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Implementation of shared decision making in a clinical setting: how to make it fit in the daily workflow
Protocol for the development and testing strategies for the implementation of shared decision making in a clinical setting.

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Implementation of shared decision making in a clinical setting: how to make it fit in the daily workflow

Protocol for the development and testing strategies for the implementation of shared decision making in a clinical setting.

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Abstract

Background and aim

The majority of patients diagnosed with early stage breast cancer are in a position to choose between having a mastectomy or lumpectomy with radiation therapy (breast conserving therapy). Since the long-term survival rates for mastectomy and for lumpectomy with radiation therapy are comparable, patients' informed preferences are important for decision making. Although most clinicians believe they do involve patients in the decision-making process, the information that women with breast cancer receive regarding the surgical options is often rather subjective, and does not invite patients to express their preferences. Shared decision making is meant to help patients clarify their preferences, resulting in greater satisfaction with their final choice. Patient decision aids can be very supportive in shared decision making. We present the protocol of a study to beta test a patient decision aid and optimise strategies for the implementation of shared decision making regarding the treatment of early-stage breast cancer in the actual clinical setting.

Methods/Design

This paper concerns a pre-post implementation study, lasting from October 2014 to June 2015. The intervention consists of implementing Shared Decision Making using a patient decision aid. The intervention will be evaluated using qualitative and quantitative measures, acquired prior to, during and after the implementation of Shared Decision Making. Outcome measures are knowledge about treatment, perceived Shared Decision Making and decisional conflict. We will also conduct face-to-face interviews with a purposive sample of these patients and their care providers, to assess their experiences with the implementation of Shared Decision Making and the patient decision aid.

Discussion

The outcomes and findings of this study will be used as a basis to finalise a multi-faceted implementation strategy with the intention of testing the implementation of SDM and a patient decision aid in terms of cost-effectiveness, in a multicentre cluster RCT.

Study registration: NTR TC 4879

Keywords

Shared decision making

Quality improvement

Patient preferences

Patient participation

Decision support techniques

Introduction

Several studies have revealed that mastectomy and breast conserving surgery with radiation therapy are comparable in terms of local control and long-term survival.[1] In addition, some studies found no difference in quality of life between patients treated with breast conserving treatment or mastectomy, while other studies reported higher quality of life after breast-conserving treatment compared with mastectomy.[2] Many patients with early-stage breast cancer face the dilemma of choosing between these two options when considering breast surgery. Deciding between these two can be regarded as being influenced by patient preferences.

Evidence is growing that patient preferences may vary substantially between individuals.[3] In addition to survival, important factors in the decision-making process are the patient's age, family history and preference for reconstruction and quality of life. At the time of diagnosis, patients with breast cancer have their own values, concerns and knowledge, which can influence their treatment preferences.[2].

There is also increasing evidence that most patients want to be involved in treatment decisions.[4] For many patients, greater involvement in cancer treatment decisions can improve their knowledge about treatment benefits, enhance their satisfaction with the decision and improve their quality of life.[5, 6] It is important to present the information to patients as neutrally as possible and to involve them in the decision, in order to achieve a tailor-made, personalised treatment plan. Shared decision making (SDM) is regarded as a promising model to achieve such patient involvement. SDM has been defined as: 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences".[7]

Nevertheless, there is a problem with the implementation of SDM in clinical practice. Physicians typically feel they do not have the time, or lack the skills, to offer a complete and balanced presentation of the pros and cons of suitable medical options.[8] One measure to support SDM would be to use a patient decision aid, [9-11] which provides information facilitating discussion and deliberation about treatment options. There is strong evidence that these aids are effective in achieving informed preferences and decisions that are more in line with patient preferences.[4] The distribution and use of patient decision aids is also associated with increased knowledge about options and decreased decisional conflict.[10]

We feel that integrating a patient decision aid in the daily workflow at the clinic is the first move towards implementing more uniform and objective SDM in an actual oncology setting. In the USA and the UK, patient decision aids have been implemented as part of a usual care program in breast cancer centres. Both programs consist of various decision aid materials, including videos and booklets. In addition, both programs provide tools involving question listing, audio recording and note taking services by trained associates, who are either premedical interns or professional counsellors.[6, 12, 13] Although these are excellent initiatives, one should be cautious about merely copying these approaches, as implementation should take political, cultural and economic conditions into consideration [14, 15]

The challenge is to feasibly embed SDM and the patient decision aid in the clinical practice workflow. It is well-known that the implementation of new methods in clinical practice can be difficult, as clinicians have busy schedules filled with daily routines and there is often no obvious motivation nor time to change them.[16] Implementation strategies which do not focus on the problems that health professionals experience are less effective in accomplishing change. [1]

One single intervention is probably insufficient to achieve successful implementation of SDM using patient decision aids in clinical practice, so a systematic approach and carefully planning of implementation activities is needed.[15] Achieving successful implementation requires devoting attention to the process of developing the patient decision aid, its scientific basis, its format and its content. The Implementation of Change Model describes the involvement of different target groups in the 'development, testing and execution of an implementation'.[15].

