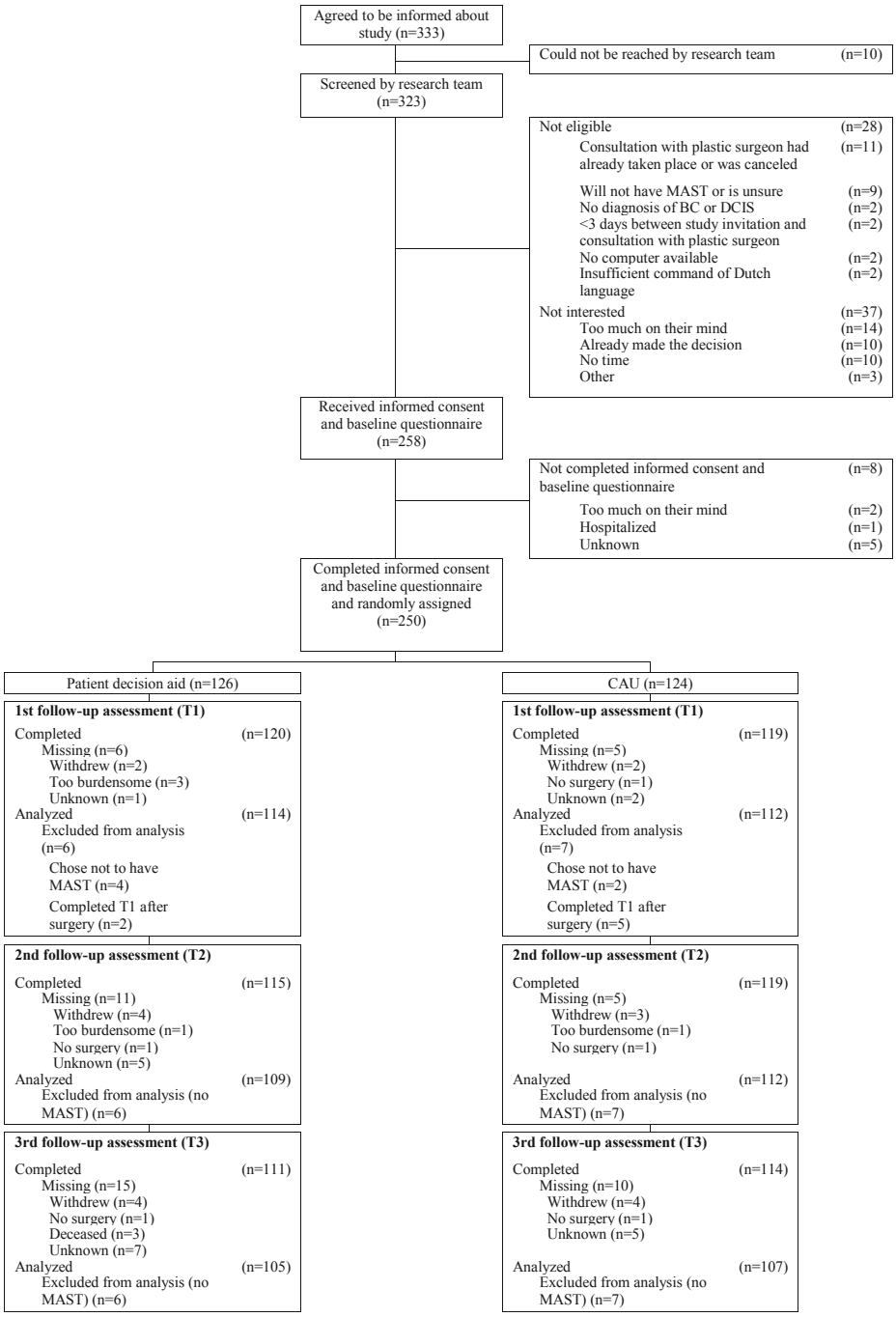

Figure 1. CONSORT diagram.
Abbreviations: **MAST** mastectomy; **BC** breast cancer; **DCIS** ductal carcinoma in situ; **CAU** care-as-usual. **T1** 1 week after consultation plastic surgeon; **T2** 3 months after surgery; **T3** 12 months after surgery.

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.

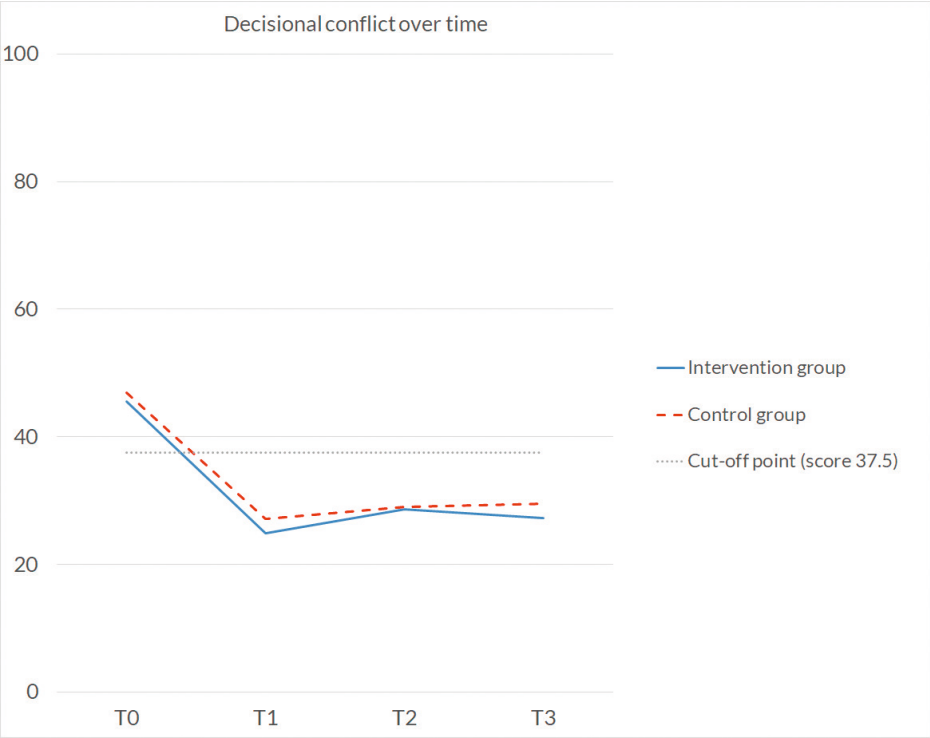

Figure 2. Change over time in decisional conflict (combined score without Effective Decision Making subscale). Cut-off point at score 37.5: scores > 37.5 are associated with decision delay and feeling unsure about implementing decisions. **T0** baseline; **T1** 1 week after consultation plastic surgeon;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

Chapter 6

Patients' and plastic surgeons' experiences with an online patient decision aid for breast reconstruction: considerations for nationwide implementation

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Submitted

ABSTRACT

BACKGROUND

Women diagnosed with breast cancer undergoing a mastectomy often have the option to undergo breast reconstruction (BR). BR decisions are complex and have considerable impact. We developed a patient decision aid (pDA) to support patients' BR decision making. Here, we assess patients' and physicians' use of the BR pDA and their views on the barriers and facilitators for widespread implementation.

METHODS

Participants completed a questionnaire, and back-end data of the pDA was analyzed.

RESULTS

Of 116 eligible patients, 113 patients accessed the BR pDA (median age: 50 years and 50% were highly educated). Most patients (72%) were satisfied with the pDA and 74% would recommend the BR pDA to other women facing the same choice. Patients' preferences regarding how much, what kind and how to present information varied. Plastic surgeons (N=22; 71% response) were satisfied with the pDA. Their key factors for implementation included the perceived match between information and clinical practice, costs, impact on patients, and support from peers and management for the tool.

CONCLUSIONS

As the BR pDA was highly valued by its end users, the identified factors for implementation should be taken into account.

BACKGROUND

Women considering a mastectomy for breast cancer or ductal carcinoma in situ (DCIS) often have the option to undergo a breast reconstruction (BR). Decision making about whether to undergo BR is a preference-sensitive decision that needs to be driven by patients' informed preferences. BR can improve the quality of life of women undergoing a mastectomy, but women can also experience complications from treatment (e.g., bleeding, infection and wound healing problems) and need more time to recover (1-3). In addition to deciding whether to undergo a BR, women need to make decisions about the type (e.g., autologous vs. implant reconstruction) and timing (e.g., immediate with the mastectomy, vs. delayed) of the reconstructive procedure. These are often complex decisions that can significantly impact women's lives.

Studies have reported suboptimal BR knowledge and low decisional preparedness among women making BR decisions (4, 5). A study investigating women's expectations regarding their wellbeing immediately after BR found that often expectations were unmet and that women with unmet expectations were more likely to experience decisional regret (6). Knowledge and decisional preparedness can be improved with a patient decision aid (pDA) providing evidence-based information, patient experiences, and values clarification tasks. pDAs have been shown to reduce decisional conflict and increase knowledge in many different clinical contexts (7). We developed an online pDA for Dutch women with pre-malignant or invasive breast lesions considering immediate BR (8). The effectiveness of the pDA was evaluated in a randomized controlled trial (RCT). We did not find a significant improvement in terms of decision quality or health outcomes when comparing the BR pDA to a standard information leaflet (9). However, women who used the BR pDA felt better prepared for their consultation with the plastic surgeon and for decision making compared to those who did not use the pDA.

With the ongoing efforts to implement shared decision making in clinical practice, the number of pDAs is growing (7). However, implementation of pDAs remains a challenge (10). Here, we report on patients' and plastic surgeons' usage of and satisfaction with our BR pDA and their suggestions for improvements. The lessons learned from our experiences can help other pDA developers.

METHODS

PARTICIPANTS

Patients participating in the Dutch BR pDA RCT

The RCT and study population is described in detail elsewhere (9, 11). In brief, participants were women diagnosed with invasive breast cancer and/or DCIS who had the intent to undergo a mastectomy, were eligible for immediate BR, and had been referred to a plastic surgeon. A total of 116 out of the 126 (92%) women allocated to the pDA arm (i.e., intervention arm) of the RCT were included in this process evaluation. We excluded women (n=6) who did not complete the first follow-up questionnaire (T1; one week after consultation with a plastic surgeon) and

we excluded four women who no longer met the inclusion criteria as they had already planned to have breast conserving surgery at the time of completing the first follow-up questionnaire.

Plastic surgeons

Plastic surgeons who were working in one of the eight hospitals participating in the RCT and who had consultations with breast cancer or DCIS patients during the trial's recruitment period were invited to complete an anonymous online questionnaire. The questionnaire was sent to them in the final month of recruitment for the trial (April 2019).

BR PDA

For a detailed description of the BR pDA consult the protocol and the paper describing the development of the pDA (8, 11). Briefly, the pDA consists of three parts (Figure 1 provides an overview); first, a consultation sheet on which surgical oncologists indicate the patients' options and provide a personalized link to the pDA. Second, the online tool (available at https://br.keuzehulp.nl (in Dutch)) in which patients receive an overview of reconstructive options, pros and cons of each option, information on consequences of each option for patients' daily life, exercises to clarify personal values, and stories depicting the experiences of patients who had previously decided about BR. The pDA also includes illustrations of the different types of BR. Patients can select the information that they want to read. Third, upon completion of the online tool, a summary sheet is generated with patients' considerations, preferences and questions to help inform and guide the discussion between the patient and her plastic surgeon.

