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

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Chapter 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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