Objectives and research questions

The objective of this project is to pilot-test and optimise strategies for the implementation of SDM for patients with early-stage breast cancer in an actual clinical setting.
Our hypothesis is that a multi-facetted strategy would enable us to implement SDM in such a way that it meets the needs and demands of both professionals and patients, without disrupting daily practice.

Primary research questions to support the development of the implementation strategy are:

1. What are the perceived barriers and facilitators, needs and preferences of patients and the professionals of the breast cancer team with regard to:

- the integration of the patient decision aid in patient care, making it acceptable for integration in the clinical workflow;
- the model of SDM, i.e. how, when and by whom it should be integrated in the clinical pathway;
- coaching of the professionals or instructions for SDM.

Secondary research questions to support the design of a large-scale study to evaluate the final implementation strategy are:

2 What is the impact of the implementation of the patient decision aid on the process of SDM, on the patients' knowledge, and on decisional conflict?

2b To what extent does the decision aid produce changes in the intended (i.e. preferences) and final treatment decisions by doctors and patients?

Method

General design

The design of the study is a pre-post implementation to beta test the patient decision aid and develop related implementation strategies in the clinic, involving quantitative and qualitative methods (Figure 1). For the sake of readability, the methods are described below in the sequence in which they are carried out, starting with the quantitative data collection (which is not in line with the above sequence of the research questions).

In the pre-implementation period (3 months), data are collected from early breast cancer patients (N=40) receiving care as usual. During the implementation period (5 months) data are collected from women (N=40) taking part in the process of SDM using the patient decision aid. This study will last from 1 October 2014 to 1 June 2015.

Setting

Data collection takes place in four Dutch hospitals in the western, central and southern parts of the Netherlands.

Participants

Patients

Each hospital will include 10 patients with newly diagnosed early breast cancer (stage I or II) who are eligible for breast conserving therapy or mastectomy as their primary therapy during the pre-intervention period. During the intervention period, each hospital will again include 10 patients (mother sample) with newly diagnosed early breast cancer (stage I or II) who are

eligible for breast conserving therapy or mastectomy as their primary therapy. From this sample, four patients of each hospital will be included to take part in the qualitative study during the post-intervention period (Table 1).

Table 1 Recruitment of patients

	Pre-intervention		Intervention		Post-intervention	
	Quantitative data collection		Quantitative data collection		Qualitative data collection	
	Hospital	Number of patients	Hospital	Number of patients	Hospital	Number of Interviews
Patients	H. 1 H. 2 H. 3 H. 4	10 10 10 10	H. 1 H. 2 H. 3 H. 4	10 10 10 10	H. 1 H. 2 H. 3 H. 4	4 out of the 10 4 out of the 10 4 out of the 10 4 out of the 10
Professionals					H1 H2 H3 H4	All participating professionals, but at least 1 surgeon and nurse per hospital

Inclusion criteria

The study will include patients diagnosed with stage I or II breast cancer, provided the two treatment options, mastectomy or breast conserving surgery with radiotherapy, are applicable. Eligible patient should be able to speak and understand Dutch.

Eligible patients will be identified at the multidisciplinary meetings of the breast cancer oncology team. The surgeon or nurse revealing the cancer diagnosis to the patients will inform them about this study. They will also provide the patients with an information letter to inform them about the aim and procedure of the study and the importance of their participation: the letter includes an informed consent form.

Handling of personal data will be in accordance with the Dutch Personal Data Protection Act and Medical Research (Human Subjects) Act).

The study has been approved by the Maastricht University Medical Centre (MUMC) ethics committee.

Professionals

In each hospital, all breast surgeons, radiation oncologists, nurse practitioners and nurses taking part in the education and decision-making process will be invited to participate in the intervention.

Intervention

The intervention consists of instruments and activities to implement SDM, including the patient decision aid, in the clinic.