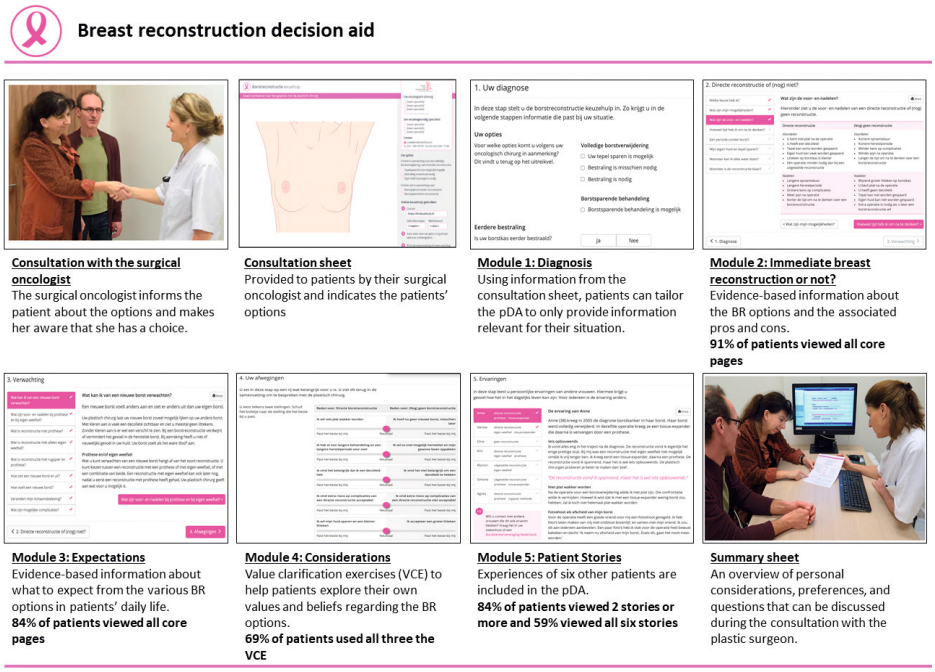

Figure 1. Overview of the BR pDA components and usage

MEASURES

Patients

Three sources of patient data were used for the purposes of this process evaluation, namely: 1. Patient questionnaires: data were collected in the baseline and the first follow-up questionnaire (T1; one week after consultation with a plastic surgeon) that patients completed as part of the RCT evaluating the effectiveness of the BR pDA. With the baseline questionnaire socio-demographic and clinical characteristics were obtained, specifically age, country of birth, education level, marital status, employment status, perceived skills in internet usage, diagnosis, history of breast cancer. In the first follow-up questionnaire (T1), information was obtained regarding patients' use of, satisfaction with and perceived usefulness of the pDA. Also, patients' feedback on the pDA was obtained via a non-compulsory open-ended question (i.e., 'If you have any additional remarks regarding the Breast Reconstruction Decision Aid, you can insert them here').

2. Data from the backend of the BR pDA: individual-level data on pDA use by patients participating in the trial were recorded in the pDA, specifically: how much time they spent viewing the pDA, and which components they viewed. Furthermore, patients' feedback on the pDA was collected directly after using it via a non-compulsory open-ended question (i.e., 'What did you like and what could be improved?').

Plastic surgeons

A study-specific questionnaire among plastic surgeons measured: (1) socio-demographic characteristics (i.e., age, gender, number of years of clinical experience, and type of hospital they work at), (2) their use of the pDA, (3) their satisfaction with the pDA, and (4) their perception of the impact of the pDA on the consultation and the patient. Additionally, via non-compulsory open-ended questions, plastic surgeons were asked for: (5) their reasons to continue or discontinue usage of the pDA after the RCT, (6) the conditions under which they would continue using the pDA after the RCT, and (7) their suggestions for improvement for the pDA (see supplement for study questionnaire).

ANALYSES

Descriptive analyses were performed to describe socio-demographic characteristics of patients and plastic surgeons. Answers to open-ended questions from patients and plastic surgeons were categorized into topics by one researcher (EGE) and a second researcher (JtS) reviewed the categorization with discrepancies being resolved through consensus. Then two researchers (EGE, JtS) independently organized these topics into barriers, facilitators, and suggestions for improvements according to the Consolidated Framework for Implementation Research (CFIR) (12). The CFIR is a framework of constructs that have been associated with effective implementation. We used the CFIR to systematically organize the potential barriers and facilitators of successful long-term implementation of the BR pDA described by patients and physicians according to validated constructs associated with effective implementation. Discrepancies were resolved through consensus.

RESULTS

PATIENTS' PERSPECTIVE

The median age of patients was 50 years (SD 11), 71% had been diagnosed with invasive breast cancer and 29% with DCIS only (Table 1). Most patients were born in the Netherlands (93%) and had an intermediate (47%) or high (50%) educational level.

Table 1. Patient characteristics (N= 116)

	N (%)
Age (mean (SD))	50 (11)
Born in the Netherlands (yes)	108 (93)
Education level	
Low (i.e., primary school, lower vocational education)	4 (4)
Intermediate (i.e., secondary school, intermediate vocational education)	53 (47)
High (i.e., higher vocational education, university)	57 (50)
Missing	2
Marital status (married/in a relationship)	105 (91)
Employment status	
Full or part-time work (yes)	58 (50)
Self-employed (yes)	17 (15)
Self-rated internet skills	
(Very) good	84 (72)
Average	32 (28)
(Very) bad	0 (0)
Diagnosis	
DCIS	34 (29)
Invasive breast cancer	61 (53)
Invasive breast cancer and DCIS	21 (18)
Radiotherapy indicated (yes/maybe)	65 (56)
Prior breast cancer or DCIS diagnosis (yes)	17 (15)
Type of hospital patients were treated at	
Oncology hospital	69 (60)
Academic medical center	13 (11)
General hospital	34 (29)

Abbreviations: **SD** standard deviation; **DCIS** ductal carcinoma in situ

Patients' use of the pDA

In total, 113 out of 116 (97%) patients included in this study logged into the pDA. Half of the patients (52%) visited the pDA once, while the other half (46%) visited the pDA multiple times (median number of sessions: 1 (range: 1-6 sessions)). Overall, 79% of patients spent 30 minutes or more viewing the pDA (median of 51 minutes (range: 9-351 minutes)). The pages with information regarding BR options, pros and cons, and what to expect from BR were viewed by more than 85% of the patients (Figure 1). The values clarification exercises aimed at helping patients to weigh their options were viewed by more than 90% of patients. The items to indicate treatment preference were used by: 88% to indicate preference BR yes vs. no, and 72% to indicate preference for BR with own tissue vs. implant. The patient stories were viewed by on average 76% (range: 66-95%) of the patients who logged into the pDA. Ninety-one patients (81%) viewed all main components of the pDA, defined as having viewed all pages with information (i.e., module 2 and module 3), the value clarification exercises and one or more patient stories. In the questionnaire, 111 (98%) patients indicated that they had reviewed the pDA prior to their consultation with their plastic surgeon. Seventy-seven (68%) respondents indicated that they had taken a printout of the summary sheet to the consultation with the plastic surgeon; 59 (56%) indicated that the pDA summary had been discussed during the consultation.

Patient satisfaction with the pDA

Table 2 provides an overview of patients' satisfaction with and perception of the usefulness of the pDA. Eighty-one patients (72%) indicated that they were satisfied with the pDA in general. When asked about their satisfaction with the amount of information, 68 (61%) patients thought it was just right, 9 (8%) patients thought it was too much, and 35 (31%) thought it was not enough. All main components of the pDA were considered useful by most patients in helping them to decide. Overall, 98 (88%) patients indicated that the pDA was easy to use and 83 (74%) women indicated that they would recommend the pDA to other women facing the same choice.

Table 2. Overview of patients' use and satisfaction with the BR pDA (N=113)

	N (%)
Usage of pDA	
Time spent on pDA (minutes), median (IQR, range)	51 (61, 9-351)
<15 minutes	5 (4)
16-30 minutes	19 (17)
31-90 minutes	60 (53)
>90 minutes	29 (26)
When did you look at the BR pDA?	
Prior to the consultation with my plastic surgeon	99 (88)
After the consultation with my plastic surgeon	1 (1)
Both prior to and after the consultation with my plastic surgeon	12 (11)
Missing	1
Did you take the pDA summary to the consultation with your plastic surgeon?	
Yes	77 (69)
No	35 (31)
Missing	1
Did you discuss the pDA summary during the consultation with your plastic surgeon?	
Yes	59 (56)
No	47 (44)
Missing	7
How satisfied are you in general with the BR pDA?	
Unsatisfied	7 (6)
Neither satisfied nor unsatisfied	24 (21)
Satisfied	81 (72)
What did you think of the amount of information in the BR pDA?	
Too much	9 (8)
Just right	68 (61)
Not enough	35 (31)
Missing	1
To what extent did components of the BR pDA help you with making a decision about BR? (Not at all / somewhat / very useful)	
Tables with pros and cons of each option	11 (10) / 44 (39) / 57 (51)
Value clarification exercises	23 (21) / 54 (48) / 35 (31)
Patient stories	20 (18) / 40 (36) / 52 (46)
Summary sheet	18 (16) / 51 (46) / 43 (38)
The BR pDA was easy to use	
Disagree	4 (4)

Neutral	10 (9)
Agree	98 (88)
Missing	1
Would you advice others facing the same treatment decision to use the BR pDA?	
No	5 (5)
I don't know	24 (21)
Yes	83 (74)
Missing	1

Abbrevations: **BR** breast reconstruction; **pDA** patient decision aid. Percentages do not always add up to 100% due to rounding off.

PLASTIC SURGEONS' PERSPECTIVE

Twenty-two of 31 (71%) participating plastic surgeons (partly) completed the questionnaire (Table 3). At least one plastic surgeon of each participating hospital completed the questionnaire. The median age of participating plastic surgeons was 44 years (range: 29-61), and 73% was female.

Table 3. Characteristics of plastic surgeons (N=22)

	N (%)
Age (Md. (range))	43.5 (29-61)
Gender (female)	16 (73)
Clinical experience (Md. (range))	7.5 (1-27)
5 years or less	8 (44)
6-10 years	4 (22)
More than 10 years	6 (33)
Missing	4
Type of hospital*	
Oncology hospital	6 (26)
General (teaching) hospital	11 (48)
Academic hospital	6 (26)
Frequency of discussing the pDA with a patient	
Never	8 (36)
1-3 times	8 (36)
4-10 times	4 (18)
More than 10 times	2 (9)

*Numbers do not always add up to 22, because one plastic surgeon worked in two participating hospitals.