A draft patient decision aid has been developed by a research team from MUMC and the Amsterdam Academic Medical Centre (AMC), based on existing patient decision aids (www.kiesbeter.nl), the Dutch clinical practice guideline on breast cancer, additional literature and expert opinion. This draft was alpha tested in a first trial round for professionals and patients. The decision aid is an easy-to-use website, which is made available to patients included in the study through a link and a password. It offers an explanation of the surgical options, as well as a brief overview of considerations that could be relevant to women regarding their own values, preferences and concerns and enables patients to navigate through the decision aid. Comprehensive information is presented about mastectomy and breast-conserving surgery, including numerical information about survival and recurrence rates, pros and cons of both treatments and side-effects. The verbal information is supported by pictures and graphs. Finally, the information is summarised in a factsheet. The decision aid further includes a number of questions to help women identify their values.[17] To make the information more accessible during the consultation, we have developed an additional options grid, in the form of a one-page table summarising the treatment options, which can also be used at home.

The patient decision aid will be made available to clinicians in February 2015. Participating clinicians need to learn to use the patient decision aid correctly. To achieve this, they will be instructed regarding SDM and its favourable effects. The instructions include a compact e-learning component with role-modelling and suggestions for integrating the patient decision aid in the clinical pathway and for task delegation. This will be provided in a tailored manner, with a certain degree of local adaptation allowed for each hospital and department.

Data collection and analysis

Quantitative data (see below) will be collected from 10 patients of each hospital during the pre-implementation period (1 November 2014 – 1 February 2015) and from 10 patients of each hospital during the intervention period (1 February 2015 – 1 May 2015), using

consecutive sampling of patients who fill in the questionnaires. In addition, 4 of the 10 patients included during the intervention period will be recruited by surgeons and nurses for collection of qualitative data (see below) from 1 May 2015 to 1 June 2015, that is, after the intervention. These patients will be selected using convenience sampling.

The results from both study groups will be compared by descriptive statistical procedures to identify differences between the two groups .

Quantitative data

Variables and instruments

A variety of instruments will be used to assess different outcome measures (table 2):

- Patients' knowledge about breast cancer and treatment options will be assessed using an adapted breast cancer information test.[18] This scale includes knowledge-type questions about early stage breast cancer treatment. Questions are answered using true or false.
- Decisional conflict will be assessed using the Decisional Conflict Scale (DCS).[19] This 16-item scale captures factors associated with decisional conflict or uncertainty. The DCS has three subscales: decisional uncertainty, factors that contribute to uncertainty, and perceived effective decision. Each of these items is scored on a five-point Likert scale from 1 (*strongly agree*) to 5 (*strongly disagree*).
- The process of SDM will be assessed by the perceptions of patients and clinicians, using the SDM Q9 instrument.[20] The Dutch version of the SDM Q9 has recently been validated. The instrument has a dyadic approach and consists of nine statements, which can be rated on a six-point scale from 0 (*completely disagree*) to 5 (*completely agree*). Summing all items leads to a raw total score between 0 and 45.
- The process of SDM will also be assessed by an independent observer from audio recordings of the consultations. The audio tapes will be rated with the Observer OPTION (Observing patient involvement) scale $^{12\ item}$ by two researchers.[21] The Observer OPTION scale $^{12\ item}$ consists of a set of competences, including problem definition, explaining legitimate choices, portraying options and communication risk, and conducting the decision process. The instrument aims to measure to what extent the patient is involved in the decision about the treatment, and consists of 12 items. The measurement level is ordinal with scores of 0 to 4.
- An audit will be conducted on the actual decision taken.
- The time that participants spend reading the patient decision aid will be recorded.

- The time spent by the professionals on consultation will be determined from the audio recordings.

Qualitative data

Variables and instruments

Information on the patient decision aid will be obtained from patients by means of semi-structured interviews which will be conducted during the post-intervention period.[22] An interview guide will be prepared for the patient interviews. The questions will focus on the content, presentation and navigation (user-friendliness) and the perceived usefulness of the patient decision aid (utility), and on the patients' experiences with the SDM process.

Qualitative data from the clinicians will be obtained through focus group or face-to-face discussions to evaluate the SDM and the use of the decision aid, during the post-intervention period. A question route [23] will be defined moving from general to more specific issues, focusing on their perceptions and experiences of applying SDM and the patient decision aid, as well as general appreciation and the intention to recommend the patient decision aid to colleagues. We will also discuss barriers and facilitators (positive features, changes needed, relevance, timing of use).

The interviews with patients and the discussions with the clinicians will be audiotaped and transcribed verbatim. Both data sets will be analysed using the constant comparison method.[24]

	Pre-intervention period		Intervention period		Post-intervention period
	Nov 2014 – Jan 2015	Feb 2015	Feb - May 2015	June 2015	May – June 2015
	Quantitative collection among patients		Quantitative collection among patients		Qualitative collection among patients and professionals
Measures					
Time to read the patient decision aid			X		
Knowledge about breast cancer and treatment (breast cancer information test)	X		X		
Decisional Conflict Scale (DCS)		X		X	
Perceived shared decision making (SDM-Q9)	X		X		
Process of shared decision making objectivized (OPTION)	X		X		
Consultation time	X		X		
Experiences,					X
Perceptions of feasibility,					X
Usability,					X
Utility,					X
Satisfaction					X

Discussion

Design

The design combines the strengths of quantitative and qualitative research.[25] The qualitative data obtained, which are based on human experience, will be examined in detail and in depth. The data will be used to assess the usability of the patient decision aid and the barriers and facilitators for the implementation of the decision aid in a small group, including both professionals and patients. We aim to evaluate the feasibility of the measurement instruments and the potential effect of the implementation strategies (instructions and patient decision aid) on the performance and experience of SDM compared to a historical control group, to enable a power calculation for a large multicentre RCT.

Sample size

Limitations of the sampling process: in view of the available time, the size of the target group and the nature of the intervention, it is not possible to conduct a random sampling. During the course of the study, all patients with early stage breast cancer in the participating hospitals will be invited to participate, until we reach the number of 10 participants for each hospital. Thus, over a certain period, the entire accessible population will be studied.[26] Inviting all members of the accessible population reduces the risk of bias. According to Johanson [27], a number of 30 to 40 patients is recommended for a pilot study whose purpose is a preliminary survey . The sample size in this study meets these recommendations.

Sample size for qualitative data collection in qualitative studies tends to be small. The number of participants needed depends on the point where data saturation is reached. Data saturation is expected to occur after 12 participants have been interviewed, provided these patients are not verbally vulnerable.[25] Since little is known about SDM and the use of patient decision aids in the clinical setting with respect to this data, this study will include 20 patients who are exposed to the intervention. We thus expect that data saturation will occur, and that the process will yield rich and in-depth findings.

Implementation of the intervention

Achieving success requires a systematic approach and careful planning of the implementation strategy. Joseph-Williams (2013) argues that barriers could be overcome by behavioural changes at the level of the patient, clinicians/healthcare team and the organisation in daily care. In this study we primarily focus on the clinicians/healthcare team and the organisation, since interventions are successfully implemented when barriers regarding these factors are overcome. [1, 28]

Worldwide training programs on SDM vary greatly in what they offer and how they present it. In addition, evidence of their effectiveness is inconclusive [29]. We have opted for e-learning because the purpose in this study is to examine the support and assistance required to develop suitable educational programmes in an RCT. E-learning might be a promising strategy to support the implementation of SDM and patient decision aids in actual clinical settings.

Measures

The SDMQ9 is a recently developed instrument measuring the perceptions of the stakeholders of the SDM process [30]. We decided to use this instrument because of the dyadic approach in SDM. Both doctors and patients are acknowledged and seen as equally involved in the consultation and decision making. A study concerning the use of the Dyadic OPTION scale supports this dyadic approach [31].

The process of SDM will be analysed in this study by means of the OPTION scale. This scale has been validated and is based on the phases of SDM. In her review, Stacey found two studies using the OPTION scale to evaluate the interaction between patient and professional. More recently, the Observer OPTION$^{5\ item}$ was introduced as an instrument focussing on essential aspects of SDM, providing shorter measurements. Despite its promising results, it needs more empirical work [32] to explore its scientific value. To our knowledge, there are few studies combining all of these measurements to gain extensive insights into the process of SDM and the implementation of a patient decision aid.

We originally intended to measure decisional conflict immediately after the completion of surgical treatment. But based on recommendations by of the professionals, whose experience is that satisfaction or regret does not occur until later in the process, we decided to measure decisional conflict three months after the surgical treatment.

In conclusion, this study seeks to examine the main obstacles and success factors for the implementation of SDM using a patient decision aid, and to determine the most favourable way to integrate this in the clinical pathway. In addition, we will investigate the impact of this implementation on several outcome variables. These will be used as a basis to design a multi-faceted complex implementation strategy, with the intention of testing the implementation of SDM and a patient decision aid in a multicentre cluster RCT.

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_Pag 2. _____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Pag 3. and 4.	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Pag. 7 _____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Pag 7 _____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Pag 7 _____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Pag 8 and 8 _	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Pag 5 _____	_____

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Pag 10 table 2	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Not relevant	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not relevant	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Not relevant	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not relevant _	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

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Protocol for a pre-post implementation study on shared decision making in the surgical treatment of women with early stage breast cancer.