Use of the pDA during consultations

Fourteen plastic surgeons indicated that they had discussed the pDA during the consultation with at least one patient. Most of them discussed the summary sheet (n=9) or asked whether the patient had used the pDA (n=11), and some viewed the pDA together with the patient (n=2). Eight respondents never discussed the pDA with a patient and the reasons provided were: not having had consultations with patients who had been randomized to the pDA arm (n=4), not knowing the pDA well (n=2), having sufficiently involved patients in treatment decision making without the pDA (n=2), and patients not having brought up the pDA (n=2).

Plastic surgeons' satisfaction with the pDA

Of the 14 plastic surgeons who discussed the pDA nine were (very) satisfied, four were neither satisfied or dissatisfied and 1 was dissatisfied. Eleven out of 14 respondents thought that the use of the pDA was of added value, specifically: patients are better prepared for the consultation (n=11), the consultation is more effective (n=7), patients get reliable information (n=6) and the pDA helps increase patient participation in the decision making process (n=4). The 14 plastic surgeons who had discussed the pDA with their patients, indicated that using the pDA impacted the following aspects of the consultation: content of the consultation (n=10), level of patient participation in decision making (n=10), patients' treatment preference (n=7), duration of the consultation is longer (n=6) and the number of questions that patients asked (n=6). Nine plastic surgeons would recommend using the pDA to other plastic surgeons. Ten respondents wished to continue using the BR pDA after closure of the trial.

VIEWS OF PATIENTS AND PLASTIC SURGEONS ON BARRIERS AND FACILITATORS FOR IMPLEMENTATION OF THE PDA AND SUGGESTIONS FOR IMPROVEMENTS

In total, 79 patients (68%) and 21 plastic surgeons provided feedback on barriers and facilitators for implementing the pDA and/or suggestions for improvements of the pDA by answering at least one of the open-ended questions. Table 4 shows an overview of the barriers and facilitators and the suggested improvements. The CFIR construct most often touched upon by patients was Design Quality & Packaging. The facilitators for implementation of the pDA recurrently listed by patients were: availability of clear and extensive information, availability of patient stories, the pDA being perceived as an effective tool to prepare for consultation and it helps to reflect. The barriers for implementing the pDA recurrently listed by patients were: information on specific topic(s) is missing, more illustrations/photos and experiences of other patients need to be added, and the values clarification exercise was perceived by some patients not to be helpful (e.g. not all considerations were included). Patients' suggestions for improvements related mainly to missing or desiring more information on specific topics such as: specific types of BR (e.g., a combination of implant-based and autologous BR), bilateral mastectomy, advice on which hospital is best for specific types of reconstruction, and DCIS-specific considerations.

Plastic surgeons' feedback regarding the pDA related mostly to the CFIR constructs Implementation Climate, Compatibility, Relative Priority, Available Resources, Relative Advantage, and Adaptability of the intervention. Across the constructs of the CFIR, facilitators were: being involved in the development of the tool, the intervention fitting into the clinical workflow, perception that the tool provides good quality information to patients and can reduce consultation time as patients are better prepared. Barriers across the CFIR constructs were: the perception that information in the tool does not match current practice at their hospital, costs, the perception that the tool has a negative impact on patients (e.g., information not (fully) understood or causing confusion) and the potential lack of enthusiasm from peers and/or management to adopt the pDA after the trial. Suggestions for improvement related to allowing modules in the pDA to be personalized to match BR options provided at specific hospitals and embedding the pDA in the patient electronic record system.

Table 4. Patients' and plastic surgeons' statements regarding barriers, facilitators and suggestions for improvement organized according to the Consolidated Framework for Implementation Research Constructs

	Patients			Plastic surgeons		
Construct	**Barrier**	**Facilitator**	**Suggestion for improvement**	**Barrier**	**Facilitator**	**Suggestion for improvement**
I. INTERVENTION CHARACTERISTICS						
Intervention Source					Participation in development pDA	
Evidence Strength & Quality				Depends on findings trial regarding effectiveness	• Depends on findings trial regarding effectiveness • Proof that pDA improves patient outcomes and/or reduces duration of consultations	
Relative Advantage	Little perceived added value to support decision making	• Effective tool to prepare for consultation and helps to reflect • Gives clarity		• No perceived added value • Does not reduce number of questions from patients • The perception of patients not being satisfied with pDA • Information was not completely understood by patients • pDA causes information overload in patients	• Good information is essential for patients • Patients are better prepared for consultation after pDA use • Provides information to patients • Can reduce consultation time • Improves communication with patient	
Adaptability	Information does not match hospital's clinical practice			Information does not match hospital's clinical practice	Depends on tailoring pDA to match hospital practice. For example, with modules that can be adapted to hospital-specific practices	Modules should be adapted to hospital-specific practices

Table 4. Continued

	Patients			Plastic surgeons		
Construct	**Barrier**	**Facilitator**	**Suggestion for improvement**	**Barrier**	**Facilitator**	**Suggestion for improvement**
Design Quality & Packaging	• Information missing on specific topic(s) • Values clarification exercise is not perceived as helpful • Specific information is not clear • Information is not new • Summary sheet has no added value • Experiences of other patients are not perceived as helpful • Information does not match diagnosis DCIS	• Availability of clear and extensive information • Availability of personal stories • Digital format • Availability of summary sheet • Easy to relate to own circumstances • Step-by-step guidance through the options	• More illustrations/ add photos • Add more experiences of other patients • Place experiences of other patients prior to values clarification exercises • Add place to make notes or write down questions on summary sheet • Content can be made more concise • Only show experiences of other women by clicking on a link			
Cost				Depends on costs	• Depends on costs • Period of no/ reduced costs for usage of pDA untill results of trial	
III. INNER SETTING						
Implementation Climate.				Depends on colleagues and breast cancer team	• Depends on colleagues and breast cancer team • Motivated nurse specialists and/or surgeons to provide pDA to patients	

Table 4. Continued

	Patients			Plastic surgeons		
Construct	**Barrier**	**Facilitator**	**Suggestion for improvement**	**Barrier**	**Facilitator**	**Suggestion for improvement**
Compatibility			• Adjust timing of pDA handout so that surgical options are clear • pDA is more suited for further reading after consultation with plastic surgeon		pDA should be given well in advance of consultation with plastic surgeon for patients to have sufficient time to use it	Incorporation of results in electronic patient record system
Relative Priority				Depends on policy in hospital	Depends on policy in hospital	
Available Resources					Digital link via breast cancer nurse	
Access to Knowledge & Information	Not clear how to fill in the treatment options used to tailor the pDA if these are not provided by surgeon		Desire for more information about what to expect from pDA		• Instruction • Clarity about which patient used the pDA	
IV. CHARACTERISTICS OF INDIVIDUALS						
Knowledge & Beliefs about the Intervention	It is an impersonal method of information provision					
Other Personal Attributes					Motivation	
V. PROCESS						
Engaging						Active involvement and instruction

DISCUSSION AND CONCLUSION

DISCUSSION

As part of a trial investigating the effectiveness of a new Dutch BR pDA, we assessed patients' and plastic surgeons' use of and satisfaction with the pDA. The uptake of the BR pDA was high among patients. Most patients and plastic surgeons were satisfied with the tool and found it to be of added value in the decision-making process. Most plastic surgeons who had used the pDA in clinical practice would recommend it to colleagues and wished to continue using it after the end of trial. Furthermore, our study identified key facilitators and barriers for implementation of the pDA and suggestions for improvement of the pDA from both patients' and plastic surgeons' perspective.

What stands out most from our results is the extent to which preferences and information needs regarding the pDA differ among patients. For example, while most patients highly valued the availability of patient stories, other patients considered them distressing, and again other patients thought that more stories should be added to represent a wider variety of patients. Also, patients varied in their valuation of the values clarification exercises. Some patients found them too brief and wanted more statements to be included to reflect the complexity of the choice better, whilst others found them to be useful as they were. The variation in patients' information needs regarding the pDA was further reflected by the variation in the perceived usefulness of the main components of the pDA. These findings emphasize the need for pDAs to be flexible and allow users to tailor the amount of information and the type of information they access on the various topics contained within the tool.

Overall, our results regarding patients' and plastic surgeons' barriers, facilitators and suggestions for improvements that could help the successful widespread implementation of our pDA beyond the trial are in line with the findings recently reported by Joseph-Williams and colleagues from the International Patient Decision Aid Standards Collaboration (10). Plastic surgeons' main points deemed important for implementation align with their key recommended pDA implementation strategies, specifically: (1) feeling involved in the production of the pDA, (2) making sure the whole breast care team involved in implementation of the pDA are aware of what they need to do and underscore the relevance, (3) support from management/senior colleagues for the use of the pDA, and (4) quantifying the impact of the pDA to show its added value in terms of patient outcomes (10).

An important potential barrier to widespread implementation of the pDA reported by plastic surgeons was a perceived mismatch between the BR options described in the tool and the options available at their hospital. From conversations with plastic surgeons whilst developing the pDA and about their experiences with the pDA during the trial, there were two specific patient groups in which they perceived this mismatch. The first group of patients were patients with an indication for adjuvant radiotherapy. In line with the national BR guideline (13), in our BR pDA it was stated that: *"If it is already clear before the operation that you need radiation*,

delayed breast reconstruction is often advised". However, in some of the participating hospitals, immediate BR is also offered to patients with an indication for adjuvant radiotherapy. Some of these patients were surprised to hear from their plastic surgeon that immediate BR was an option for them, and plastic surgeons commented that they had to reassure these patients that immediate BR was a valid option for them. The second group of patients that led to this perceived mismatch were patients with a preference for immediate autologous BR. While some Dutch hospitals offer immediate autologous BR to patients, most hospitals that can perform autologous BR only offer this as an immediate procedure to patients having a salvage or a prophylactic mastectomy, or as a two-stage or delayed procedure. Some plastic surgeons commented that they had difficulties to explain patients with a preference for immediate autologous BR after having used the pDA that this option was not available to them (at least not in their hospital). To improve the pDA, plastic surgeons suggested to make some of the pDA's information modules optional, thereby allowing them to 'turn off' modules for options that are not available at their hospitals. This could certainly help the tool integrate better into their existing practice and thereby facilitate widespread implementation. However, in the development of the pDA, we made the conscious choice to provide information on all the BR options presented in the national clinical guidelines. Moreover, besides the practical difficulties of such an adjustment, making information optional depending on hospital practice goes against a key principle of shared decision making, namely that patients should be informed of all options that are medically viable in their situation (14). It raises the question whether it is ethical not to provide patients with information about a treatment option not offered at their hospital, but that would be a medically viable option for them if they were treated at another hospital. This can be a point of tension between pDA developers and healthcare providers as incorporating options that a specific hospital does not offer, not only leads to disappointment if a certain option cannot be provided in a particular hospital, but can also have financial implications if a patient chooses to go to another hospital. For our pDA, we added information (for these two specific situations) to emphasize options may vary among hospitals. In general, more attention should be given to ways in which pDAs can fully and transparently inform patients about the available options, without them getting false expectations. This to prevent potential dissatisfaction with pDA usage among patients and healthcare professionals, and hindering implementation.