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Primary Subject Heading:	Communication
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Abstract

Background and aim

The majority of patients diagnosed with early stage breast cancer are in a position to choose between having a mastectomy or lumpectomy with radiation therapy (breast conserving therapy). Since the long-term survival rates for mastectomy and for lumpectomy with radiation therapy are comparable, patients' informed preferences are important for decision making. Although most clinicians believe they do involve patients in the decision-making process, the information that women with breast cancer receive regarding the surgical options is often rather subjective, and does not invite patients to express their preferences. Shared decision making is meant to help patients clarify their preferences, resulting in greater satisfaction with their final choice. Patient decision aids can be very supportive in shared decision making. We present the protocol of a study to beta test a patient decision aid and optimise strategies for the implementation of shared decision making regarding the treatment of early-stage breast cancer in the actual clinical setting.

Methods/Design

This paper concerns a pre-post implementation study, lasting from October 2014 to June 2015. The intervention consists of implementing Shared Decision Making using a patient decision aid. The intervention will be evaluated using qualitative and quantitative measures, acquired prior to, during and after the implementation of Shared Decision Making. Outcome measures are knowledge about treatment, perceived Shared Decision Making and decisional conflict. We will also conduct face-to-face interviews with a sample of these patients and their care providers, to assess their experiences with the implementation of Shared Decision Making and the patient decision aid.

Discussion

The outcomes and findings of this study will be used as a basis to finalise a multi-faceted implementation strategy with the intention of testing the implementation of SDM and a patient decision aid in terms of cost-effectiveness, in a multicentre cluster RCT.

Study registration: NTR 4879

Keywords

Shared decision making

Quality improvement

Patient preferences

Patient participation

Decision support techniques

Introduction

Several studies have revealed that mastectomy and breast conserving surgery with radiation therapy are comparable in terms of local control and long-term survival.[1] In addition, some studies found no difference in quality of life between patients treated with breast conserving treatment or mastectomy, while other studies reported higher quality of life after breast-conserving treatment compared with mastectomy.[2] Many patients with early-stage breast cancer face the dilemma of choosing between these two options when considering breast surgery. Deciding between these two can be regarded as being influenced by patient preferences.

Evidence is growing that patient preferences may vary substantially between individuals.[3] In addition to survival, important factors in the decision-making process are the patient's age, family history and preference for reconstruction and quality of life. At the time of diagnosis, patients with breast cancer have their own values, concerns and knowledge, which can influence their treatment preferences.[2].

There is also increasing evidence that most patients want to be involved in treatment decisions.[4] For many patients, greater involvement in cancer treatment decisions can improve their knowledge about treatment benefits, enhance their satisfaction with the decision and improve their quality of life.[5, 6] It is important to present the information to patients as neutrally as possible and to involve them in the decision, in order to achieve a tailor-made, personalised treatment plan. Shared decision making (SDM) is regarded as a promising model to achieve such patient involvement. SDM has been defined as: 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences".[7]

Nevertheless, there is a problem with the implementation of SDM in clinical practice. Physicians typically feel they do not have the time, or lack the skills, to offer a complete and balanced presentation of the pros and cons of suitable medical options.[8] One measure to support SDM would be to use a patient decision aid, [9-11] which provides information facilitating discussion and deliberation about treatment options. There is strong evidence that these aids are effective in achieving informed preferences and decisions that are more in line with patient preferences.[4] The distribution and use of patient decision aids is also associated with increased knowledge about options and decreased decisional conflict.[10]

We feel that integrating a patient decision aid in the daily workflow at the clinic is the first move towards implementing more uniform and objective SDM in an actual oncology setting. In the USA and the UK, patient decision aids have been implemented as part of a usual care program in breast cancer centres. Both programs consist of various decision aid materials, including videos and booklets. In addition, both programs provide tools involving question listing, audio recording and note taking services by trained associates, who are either premedical interns or professional counsellors.[6, 12, 13] Although these are excellent initiatives, one should be cautious about merely copying these approaches, as implementation should take political, cultural and economic conditions into consideration [14, 15]

The challenge is to feasibly embed SDM and the patient decision aid in the clinical practice workflow. It is well-known that the implementation of new methods in clinical practice can be difficult, as clinicians have busy schedules filled with daily routines and there is often no obvious motivation nor time to change them.[16] Implementation strategies which do not focus on the problems that health professionals experience are less effective in accomplishing change. [1]

One single intervention is probably insufficient to achieve successful implementation of SDM using patient decision aids in clinical practice, so a systematic approach and careful planning of implementation activities is needed.[15] Achieving successful implementation requires devoting attention to the process of developing the patient decision aid, its scientific basis, its format and its content. The Implementation of Change Model describes the involvement of different target groups in the 'development, testing and execution of an implementation'.[15].

Objectives and research questions

The objective of this project is to pilot-test and optimise strategies for the implementation of SDM for patients with early-stage breast cancer in an actual clinical setting.
Our hypothesis is that a multi-facetted strategy would enable us to implement SDM in such a way that it meets the needs and demands of both professionals and patients, without disrupting daily practice.

Primary research questions to support the development of the implementation strategy are:

1. What are the perceived barriers and facilitators, needs and preferences of patients and the professionals of the breast cancer team with regard to:

- the integration of the patient decision aid in patient care, making it acceptable for integration in the clinical workflow;
- the model of SDM, i.e. how, when and by whom it should be integrated in the clinical pathway;
- coaching of the professionals or instructions for SDM.

Secondary research questions to support the design of a large-scale study to evaluate the final implementation strategy are:

2 What is the impact of the implementation of the patient decision aid on the process of SDM, on the patients' knowledge, and on decisional conflict?

2b To what extent does the decision aid produce changes in the intended (i.e. preferences) and final treatment decisions by doctors and patients?

Method

General design

The design of the study is a pre-post implementation to beta test the patient decision aid and develop related implementation strategies in the clinic, involving quantitative and qualitative methods. For the sake of readability, the methods are described below in the sequence in which they are carried out, starting with the quantitative data collection (which is not in line with the above sequence of the research questions).

In the pre-implementation period (3 months), data are collected from early breast cancer patients (N=40) receiving care as usual. During the implementation period (5 months) data are collected from women (N=40) taking part in the process of SDM using the patient decision aid. This study will last from 1 October 2014 to 1 June 2015.

Setting

Data collection takes place in four Dutch hospitals in the western, central and southern parts of the Netherlands.

Participants

Patients

Each hospital will include 10 patients with newly diagnosed early breast cancer (stage I or II) who are eligible for breast conserving therapy or mastectomy as their primary therapy during the pre-intervention period. During the intervention period, each hospital will again include 10 patients (mother sample) with newly diagnosed early breast cancer (stage I or II) who are

eligible for breast conserving therapy or mastectomy as their primary therapy. From this sample, four patients of each hospital will be included to take part in the qualitative study during the post-intervention period (Table 1).

Table 1 Recruitment of patients

	Pre-intervention		Intervention		Post-intervention	
	Quantitative data collection		Quantitative data collection		Qualitative data collection	
	Hospital	Number of patients	Hospital	Number of patients	Hospital	Number of Interviews
Patients	H. 1 H. 2 H. 3 H. 4	10 10 10 10	H. 1 H. 2 H. 3 H. 4	10 10 10 10	H. 1 H. 2 H. 3 H. 4	4 out of the 10 4 out of the 10 4 out of the 10 4 out of the 10
Professionals					H1 H2 H3 H4	All participating professionals, but at least 1 surgeon and nurse per hospital

Inclusion criteria

The study will include patients diagnosed with stage I or II breast cancer, provided the two treatment options, mastectomy or breast conserving surgery with radiotherapy, are applicable. Eligible patient should be able to speak and understand Dutch.

Eligible patients will be identified at the multidisciplinary meetings of the breast cancer oncology team. The surgeon or nurse revealing the cancer diagnosis to the patients will inform them about this study. They will also provide the patients with an information letter to inform them about the aim and procedure of the study and the importance of their participation: the letter includes an informed consent form.

Handling of personal data will be in accordance with the Dutch Personal Data Protection Act and Medical Research (Human Subjects) Act).

The study has been approved by the Maastricht University Medical Centre (MUMC) ethics committee.

Professionals

In each hospital, all breast surgeons, radiation oncologists, nurse practitioners and nurses taking part in the education and decision-making process will be invited to participate in the intervention.

Intervention

The intervention consists of instruments and activities to implement SDM, including the patient decision aid, in the clinic.

A draft patient decision aid has been developed by a research team from MUMC and the Amsterdam Academic Medical Centre (AMC), based on existing patient decision aids (www.kiesbeter.nl), the Dutch clinical practice guideline on breast cancer, additional literature and expert opinion. This draft was alpha tested in a first trial round for professionals and patients. The decision aid is an expected to be easy-to-use website, which is made available to patients included in the study through a link and a password. It offers an explanation of the surgical options, as well as a brief overview of considerations that could be relevant to women regarding their own values, preferences and concerns and enables patients to navigate through the decision aid. Comprehensive information is presented about mastectomy and breast-conserving surgery, including numerical information about survival and recurrence rates, pros and cons of both treatments and side-effects. The verbal information is supported by pictures and graphs. Finally, the information is summarised in a factsheet. The decision aid further includes a number of questions to help women identify their values.[17] To make the information more accessible during the consultation, we have developed an additional options grid, in the form of a one-page table summarising the treatment options, which can also be used at home.