While the uptake of the pDA was good amongst patients, only half of patients reported that they had discussed the summary sheet of the pDA during the consultation with their plastic surgeon. From our data, it remains unclear why half of the patients did not discuss the pDA during the consultation, and how patients valued this. For shared decision making to take place, patients' considerations and preferences should be discussed and considered in the decision (14). Although it is possible that patients who reported that they had not discussed the summary sheet may have discussed their considerations and preferences without explicitly referring to the summary sheet, an exploratory analysis in our population (data not shown) suggests that patients who discussed the summary sheet of the pDA during the consultation perceived significantly higher levels of shared decision making (as measured by the SDM-Q-9

(15, 16)) than patients who had not discussed the summary sheet. It seems that to achieve optimal impact of the pDA, discussing the summary sheet during the consultation should be encouraged. The recommended strategy for implementing pDAs, as described by Joseph-Williams (10), is for the healthcare professional to be the one to invite patients to discuss the pDA and thereby making it clear to patients that their contribution in the decision-making process is valued and important. Interestingly, plastic surgeons indicated that patients bringing up the pDA during the consultation would prompt them to discuss it. This suggests that it is important to clarify roles.

This study has some limitations. First, it is an evaluation carried out during a trial and may not fully reflect implementation in routine clinical practice. The three main differences in implementation of pDA during the trial as compared to routine clinical practice were: (1) the link to the pDA was provided to patients by the research team via email instead of by the surgical oncologist during a consultation, (2) patients received a reminder by email on the possibility to use the pDA from the research team two days before their consultation with their plastic surgeon, and (3) the research team made notes of patients' allocation in their electronic medical record to incite plastic surgeons to discuss the pDA with patients. As these logistic adjustments might have influenced usage of the pDA among patients and plastic surgeons (both positively and negatively), it is important to keep monitoring usage after closure of the trial. Second, participating patients might not fully reflect the total patient population. For example, because specific patient subgroups did not meet the inclusion criteria (e.g., women with a language barrier) or due to selection (e.g., women who wanted to participate in the decision-making process were overrepresented). Further, not all plastic surgeons at participating centers completed the questionnaire and physicians' answers on the open-ended questions intended to clarify their views and preferences were often very concise. However, at least one plastic surgeon from each hospital participating in the trial did complete the questionnaire. Using interviews instead of a questionnaire, particularly to get insights into plastic surgeons' views could have yielded more information. However, the themes we have identified in our data generally match those identified in a previous interview study evaluating an Australian BR pDA (17), suggesting that although physicians' answers were concise, they were informative, and we were able to identify relevant topics. Important strengths of this evaluation study are that we assessed experiences with the pDA from both patients and plastic surgeons, and we had access to backend data to see the actual use of the pDA.

CONCLUSION

This evaluation study suggests that our Dutch BR pDA is a well-used resource valued by its end users. The great variation in patients' information needs means that pDAs should allow patients to tailor the amount and presentation of information for these tools to be of even more benefit to a wider range of patients.

PRACTICE IMPLICATIONS

This evaluation study embedded within an effectiveness RCT provides important insights into the end users' experiences with the pDA, and helps to understand user, intervention and organizational factors that can influence implementation of the pDA into clinical routine practice. The results of this evaluation study were used to further optimize the tool by for example adding (more) information on topics patients were missing or felt should be expanded upon. As the number of pDAs is rapidly increasing, but the implementation into clinical routine practice is still lagging behind [10], process evaluation studies like ours are off great added value to help speed up the implementation.

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SUPPLEMENTAL INFORMATION

SURVEY ON HEALTHCARE PROFESSIONALS' EXPERIENCES WITH THE PDA

Demographics

1. What is your age? [open text field]
2. What is your gender? (Male / Female)
3. What is your position? (Plastic surgeon / Physician in training to be a plastic surgeon / Other, namely: [open text field])
4. How many years have you been working in the above position? [open text field].
5. In which hospital are/were you employed during the TANGO study?

Use of the decision aid

1. Have you reviewed the content of the decision aid? (Yes / No / Don't know (anymore))
2. How often have you discussed the decision aid with a patient? (Never / 1 to 3 times / 4 to 10 times / More than 10 times)
3. **If Q2 = never:** What is the reason you have never discussed the decision aid with a patient? Multiple answers possible. (I have not spoken to any patients who had used the decision aid / I do not know the decision aid well / I do not support the content of the decision aid / I expect it to cost me extra time / With my current working method, I involve patients sufficiently in the choice of treatment / I do not expect that discussing the decision aid will add anything / The patient did not bring it up / Other, namely: [open text field])
4. **If Q2 = never:** When would you discuss the decision aid with your patient? [open field]

If Q2 = never: *skip questions 1 and 2 in section 'Experience with the decision aid', and continue with question 3.*

Experience with the decision aid

1. How satisfied are you with using the decision aid? (Very satisfied / Satisfied / Not satisfied, not dissatisfied / Dissatisfied / Very dissatisfied)
2. Would you recommend other (plastic) surgeons to use the decision aid? (Yes / No / Don't know)
3. Do you experience added value from the decision aid? (Yes / No)
4. **If Q2 = Yes:** What do you experience as added value? Multiple answers possible (I can involve the patient more in the choice / The patient is better prepared for the conversation / The conversation is more effective / The conversation is more enjoyable / The patient receives reliable information / The patient is more satisfied / Other, namely: [open field])
5. Do you experience barriers in using the decision aid? (Yes / No)
6. **If Q5 = Yes:** What do you experience as barriers? Multiple options can be selected (I have to change my working method / It costs me extra time / The patient asks more or more difficult questions / The information in the decision aid does not fit well with the practice of my hospital / Other, namely: [open field])
7. Does discussing the decision aid with a patient affect the length of the consultation? (Yes, the consultation is shorter / Yes, the consultation is longer / No / Don't know)

8. Has the use of the decision aid influenced: the number of questions the patient asked during the consultation/the patient's involvement in the treatment choice/the patient's preference regarding breast reconstruction/the content of the consultation? (Yes / No / Don't know)
9. Do you have any suggestions for improvement of the decision aid? [open text field].
10. Would you like to continue using the decision aid after completion of the TANGO study? (Yes / No / Don't know)
11. What is your reason for wanting to continue using the decision aid or not? [open text field]
12. **If Q9 = yes or don't know:** What do you need to continue using the decision aid? [open text field]

Chapter 7

Discussion

Women who undergo mastectomy as a treatment for invasive breast cancer or ductal carcinoma in situ often face the decision of whether to have breast reconstruction (BR). This decision can be challenging, particularly given that it needs to be made during the stressful period shortly after hearing the cancer diagnosis. Patient preferences play a crucial role in this decision, and it is important to provide women with the necessary information and support to make the best decision for their individual circumstances. In this project, we aimed to support women in making an informed decision about immediate BR by developing and implementing an online patient decision aid (pDA). Additionally, we aimed to evaluate the efficacy of this pDA in reducing decisional conflict compared to an information leaflet.
This thesis focuses on:

Part 1. The development of a breast reconstruction patient decision aid and the experiences with the patient decision aid

A. What are the information needs of patients and healthcare professionals regarding the decision about breast reconstruction?
B. Is the pDA acceptable and usable for patients and healthcare professionals?
C. What are the experiences of patients and plastic surgeons with the pDA in terms of usage and satisfaction with the tool?

Part 2. Decisional conflict about breast reconstruction and the effect of the patients decision aid on decisional outcomes and patient-reported health outcomes

D. What are the levels of decisional conflict in patients considering immediate breast reconstruction, and what factors are associated with clinically significant decisional conflict?
E. Is the pDA effective as compared to care-as-usual?
    a. What is the effect of the pDA in reducing decisional conflict?
    b. What is the effect of the pDA on the decision-making process, decision quality, and patient-reported health outcomes?

PART 1. THE DEVELOPMENT OF A BREAST RECONSTRUCTION PATIENT DECISION AID AND THE EXPERIENCES WITH THE PATIENT DECISION AID

Together with a multidisciplinary working group, we developed an online pDA for women considering immediate BR. The development was guided by the International Patient Decision Aids Standards (IPDAS-criteria) (1, 2), and included the assessment of information needs and the experiences with the pDA among patients and healthcare professionals (HCPs).

A. *What are the information needs of patients and healthcare professionals regarding the decision about breast reconstruction?*

As described in chapter 2, interviews amongst patients identified three major themes reflecting the experiences and information needs about the reconstruction decision. The first theme 'Challenging period to make a decision' included patients reflections on the decision-making period as a rollercoaster, feeling overwhelmed by their emotions, and having to process a

large amount of information in a short period of time. The second theme 'Diverse motivations for a personal decision' included a wide variety of patients' personal motivations for their decision, and their notion of the importance of clearifying personal values to make this decision. The third theme 'Information needed to make a decision' included patients' expressions of their need for objective, reliable and personalized information and the topics that patients considered important to make a decision (e.g., What will it look and feel like? When can I resume my daily activities? How does it effect my daily life?). Our findings demonstrated unresolved information needs amongst patients deciding about reconstruction, consistent with the findings of previous studies (3-9).

In the interviews, patients expressed a need to learn about the experiences of other women to gain more insight into the effects of BR on their daily lives and what to expect from BR (chapter 2). This need has also been reported in prior studies in BR patients (5, 10). To better illustrate the impact of the different BR options on women's daily life after surgery, we added six patient stories to our pDA (chapter 2). These narratives were positively evaluated by patients participating in our trial; 82% of participants perceived the stories as somewhat or very useful for decision making (chapter 6). Patient narratives have been suggested to potentially enhance the effectiveness of pDAs in some situations, as they can increase knowledge and engagement (11). However, potential negative effects of narratives that run counter to the intended purpose of a pDA, such as bias and persuasion, have also been reported (11). We aimed to inform, engage, and comfort patients with the narratives, and prevent bias such as persuasion in our pDA. For this purpose, we added one patient story for each BR option included in the pDA, provided balanced information by describing both positive and negative aspects of each option, and checked the representiveness of our stories with working group members and participants in acceptability and usability testing. However, more research is required to study the effects of narratives in pDAs on the decision-making process and outcomes and to find out how patient narratives can optimally support patients in decision making (e.g. what number, in what form, and what types of narratives) (11).

What stood out from our results from acceptability testing of the pDA among patients (chapter 2), and from the experiences with the pDA among trial participants (chapter 6), was the extent to which preferences and information needs regarding the pDA *differ* among patients. Patients differed in the preferred amount of information and the preferred level of detail in the pDA. These findings emphasize the need for pDAs to be flexible and allow users to tailor the amount and type of information and the levels of detail they access on the various topics contained within the tool (12). In our tool, patients were free to select the information they desired and skip parts they did not want to read. However, in the future, more tailoring can be achieved by adding more detailed information on topics such as specific types of BR, bilateral mastectomy, and considerations specific for DCIS, that can be optionally read.

Our study is one of the few studies to address attitudes and preferences towards SDM regarding BR from the perspective of the HCP. We found that HCPs stressed the importance

of better informing patients about BR as preparation for consultation with the plastic surgeon, and that they were positive about the development of a pDA, in line with the few previous studies (7, 13, 14).