The patient decision aid will be made available to clinicians in February 2015. Participating clinicians need to learn to use the patient decision aid correctly. To achieve this, they will be instructed regarding SDM and its favourable effects. The instructions include a compact e-learning component with role-modelling and suggestions for integrating the patient decision aid in the clinical pathway and for task delegation. This will be provided in a tailored manner, with a certain degree of local adaptation allowed for each hospital and department.

Data collection and analysis

Quantitative data (see below) will be collected from 10 patients of each hospital during the pre-implementation period (1 November 2014 – 1 February 2015) and from 10 patients of each hospital during the intervention period (1 February 2015 – 1 May 2015), using

consecutive sampling of patients who fill in the questionnaires. In addition, 4 of the 10 patients included during the intervention period will be recruited by surgeons and nurses for collection of qualitative data (see below) from 1 May 2015 to 1 June 2015, that is, after the intervention. These patients will be selected using convenience sampling.

The results from both study groups will be compared by descriptive statistical procedures to identify differences between the two groups .

Quantitative data

Variables and instruments

A variety of instruments will be used to assess different outcome measures (table 2):

- Patients' knowledge about breast cancer and treatment options will be assessed using an adapted breast cancer information test.[18] This scale includes knowledge-type questions about early stage breast cancer treatment. Questions are answered using true or false.
- Decisional conflict will be assessed using the Decisional Conflict Scale (DCS).[19] This 16-item scale captures factors associated with decisional conflict or uncertainty. The DCS has three subscales: decisional uncertainty, factors that contribute to uncertainty, and perceived effective decision. Each of these items is scored on a five-point Likert scale from 1 (*strongly agree*) to 5 (*strongly disagree*).
- The process of SDM will be assessed by the perceptions of patients and clinicians, using the SDM Q9 instrument.[20] The Dutch version of the SDM Q9 has recently been validated. The instrument has a dyadic approach and consists of nine statements, which can be rated on a six-point scale from 0 (*completely disagree*) to 5 (*completely agree*). Summing all items leads to a raw total score between 0 and 45.
- The process of SDM will also be assessed by an independent observer from audio recordings of the consultations. The audio tapes will be rated with the Observer OPTION (Observing patient involvement) scale $^{12\ item}$ by two researchers.[21] The Observer OPTION scale $^{12\ item}$ consists of a set of competences, including problem definition, explaining legitimate choices, portraying options and communication risk, and conducting the decision process. The instrument aims to measure to what extent the patient is involved in the decision about the treatment, and consists of 12 items. The measurement level is ordinal with scores of 0 to 4.
- An audit will be conducted on the actual decision taken.
- The time that participants spend reading the patient decision aid will be recorded.

- The time spent by the professionals on consultation will be determined from the audio recordings.

Qualitative data

Variables and instruments

Information on the patient decision aid will be obtained from patients by means of semi-structured interviews which will be conducted during the post-intervention period.[22] An interview guide will be prepared for the patient interviews. The questions will focus on the content, presentation and navigation (user-friendliness) and the perceived usefulness of the patient decision aid (utility), and on the patients' experiences with the SDM process.

Qualitative data from the clinicians will be obtained through focus group or face-to-face discussions to evaluate the SDM and the use of the decision aid, during the post-intervention period. A question route [23] will be defined moving from general to more specific issues, focusing on their perceptions and experiences of applying SDM and the patient decision aid, as well as general appreciation and the intention to recommend the patient decision aid to colleagues. We will also discuss barriers and facilitators (positive features, changes needed, relevance, timing of use).