The results on the information needs of patients and HCPs guided the development of our pDA. Furthermore, these findings, especially from patients, can inform clinicians working with patients considering BR about the information they provide them, and the attributes that need to be taken into account when deciding about BR.

B. *Is the pDA acceptable and usable for patients and healthcare professionals?*

In the development phase, we tested whether patients, HCPs and representatives of the breast cancer patient organization considered the pDA acceptable and usable. In general, participants were positive about the content and the look-and-feel of the pDA and considered the tool easy-to-use (chapter 2). These positive results are also reflected in the experiences with the pDA among the larger group of patients facing the decision of immediate BR and HCPs who participated in our trial, as most participants were satisfied with the tool, and most patients indicated that the pDA was easy to use (chapter 6).

C. *What are the experiences of patients and plastic surgeons with the pDA in terms of usage of and satisfaction with the tool?*

Nearly all patients in our trial accessed the pDA before their consultation with a plastic surgeon (chapter 6). Patients spent a median time of close to one hour using the pDA. The vast majority of patients viewed all main components of the pDA. Our results demonstrate that it is feasible for patients to use the pDA even within the short time span between presurgical consultations with an oncological surgeon and a plastic surgeon.

There seems to be room for improvement in the integration of the pDA into the consultation with a plastic surgeon. Less than 60% of the patients reported discussing the pDA's summary sheet with their plastic surgeon. It remains unclear why patients did not discuss the summary sheet with their plastic surgeon and how they valued this, as we did not include questions about this in the questionnaire and did not observe the consultations. For shared decision making (SDM) to occur, patients' considerations and preferences should be discussed and considered in the decision (15). It is possible that these patients discussed their considerations and preferences with their plastic surgeon without explicitly referring to the summary sheet. However, an exploratory analysis in our intervention group showed that patients who discussed the summary sheet during consultation reported higher levels of SDM than patients who reported not having discussed the summary sheet during consultation (chapter 6). Also, prior studies support the theory that explicit invitation from HCPs for the patients to engage with the pDA during decision-making consultations is important to encourage them to share their preferences, ask questions, and engage in decision making (16). Discussing the

summary sheet in consultation should therefore be encouraged. From the responses of plastic surgeons, we learned that their reasons for not discussing the pDA included not being well-acquainted with the pDA, and patients not having brought up the pDA. Therefore, improving plastic surgeons' knowledge about the pDA, and clearifying roles by encouraging them to invite patients to discuss the summary sheet might enhance the implementation of the pDA and its impact on improving SDM (16).

The majority of plastic surgeons were satisfied with the pDA (chapter 6). Plastic surgeons perceived that the pDA had impact on several aspects of their consultations, such as the content and the level of patient participation.

Factors that can facilitate or hinder nationwide implementation of the pDA were identified among patients and plastic surgeons (chapter 6). From patients' perspective, the facilitators and barriers for implementation of the pDA were mainly related to the content of the tool and its perceived effects. Facilitators included the availability of clear and extensive information in the pDA, availability of patient stories in the pDA, and the pDA being perceived as an effective tool to prepare for consultation. The barriers for implementing the pDA included the perception of missing information, the need for more illustrations/photos and patient stories, and the perception that the values clarification exercise was not helpful. Facilitators from the perspective of plastic surgeons included being involved in the development of the tool, the intervention fitting into the clinical workflow, the perception that the tool provides good quality information to patients and can reduce consultation time as patients are better prepared. Barriers included the perception that information in the pDA did not match the practice at their hospital, costs, and the potential lack of enthusiasm from peers and/or management to adopt the pDA after the trial. Overall, these results regarding barriers and facilitators are in line with the findings reported in prior studies (16).

PART 2. DECISIONAL CONFLICT ABOUT BREAST RECONSTRUCTION AND THE EFFECT OF THE PDA ON DECISIONAL OUTCOMES AND PATIENT-REPORTED HEALTH OUTCOMES

D. *What are the levels of decisional conflict in patients considering immediate breast reconstruction, and what factors are associated with clinically significant decisional conflict?*

At baseline (i.e., before a decision was made), the majority of breast cancer patients considering immediate BR in our trial (68%) experienced clinically significant decisional conflict (CSDC) (defined as a score > 37.5 on decision conflict) (chapter 4). To our knowledge, this is the first study in which decisional conflict regarding immediate BR was assessed in a large sample of BC patients. The levels of decisional conflict in our sample (mean score of 46 on a range of 0 to 100) are relatively high as compared to baseline scores regarding a variety of other health-related decisions (mean score of 29 ranged from 1.5 to 88.0 out of 100) (17), and to scores in two studies in small samples of BC patients considering immediate BR (mean score of 33 in both

studies) (3, 18). The specific population, the complexity of the decision, and the timing of our assessment might all have contributed to evoking higher decisional conflict in our sample (17).

We found that having CSDC at baseline was associated with the preference for BR and levels of anxiety (chapter 4). Compared to patients with a strong preference for BR, those with a) a *slight* preference *for* BR, b) *no preference* for or against BR, and c) a *strong* preference for *no* BR were more likely to experience CSDC. Especially the finding that patients with a strong preference for *not* having BR had more CSDC than patients with a strong preference for BR was surprising. More research, including more women with a preference for *not* having BR, is needed to confirm this association and understand it. From the interviews with patients that were conducted as part of the needs assessment, we understood that BR was communicated as something positive. One participant who underwent mastectomy without BR said, *"Immediate reconstruction was discussed as the most reasonable course of action. I met all the criteria. It felt like I had a privilege. But did I really want it myself? When I carefully considered it, I discovered that it* [immediate BR] *didn't suit me at all."* Recent qualitative studies on the experiences with decision making in women who underwent mastectomy without BR showed that some women felt unsupported in their decision not to undergo BR by their clinicians, and that they missed information about the option of mastectomy without BR (19, 20). Therefore, it seems interesting to investigate the role of the communication about BR and patients' perceived support for their preferred option in the levels of decisional conflict in women favoring no BR after mastectomy. Furthermore, our study showed that patients with more anxiety were more likely to experience CSDC. This association has been reported in other populations (21-23), and is in line with the conceptual framework of decisional conflict (24). No other explored factors, including sociodemographic and clinical characteristics, and patient-reported outcomes such as baseline knowledge, were associated with having CSDC in our sample. To identify who is at particular risk for having decisional conflict about immediate BR more research is warranted. Factors that were associated with decisional conflict in other studies such as satisfaction with information and communication (25), and the perceived involvement in decision making (26) should be included. Knowing who is at particular risk for decisional conflict about having immediate BR may be useful to identify patients who need additional decision support. However, our pDA was developed for all women considering immediate BR after mastectomy, and we argue that using the pDA may be valuable and informative for both women with and without decisional conflict.

Over time, decisional conflict decreased in both groups in our trial (chapter 5). Levels of decisional conflict were high at baseline (above the threshold for CSDC) and decreased in the follow-up assessments to levels that are associated with implementing decisions (scores ≤ 25). This trajectory of decisional conflict over time is comparable to the trajectory of conflict reported in other studies evaluating the impact of decision support interventions in other patient groups (17).

Decisional conflict is the most commonly used outcome measure in studies on the efficacy of pDAs (27-29). However, important to note that certain levels of decisional conflict, especially *before* decision making, are not necessarily bad. Decisional conflict might for example increase when patients receive more information about a complex decision. Furthermore, patients who are not adequately informed, may perceive themselves as knowledgeable (not knowing the information that they miss), and have no decisional conflict. It might therefore be questioned whether decisional conflict is a good primary endpoint in studies on the efficacy of pDAs (30). One can imagine that pDAs might even temporarily increase decisional conflict by creating more awareness for the inherent complexity of a certain decision and more involvement of the patient in the decision (31). This hypothesis emphasizes the importance of longitudinal assessment of decisional conflict as an endpoint, both during the process of decision making and after that a decision has been made. Furthermore, this highlights the importance of assessing decisional conflict in combination with other outcomes such as knowledge and decisional regret.

E. *Is the pDA effective as compared to care-as-usual?*

The benefit of the pDA in improving patients' preparedness for decision making (described in chapter 5) is in line with healthcare professionals' expectations that a BR pDA would help patients to prepare for the consultation (32), and the qualitative experiences of patients and healthcare professionals with using a BR pDA, both in our trial (chapter 6) and in other studies (14, 33). To our knowledge, none of the quantitative studies on the efficacy of a pDA in women considering BR included this outcome measure, limiting comparison (34, 35). However, these findings align with the benefits on patients' perceived preparedness for decision making by the use of pDAs in two other health decisions (36, 37).

The absence of benefits of the pDA on other outcomes related to the decision-making process, the decision quality and health outcomes are in contrast with a growing body of evidence (27). Several factors related to the study design may have contributed to the absence of benefits of our pDA, as compared to other studies with positive results. The effects of our pDA might be underestimated as the control group received an extensive information leaflet. In a Cochrane review by Stacey et al. (2014), more detailed decision aids were found better than simple decision aids for improving people's knowledge and lowering decisional conflict (38). The authors suggested that the small differences in knowledge and decisional conflict when detailed pDAs were compared to simple pDAs is likely due to the overlapping information presented in the two interventions. More specifically in the context of decision making about BR, two studies comparing a detailed pDA with a less detailed pDA excluding value clarification or with an extensive information leaflet found no benefit of the detailed pDA (39, 40). Furthermore, although the information leaflet provided to our control group is widely available in Dutch hospitals and on the internet, we assume that, by actively providing the leaflet to the control group before they had their consultation with a plastic surgeon, more patients read the leaflet than in a typical care-as-usual setting, and possibly they read the it more carefully.

This could have positively benefitted the decision-making process in our controls in that the information led to decreased decisional conflict, increased knowledge about BR, and higher perceived levels of involvement in decision making in our controls. Furthermore, contamination bias might have occured. Study participation itself (including being informed about the study and its purpose) might have increased awareness for the importance of information provision and SDM about immediate BR among patients and healthcare professionals participating in our trial. This increased awareness might have influenced factors such as patients' involvement in decision making and patient-doctor communication in both groups.

However, the lack of benefits of our pDA on the outcomes may also be explained by multiple other factors. More research is necessary to identify factors explaining different findings regarding the efficacy of pDAs. Factors such as the population, decision type, decision context, characteristics and timing of the pDA, and the implementation of the pDA may all play a role. A review focusing on decisional conflict demonstrated that the largest improvements in decisional conflict after decision support interventions, including pDAs, were found in decision makers who were ill, male, or made decisions for themselves (17). As suggested by Garvelink et al. (2019), meta-analyses could inform hypotheses about the expected effects of decision support interventions (17).

METHODOLOGICAL CONSIDERATIONS

LIMITATIONS

Some limitations should be considered when interpreting our results.

Our BR pDA is not accessible to patients without internet access or those who don't speak Dutch. For patients without internet access, the availabilty of a printed copy of content may be a solution, as well as the possibility to access the pDA on a computer or tablet in the hospital (if available). To make the pDA accessable for non-Dutch speaking patients, the content of the tool could be adapted to other languages. For now, we recommend physicians to encourage non-Dutch speaking patients to use the pDA with a relative who speaks Dutch and who can translate.

While the design of a randomized controlled trial (RCT) is considered the gold standard for evaluating interventions, it may have led to contamination bias as described in more detail in the previous section 'Is the pDA effective as compared to care-as-usual?'**.** However, alternative designs such as a pre-post design or a stepped wedge cluster RCT would have introduced other potential biases, such as time effects and selection bias, as well as practical concerns like difficulties with recruiting a control group. Therefore, we chose the RCT design despite its limitations.

The efficacy of our pDA may be underestimated by providing patients in the control group the information leaflet, especially before they had their consultation with a plastic surgeon. As described in the previous section 'Is the pDA effective as compared to care-as-usual?', the information leaflet provided to the control group was extensive. Furthermore, typical care-

as-ussual patients would probably not have been provided with the leaflet in such a structural way, and not necessarily before the consultation with a plastic surgeon. In the questionnaire to assess the experiences of plastic surgeons with the pDA during the trial (described in chapter 6), two questions were added regarding the provision of the information leaflet to patients in routine clinical practice. Plastic surgeons' responses supported our hypothesis that. Only 11 of the 22 plastic surgeons reported that their patients receive the information leaflet as standard education in their hospital. Furthermore, only five of the 22 plastic surgeons reported that their patients usually receive the information leaflet *before* consultation with them.

An extra assessment in our trial of outcomes such as decisional conflict and knowledge *after* pDA usage and *before* consultation with a plastic surgeon would have allowed us to better distinguish effects of the pDA from the effects of the consultation itself. This time point seems especially interesting, as our trial showed that patients felt better prepared for decision making and for consultation with their plastic surgeon by the pDA. We did not include this extra assessment as this was considered not feasible due to the limited time period between usage of the pDA and consultation with a plastic surgeon (sometimes < 24 hours) and the burden on patients of an additional questionnaire.

Furthermore, the omission of a baseline assessment with the Effective Decision Making subscale limits our conclusions regarding patients' baseline decisional conflict and the efficacy of the pDA. However, we considered the timing of this subscale that includes items such as *'I am satisfied with my decision'*, and *'My decision shows what is important to me'* inappropriate at our baseline. We used a combined score without the Effective Decision Making subscale as alternative, as was done in other studies (29, 41).

Some factors that limit the generalizability of our findings are important to consider. First, the educational level of patients participating in our studies, both in the development of the pDA, as well as in the trial, was relatively high. As a result, it remains uncertain whether the pDA is consistent with decision support needs of patients with lower educational levels, and what the impact is of the pDA in this subgroup of patients. Related to this, we lack data on health literacy of participants in our study. However, as these women have been underrepresented in previous project focusing on implementing SDM (42), and based on the high levels of education in our samples, we suppose that this group is underrepresented. To ensure the accessibility of the pDA for all patients, irrespective of their educational and health literacy levels, the texts in the pDA were written on a B1 language level (characterized by use of common words and short, simple and active sentences) (43), and illustrations were incorporated to visualize parts of the text. Pictorial health information has been found to improve understanding and recall in comparison to text alone, particularly benefitting patients with less formal education and lower health literacy (44, 45). Second, the majority of participants in our trial (60%) were recruited from a tertiary comprehensive cancer center. These patients have been suggested to be a special subgroup of patients, and the standards of information provision and patient involvement in decision making may differ from other types of hospitals. However, we adjusted

for hospital in our analyses, and an explorative analysis excluding participants of this tertiary comprehensive cancer center showed comparable results regarding the pDA's efficacy.

Both our study on baseline decisional conflict (chapter 4) and our evaluation of the experiences of patients and HCPs with the pDA (chapter 6) were carried out during our trial evaluating the effect of the pDA. Participating patients might therefore not fully reflect the total patient population. For example, because specific patient subgroups did not meet the inclusion criteria of the trial (e.g., women with a language barrier) or due to selection (e.g., women who had decision support needs and/or who wanted to be actively involved in the decision-making process were overrepresented). This may for example have led to an overestimation of the levels of baseline decisional conflict, as women who had decision support needs were more willing to participate in the trial.

Furthermore, the experiences with the pDA (chapter 6) may not fully reflect implemention of the pDA in routine clinical practice, Three minor adjustments were made in the implemention of the pDA during the trial, that could have influenced the experiences with the tool. First, patients in the trial received access to the pDA by an email from the researchers after consultation with their oncological surgeon, instead of by a consultation sheet from their oncological breast surgeon during consultation. Second, patients received a reminder of the possibility to use the pDA. Third, plastic surgeons were informed about whether or not a patient had access to the pDA by a note in patients' electronic medical record. Given these limitations, it is crucial to continue monitoring the experiences of patients and HCPs after trial completion. This will help us to gain a better understanding of the experiences with the pDA in real-world clinical settings.

Finally, we did not observe the interaction between patients and their clinicians during consultations. Adding such observations could provide more detailed insights into the usage of the pDA and its effect on the SDM process, and could identify areas for improvement in the SDM process during these clinical encounters (46).

STRENGTHS

Several strengths of this project are worth highlighting.

The first strength is the rigorous development process of our pDA, with the focus on nationwide sustainable implementation. In developing our pDA, we included all relevant stakeholders from the beginning. This resulted in a pDA that incorporated information needs and preferences of both patients and healthcare professionals, and ensured that the pDA was relevant, understandable, and useful for the target population. Active involvement of the Dutch Breast Cancer Patient Organization further stimulated implementation of the pDA. The importance of co-design in developing and implementing a pDA has been increasingly recognized (16, 47, 48).

Another strength of our project was the partnership with ZorgKeuzeLab, a social enterprise specialized in the development and implementation of pDAs. They had already developed pDAs for a variety of health choices, including choices that women with breast cancer may face in their treatment such as the choice for breast-conserving surgery versus mastectomy (49, 50). Our collaboration with ZorgKeuzeLab ensured that these pDAs complemented and integrated with each other, could facilitate implementation of our pDA after the trial as hospitals could implement multiple pDAs from one provider, and facilitated continuous quality improvements to the pDA (e.g., enhancements to one of the pDAs can be readily applied to the other pDAs). This partnership also ensured that maintenance and updates of the pDA were guaranteed after the end of the project. However, this partnership also raises questions, as it implied an initial loss of public accessibility to the pDA due to a required login code and potential profit for a commercial company. As a social enterprise, ZorgKeuzeLab has made the pDA publicly accessible via https://br.keuzehulp.nl/inlogcode for patients who do not receive the pDA in their hospital. However, this is contingent on having a sufficient number of hospitals that take out a subscription with them to ensure that they can provide guidance to healthcare providers in using the pDA as intended, as well as generate income to ensure the continuity in the maintenance and availability of the pDA.

Strengths of our study to evaluate the efficacy of the pDA included the design of a randomized controlled trial and the long follow-up as compared to prior studies. The high participation rate and low attrition rate are considered other strengths.

Finally, besides studying the efficacy of our pDA as described in chapter 5, we also reported on process measures such as satisfaction with and usage of the tool among patients and plastic surgeons (chapter 6). These data provided more detailed insights into the experiences of end-users with the pDA, which in its turn gave more context to the results regarding the efficacy of the tool and provided important suggestions to improve the tool and its future implementation.

FUTURE DIRECTIONS

In this project, we aimed to support women in making informed decisions about immediate BR by developing and evaluating an online pDA. In line with this purpose, here are some thoughts about how to further improve the information provision and the SDM process about immediate BR.

The pDA itself may be further optimized in several ways. For example, by adding more illustrations to our pDA. This can increase accessability of the tool for patients, and especially women with low health literacy (44, 45), and meets a need for more illustrations expressed by patients (chapter 6). Also, adding photos of patients with and without BR to the pDA should be considered to further support patients in getting prepared for decision making and having realistic expectations of surgery. These photos should be optional to look at, as not all patients want to see these. In developing our pDA, it was considered unfeasible in the available time and resources of the project to have high quality photos from a diverse group of patients

with different reconstructions before- and after surgery. Furthermore, plastic surgeons preferred to show patients photos themselves, tailored on the individual patient, and be able to give explanations and respond to patients' reactions on seeing the photos. Differences in practices such as scar locations among hospitals raised concerns that photos might create false expectations and limit the nationwide adoption of the pDA. However, as photos meet an expressed need of women when deciding about BR, it would be valuable to further study how and under what conditions photos could be added to the pDA, and what the impact of showing photos is on the decision-making process.

Another opportunity to improve SDM about BR and, more specifically, our pDA is the growing availability of (inter)national outcome data after different surgical options, collected in for example (inter)national breast cancer registries. In our pDA, we chose not to present numerical estimates of outcomes such as quality of life or risk of complications of the BR options, as either reliable data were missing, or there was no consensus among working group members who developed the pDA regarding the numbers that should be included. Instead of numerical estimates, we only used verbal labels in the pDA, such as 'low' or 'high' risk of complications, and suggested that patients could discuss more details with their phycisian. More transparancy on available, reliable outcome data could provide patients and HCPs with important input for SDM. Especially, tailored outcome data for example based on personal risk factors could provide patients with personally relevant information (51). Politi and colleagues (2020) used a personalized risk predictor for complications after BR based on factors like BMI, radiation, age and smoking status in their BREASTChoice tool (52). This tool was perceived as highly usable by patients, and the personalized risk profile information was considered helpful (53). Advancements in artificial intelligence can further facilitate the use of personalized estimations of outcomes in SDM, and have already been successfully incorporated in pDAs (54, 55). Remarkably, patients participating in the needs assessment did not report any desire for being given numerical estimates of outcomes such as quality of life or complications, neither did participants in usability testing and in the trial report to have missed them. A first step might therefore be to investigate whether patients want to be informed with personalized outcomes when deciding about BR, and if so, in what format these can be optimally communicated. Although, from an ethical perspective and from the theory of SDM, patients should be given at least the opportunity to be informed with available (personalized) outcome data.

In future projects aiming at implementing SDM, other effective strategies beyond the usage of a pDA, should be undertaken to optimize the decision-making process regarding BR. For example, training of HCPs in their SDM skills. Patient decision aids are not intended as stand alone interventions, but as adjuncts to the consultation. The behavior and communication of clinicians during these consultations are essential for the application of SDM. Training professionals on SDM has been found to have positive effects on the application of SDM, and has been suggested as an effective strategy to implement pDAs in routine clinical practice (16, 56, 57). In our project, training was limited to a 30-minute meeting prior to the start of the trial. In this meeting, team members were introduced to the study and the pDA. However, as

some plastic surgeons reported that they did not discuss the pDA with their patients as they were not well-aquainted with the pDA, more training could have been beneficial.

FUTURE STEPS FOR RESEARCH

Based on the literature and our study on ways how to support women with breast cancer in making informed decisions about BR several knowledge gaps remain.

As Dutch SDM initiatives are still growing and pDAs are increasingly produced, more attention should be given to ways of reducing time and resources for developing and testing pDAs, while maintaining their quality and monitoring their effects. Our project of developing and evaluating our pDA using an RCT was a resource-intensive excersise spanning multiple years. Although an Australian BR pDA was available (33), we argued that simply translating this tool into Dutch would not be sufficient, and we started our development from scratch. This approach is consistent with other studies that highlight the importance of contextual adaptations of an intervention validated elsewhere to ensure it is fully acceptable for the new context (58-60). To reduce the need for extensive development, several proposals have been made, such as the use of well-tested theory-based pDA templates and the use of existing evidence on decision support needs (instead of the performance of a needs assessment as part of the project) (47, 61).

This project focused on women considering immediate BR after mastectomy treated for invasive breast cancer and/or DCIS, and excluded women considering BR for other indications (such as women at risk for developing BC considering *prophylactic* mastectomy with or without BR) and on other timings (such as women considering delayed BR after they had already underwent mastectomy in the past). More research is required to understand the information needs of other subgroups of women considering the complex decision of BR and ensure optimal decision support, as at least some of these groups of women are known to have unmet information needs (62, 63). A recently started project (OPTIONS-study) will provide valuable insights on current decisions and information needs of women at risk for breast cancer and will deliver interventions to support these women and their HCPs in decision making.

A 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. Future projects focusing on outcomes of BR such as these, should take this long-term follow up into consideration.

CLINICAL IMPLICATIONS OF FINDINGS

Patients who utilized the pDA benefitted from the pDA by feeling better prepared for decision making. Furthermore, they highly valued the pDA. Plastic surgeons also expressed a positive attitude toward using the pDA in clinical practice. Therefore, we conclude that our rigourously developed BR pDA is a valid means of supporting women in making complex decisions about immediate BR in clinical practice. The tool is currently available for all women considering

immediate BR in the Netherlands. Efforts should be made to maintain the pDA and keep the content up to date with new BR options and latest evidence, support its nationwide implementation and keep monitoring the experiences of its end-users in routine clinical practice.

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Appendices

SUMMARY

The decision for immediate breast reconstruction (BR) is a preference-sensitive decision. For preference-sensitive decisions, shared decision making is propagated but not yet properly implemented. In women considering BR, prior studies identified unmet decision support needs. Patient decision aids (pDAs) have been found to support the process of shared decision making in a variety of healthcare decisions.

With this thesis we aimed to optimally support women in making an informed decision about BR. For this purpose, we developed and evaluated an online pDA for breast cancer patients considering immediate BR after mastectomy.

We addressed the following research questions:

1. What are the information needs of patients and healthcare professionals regarding the decision about breast reconstruction?
2. Is the pDA acceptable and usable for patients and healthcare professionals?
3. What are the levels of decisional conflict in patients considering immediate BR, and what factors are associated with clinically significant decisional conflict?
4. Is the pDA effective as compared to care-as-usual?
    a. What is the effect of the pDA in reducing decisional conflict?
    b. What is the effect of the pDA on the decision-making process, decision quality, and patient-reported health outcomes?
5. What are the experiences of patients and plastic surgeons with the pDA in terms of usage and satisfaction with the tool?

In **chapter 2** we describe the steps in which we developed the pDA. First, we established a multidisciplinary team of 16 experts including plastic surgeons, oncological surgeons, psychologists, industrial designers, and researchers to co-create the pDA. Hereafter, we assessed patients' and healthcare professionals' information needs regarding the decision for BR. Interviews with 17 women who considered BR after mastectomy in the past demonstrated that patients had unmet information needs regarding their BR decision. Patients emphasized the challenging period in which they had to make a decision and reported a variety of personal motivations for their BR decision. For example women reported a desire for improving their body image after mastectomy with BR, or to recover as fast as possible after mastectomy without BR. They emphasized the importance of identifying personal values regarding the BR decision. Furthermore, patients reported a need for a clear overview of reconstructive options, information about the consequences of each option on patients' daily lives, and experiences of other women who previously faced the decision. Thirty-three healthcare professionals completed a study-specific questionnaire about their preferences for information about BR. They valued the development of a pDA, especially to prepare patients for consultation. In concordance with patients' and healthcare professionals' needs, the content, design and

technical system of the pDA were created. The developed pDA 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. As a final step in the development of the pDA, we tested the tool's acceptability and usability by using a think-aloud approach in six patients and by interviews with seven healthcare professionals and seven representatives of the Dutch Breast Cancer Patient Organization. Both patients and healthcare professionals perceived the pDA as informative, helpful and easy to use.

In **chapter 3** we describe the design of our multicenter randomized controlled trial to assess the efficacy of the pDA in reducing decisional conflict, improving the decision-making process, decision quality and health outcomes in breast cancer patients considering immediate BR. Women with breast cancer or ductal carcinoma in situ who will undergo a mastectomy and are eligible for immediate BR were invited to participate. Patients were allocated to either the intervention group receiving care-as-usual with access to the pDA, or the control group receiving care-as-usual including a widely available information leaflet. Participants completed online questionnaires at baseline prior to consultation with a plastic surgeon, 1 week after the consultation, and at 3 and 12 months after surgery. The primary outcome was decisional conflict, measured using the Decisional Conflict Scale. Secondary outcomes reflected the decision-making process (i.e. satisfaction with information, satisfaction with the plastic surgeon, preparedness for decision making, patients' perceived levels of shared decision making during consultation with their plastic surgeon, and patients' perceived level of involvement in decision making), decision quality (i.e. decision regret, and knowledge of BR), and patient-reported health outcomes (i.e. patients' actual choice regarding breast reconstruction, patient satisfaction with breast, satisfaction with outcome, body image, sexual functioning, breast symptoms, and anxiety).

In **chapter 4** we report on the levels of decisional conflict in patients considering immediate BR, and the identified factors associated with clinically significant decisional conflict (score > 37.5 on decisional conflict). For this purpose, we analyzed baseline data of our randomized controlled trial evaluating the efficacy of the pDA. Participants (N = 250) completed questionnaires assessing sociodemographic and clinical characteristics, decisional conflict and other patient-reported outcomes related to decision making such as BR preference, knowledge, information resources used, preferred involvement in decision making, information coping style, and anxiety. Multivariable logistic regression analysis was performed to identify factors associated with clinically significant decisional conflict. A majority of breast cancer patients considering immediate BR after mastectomy (68%) experienced clinically significant decisional conflict. Patients with a *slight* preference *for* BR, with *no preference* for or against BR, and with a *strong* preference for *no* BR were more likely to experience clinically significant decisional conflict than patients with a *strong* preference *for* BR. Furthermore, patients with more anxiety were

more likely to experience clinically significant decisional conflict. The findings emphasize the need for decision support, especially for patients who do not have a strong preference for BR.

Chapter 5 presents the results on the efficacy of the pDA in reducing decisional conflict, improving the decision-making process, decision quality and health outcomes. 250 patients from eight hospitals participated. Decisional conflict decreased in the course of time in both the intervention- and the control groups, with no between group differences. Patients in the intervention group felt better prepared for decision making than controls, measured by the Preparation for Decision Making Scale at one week after consultation with a plastic surgeon. No significant between group differences were observed in any other outcome.

Chapter 6 describes patients' and plastic surgeons' usage of and satisfaction with the pDA during the trial and their views on barriers and facilitators for widespread implementation. For this study, the intervention group of the trial completed process measures in the questionnaire at one week after consultation with a plastic surgeon and 22 plastic surgeons who participated in the trial completed a study-specific questionnaire. Also, usage data collected at the back-end of the pDA was analyzed. Almost all patients (97%) accessed the pDA. Most of them were satisfied with the pDA and would recommend the pDA to other women facing the same choice (72% and 74%, respectively). Patients' preferences for the type, the amount and the presentation of information they desired varied. Plastic surgeons were also satisfied with the pDA. Their key factors for implementation included the perceived match between information and clinical practice, costs, impact on patients, and support from peers and management for the tool.

Chapter 7 highlights the main findings of this thesis, including the limitations and strengths of our study, and suggestions for future research and clinical practice. This study resulted in the development of a pDA to support women with breast cancer and ductal carcinoma in situ in making informed decisions about immediate BR after mastectomy. The pDA addressed the information needs of patients and healthcare professionals, and was highly valued by the end users. Patients benefited from the pDA by feeling better prepared for decision making regarding immediate BR, compared to care-as-usual including a widely available information leaflet. However, our randomized controlled trial showed that the pDA had limited added value for patients' decision making in terms of decisional conflict, decision-making process, decision quality and patient-reported health outcomes. Several limitations of this thesis should be acknowledged, related to the study design and the generalizability. Several strengths are also worth mentioning, such as the rigorous developmental process of the pDA. Future research should focus on explaining the heterogeneous results regarding the efficacy of pDAs in different contexts and on ways how to optimally support other subgroups of women deciding about BR who were excluded in this project. Other strategies to implement shared decision making beyond the usage of a pDA, such as training of healthcare professionals in their SDM skills, should be undertaken to further optimize the decision-making process regarding BR. In clinical practice, efforts should be made to further optimize and maintain the pDA and on nationwide implementation of the tool in routine clinical practice.

SAMENVATTING (SUMMARY IN DUTCH)

De beslissing voor directe borstreconstructie na een volledige borstverwijdering is een voorkeursgevoelige beslissing. Voor voorkeursgevoelige beslissingen wordt samen beslissen steeds vaker beschouwd als de beste aanpak. Samen beslissen is echter nog niet goed geïmplementeerd in de spreekkamer. Keuzehulpen kunnen het proces van samen beslissen ondersteunen. Eerdere studies hebben aangetoond dat vrouwen die borstreconstructie overwogen onvervulde informatiebehoeften hadden.

Met dit project wilden we vrouwen optimaal ondersteunen bij het nemen van een geïnformeerde beslissing over borstreconstructie. Hiertoe hebben we een online keuzehulp ontwikkeld voor borstkankerpatiënten die directe borstreconstructie overwegen na een volledige borstverwijdering. Vervolgens hebben wij het effect van de keuzehulp onderzocht.

In dit proefschrift beantwoorden we de volgende onderzoeksvragen:

Als input voor de ontwikkeling van een keuzehulp voor borstkankerpatienten die borstreconstructie overwegen;
  - Welke informatiebehoeften hebben borstkankerpatiënten en zorgverleners bij het nemen van een beslissing over borstreconstructie?
  - Is de keuzehulp acceptabel en bruikbaar voor patiënten en zorgverleners?
- Hoeveel keuzestress hebben patiënten die directe borstreconstructie overwegen, en welke factoren zijn geassocieerd met klinisch significante keuzestress?
- Is de keuzehulp effectief vergeleken met standaard zorg?
  - Wat is het effect van de keuzehulp op het verlagen van keuzestress?
  - Wat is het effect van de keuzehulp op het verbeteren van het besluitvormingsproces, de kwaliteit van de beslissing, en patiënt gerapporteerde gezondheidsuitkomsten?
- Wat zijn de ervaringen van patiënten en plastisch chirurgen met de keuzehulp wat betreft het gebruik van en de tevredenheid met de interventie?

In **hoofdstuk 2** worden de stappen beschreven waarin we de online keuzehulp hebben ontwikkeld. Ten eerste hebben we een multidisciplinair team opgericht met 16 experts bestaande uit plastisch chirurgen, oncologisch chirurgen, psychologen, industrieel ontwerpers en onderzoekers. Vervolgens hebben we de informatiebehoeften van patiënten en zorgverleners met betrekking tot de beslissing voor borstreconstructie in kaart gebracht. Interviews met 17 vrouwen die in het verleden een borstreconstructie na een mastectomie hebben overwogen toonden aan dat patiënten onvervulde informatiebehoeften hadden met betrekking tot hun beslissing over borstreconstructie. Patiënten benadrukten de uitdagende periode waarin ze een beslissing moesten nemen. Patiënten benoemden verschillende persoonlijke motieven voor hun beslissing. Voorbeelden hiervan zijn de wens om met een borstreconstructie het lichaamsbeeld te verbeteren na de mastectomie en de wens om zo snel mogelijk te herstellen na een mastectomie zonder borstreconstructie. Patiënten benadrukten

het belang van het identificeren van hun persoonlijke waarden in het nemen van de beslissing. Daarnaast gaven zij aan behoefte te hebben aan een duidelijk overzicht van reconstructieve opties, informatie over de consequenties van de opties voor het dagelijks leven, en de ervaringen van andere vrouwen die eerder voor dezelfde beslissing stonden. Zorgverleners waardeerden de ontwikkeling van een keuzehulp, met name ter voorbereiding van patiënten op het consult. In overeenstemming met de behoeften van patiënten en zorgverleners werd de inhoud, het ontwerp en het technische systeem van de keuzehulp gecreëerd. De ontwikkelde keuzehulp bevatte drie onderdelen: 1) een uitreikvel voor oncologische chirurgen om de keuze te introduceren; 2) een website die patiënten zelfstandig thuis kunnen doornemen met een overzicht van de reconstructieve opties, de voor- en nadelen van elke optie, informatie over de consequenties van elke optie voor het dagelijks leven, waardeverhelderingsoefeningen, en ervaringsverhalen van andere patiënten; en 3) een samenvatting met daarop de waarden, voorkeuren en vragen van de patiënt om het gesprek met de plastisch chirurg te informeren en ondersteunen. Als laatste stap in de ontwikkeling van de keuzehulp hebben we een gebruikersonderzoek uitgevoerd door middel van een think-aloud procedure met zes patiënten en interviews met zeven zorgverleners en zeven vertegenwoordigers van de Borstkankervereniging Nederland. Zowel patiënten als zorgverleners beschouwden de keuzehulp als informatief, nuttig en gemakkelijk te gebruiken.

In **hoofdstuk 3** beschrijven we de opzet van onze multicenter gerandomiseerde gecontroleerde trial om de effectiviteit van de online keuzehulp te evalueren in het verminderen van keuzestress, het verbeteren van het besluitvormingsproces, de kwaliteit van de beslissing, en patiënt gerapporteerde gezondheidsuitkomste. Vrouwen met borstkanker of ductaal carcinoom in situ (DCIS) die een mastectomie ondergaan en geschikt zijn voor directe borstreconstructie, werden uitgenodigd om deel te nemen. Deelnemers werden verdeeld over twee groepen: de interventiegroep, die standaardzorg kreeg met toegang tot de online keuzehulp en de controlegroep, die standaardzorg kreeg met een bestaande informatiefolder over borstreconstructie. Deelnemers vulden online vragenlijsten in: baseline (T0), één week na het consult met een plastisch chirurg (T1), en 3 (T2) en 12 maanden (T3) na de mastectomie (met of zonder directe reconstructie). De primaire uitkomstmaat was keuzestress. De secundaire uitkomstmaten hebben betrekking op het keuzeproces (tevredenheid met de informatie, tevredenheid met de plastisch chirurg, de ervaren voorbereidheid om te beslissen, de ervaring van samen beslissen tijdens het consult met de plastisch chirurg en de ervaren betrokkenheid bij het besluitvormingsproces), de kwaliteit van de beslissing (spijt en kennis over borstreconstructie) en de patiënt gerapporteerde gezondheidsuitkomsten (de gemaakte beslissing, tevredenheid met de borst, tevredenheid met het resultaat, lichaamsbeeld, seksueel functioneren, borstsymptomen en angst).

In **hoofdstuk 4** presenteren we onze studie om keuzestress in kaart te brengen bij patiënten die directe borstreconstructie overwegen en om factoren te identificeren die geassocieerd zijn met klinisch significante keuzestress (score > 37.5 op de Decisional Conflict Scale). Hiertoe hebben we de baselinemeting van onze gerandomiseerde gecontroleerde trial

geanalyseerd. Deelnemers vulden vragenlijsten in over sociodemografische en klinische kenmerken, keuzestress en andere patiënt gerapporteerde uitkomsten met betrekking tot de besluitvorming, zoals voorkeur voor borstreconstructie, kennis over borstreconstructie, gebruikte informatiebronnen, gewenste betrokkenheid bij de besluitvorming, informatie-coping stijl en angst. Multivariabele logistische regressieanalyse werd uitgevoerd om factoren te identificeren die geassocieerd zijn met klinisch significante keuzestress. Een meerderheid van de borstkankerpatiënten die directe borstreconstructie overwegen na een mastectomie (68%) rapporteerde klinisch significante keuzestress. Patiënten met een lichte voorkeur voor reconstructie, zonder voorkeur voor of tegen reconstructie, en met een sterke voorkeur voor geen reconstructie hadden meer kans op klinisch significante keuzestress dan patiënten met een *sterke* voorkeur voor reconstructie. Bovendien hadden patiënten met meer angst meer kans op klinisch significante keuzestress. De bevindingen benadrukken de noodzaak van ondersteuning bij de beslissing, vooral voor patiënten die geen sterke voorkeur hebben voor borstreconstructie.

Hoofdstuk 5 presenteert de resultaten van de effectiviteit van de keuzehulp bij het verminderen van keuzestress, het verbeteren van het besluitvormingsproces, de kwaliteit van de keuze, en de patiënt gerapporteerde gezondheidsuitkomsten. Keuzestress nam in de loop van de tijd af in zowel de interventie- als de controlegroep, zonder verschillen tussen de groepen. Deelnemers in de interventiegroep voelden zich 1 week na het consult met de plastisch chirurg (T1) beter voorbereid op het nemen van de beslissing dan de controlegroep. Er werden geen significante verschillen tussen de groepen waargenomen in enige andere uitkomsten.

Hoofdstuk 6 beschrijft de gebruik van de online keuzehulp door patiënten en plastische chirurgen, de tevredenheid met de keuzeondersteuning, en barrières en bevorderende factoren voor implementatie van de keuzehulp. Bijna alle patiënten (97%) logden in op de keuzehulp. De meeste van hen waren tevreden met de keuzehulp en zouden de interventie aanbevelen aan andere vrouwen die dezelfde keuze moeten maken (resp. 72% en 74%). De voorkeuren van patiënten met betrekking tot de hoeveelheid informatie, het type informatie, en de presentatie van de informatie varieerden. Ook plastische chirurgen waren tevreden met de keuzehulp. Zij noemden als belangrijke factoren voor implementatie de overeenkomst tussen de informatie in de keuzehulp en de klinische praktijk, kosten, de impact op patiënten, en ondersteuning vanuit collega's en management voor inzet van de interventie.

Hoofdstuk 7 belicht de belangrijkste bevindingen van dit proefschrift, inclusief de limitaties en sterke punten van ons onderzoek, en suggesties voor toekomstig onderzoek en klinische praktijk. Dit onderzoek resulteerde in een online keuzehulp om vrouwen met borstkanker en DCIS te ondersteunen bij het nemen van geïnformeerde beslissingen over directe borstreconstructie na een mastectomie. De online keuzehulp voldeed aan de informatiebehoeften van patiënten en zorgverleners en werd gewaardeerd door patiënten, zorgverleners en leden van de Borstkankervereniging Nederland. Patiënten voelden zich

door de keuzehulp beter voorbereid op het nemen van een beslissing over reconstructie. Onze gerandomiseerde gecontroleerde trial toonde echter aan dat de keuzehulp beperkte toegevoegde waarde had voor de besluitvorming over directe borstreconstructie wat betreft het besluitvormingsproces, de kwaliteit van de keuze en patientgerapporteerde gezondheidsuitkomsten. Verschillende beperkingen van de studies worden beschreven, met betrekking tot de onderzoeksopzet en de generaliseerbaarheid van de resultaten. Ook worden sterke punten beschreven zoals het grondige ontwikkelingsproces van de keuzehulp. Toekomstig onderzoek zou zich moeten richten op het verklaren van heterogene resultaten met betrekking tot de effectiviteit van keuzehulpen in diverse contexten en op manieren om ook andere groepen vrouwen te ondersteunen bij de beslissing over borstreconstructie die zijn geëxcludeerd in dit project. Om de besluitvorming over borstreconstructie te optimaliseren dient meer aandacht te worden besteed aan andere effectieve strategieën voor het implementeren van samen beslissen, zoals het trainen van zorgverleners in hun vaardigheden op dit gebied. In de klinische praktijk zouden inspanningen zich moeten concentreren op het onderhouden en implementeren van de keuzehulp.

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ABOUT THE AUTHOR

Jacqueline ter Stege was born on December 15, 1985, in Woerden, the Netherlands. She completed her secondary education at the Erasmiaans Gymnasium in Rotterdam in 2004. She relocated to Delft, where she started a Bachelor's Degree in Industrial Design Engineering at Delft University of Technology. After the first year, she recognized her greater interest in human behavior and switched to studying Psychology at Leiden University, while maintaining Delft as her residence throughout most of her student years. Upon completing her Master's Degree in Clinical Neuropsychology at Leiden University in 2011, she ventured into the professional realm. She served as a research assistant on two studies on the neurocognitive functioning of children and men treated for an HIV-infection at the University Medical Center Amsterdam. Simultaneously, she took on a role as a project member at the Dutch Skin Foundation, gaining experience in the development, evaluation, and implementation of e-health applications. These experiences ignited her aspiration for conducting scientific research. In 2015, she initiated her Ph.D. project (TANGO project) at the Department of Psychosocial Research and Epidemiology at the Netherlands Cancer Institute (NKI-AVL), supervised by Prof. Dr. Eveline M.A. Bleiker, Dr. Hester S.A. Oldenburg, and Dr. Leonie A.E. Woerdeman.

Throughout her Ph.D. project, she actively contributed to the scientific committee of the Dutch Association of Psycho-Oncology and served as the chair of the Early-Career Research Network. In addition to her primary project, she engaged in multiple projects related to male breast cancer, the uptake of genetic testing in patients with a hereditary risk of cancer, informing family members at risk for cancer, and exploring information needs in breast cancer patients deciding about radiotherapy.

After her time as a Ph.D. student at the NKI-AVL, she worked as a project leader at Santeon, where she focused on utilizing outcome data for shared decision making. As of January 2024, she holds the position of registry coordinator at the Dutch Institute for Clinical Auditing (DICA).