The interviews with patients and the discussions with the clinicians will be audiotaped and transcribed verbatim. Both data sets will be analysed using the constant comparison method.[24]

Table 2: Outcome measures

	Pre-intervention period		Intervention period		Post-intervention period
	Nov 2014 – Jan 2015	Feb 2015	Feb - May 2015	June 2015	May – June 2015
	Quantitative collection among patients		Quantitative collection among patients		Qualitative collection among patients and professionals
Measures					
Time to read the patient decision aid			X		
Knowledge about breast cancer and treatment (breast cancer information test)	X		X		
Decisional Conflict Scale (DCS)		X		X	
Perceived shared decision making (SDM-Q9)	X		X		
Process of shared decision making objectivized (OPTION)	X		X		
Consultation time	X		X		
Experiences,					X
Perceptions of feasibility,					X
Usability,					X
Utility,					X
Satisfaction					X

Discussion

Design

The design combines the strengths of quantitative and qualitative research.[25] The qualitative data obtained, which are based on human experience, will be examined in detail and in depth. The data will be used to assess the usability of the patient decision aid and the barriers and facilitators for the implementation of the decision aid in a small group, including both professionals and patients. We aim to evaluate the feasibility of the measurement instruments and the potential effect of the implementation strategies (instructions and patient decision aid) on the performance and experience of SDM compared to a historical control group, to enable a power calculation for a large multicentre RCT.

Sample size

Limitations of the sampling process: in view of the available time, the size of the target group and the nature of the intervention, it is not possible to conduct a random sampling. During the course of the study, all patients with early stage breast cancer in the participating hospitals will be invited to participate, until we reach the number of 10 participants for each hospital. Thus, over a certain period, the entire accessible population will be studied.[26] Inviting all members of the accessible population reduces the risk of bias. According to Johanson [27], a number of 30 to 40 patients is recommended for a pilot study whose purpose is a preliminary survey . The sample size in this study meets these recommendations.

Sample size for qualitative data collection in qualitative studies tends to be small. The number of participants needed depends on the point where data saturation is reached. Data saturation is expected to occur after 12 participants have been interviewed, provided these patients are not verbally vulnerable.[25] Since little is known about SDM and the use of patient decision aids in the clinical setting with respect to this data, this study will include 20 patients who are exposed to the intervention. We thus expect that data saturation will occur, and that the process will yield rich and in-depth findings.

Implementation of the intervention

Achieving success requires a systematic approach and careful planning of the implementation strategy. Joseph-Williams (2013) argues that barriers could be overcome by behavioural changes at the level of the patient, clinicians/healthcare team and the organisation in daily care. In this study we primarily focus on the clinicians/healthcare team and the organisation, since interventions are successfully implemented when barriers regarding these factors are overcome. [1, 28]

Worldwide training programs on SDM vary greatly in what they offer and how they present it. In addition, evidence of their effectiveness is inconclusive [29]. We have opted for e-learning because the purpose in this study is to examine the support and assistance required to develop suitable educational programmes in an RCT. E-learning might be a promising strategy to support the implementation of SDM and patient decision aids in actual clinical settings.

Measures

The SDMQ9 is a recently developed instrument measuring the perceptions of the stakeholders of the SDM process [30]. We decided to use this instrument because of the dyadic approach in SDM. Both doctors and patients are acknowledged and seen as equally involved in the consultation and decision making. A study concerning the use of the Dyadic OPTION scale supports this dyadic approach [31].

The process of SDM will be analysed in this study by means of the OPTION scale. This scale has been validated and is based on the phases of SDM. In her review, Stacey found two studies using the OPTION scale to evaluate the interaction between patient and professional. More recently, the Observer OPTION$^{5\ item}$ was introduced as an instrument focussing on essential aspects of SDM, providing shorter measurements. Despite its promising results, it needs more empirical work [32] to explore its scientific value. To our knowledge, there are few studies combining all of these measurements to gain extensive insights into the process of SDM and the implementation of a patient decision aid.

We originally intended to measure decisional conflict immediately after the completion of surgical treatment. But based on recommendations by of the professionals, whose experience is that satisfaction or regret does not occur until later in the process, we decided to measure decisional conflict three months after the surgical treatment.

In conclusion, this study seeks to examine the main obstacles and success factors for the implementation of SDM using a patient decision aid, and to determine the most favourable way to integrate this in the clinical pathway. In addition, we will investigate the impact of this implementation on several outcome variables. These will be used as a basis to design a multi-faceted complex implementation strategy, with the intention of testing the implementation of SDM and a patient decision aid in a multicentre cluster RCT.

Funding

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Author Contributions:

WS is the principal investigator of the study. WS, AB, TvdW developed the study protocol. TvdW obtained research funding. WS, AM, TvdW, LB, MS, CH all participated in the final design of the study and drafting/revising of this manuscript. All authors read and approved the final manuscript.

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_Pag 2. _____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Pag 3. and 4.	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Pag. 7 _____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Pag 7 _____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Pag 7 _____	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Pag 8 and 8 _	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Pag 5 _____	_____

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Pag 10 table 2	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Not relevant	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not relevant	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Not relevant	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not relevant _	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist