Towards Equity and Equality in Healthcare

Accelerating the implementation of shared decision-making in routine (oncology) practice

Haske van Veenendaal

PhD Thesis

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Op weg naar gelijkheid in de zorg

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Contents

Chapter 1

Introduction

In truth,
whatever is worth doing at all,
is worth doing well

(Philip Dormer Stanhope)

Introduction

The difficulty of applying shared decision-making (SDM) can be well illustrated by a clinical example. Patients facing the diagnosis of breast cancer have a choice between breast-conserving surgery (lumpectomy) or amputation of the entire breast (mastectomy). Radiation is normally necessary after a breast-conserving operation, but this is not common after a mastectomy. The 10-year survival hardly differs between patients who undergo one or the other procedure: it is equally safe, but the cosmetic consequences are different. In theory, there may also be an option to undergo no treatment, but then the tumour will continue to grow and may eventually cause a wound that becomes painful.

Mrs. Kong-sang is of Chinese descent and has come in with a suspicious spot in her left breast tissue. She has a limited command of the Dutch language and is accompanied by her son who translates parts of the conversation for her.

At the start of the consultation, the breast cancer diagnosis is communicated to her. In (simple) Dutch she indicates to the surgeon and nurse that she understands the diagnosis. She goes on to say that they “need to remove the entire breast because she is afraid of the cancer and the possibility of it coming back’. It is clear to the doctor that the patient prefers a mastectomy, and he confirms the possibility of performing an amputation. The doctor suggests scheduling the surgery in the short term. He briefly explains what is needed before the procedure can be performed. The option of breast-conserving surgery is not discussed. She is referred to the oncologist to discuss whether or not to have chemotherapy.

Then the patient and her son are left with the specialised nurse to be informed of what will happen next. They are asked if they have any questions. The patient ‘wants the whole breast gone’. The nurse confirms once again that it has been decided to amputate the entire breast. She assures the patient that she is well informed and that the patient is invited to participate in the decision-making process. She explains that SDM is a spearhead for the team and concludes by asking if the patient has any questions. The patient then starts formulating a question but has difficulty finding the right words. The patient turns to her son, and they speak briefly in her native language. Then the son asks the nurse whether ‘removing a small part of the breasts is also possible’? The nurse responds quickly by indicating that there is indeed a choice. And that both options are equally safe. The follow-up of the consultation is focused on the advantages and disadvantages of both options and what the patient considers important. Ten minutes later they decide together to undergo breast-conserving surgery with radiation.

This example first seems an easy target for applying SDM, but it is not. The removal of her entire breast was narrowly avoided. Provided she is well-informed and involved in the decision-making process, she will make the decision for breast-conserving surgery together with her practitioner. It illustrates that:

1. In daily practice, every patient is different and requires a tailored approach to achieve the desired level of SDM (‘**equity**’, i.e. adjusting the way individuals are considered based on their circumstances so that similar outcomes are achieved for everyone [1]).
2. People become vulnerable when confronted with an (oncological) disease, which hinders an equal cooperation of clinician and patient, which is a crucial condition for an optimal process of SDM (‘**equality**’, i.e. considering individuals equally regardless of their circumstances [1]. Note: Equality here means that patient and clinician are equal as people, not that all patients are treated equally).
3. In practice, several challenges arise in the application of SDM. This requires an effective and organised effort to strengthen the day-to-day application (**implementation**).

The example shows that this is particularly challenging for some patients and in some situations. Although in current practice a certain degree of SDM already takes place, applying SDM on a desired level and reaching equity and equality must be perceived as an art that requires skills. One that matters, because patients may regret choices that were not made after a thorough decision-making process. What actions could enhance the surgeon and the nurse to maximize the patient’s chances of making a decision together that best reflects her preferences? This case also illustrates that SDM is teamwork by definition. It is an interprofessional achievement in which organisational aspects, such as the availability of consultation time, information for empowerment of patients, guidelines, et cetera, can have a facilitating or hindering effect on the extent to which SDM can take place. In this thesis we explored how to better empower clinical teams to adopt SDM as a more effective form of communication.

What is shared decision-making?

The concept of SDM is believed to have originated 50 years ago [2]. Initially, a ‘contractual model’ was introduced, in which autonomy and responsibility for medical decisions could be shared based on mutual agreements. Consideration was given to how the relationship between patient and clinician can be based on good ethical principles. Two decades later, four models of patient communication have emerged as part of the doctor-patient relationship, with the deliberative model reflecting SDM [3]. In 1997 the term SDM appears for the first time in the scientific literature [4]. This was followed by a special issue in 1999 of the British Medical Journal, titled 'Embracing partnership', appearing with a couple dancing the tango on the cover [5]. Patients and relatives were found to have vastly different perspectives on what is important in communication [6], so it is imperative that they collaborate with their clinicians to achieve high-quality care [7]. This is seen as the beginning of a growing community focused on SDM. The rise in patient autonomy and patients' preference for participation in their healthcare decisions, reflects the shift from a predominantly paternalistic to deliberative or participatory nature of clinical decision making [7]. SDM is defined *as a collaborative process that integrates patient values and preferences with clinical evidence about available options and their risks and benefits, to arrive at patient-centred decisions about diagnosis, treatment or follow-up when more than one medically reasonable option is available* [8, 9].

In Western healthcare settings, SDM is seen as the pinnacle of patient-centred care [10,11], and an important pillar of value-based healthcare [12]. Over time, the scope of SDM seems extending not only to decision making in equipoise situations or preference-sensitive decisions, but also to choices that have a major impact on the patient's life, requiring the patient's commitment in carrying out the decision, or even to any decision [11,13,14].

Several SDM-models have been developed to address core elements of the process that is meant to take place [15,16]. These models share major components, but a uniform vision is still missing [15]. In the Netherlands, however, there is consensus about which elements of SDM are considered essential [17,18]:

1. The professional informs the patient that a decision is to be made and that the patient's opinion is important.
2. The professional explains the options and the pros and cons of each relevant option.
3. The professional and patient discuss the patient's preferences; the professional supports the patient in deliberation.
4. The professional and patient discuss patient's decisional role preference, make or defer the decision, and discuss possible follow-up.

Why is it important that shared decision-making is implemented (in oncology)?

SDM enables an active role and transform the patient-clinician relationship from the paternalistic model into a shared approach, especially in the context of preference-sensitive decisions [19,20]. The popularity of SDM stems from the positive effects that SDM and its promoting interventions and tools, such as decision aids, have shown for more than a decade: it improves knowledge, risk perception and congruence between informed values and health choices [21]. Patients probably have a more active role in decision making and more accurate risk perceptions and decision aids may improve values-congruent choices without having adverse effects on anxiety, health outcomes or satisfaction. These effects may appear to be even stronger in low-skilled health groups [22,23]. Similar results of SDM interventions, such as an improved confidence of patients in treatment decisions, satisfaction with treatment, and trust in their clinicians are also reported in oncology [24,25]. In addition, most patients prefer to be actively involved in decision-making, a trend that increases over time [26]. Moreover, SDM seems to improve clinician engagement with their patients - which is in line with the positive experiences reported by clinicians - and may thereby reduce burnout and promote well-being [27].

What makes applying shared decision-making in oncology (extra) challenging?

Equality and equity are highly relevant in the oncology setting, and SDM can be particularly valuable in the field of oncology. In particular, the diagnosis of cancer brings emotional distress, which affects the patient's information recall and decision-making process [28,29], making it difficult to participate in decision-making on an equal footing with the clinician. In addition, treatment choices and cancer mortality rates vary significantly by educational level [30], demonstrating that people do not have equal opportunities when it comes to the outcome of the decision-making process in today's health care system.

Positive effects of SDM are also reported in oncology [31], but its implementation might be extra challenging [32,33,34]. For most of the 123,000 Dutch patients who are diagnosed with cancer each year [35], a number that will rise particularly in Western societies [36,37], multiple diagnostic, treatment- and lifestyle options are available with side-effects that affect the patients' quality of life [31,32]. An increasing number of (former) cancer patients are living with long-term consequences of their treatment, as a result of improved life expectancy [38]. One of the obstacles for SDM in oncology, is that patients and clinicians differ in what they see as most important to cancer decisions [30,39]. An example of this is that clinicians appear to be more concerned about treatment-related side effects, while patients are more concerned about side effects affecting their quality of life (e.g., loss of libido, fatigue, hot flashes) [40]. The relatively high level of uncertainty about the benefits and risks of the treatment (especially the side effects, also in the longer term) [32,34,41], as well as the focus that both clinicians and patients may have on 'fighting cancer' makes adequate application of SDM more difficult [42,43]. In addition, relatively large oncology teams must be able to guarantee continuity in the decision-making process about different decisions at different times with different clinicians [31]. Observations of consultations in multiple cancer care settings show considerable room for improvement, for example for discussing the option to choose no (further) treatment [44], and exploring a patient's expectations (as part of SDM step 3) [45,46].

How can implementation science help?

SDM has proven to be an effective form of communication, but its adoption in routine clinical practice is limited [47,48]. Establishing effectiveness of an innovation does not guarantee its uptake into routine practice [49]. Leonardo da Vinci's put his finger on the sore spot as early as the 16th century: 'I have been impressed with the urgency of doing. Knowing is not enough, we must apply' [50]. He argued for creative use of knowledge and user-oriented knowledge generation. This transfer of knowledge from research to practice and policy can be presented as a pipeline in which the quality of the research delivered to practitioners and policymakers is safeguarded in successive steps. It takes on average more than ten years for new knowledge to take root in healthcare [51], because the relevance and adaptation of research to the needs and circumstances of that practice is generally lacking [51,52]. That is where implementation science comes into play: 'the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services' [53]. Rogers was (one of) the implementation front-runners: he outlined the spread of innovations as a social process with multiple determinants beyond the evidence supporting the innovation itself [54]. Essential to implementation science is that it does not focus on the effect of innovations, but rather on determining the factors that influence their adoption in everyday practice. Identifying barriers and facilitators to adoption at multiple context levels and designing appropriate implementation strategies accordingly can accelerate the adoption of evidence-based clinical innovations [55].

In the field of SDM, the empirical measurement of the interaction of clinicians and patients – an essential element according to the definition – was often lacking [56]. Instead, the emphasis was initially mainly on the development of decision aids, rather than other approaches to SDM [57]. In these studies, decision aids were investigated without the involvement of clinicians, and it is the very research on the extent to which SDM is applied in practice that reported considerable room for improvement [45,58]. In line with this development, incorporating patient values became essential for evidence-based medicine and quality improvement [59]. Translating scientific evidence into practice, including incorporating the patient perspective into guideline recommendations [60], did not prove easy. Lack of scientific evidence or its interpretation complicated the formulation of unambiguous recommendations in guideline working groups, and the guideline development methodology at the time left little room for tailored joint decisions by patients and clinicians based on scientific evidence and patient values [61,62]. This increased the call for SDM implementation [29,31,63,64], especially multilevel approaches focused on the levels of the team, organisation, and healthcare system [57,65,66].

Barriers to and facilitators of implementation can occur at different implementation levels: the innovation itself, the users of the innovation (patients and clinicians), the organisational context and socio-political context [67,68]. Considering each of these levels increases the likelihood of designing an effective implementation of change [68,69]. Examples of factors that are relevant in relation to SDM, are clinicians' attitudes toward SDM, lack of understanding in how to use decision aids and understand and undertake SDM, clinicians' belief that patients do not want decisional responsibility, competing clinical demands and the belief that SDM takes more time [63]. Many clinicians think that they already adequately involve their patients in decision making, and do not view SDM as core to their profession [70]. They have concerns about the workflow disruption that may be involved with implementing the process of SDM but benefit from SDM training and dedicated clinical leadership and need more incentives that stimulate the adoption of SDM in practice [45]. Patients are reluctant to actively participate in consultations, as they worry about being inadequate, bothersome, or claiming too much time [71]. As clinicians remain primarily responsible for the course of events in consultations, especially when patients are vulnerable as they are facing a serious condition, new effective approaches to (interprofessional) clinician training [72], are essential for designing successful implementation approaches.

Aim and research questions of the thesis

Driven by its positive results and expectations, SDM has evolved into an ethical necessity. The Dutch government, healthcare insurers, professional societies and patient organisations have set SDM high on the agenda [17] and want to actively support the implementation of SDM in policy statements or by financing implementation initiatives. However, as there is a lack of guidance about how to adopt SDM in routine practice, especially regarding approaches that involve a combination of promising interventions to boost the uptake of SDM in healthcare, the aim of our investigation was therefore to formulate, prioritize and test multilevel approaches for the implementation of SDM in daily practice.

The following question is central to this thesis: **what are contributing factors to a wider adoption of (a process of) shared decision-making in healthcare?**

Subquestions for this research are:

- What is an effective design of an implementation process to accelerate the adoption of SDM in clinical practice, addressing barriers and facilitators at the level of the innovation (e.g., decision aids, SDM-models, etc.), the user (patient and clinician), the social context (e.g., guidelines, care pathways, peer pressure) and the socio-political context (e.g., financing, legal aspects)?
- Does the introduction of additional reflection time (time-out) for people with breast cancer and implementation support for clinicians lead to more adoption of SDM by healthcare clinicians, a higher perceived involvement of patients in decision-making and other decisions, and what are hindering and facilitating factors?
- How can promising interventions in the field of clinician training, team collaboration, effective design of clinical pathways be incorporated in effective SDM implementation approaches?
- What are the experiences of oncology clinicians with the participation in a SDM implementation programme?

Outline of the thesis

In this dissertation, current issues in the field of the implementation of SDM in daily (oncological) care practice are investigated and discussed.

In **Chapter 2** the results of focus groups and interviews with SDM frontrunners are shown: what would be the design of an effective approach for the implementation of SDM in the Netherlands? What obstacles must be taken into account and how can they be overcome?

This is a prelude to **Chapter 3** in which a multilevel approach for the implementation of breast cancer in the operative phase is designed and applied to 6 breast cancer teams within one region (Utrecht). This approach is theoretically based on the implementation framework of Fleuren [64] and is substantiated with relevant literature. These 6 hospital teams, as well as patients, work together in this as an improvement collaborative to enhance peer learning, and they themselves contribute to a tailor-made implementation of the devised approach.

After evaluating and refining this multilevel implementation experience through a 'team-of-teams' approach, the programme is replicated in 5 other breast cancer teams, now in the systemic therapy phase. The training approach has improved, and the number of joint team meetings has decreased. In **Chapter 4** is reported whether these changes make it easier for clinicians to adopt SDM.

When we expose clinicians to an implementation programme, it is valuable to know how programme participants experience this themselves and what recommendations they have for improving the programme. In **Chapter 5** the experiences and recommendations of participants collected in a mixed-methods study of 11 hospital teams, are presented.

A systematic review and meta-analysis were conducted in **Chapter 6** to examine the barrier most commonly reported by clinicians to practice SDM: Is it true that increased use of SDM leads to longer patient consultation times? And are there any characteristics of SDM-promoting interventions that increase or decrease the risk of prolonging consultation time?

Most of the research in this dissertation focuses on the role of the clinician and the processes and context of the healthcare organisation. In **Chapter 7** a questionnaire study among a broad group of oncology patients is reported: how did they experience the decision-making process and which aspects would they like to draw more attention to?

Many of the lessons learned from the previous studies in this thesis are brought together in **Chapter 8**. In this study a protocol for a digital and widely scalable SDM learning module is described with the aim to improve the skills of clinicians in oncology, but also for an even wider application.

The discussion of the results of the research work in this thesis can be found in **Chapter 9.** This provides future directions for both research and practice.

The thesis is concluded with a summary, also in Dutch, a word of thanks, and personal information about the author.

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Chapter 2

Accelerating implementation of shared decision-making in the Netherlands: An exploratory investigation

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Abstract

Objective: To prioritize strategies to implement shared decision-making (SDM) in daily practice, resulting in an agenda for a nationwide approach.
Methods: This was a qualitative, exploratory investigation involving: Interviews (N = 43) to elicit perceived barriers to and facilitators of change, focus group discussions (N = 51) to develop an implementation strategy, and re-affirmation through written feedback (n = 19). Professionals, patients, researchers and policymakers from different healthcare sectors participated. Determinants for change were addressed at four implementation levels: (1) the concept of SDM, (2) clinician and/or patient, (3) organisational context and (4) socio-political context.
Results: Following the identification of perceived barriers, four strategies were proposed to scale up SDM: 1) stimulating intrinsic motivation among clinicians via an integrated programmatic approach, 2) training and implementation in routine practice, 3) stimulating the empowerment of patients, 4) creating an enabling socio-political context.
Conclusion: Clinicians mentioned that applying SDM makes their job more rewarding and indicated that implementation in daily practice needs ground-up redesign. The challenge is to effectively influence the behaviour of clinicians and patients alike, and adapt clinical pathways to facilitate the exploration of patient values.
Practice implications: Stakeholders should connect nationwide initiatives to pool information, and make the healthcare system supportive of implementing SDM.

Highlights

- Effective implementation of SDM should start bottom-up to align with each clinical context.
- Effectively engaging physicians is critical to making SDM part of usual care.
- Adapting clinical pathways and clinician and patient behaviour is key to implementation.
- At the national level, fragmented but promising initiatives should be coordinated.

Introduction

Shared decision-making (SDM) combines patient-centred communication skills with evidence-based medicine to achieve high-quality patient care [1]. It facilitates a process of collaboration and deliberation, based on “team talk,” “option talk,” and “decision talk” [2]. Professionals may use several steps and accompanying communication strategies to implement SDM [3]. While there is convincing evidence for the use of patient decision aids to support SDM [4], most of these aids have not subsequently been implemented in the complexity of clinical practice. Observed levels of patient involvement during clinical consultations suggest there is considerable room for improvement [5].

Tailored interventions can be used to overcome barriers and enable the desired change [6–10]. Barriers to and facilitators of implementation – or determinants for change – can occur at four implementation levels: (1) the innovation (the concept of SDM), (2) users of the innovation, (3) organisational context and (4) socio-political context [10]. Considering each of these levels increases the likelihood of designing an effective implementation of change [9–11]. With regard to the concept of SDM (1), opinions differ about what SDM entails and how best to put it into practice [2,12]. At the level of the patient (2), an inability or lack of motivation to appraise information can hinder SDM [13]. Patients are reluctant to actively participate in consultations, as they worry about being inadequate, bothersome, or claiming too much time [14]. Patients often think that “the doctor knows best” and do not feel that it is important to contribute their personal preferences/circumstances [15]. Among clinicians (2), prominent barriers include time constraints and a perceived lack of applicability due to patient characteristics or the clinical situation [16]. Changing the attitudes and behaviour of clinicians is seen to be key to the implementation of SDM, because many clinicians think that they already involve patients in decisions, and do not view SDM as core to their clinical role [17]. A barrier at the organisational level (3) is clinician concern about current workflow disruption [18]. The lack of incentives that stimulate the adoption of SDM in practice has been noted as a socio-political barrier (4) to implementation [18].

Training clinicians, empowering patients, making high-quality patient decision aids easily accessible, and creating feedback through rewarding incentives could boost the uptake of SDM in healthcare [15–17,19–25]. The Dutch government, healthcare insurers, professional societies and patient bodies have actively supported the implementation of SDM either in policy statements or by financing implementation initiatives. They too report a lack of guidance about how to adopt SDM in routine practice [26]. The aim of our investigation was therefore to formulate and prioritize strategies for the implementation of SDM, based on identification of barriers for change, and resulting in an agenda for a nationwide approach. We selected front-runners in SDM implementation from various backgrounds to involve participants who can speak from experience. Having overcome barriers for change, we thought that they could help us to understand what it takes to successfully apply SDM in daily practice. This may yield new insights into how effective implementation in a local context can be aligned with a nationwide approach.

Methods

Study design

This qualitative exploration used different methods to enhance data validity [27], in line with the Standards for Reporting Qualitative Studies (SRQR) [28]. Semi-structured interviews, focus groups, and re-affirmation through written feedback were applied to explore how implementation can be accelerated. We combined individual interviews with two large focus groups to collect in-depth knowledge about SDM implementation in daily practice from different perspectives. Key literature [15,16,19–23], on barriers to and facilitators for implementing SDM was used to prepare the interviews, focus groups and reports, overseen by a six-member steering group. The interview guide, developed by the researchers (HV, GH) following discussion with the steering group, is shown in the Appendix.

Participants

We recruited Dutch SDM experts in the period between January 2015 and April 2016. We used purposeful sampling [29,30], for the identification and selection of clinicians from different healthcare areas, researchers, patient advocates and policymakers (all knowledgeable in SDM implementation, i.e. integrating decisions aids locally, training SDM, adapting clinical pathways, or creating (local or national) preconditions for SDM implementation).

A list of eligible candidates (N = 35) for the interviews and two focus groups (N = 58) were drawn up by the steering group. All participants were employed in primary and secondary healthcare (including mental healthcare), long-term care, patient advocacy, policymaking (including healthcare insurance), management, research, or in companies that develop or implement decision aids. Recruitment of participants continued until the investigators concluded that participants no longer provided new insights. Four additional participants were recruited in the course of the study based on the recommendations of participants, to cover adjacent areas such as ethics.

Procedures and data analysis

Face-to-face or telephone interviews were carried out to identify barriers for implementation. Participants were asked to (a) describe promising regional and national SDM initiatives, (b) describe barriers for implementation, and (c) suggest who should be involved in overcoming these barriers. Second, two focus groups were conducted to (d) categorize and prioritize activities in accelerating the implementation of SDM and (e) to use this information to draw up a supportive national agenda. Participants were (f) asked to suggest stakeholders for carrying out these activities.

Full verbatim transcripts were not made. Interviews were summarized as field notes and focus groups as written meeting minutes (HV, GH) and checked by the participants. These notes were read by one investigator, who then independently analysed meaningful observations using the determinant framework [10]. After analysing the interviews, two investigators selected discussion themes for the focus groups. The first focus group (n = 27) was geared towards hospital care, the second (n = 24) was expanded to general practice, mental healthcare and long-term care. Both focus groups lasted 3 h (with a 30-minute break). If participants were unable to attend the meeting, they arranged a replacement. Preliminary results of the interviews were presented during the focus groups; presentation of key findings was followed by an in-depth discussion about which implementation approach appeared to be most effective.

After the second focus group, overarching concepts were described in a draft report and discussed in the steering group, together with the meeting minutes, in order to identify key elements for a Dutch national agenda to scale up SDM. This resulted in a second draft report, which was then sent for feedback to all participants, and subsequently finalized in version 3.

Results

Participants

Forty-three interviews, 23 face-to-face and 20 by telephone, were carried out (Table 1) with a 100% response rate. Clinicians (33%) and researchers (35%) were strongly represented in the interviews. A total of 51 participants who were knowledgeable in SDM implementation attended two focus groups. Of the 30 participants invited to join the first focus group, 27 (90%) attended. Two participants had previously been interviewed. Participants were all employed by hospitals, and the topic

Table 1. Backgrounds of participants. Values are expressed as numbers (percentages).

Method	Healthcare professional	Patient advocate	Researcher	Policy maker	Other
Interviews (N=43)	14 (33)	3 (7)	15 (35)	7 (16)	4 (9)
Focus group					
1 (N=24)	5 (21)	2 (8)	6 (25)	10 (42)	1 (4)
2 (N=27)	11 (41)	3 (11)	8 (30)	5 (19)	0 (0)
Total (N=51)	16 (31)	5 (10)	14 (27)	15 (29)	1 (2)
Written comments on the consultation round (N=19)	2 (11)	2 (11)	12 (63)	3 (16)	0 (0)
Total number of participants	32	10	41	25	5

therefore focused on hospital care. Of the 24 participants (out of 28 invited; 86%) in the second focus group, nine (28%) had been previously interviewed. The majority (64%) of the participants worked in a clinical setting. The remainder (36%) worked in general practice, mental healthcare, or long-term care. Nineteen participants provided a total of 75 written comments on the (draft) study findings. Participants' comments and text changes proposed by the researchers (HV, GH) were distributed to the participants before finalizing the text. Analysis of the data and writing of the report took place from May 2016 to December 2016.

Barriers for the implementation of SDM

Barriers for implementation as indicated in the interviews are provided in Table 2. All groups of participants indicated that the lack of clarity about what SDM entails is felt more prominently by clinicians and patients than by managers and policymakers. Participants highlighted the risk that SDM is merely seen to involve the provision of decision aids to patients. The application of SDM was perceived to enhance work satisfaction and the relationship between clinicians and patients. Clinicians were unclear about the type of decisions/ consultations SDM could be advantageous for. Especially within the group of clinicians, misjudgement of the patients' preferences, lack of knowledge about what sharing decisions for one's behaviour in daily practice means, lack of skills, and a lack of role models were all perceived to be relevant factors. Motivated clinicians experienced barriers within the organisation when applying SDM; poor team- and management-support; lack of valid and clear patient information or high-quality decision aids, national guidelines that recommend only one option; and the failure of policymakers and external bodies to effectively support SDM. Moreover, the instruments that clinicians use for quality assurance – accreditation, and process redesign – were

Table 2. Perceived barriers for the implementation of SDM in random order per implementation level (C= clinicians; P = patients; M = policy makers; SDM = Shared decision making)

Implementation level	Barriers
1. Concept of SDM itself	• Concept of SDM is unclear for C & P • No common language for SDM • Unclear to healthcare workers when to apply SDM • Applying SDM is simplified into only handing over a decision aid
2a. Healthcareprofessional	• Negative attitude towards SDM • Misjudgement of patient preferences • Lack of knowledge about how to apply SDM • Lack of ability & skills in relation to applying SDM • No recognition that SDM is not applied ('we are already doing it')
2b. Patient	• Lack of awareness that multiple options exist • Lack of initiative in decision making • Fear of P to be seen by C as 'someone causing trouble' • One of three P has low health literacy • Relative knowledge backlog in relation to P
3. Organisational context	• Lack of role models amongst peers of C • Lack of team support for C • Lack of unambiguous information
4. Socio-political context	• Lack of support from M • Lack of reward from external bodies • Lack of flexibility in relation to applying SDM in national guidelines • Availability of high quality decision aids is fragmented • Quality instruments that C use are not aligned • SDM is part of existing act (WGBO), but lack of maintenance

found to be unsuitable for SDM. Clinicians noted that quality instruments focus on standardizing and increasing efficiency rather than having an eye for the individual differences between patients and incorporating these in the process of decision-making in practice.

Designing a nationwide approach to the implementation of SDM

From the focus groups, it became clear that an integrated approach for implementation was preferable to a more straightforward 'barrier-solution approach'. Experts indicated that a successful strategy requires different stakeholders working at different implementation levels simultaneously. By integrating strategies in overarching elements, a shared ambition becomes feasible and stakeholders can contribute in their own way and at their own pace. The following implementation strategies were identified, comprising four elements addressing several of the four implementation levels, and involving different stakeholders for each strategy (Table 3).

Table 3. Prioritized strategies for the implementation of SDM

Element for implementation agenda	Strategy (level of implementation: 1 = concept of SDM, 2 = health professional and/or patient, 3 = organizational context and 4 = socio-political context) (Stakeholder involvement: PB = professional bodies, PO = patient organizations, HI = healthcare insurance companies, GO = government, LM = local (quality) managers, RI = research institutes)
Integrated programmatic approach to build intrinsic motivation	Implement SDM via an integrated ‘national’ program to facilitate the connection of fragmented initiatives, increase critical mass and speed up the exchange of lessons learned regarding applied implementation strategies at national level (4) (PB, PO, HI, GO, LM, RI). Send a repetitive and consistent message that engages clinicians and patients to practice SDM and to facilitate a receptive culture in which SDM is perceived as usual practice (1, 2) (PB, PO, HI, GO, LM). Motivate clinicians to relinquish old habits and change care processes in order to better accommodate individual patient preferences, both in their team and in their organization (2) (PB, PO, LM). Place incentives accordingly (4) (PB, PO, HI, GO, LM). Incorporate SDM into professional curricula and inter-professional training programs (2, 4) (PB, LM). Monitor the progress of implementation and continuously connect the initiatives of professional bodies, patient organizations and healthcare insurance companies (4) (PB, PO, HI, LM). Adapt quality instruments, professional role descriptions, financial incentives and technological innovation (3, 4) (PB, HI, GO, LM). Offer legitimation and support via research institutes and government, and collaborate with industries (4) (PB, PO, GO, RI). .
Training and implementation of SDM in routine practice	Set up a follow-on series of implementation initiatives to seek ways to maximize the effect of SDM in clinical practice (2), covering the four implementation levels, and targeting issues relevant at the local context, including management support and ownership by clinicians (1, 2, 3, 4) (PB, PO, HI, GO, LM). Evaluate the experiments prospectively in order to better match the design of implementation support with the specific contexts in which they are applied (4) (PB, PO, LM, RI). Utilize existing professional exchange structures to reinforce knowledge sharing (2, 4) (PB). Pay special attention to process (re)design, including time-outs for patients in order to process information (3) (PB, PO, LM, RI). Test solutions for situations in which SDM may lead to loss of income for (some of the) clinicians in the organization (4) (HI, GO, LM, RI). Implement training methods that include reflective elements and real-time feedback on the clinicians’ performance (2) (PB, LM).

Table 3. - Continued Prioritized strategies for the implementation of SDM

Element for implementation agenda	Strategy (level of implementation: 1 = concept of SDM, 2 = health professional and/or patient, 3 = organizational context and 4 = socio-political context) (Stakeholder involvement: PB = professional bodies, PO = patient organizations, HI = healthcare insurance companies, GO = government, LM = local (quality) managers, RI = research institutes)
Stimulating the empowerment of patients and citizens	Help citizens and patients prepare for consultations with their clinicians, especially people with low health literacy (1, 2) (PB, PO, HI, GO). Make high-quality patient decision-making support tools available on a central public platform and give access to patient records (1) (PB, PO, HI, GO). Stimulate the involvement of patients at micro-, meso- and macro-levels, before, during and after implementation (1, 2, 3, 4) (PB, PO, HI, GO, LM).
Creating a rewarding socio-political context	Employ ground-up leadership by managers and policy makers within the context of scarcity in finance, resources, and time to make sure that the implementation of SDM is not held back by logistical, financial, and administrative factors (3, 4) (GO, LM). Adjust consultation time in line with patients' individual needs and pay attention to lack of reimbursement for time spent on SDM (4) (PB, HI, GO, LM). Anticipate budget shifts, organize the redesign of care pathways and ICT, redistribute tasks between team members, and allow flexibility with regard to national guidelines and other regulations that are imposed by external stakeholders (3,4) (PB, HI, GO, LM).

An integrated programmatic approach to build intrinsic motivation

Fragmented but promising initiatives should be connected on a national scale in order to pool information and speed up the exchange of lessons learned regarding implementation. Participants emphasized the importance of the intrinsic motivation of clinicians as SDM was perceived as making the clinician's profession more fun and challenging. The challenge remains how to appeal to - and leverage - clinicians' values and professional motivation to deliver truly patient-centred care. This could emerge as a key driver for clinicians to let go of old habits and change care processes to better accommodate individual patient preferences, both in their teams and in their organisations. Relevant parties surrounding clinical practice must also support implementation. Professional bodies, patient organisations, healthcare insurance companies, managers and government, should all monitor the progress of implementation and continuously strive to connect initiatives without slowing each other down because of their own delays and barriers. Inter-professional training targeting clinicians to help them understand which competencies are needed to apply SDM in daily practice, should be incorporated into professional curricula and training programmes. Simplistic financial incentives based on 'box-checking' behaviour demotivate clinicians. National parties could facilitate the implementation of SDM e.g. by putting innovators in the spotlight, adapting quality instruments (guidelines, standards, accreditation, process redesign) and professional role descriptions, providing financial incentives such as reimbursement of extended or extra consultations, and incorporating technological innovation (e.g. providing patients access to their medical records, question prompting, and tailored patient information services).

Training and implementation of SDM in routine practice

Participants indicated that future implementation initiatives in clinical practice should engage a new group of clinicians, patients, and policymakers, i.e. both the early and late adopters, to make SDM part of usual care. Pivotal to this implementation would be a consideration of working mechanisms in specific local contexts with a focus on process redesign and professional behaviour that supports the application of SDM in daily practice (i.e. by giving feedback to clinicians on their actual SDM performance). These experiments should focus on measuring the process of implementation in routine practice rather than proving the effectiveness of SDM once again.

Knowledge-sharing should be reinforced by including SDM in audits and regional network meetings, especially knowledge of process (re)design, Thus, we need to learn how to design local care pathways that facilitate time-outs for patients to process information and clarify preferences in decision-making, rather than merely improve efficiency. This would encompass several issues related to the scheduling of appointments, the effective use of decision tools and patient records, how clinicians work in a team (and contribute to multidisciplinary consultations), and who communicates what during the patient journey. National guidelines and other standards should be adjusted, and recommendations should highlight preference-sensitive decisions, indicating uncertainty and facilitating option awareness by describing alternative options.

Participants stressed that training will be vital in order to overcome the belief among clinicians that applying SDM does not differ much from their current practice. Effective training methods should include reflective elements and video/audio-feedback on the clinicians' performance. Feedback should be non-judgmental and individual, in order to help clinicians understand what exactly SDM means for their own daily practice. These individual training modules could be combined with e-learning, role play, workplace learning, and group discussions. The involvement of senior professionals in the training would be mutually beneficial.

Stimulating the empowerment of patients and citizens

Participants emphasized that citizens and patients alike need to know what SDM involves and why it might help. A national campaign, such as 'Ask 3 Questions', might convince patients about their role in decision-making and may encourage their clinicians to apply SDM. Patient records should become available and high-quality patient decision-making support tools for a significant number of health problems, should be made accessible via a public platform. Guideline recommendations could be linked to decision aids, integrated with patient records, and connected to clinical pathways. A Dutch guideline has been developed to define quality criteria for the development decision support tools, in alignment with clinical guidelines. Involving patients at the micro-, meso- and macro-levels, before, during and after implementation of SDM, should become standard procedure. Developing professional education should ideally include the participation of patient advocates and vice versa. Development of decision-making support tools should also be a joint effort involving patients and clinicians.

Creating a rewarding socio-political context

Participants could not point out exactly which socio-political issues hinder or facilitate them in terms of applying SDM but did indicate that promising SDM initiatives were held back by logistical, financial, and administrative factors. Stakeholders may wish to implement instruments that are often theoretically sound, but unknown and unfit for use in local practice. Clinicians felt that they had received insufficient support from directors, managers and policymakers in terms of adapting legislation to facilitate implementation of SDM in the consulting room. A real step forward requires local managers and leaders to enable a change of culture in which patient values and quality of life are the key drivers for health care delivery, and rules, standards and regulations are implemented accordingly. Performance indicators, including observation of consultations, can provide insights into team performance regarding SDM. These indicators can be used for improvement and also for governance, external review, and to design and implement supportive financial incentives. Respondents also proposed that general practitioners should get more time to coach patients, including those who are treated in hospital. Managers can play an important role by anticipating budget shifts, facilitate the redesign of care pathways, using supportive information technology, redistributing tasks between team members, and being more flexible with regard to guideline recommendations and other regulations that are imposed by external stakeholders. On a regional or national level, incentives such as the reimbursement of extra consultations as part of a programmatic approach are required.

Discussion and conclusion

Discussion

In the Netherlands, SDM is a topic of active debate [26,31]. Our exploratory study yielded strategies to foster a nationwide implementation of SDM in daily practice at national, organisational and individual levels. Key recommendations include an intrinsic and supportive approach to help clinicians to adopt new behaviour based on doing what is best for each individual patient, and the setting up of a ‘national’ programme for a systematic approach to implementation involving all stakeholders. This means training clinicians and giving feedback on individual performance and empowering patients to actively participate in the decision-making process. Directors, managers and policymakers should work in parallel to design a healthcare system supportive of implementing SDM in the consulting room.

Frontrunners in SDM implementation mentioned that applying SDM makes their job more rewarding. This may be a driver to better engage clinicians in a process of sense making [32], so that they understand what SDM means for their daily work. It is clear that SDM implementation influences every aspect of clinical practice, from practical matters such as the scheduling of appointments, to more complex issues such as how clinicians feel about their profession or are able to work in a (multidisciplinary) team, in addition to how guidelines should be developed and applied. Effective SDM implementation is an evolving process, starting locally at the coalface of care. It demands an integrated multilevel approach that utilizes the mechanisms that innovators have shown to be effective.

The barriers for implementation we identified corroborate those that others have reported [16,23]. Our results confirm that interventions targeting both patients and clinicians seem more promising than those targeting only one or the other [22]. Moreover, our study provides suggestions for helping clinicians understand what SDM really entails [2], and for increasing clinician support in order to facilitate meaningful SDM [33].

However, the frontrunners did not mention previously identified barriers such as time, competing demands from other medical problems and the psychological burden of deliberation. It is possible that innovators are highly motivated and have learned to effectively work around such barriers.

Next, we reinforce the earlier pleas for building systematic implementation strategies [15–17,19,20,22,23,34]. Our findings will be useful for implementing the next steps in engaging both clinicians and patients in SDM [15,17,20,33], and gaining a better understanding of the nature of professional and organisational resistance to SDM [12]. The goal is that SDM becomes an intrinsic part of a clinician's role. Ideally, SDM should be integrated in medical decision-making, shifting the paradigm towards a role in which coaching the patient in difficult decisions is key for clinicians [35,36], and providing a counterbalance to the introduction of many standardized procedures and to some of the criticisms raised against evidence-based medicine [37].

Our recommendation to include SDM in the curricula and in inter-professional training programmes, using reflective elements and real-time feedback on performance via recurrent audio, video, or real-life observations of consultations (i.e. using OPTION [38] or MAPPIN'SDM [25]), has already been found to be effective in improving SDM competencies [25].

Many strategies have been developed to increase the speed of implementation [39,40], and yet, the uptake of SDM in daily practice has been slow [5]. Our findings underline that we need to better understand the impact of SDM on patients and clinicians in their particular working context [17,41–43]. Our study also suggests the need for reorganising processes in healthcare organisations, e.g. making changes in local care pathways and finding additional time for reflection and exploring patient values ('time-out'), even if this sometimes requires lengthier [5], or additional consultations [44].

We therefore propose that the effective implementation of SDM can be seen as a "team sport", rather than a simple trick that can be learned and applied to practice by individual clinicians. This comprises clear procedures tailored to the specific setting, procedures for setting the indication for SDM, timely prescribing patient decision aids, defining a menu of options rather than a single option in multidisciplinary (oncology) team meetings, delegating specific tasks within these teams, and safeguarding the second consultation for the preference and decision talks. Effective principles of collaborative [45] and small-scale learning [46] can help design strategies that are intrinsically rewarding and take current practice as a starting point for implementation at microsystem, team, organisation and macro-levels. In order to accelerate learning about effective change, research projects should focus on how implementation initiatives perform in different contexts, for different groups of clinicians and patients.

Strengths and limitations of this study

We gathered data about implementation strategies from Dutch experts with varying backgrounds, using a combination of methods. This enhances the internal and external validity of our outcomes. However, some of the recommendations might be more relevant to the Dutch situation, i.e. the need to adapt local and national legislation regarding SDM. Second, our purposeful sampling predominantly selected pioneers in the area of SDM. We also had a high representation of frontrunners working in clinical practice. This is consistent with our sampling strategy and is not considered to be a limitation, but rather as useful in terms of appreciating what implementing SDM in daily practice requires. It has deepened our knowledge of effective approaches that can be used to support the implementation of SDM in a local context on the one-hand, and to align it with a nationwide approach on the other. It may have contributed to the high response rate for the interviews and focus groups, as innovators in the field may have been more positively inclined towards contributing to our study. Finally, the authors are also protagonists of SDM, and have been working for years to implement SDM. This could have caused a positive interpretation bias of the field notes of the interviews and focus groups.

Third, few patient advocates were present in our sample, which might have limited our ability to accurately reflect their views. However, the participating patient advocates were employed by two umbrella organisations for patient advocacy and represent a large body of patient stakeholders.

Finally, the presentation of our findings (in subdivisions based on a theoretical framework for implementation [10]) was designed to be transparent, accurate and understandable. Before finalizing the results, every participant had the opportunity to read the draft report and to discuss it within their stakeholder group.

Conclusion

This exploratory study yielded a multilevel approach for the implementation of SDM in the Netherlands. A targeted multilevel approach such as shown in Table A3 is needed to accelerate the implementation. As clinicians remain primarily responsible for the course of events in consultations, we expect that most progress will be made by learning how to effectively engage clinicians, influence their behaviour, and alter their clinical pathways. Our sample of innovators helps us to understand how successful implementation works and to identify key components that can be used to engage clinicians in applying SDM. Frontrunners are relatively innovative and skilled in breaking through (system) barriers. To ensure that less motivated groups embrace SDM, additional efforts are needed. We therefore stress the importance of changing the socio-political system. Indeed, we call for the redesign of the entire system of incentives, and the structures and processes that inhibit deliberation and collaboration, from the ground up. SDM can potentially emerge as a key driver in healthcare reform becoming truly person-centred rather than system-driven.

Practice implications

Many Dutch key stakeholder groups - such as professional societies, patient organisations, healthcare insurance companies and government - have formulated specific ambitions to promote SDM. National government should take the lead in inviting these stakeholders to coordinate their activities on a national scale and help adapt legislation to promote SDM. Efforts to support the implementation of SDM should start bottom-up and leave room for fine tuning at a local level. The key focus should be on process redesign and professional behaviour that supports applying SDM in daily practice in a specific context. Government and healthcare insurers can provide resources for initiatives to maximize the effect of SDM in daily practice, and promising initiatives can be coordinated on a national scale. Professional bodies should take the responsibility to teach clinicians how to coach patients, and work with patients on adapting guidelines and clinical pathways. Healthcare insurers can experiment with sensible and responsible ways of reimbursement and, together with patient organisations, empower citizens and patients to engage with their clinicians. Decision support tools should be made available via a central platform. All stakeholders need to put innovators in the spotlight and make clear that applying SDM enhances work satisfaction and improves the relationship between clinicians and patients.

Ethical approval

Ethical approval was not required as no patients were included in the study. All participants agreed to participate and to have their opinions and comments used for the research.

Data sharing

A background report with all names of participants and data tables can be accessed via the funders' website: https://publicaties.zonmw.nl/fileadmin/documenten/DoelmatigheidsOnderzoek/2Rapport_Verkenning_Samen_beslissen_FINAL.pdf. De-identified data can be requested from the corresponding author at haskevanveenendaal@gmail.com.

Transparency

The corresponding author (HV) affirms that the manuscript is honest, accurate, and a transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

Author contributions

Two investigators (HV, GH) designed the study. HV obtained funding. Two investigators (HV, GH) coordinated the research activities: selection of the study participants and study design, data collection, data analysis, data interpretation, and writing of the report. All authors had full access to all of the data (including notes from interviews, focus group conferences and tables) and, can take responsibility for the integrity of the data and the accuracy of the data analysis. TW, DU, AS, LM and CH contributed to implementation of the study and data interpretation and approved the final report for publication. HV is the guarantor.

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Appendix

Appendix Interview guide

1. Background
    - What is your current affiliation?
    - In what activities are you involved that are relevant for the implementation of SDM?
2. Experiences with SDM
    - What is your experience with the implementation of SDM in practice?
    - What are the main barriers and facilitators of SDM in practice?
    - When you would consider that implementation is affected by determinants at four implementation levels: (1) the concept of SDM itself, (2) the health professional and/or patient, (3) the organisational context and (4) the socio-political context, what would you add? (added for the second series of interviews)
3. Promising strategies for acceleration of SDM in practice
    - From your personal experience with (helping) implementing SDM in practice, what would you think are the most promising strategies?
    - If there's to be a 'national agenda for the implementation of SDM' what should be prioritized?
4. Involvement of experts and stakeholders
    - If there's to be a 'national agenda for the implementation of SDM', which role is to be played by whom?
    - Do you want to recommend experts in the field of implementation of SDM that we need to involve in our exploration?
5. Any other issues that should be addressed
    - Are there any other issues you want to discuss?

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Chapter 3

Effect of a multilevel implementation programme on shared decision-making in breast cancer care

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Abstract

Background: Women with newly diagnosed breast cancer face multiple treatment options. Involving them in a shared decision-making (SDM) process is essential. The aim of this study was to evaluate whether a multilevel implementation programme enhanced the level of SDM behaviour of clinicians observed in consultations.

Methods: This before–after study was conducted in six Dutch hospitals. Patients with breast cancer who were facing a decision on surgery or neoadjuvant systemic treatment between April 2016 and September 2017 were included, and provided informed consent. Audio recordings of consultations made before and after implementation were analysed using the five-item Observing Patient Involvement in Decision-Making (OPTION-5) instrument to assess whether clinicians adopted new behaviour needed for applying SDM. Patients scored their perceived level of SDM, using the nine-item Shared Decision-Making Questionnaire (SDM-Q-9). Hospital, duration of the consultation(s), age, and number of consultations per patient that might influence OPTION-5 scores were investigated using linear regression analysis.

Results: Consultations of 139 patients were audiotaped, including 80 before and 59 after implementation. Mean (s.d.) OPTION-5 scores, expressed on a 0–100 scale, increased from 38.3 (15.0) at baseline to 53.2 (14.8) 1 year after implementation (mean difference (MD) 14.9, 95% c.i. 9.9 to 19.9). SDM-Q-9 scores of 105 patients (75.5%) (72 before and 33 after implementation) were high and showed no significant changes (91.3 versus 87.6; MD -3.7, -9.3 to 1.9). The implementation programme had an association with OPTION-5 scores (β=14.2, P<0.001), hospital (β=2.2, P=0.002), and consultation time (β=0.2, P<0.001).

Conclusion: A multilevel implementation programme supporting SDM in breast cancer care increased the adoption of SDM behaviour of clinicians in consultations.

Introduction

Approximately 14 000 Dutch women are diagnosed with breast cancer every year [1]. The emotional stress following a diagnosis of breast cancer has been shown to affect both patient information recall and the decision-making process [2,3]. Ideally, clinicians should help patients to achieve an informed decision that best fits their personal preferences, circumstances, and concerns by involving these patients in a shared decision-making (SDM) process [4,5]. SDM has been promoted in cancer care for many years [5]. Despite the need for SDM, its implementation in clinical practice remains a challenge [6,7]. In general, clinicians either find it difficult to apply SDM [8], think that they already involve patients in decisions, or do not consider SDM key to their clinical role [6]. Practical problems, such as lack of time, perceived lack of applicability due to patient characteristics or the clinical situation [9,10], and a poor fit into workflow can all negatively influence implementation of SDM [6,11,12].

Particularly in breast cancer care, implementing SDM is even more challenging, given the many treatment options available [13–16]. Clinicians must explain the risks associated with various treatments and help patients to value the different options available [13,15,17]. Multiple decisions must be made over an extended period of time and involve different clinicians working within a team [14,17]. Observed levels of SDM behaviour during breast cancer consultations show considerable room for improvement [13,17–19]. Clinicians often fail to communicate to the patient that a decision needs to be made [18,20,21]. A focus on 'fighting' the cancer may inhibit the process of valuing different treatment options, and also in considering long-term consequences [20–22].

Interventions that have been proposed to promote SDM involve training clinicians (including the participation of patients) and using decision aids [14,23–27], providing feedback on performance in consultations [12,28], incorporating time-outs in care pathways [12,29], and use of incentives [6,11,12]. In the oncology setting, suggested interventions include implementing decision aids [27,30], acknowledging uncertainty, incorporating the patient's values and preferences into SDM, involving caregivers, and making allowances for the additional time required for SDM [14].

The aim of this study was to evaluate whether a multilevel SDM implementation programme would actually help clinicians to adopt new behaviour needed for applying SDM in daily breast cancer care, and to investigate whether a potential change in clinical behaviour was noticed by patients.

Methods

An unpaired before–after implementation study was used to evaluate whether a multilevel implementation programme would enhance the level of SDM of clinicians observed in consultations in a clinical outpatient setting, using the Standards for Reporting Implementation Studies (StaRI) [31] as a guideline.

Study population and selection

Seven breast cancer outpatient clinics of hospitals in the Utrecht region of the Netherlands were asked to participate in the study. Six hospitals were included (1 university hospital, 2 teaching hospitals, and 3 general hospitals). One hospital declined to participate, as doctors were not convinced the implementation would further improve their level of SDM. All clinicians involved in the decision process with the patient regarding surgical or neoadjuvant treatments were invited to participate in the study.

The recruitment of all consecutive patients with newly diagnosed breast cancer, and who faced a treatment decision, took place between July 2016 and October 2016 (preimplementation), and between April 2017 and August 2017 (postimplementation). Each patient was informed about the study and completed an informed consent form. Each patient was included only once. Patients who did not speak Dutch were excluded, unless they were accompanied by a person who spoke Dutch fluently. Approval for the study was obtained from the medical research ethics committee (W16.019).

Implementation programme

A theoretical framework for implementation was used for the design of the programme [32]. Responding to barriers to and facilitators of implementation at each of four implementation levels supports the design of an effective implementation. Four levels were used, and key factors for effective SDM implementation were incorporated into the programme [6,7,9,10,14,24–26,33–35] (Table S1, supplementary material).

Innovation: the concept of SDM

To help clinicians grasp what SDM entails for their behaviour during consultations, clinicians were asked repeatedly to reflect, using a practical four-step model for applying SDM, on their communication behaviour during feedback sessions, training, and in daily practice [36,37].

Users of the innovation
Personal and team feedback on SDM behaviour was provided, followed by interdisciplinary team training [26].

Organisational context
Teams looked at the allocation of time (time-outs) for SDM in clinical care pathways. Rapid cycle learning was included by explaining the plan–do–study–act cycle, and by encouraging teams to experiment with new ways of working and sharing their experiences at collaborative meetings and via the researchers [38,39]. The programme was tailored to the local context: each breast cancer team defined their goals within the scope of the programme and selected tools to support the implementation of SDM.

Socio-political context
Concurrent activities that might influence the level of SDM were monitored via a logbook. A clinician from each team, together with one of the researchers, kept this logbook. Patients were involved during all phases of the programme.

Data collection

All consultations relevant to the decision-making process — meaning one or more consultations conducted by one or more clinicians from the team to make one decision about breast cancer treatment — were audiotaped. Physicians and patients were aware of this and were instructed to proceed with their consultation as normal (preintervention) or to apply what they had learnt during the intervention (postintervention).
As the primary outcome measure, the OPTION-5 was used to rate clinicians' performance in terms of involving patients in the decision-making process during real-life consultations [40].

The OPTION-5 instrument is deemed suitable for use in oncology practice and scores five key decision-making behaviours [19]. Each of the five items were rated on a scale ranging from 0 (no effort made) to 4 (exemplary effort made), and the overall mean score was expressed on a scale of 0–100. This score reflects the extent to which the clinician showed the communicative behaviour needed to involve patients in the decision-making process. Higher scores indicate better SDM behaviour during the consultation; a minimum improvement of 10 points was considered clinically meaningful.

The secondary outcome measure was the patients' perceived level of SDM during the medical consultation(s), as measured with the SDM-Q-9 [29,41,42]. The nine statements were rated on a six-point Likert-type scale ranging from 'completely disagree' (0) to 'completely agree' (5). These questions were completed at the end of the final consultation when a decision about breast cancer treatment was made. The scores of the 9 items per patient were added up and multiplied with 20/9 to provide a percentage of the maximum score, ranging from 0 (no SDM) to 100 (maximum level of SDM). A maximum of two missing items were imputed from the mean of items that were scored. Questionnaires were excluded when the patient left three or more items unanswered [41].

Sample size calculation

A preintervention mean score of 39 was assumed, which is high compared with that in other studies [43]. A relatively high score was anticipated because of the considerable variation in means across breast cancer studies, and because two-way communication in (breast) cancer care is already considered important [13,18,19,24]. A total sample size of 120 patients was calculated, based on an increase in OPTION-5 score from 39 before implementation to 49 after implementation, with a standard deviation of 13, an intra-cluster correlation rho of 0.01 (to correct for interhospital differences), an α of 0.05, a power of 80%, and an effect size of 0.77. The aim was to include a total of 180 patients to account for possibly failed recordings or dropout of teams.

Data analysis

Three raters applied the OPTION-5 coding scheme (http://www. glynelwyn.com/observer-option-5-2014.html), refined for vascular surgery and oncology [44]. The manual was adjusted to be relevant for breast cancer surgery in order to decrease raters' uncertainty in scoring the audio recordings (Table 1). The first 10 audio recordings were coded by all three raters, and resulting scores and coding rules were discussed. Next, all audio recordings were scored independently by two raters. These scores were compared, and agreement over the final score was reached. Unweighted Cohen's κ values were used to determine the inter-rater agreement [45].

Statistical analysis

Descriptive statistics are presented as percentages or mean (s.d.) values. Differences are expressed as mean differences (MDs) with their 95 per cent confidence intervals. Pearson's v2 statistic was used to analyse differences between categorical variables. The implementation programme, duration of the consultation(s), hospital/team (number of recordings, starting level, composition), age, and number of consultations per patient before and after implementation were included in the regression model for the OPTION-5 score. Statistical analysis was carried out using SPSS Statistics v. 17.0 (IBM , Armonk, NY, USA). $P<0.050$ (two-sided) was considered statistically significant.

Table 1. Refined scoring definitions for the OPTION-5 manual.

Item	Description	Specification
1	The provider draws attention to - or re-affirms - a problem where alternate treatment or management options exist, and which requires the initiation of a decision- making process. If the patient draws attention to the availability of options, and the provider responds by agreeing that the options need consideration, the item can also be scored positively.	0 - not observed 1 - problem definition 2 - listing the options 3 - equality of the options 4 - is it clear/any questions
2	The provider reassures the patient - or re-affirms - that he/she will support the patient in becoming better informed. The provider will support/explain the need to deliberate about the different options.	0 - not observed 1 - decide together 2 - mention is it a difficult choice 3 - will support irrespective of the choice of the patient 4 - both options are OK, depends on the preferences of the patient, provider has a supportive role
3	The provider gives information - or re-affirms/ checks understanding - about options that are considered reasonable (including taking ‘no action’), and supports the patient in understanding/comparing the pros and cons.	0 - no information 1 - listing the options 2 - explaining pros and cons 3 - is it clear/any questions 4 - ask the patient to repeat the information
4	The provider supports the patient to examine, voice, and explore his/her personal preference in response to the options that have been described.	0 - not observed 1 - exploring preferences 2 - exploring concerns 3 - exploring expectations 4 - integrates preferences, concerns, and expectations for recommendation
5	The provider makes an effort to integrate the patient’s preferences in terms of decisions that are either made by the patient or arrived at by a process of collaboration and discussion. *Total score 0–20* *Rescale 0–100*	0 - not observed 1 - indicates need for decision 2 - additional information to review the decision at home 3 - appointment for evaluating the decision 4 - provider indicates that the patient can abandon earlier choice

Results

Six of the seven hospitals approached participated in the study. One hospital declined to take part. One of the six participating hospital teams did not perform the postintervention measurement because they thought that feedback from a new series of consultations would not improve their practice further.

Twenty-two clinicians (surgeons, nurses, nurse specialists) participated in both measurements, and six clinicians (four nurse specialists, two nurses) participated only in the postimplementation measurement. The participating clinicians before and after the implementation were similar with regard to background and education. The logbook showed that hospital teams did not participate in any concurrent activities unrelated to the programme that may have influenced the level of SDM. Four hospital teams adjusted their clinical pathway and/or appointment scheduling to allow for the implementation of SDM and to incorporate the time needed for patients to reflect on their decisions.

Patients' ages ranged from 32 to 91 (mean 62.3) years. The options discussed were mastectomy, lumpectomy, radiotherapy, neoadjuvant chemotherapy, and conservative treatment. Other options related to these decisions, such as breast reconstruction, the use of cooling caps during chemotherapy and extra diagnostic procedures, were not scored with the OPTION-5, but clinicians did receive feedback if considered relevant for applying SDM.

Characteristics of consultations

A total of 139 consultations of patients with newly diagnosed breast cancer were recorded, including 80 consultations before and 59 after implementation. The mean number of recorded consultations was 1.8 (range 1–7) consultations per patient, with a mean (s.d.) duration of 47.7 (30.5) (range 6–91) min per patient, and no difference between before (mean (s.d.) 46.0 (29.5) min) and after (50.1 (31.8) min) implementation (MD 2.3 (95% c.i. -4.1 to 8.8) min). The SDM-Q-9 was completed by 105 patients: 72 questionnaires before and 33 after implementation (response rate 75.5%). Seven questionnaires were excluded because patients left three or more items unanswered.

OPTION-5 scores

The three raters reached acceptable levels of inter-rater agreement (κ=0.57, κ=0.54 and κ=0.61). Mean (s.d.) OPTION-5 scores increased from 38.3 (15.0) at baseline (80 patients) to 53.2 (14.8) (59 patients) after implementation (MD 14.9, 95% c.i. 9.9 to 19.9). All five teams showed higher total OPTION-5 scores after the implementation for all items (Table 2).

Perception of patients

For all 105 respondents, the mean (s.d.) score for the perceived involvement in decision-making was 89.9 (12.5). The mean (s.d.) score was 91.3 (11.5) at baseline (72 of 80 respondents; response rate 90%) versus 87.6 (14.4) after implementation (33 of 59; response rate 56%). No significant differences were observed between SDM-Q-9 scores before and after implementation (MD -3.7, 95% c.i. 1.9 to -9.3).

Table 2. Observed patient involvement ratings of breast cancer consultations per team, using OPTION-5.

OPTION score (0-100)				
Hospital team		**Mean**	**N**	**SD**
1	Pre-implementation	44.1	17	18.3
	Post-implementation	54.1	11	14.6
2	Pre-implementation	46.7	12	14.2
	Post-implementation	56.9	8	12.5
3	Pre-implementation	35.0	16	10.0
	Post-implementation	65.0	9	7.5
4	Pre-implementation	28.1	13	11.1
	Post-implementation	38.2	14	11.2
5	Pre-implementation	35.6	16	12.9
	Post-implementation	57.1	17	12.6
6	Pre-implementation	43.3	6	17.5
Total	**Pre-implementation**	**38.3**	**80**	**15.0**
	Post-implementation	**53.2**	**59**	**14.8**

P-value .003, MD (95% CI) = 14.9 (12.2 – 17.7).

Regression analysis

Linear regression analysis showed a significant correlation between the implementation programme (β=14.2, 95% c.i. 9.7 to 18.6; P<0.001) and the OPTION-5 score. Other significant factors were hospital (β=2.2, 0.8 to 3.6; P=0.002) and duration of the consultation(s) (β=0.2, 0.0 to 0.4; P<0.001). The β-coefficient indicates the change in OPTION-5 score for a 1-unit change in the predictor variable. Consequently, the implementation programme resulted in a 14.2-point rise in OPTION-5 scores, whereas every minute of consultation time led to a 0.2 rise in OPTION-5 scores. No significant correlation was found for age or number of consultations per patient.

Discussion

In this study, a multilevel implementation programme appeared to improve the adoption of SDM behaviour of clinicians, as observed during breast cancer consultations over time. This programme appears useful in the context of daily care, as five of the six hospital teams involved were able to participate fully in the programme while continuing their regular clinical care. Patients varied and different hospital teams (academic, teaching, and rural hospitals) comprising of team members from different clinical backgrounds (surgeons, nurses, nurse specialists) were included. Hence, the authors consider these results generalizable to any breast cancer treatment team.

This implementation programme was developed by using a four-level framework for designing an effective implementation strategy [32]. It was grounded in relevant theoretical literature, to include promising elements that support the adoption of SDM by clinicians in daily practice. These elements are not a predetermined set of implementation activities, but were tailored to teams and clinicians, to facilitate alignment to diverging needs of the teams and individual clinicians with regard to SDM and timeout. For example, SDM attitudes, skills, and clinical pathways differ per clinician and team [12].

Baseline scores were relatively high, reflecting the present-day focus on communication with patients with breast cancer, compared with patients with other conditions [24], and a clinical condition for which multiple options are feasible [46]. This was no barrier to further improvement, given the 15-point increase in OPTION-5 scores found after implementation. This increase is relatively high compared with that found in other studies [43], although a more intense implementation approach in palliative cancer care showed a larger increase in standardized patients [24].

Hospital team was associated with OPTION-5 scores. In most previous studies, researchers rated one consultation carried out by one clinician, whereas here the team performance per patient was rated. The implementation design responded to the needs of individual clinicians within the team and the local context. Each team defined its own goals and decided which tools to use to support SDM. Tailoring a programme to the team's needs may evoke social support within the team to improve one another's behaviour, as well as the intrinsic encouragement needed for sustainable behavioural change [6,7,12].

Providing time-out for patients in the decision-making process was an explicit element of the implementation programme. This was based on patient feedback during the implementation process and the findings of previous research indicating that application of SDM might require lengthier or additional consultations [29,43]. This did not lead to an increase in either consultation time or mean number of consultations.

Patients did not perceive a higher level of SDM, a finding consistent with previous research [47–49]. Patient satisfaction was found already to be high before implementation, in agreement with previous findings [48,50].

Future research should focus on how to incorporate SDM effectively into clinical practice by improving implementation designs, aligning implementation efforts better to the local context, and finding better ways to evaluate any influence on patients' perceptions. To gain insight into which elements of the implementation programme are most helpful to support the change of clinicians, a logical next step is to investigate the relative contribution of each part of the implementation programme by a qualitative evaluation among study participants, and by monitoring the actual participation of each team and its members. Patients often do not know what SDM entails and any communication of uncertainty might lead to dissatisfaction among women facing cancer decisions [13]. It is therefore suggested that objective measurement of SDM, such as the OPTION-5 instrument, should be included in future research.

Limitations of this study included the design without a control group. It was difficult to identify any other factors (unrelated to the implementation programme) that may have influenced SDM over time [51]. Cluster randomization by hospital was considered, but found to be too expensive. Patients, clinicians, and investigators were not blinded to the intervention and the recordings, as the investigators had to provide relevant feedback as part of the implementation. Clinicians may have attempted to provide optimal consultations, even though they were instructed to perform as usual. Previous studies, however, have indicated that audio recordings of the consultations have no significant effect on clinician behaviour [52,53]. In addition, investigators may have been biased in their scoring of the OPTION-5, as they knew whether they were listening to preimplementation or postimplementation recordings.

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Table S1. Content of the multilevel implementation programme using a 4-level framework for designing an effective implementation strategy [31].

Level of implementation	Working mechanism	Form
Tools/ theory for SDM	What means SDM and what behaviour is effective during a breast cancer consultation	Clinicians were explained a clear practical 4-step model for applying SDM and mirror the model to their current communication behaviour during consultations. The four steps were used for reflection during all programme activities (sense making). Background information about the theory of SDM, presentations of the working sessions, etc. was also made available to the teams via a website.
	Supporting the use of effective decision tools to support SDM in daily practice	Teams were provided with an overview of tools that can enhance SDM, especially in relation to breast cancer surgery, such as handy cards & decision aids. For example, the decision aid 'Ask-the-3-questions' was developed and made available to the teams via a website.
User/ behaviour	Providing individual and team feedback on actual SDM behaviour (before & after implementation)	Each team collected audio-recordings from 15 patients pre-intervention and 15 patients post-intervention. Feedback was provided on the performance regarding SDM and timeout in a team meeting (listening to and discussing fragments of consultations) and a via a report (containing feedback for the team as a whole as well as individual feedback per patient).
	Training SDM via team training & e-learning	An inter-professional team training session (2-3 hours) addressed the application of SDM and timeout in consultations, using audio fragments recorded from members of the team. The training session was tailored to the needs of the team, by adapting it to the expressed needs of the team and the results of the pre-intervention measurement. An e-learning session (45 minutes) explained the theory of SDM and outlined how to apply a four-step model in practice with a video example.

Level of implementation	Working mechanism	Form
	Peer learning via collaborative working sessions for teams	Two or more team members were asked to participate in a total of four collaborative working sessions designed to facilitate process redesign, the application of SDM, timeout, and the selection of tools for SDM. The first session took place at the start of the project, two sessions took place in between the measurements, and one closing session took place at the end of the programme.
Process/ organization	Redesign pathway including SDM and timeouts, using rapid cycle improvement	Ask and support teams to include time-out & decision-tools in pathway. The Plan-do-check-act cycle was explained to teams and teams were encouraged to experiment with new ways of working that better provide room for SDM and timeout.
	Reconsider working process in relation to SDM	Ask and support teams to adapt multidisciplinary team consultation & reassign communication tasks between team members (medical specialists, nurses & nurse specialists).
Context	Facilitating a context that supports the implementation of SDM in daily practice	Identify barriers and facilitators for implementation in the hospital and discuss ways to respond to them at the start of the project with the team coordinator. Two team members (per hospital) were interviewed about experienced barriers and facilitators of the implementation programme. This information was fed back to the teams. Obtain commitment for time investment at the start.
	Access to implementation expertise on request	Offer expertise in the implementation of SDM, timeout, and quality improvement on request of the hospital team by the project team and/or experts.
Added to the levels: patient involvement	Partnering with patients and collecting patients' perspectives on SDM and timeout	Ensure that there was patient representation in the project-team, the collaborative working sessions and local team sessions. Teams were provided with the views of ex-breast cancer patients on the preferred number of consultations and the number of days they want in between consultations. A website survey was carried out and results were shared with the teams. Each team collected the questionnaire (SDM-Q9) of 15 patients pre-intervention and 15 patients post-intervention. The results of the questionnaire were fed back to the team via a report.

Table S2. Perceived involvement in decision making (SDM-Q9) during consultations.

	SDM-Q-9		
	Mean	N	SD
Pre-implementation	91.3	72	11.5
Post-implementation	87.6	33	14.4
Total	89.9	105	12.5
MD (95% CI)	3,74 (1,25 – 6,23)		

Supplementary material

Supplementary material is available at BJS Open online.

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Chapter 4

Effects and working mechanisms of a multilevel implementation programme for applying shared decision-making while discussing systemic treatment in breast cancer

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Abstract

Background: Enhancing the application of shared decision-making (SDM) is critical for integrating patient preferences in breast cancer treatment choices. We investigated the effect of an adapted multilevel SDM implementation programme in breast cancer care.
Methods: Breast cancer patients qualifying for (neo)adjuvant systemic treatment were included in a multicentre before–after study. Consultations were audio recorded between June 2018 and July 2019 and analysed using the five-item Observing Patient Involvement in Decision-Making (OPTION-5) instrument to score SDM application by clinicians. The Shared Decision-Making Questionnaire (SDM-Q-9) was used to rate patients' perceived SDM level. Consultation duration, decision types, number of options discussed and consultations per patient were monitored. Regression analysis was used to investigate the correlated variables and programme components.
Results: Mean OPTION-5 scores increased from 33.9 ($n = 63$) before implementation to 54.3 ($n = 49$) after implementation ($p < 0.001$). The SDM-Q-9 scores did not change: 91.1 ($n = 51$) at baseline versus 88.9 ($n = 23$) after implementation ($p = 0.81$). Without increasing consultation time, clinicians discussed more options after implementation. The regression analysis showed that exposure to the implementation programme, redistribution of tasks and discussing feedback from consultations was associated with a higher level of SDM.
Conclusion: The multilevel programme helped clinicians achieve clinically relevant improvement in SDM, especially when it is tailored to (individuals in) teams and includes (e-)training, discussing feedback on consultations and redistribution of tasks.

Introduction

Breast cancer is the most common cancer in women worldwide [1]. Patients with early stage breast cancer have a (very) good long-term prognosis, with a five-year survival of 85–90% in high-income countries [2]. Chemotherapy or hormone therapy improves survival [3], but this benefit only applies to a small proportion of patients and must be weighed against the high risk of side effects. As these choices have significant implications for the patients' quality of life and clinician preferences can strongly influence treatment decisions, it is critical to explicitly integrate patient preferences in their treatment choices [4].

Shared decision-making (SDM) is a collaborative process that integrates patient values and preferences with clinical evidence about available options and their risks and benefits, to arrive at patient-centred decisions about diagnosis, treatment or follow-up when more than one medically reasonable option is available [5,6]. Especially in Western healthcare settings, SDM is considered as an important pillar of patient-centred care and value-based healthcare [5,7], and an ethical imperative [8]. Designating concrete steps that address core elements in the SDM process that is meant to take place, e.g., step models and recognizable examples, can help raising clinician's awareness and make them realize what SDM means for their own context [9,10,11].

The popularity of SDM is understandable given the positive effects: SDM-enhancing interventions such as decision aids make patients, also in low health-literacy groups, more active in decision making while making choices that better match their personal values, without adverse effects on anxiety, health outcomes or patient satisfaction [12,13,14]. Similar outcomes, such as increased patient confidence in treatment decisions, treatment satisfaction and confidence in their clinicians, are reported in oncology [15,16]. Positive experiences are also reported for clinicians, such as a lower risk of burnout [17], and encounters with breast cancer patients that are both more structured and more interesting [11]. In addition, over the years, patients themselves want to become more involved in decision-making [18]. This is especially challenging for clinicians to achieve in decisions about systemic therapy with (older) breast cancer patients, as patients might seem passive but do prefer involvement and, therefore, need explicit encouragement to participate [19].

However, determining the effectiveness of an innovation does not guarantee its inclusion in daily practice [20]. This also holds for SDM [21,22], especially in the case of (breast) cancer given its life-threatening character and the complex medical information of the many available options [23]. Therefore, implementation efforts have increased in recent years [24]. This has taught us that multilevel approaches seem necessary, using different interventions in a tailor-made approach [25,26,27]. Ultimately, implementing SDM may require that the organisational culture is transformed, and leadership and rewards focus on adopting (more) SDM as part of continuous improvement [28,29]. Direct observation of clinical encounters followed by structured feedback and coaching is educationally valuable [30] and seems promising for improving SDM behaviours [31,32,33]. Poor post-trial implementation of decision aids can be improved by incorporating them in the clinical workflow, especially by an accurate timing and an explicit report of the multidisciplinary team that treatment "is to be discussed with the patient" [34].

In a previous study on which this research builds, a multilevel implementation programme appeared to improve the adoption of SDM behaviour of clinicians over time, as observed during consultations regarding the surgical phase of breast cancer [25]. This programme was grounded in theoretical literature and used a four-level framework for designing an effective implementation strategy [35]. In an evaluation study, clinicians especially appreciated that the programme: (1) made clear how SDM was of benefit to themselves and patients, (2) contained both theory-based and practical feedback and training, (3) included a focus on the team and care pathway and (4) involved patients [11]. The feedback of the participants was used to refine the programme. While it confirmed that a multilevel systematic approach is needed to achieve SDM implementation, this and other similar studies fail to provide any clues as to which parts of the programme are most effective.

The primary aim of this study is to investigate whether an improved multilevel SDM implementation programme, which explicitly provides patients with reflection time, helps clinicians to adopt SDM while discussing systemic treatment in breast cancer and whether patients experience more involvement in decision making. This study attempts to reveal the relative contribution of programme components (working mechanisms) that lead to increased SDM application. The second study aim is to detect whether applying more SDM influences important features of consultations, such as the consultation duration, the number of options discussed and the type of decisions made.

Materials and methods

Study Design

The Standards for Reporting Implementation Studies (StaRI) was used as a guideline for the design and report on the study [36]. An unpaired before–after implementation study was used to evaluate whether a multilevel implementation programme would enhance the level of SDM of clinicians observed in consultations [25].

Study population and selection

Five breast cancer outpatient clinics in the Amsterdam region of the Netherlands were invited to participate in the study. An intake interview was conducted with each hospital. A hospital team was included if they were willing to invest the time required for the project and if training in SDM had not recently taken place. Both the clinical team and the research team had to be positive about collaboration.

All clinicians involved in the patient's decision-making process regarding systemic treatments for breast cancer were asked to participate in the study. Clinicians had to have the intention to participate in both the pre-test and the post-test. If a team did not accept the invitation, a team from another hospital was approached.
Patients qualified for inclusion if diagnosed with early-stage breast cancer with an indication to discuss (neo)adjuvant systemic treatment. Patients were eligible if they, or an accompanying person, spoke Dutch fluently. Each patient received information about the study and what their cooperation would entail. All patients completed an informed consent form. Each patient was included only once.

Ethical approval

Approval for the study was obtained from the medical ethics review board (W16.019).

Implementation programme

The initial design of the implementation programme has been described in prior publications [11,25]. It was theory-based, drew implementation lessons from previous research and paid attention to explicitly giving patients time to reflect on current choices. This theoretical framework for implementation was used to respond effectively to identified barriers to and facilitators of SDM implementation [35]. The model distinguishes four implementation levels, on which promising implementation strategies are designed: (1) Innovation: the concept of SDM; (2) Users of the innovation; (3) Organisational context; and (4) Socio-political context.

The programme was initially tested from April 2016 to September 2017, for early-stage breast cancer (surgical) treatments among six outpatient teams of hospitals in the Utrecht region [25]. At the end of the implementation, the programme was evaluated [11]. The outcomes of the evaluation of phase 1 were used to adapt the implementation programme for this study (Table S2). The following changes were made to the programme. (1) Feedback: the written feedback was individualized (if multiple clinicians were involved in the decision-making process with one patient) and described more concretely which communication behaviour would increase the existing score. (2) Training: for improving skills, an actor was present (instead of role-play by clinicians themselves) to practice SDM in consultations based on self-reported clinical cases. (3) Patient involvement: an attempt was made to strengthen the bond with a local patient representative. (4) Project team: each hospital team was given a permanent contact person and provision of information to hospital teams, especially about planning, was improved. (5) Collaborative meetings: the number of organised collaborative team meetings, was reduced from four in the previous trajectory to two meetings during this programme. This change was made because it was difficult for clinicians from different hospitals to find time in their busy schedules at the same time.

Concurrent activities that might influence the level of SDM were monitored via a logbook. A clinician from each team, together with one of the researchers, kept this logbook. Patients were involved during all phases of the programme: they participated in the design, implementation and evaluation of the programme as members of the research/project team. They contributed to the integration of the patient's perspective in providing the feedback on consultations. Moreover, for each hospital team there were local patient representatives who participated in the training and were available for questions from the team.

Data collection

Each hospital team was asked to audiotape 15 decision-making processes before and after implementation of the programme. One decision-making process measurement was defined as one or more consultations conducted by one or more clinicians from the team to make one decision about systemic breast cancer treatment. Patients and clinicians were aware of this and were instructed to proceed with their consultation as normal (pre-intervention) or to apply what they had learnt during the intervention (post-intervention). Recruitment of all consecutive patients newly diagnosed with breast cancer and facing a treatment decision, took place between June 2018 and October 2018 (pre-implementation), and between March 2019 and July 2019 (post-implementation).

As primary outcome measure, the OPTION-5 instrument was used to measure the extent to which clinicians involved their patients in the decision-making process during audio-recorded real-life consultations [37]. This instrument scores five key decision-making behaviours of the clinician and was found to be suitable for use in oncology [38]. Each of the five items can be rated on a scale ranging from 0 (no effort made) to 4 (exemplary effort made), leading to an overall mean score that is expressed as a percentage of the maximum score. The higher the score, the better the clinician's SDM behaviour was during the consultation. Each audiotaped consultation was independently rated by two researchers out of a team of three (HvV, EvW, GB) by using the OPTION-5 coding scheme (http://www.glynelwyn.com/observer-option-5-2014.html (accessed on 24 November 2022)). The coding scheme has been adapted for vascular surgery and oncology [39] and was refined to the specific context of discussing systemic treatment in breast cancer to increase inter-rater agreement when scoring the audio-recordings (Table S1). These independent scores of the two raters were compared and discussed to reach agreement on the final score. To determine the inter-rater agreement, unweighted Cohen's Kappa (κ) values were calculated. Its value ranges from −1 to 1, with values greater than 0.6 considered substantial [40].

As secondary outcome measure, patients rated their perceived involvement in the decision-making process at the end of the final consultation when a decision about breast cancer treatment was made, by completing the SDM-Q-9 questionnaire [41,42,43]. Patients scored nine statements on a six-point scale, ranging from 'completely disagree' (0) to 'completely agree' (5). To calculate a percentage of the maximum score, ranging from 0 (no SDM) to 100 (maximum level of SDM), the scores of the 9 items per patient were added up and multiplied with 20/9. Questionnaires were excluded when the patient left three or more items unanswered. If one or two values were missing, these were imputed by the mean of the items that were scored [42].

Finally, factors possibly correlated with OPTION-5 scores were recorded, and for each team, the participation of each clinician in the measurements and implementation activities of the programme was monitored (as part of the logbook) to explore the working mechanisms of the programme in terms of the relative benefit of each part of the programme. The logbook was maintained by a researcher in consultation with the contact person of each clinical team.

To identify key features of consultations, other outcomes retrieved from the audio-recorded consultations were consultation duration, number of options being discussed and type of decisions that were made.

Sample size calculation

It is conceivable that relatively high OPTION-5 scores can be observed in oncology, because good communication about (breast) cancer is generally acknowledged to be important when there is a clear (shared) decision moment from the perspective of clinicians [44,45,46]. For the calculation of an adequate sample size, a mean OPTION-5 score of 39 before the intervention was used, as was found in the previous breast cancer study [25,32]. A total sample size of recordings from 120 patients (ideally 60 in the pre-measurement and 60 in the post-measurement) was needed to perform an unpaired t-test, based on an expected improvement in mean OPTION-5 score from 39 before implementation to 49 after implementation, with a standard deviation of 13, an intra-cluster correlation rho of 0.01 (to correct for interhospital differences), an α of 0.05, a power of 80% and an effect size of 0.77. To anticipate possible recording failures or dropouts, the goal was to include a total of 150 recordings of patient encounters.

A minimal improvement of 10 points was considered clinically relevant, as clinicians' efforts in applying SDM will improve from 'minimal' to 'moderate' after an average half-point improvement on each of the five items [25].

Statistical analysis

Descriptive statistics are reported as percentages, or mean (with standard deviation; SD) or median (with interquartile range; IQR) values. Differences are presented as risk differences (RD) or mean differences (MDs) with their 95 per cent confidence intervals (95%CI). To examine differences between categorical variables, Pearson's statistic was used. Statistical analysis was carried out using SPSS Statistics v. 28.0 (IBM, Armonk, NY, USA). P values <0.050 (two-sided) were considered statistically significant.

After selecting the variables related to the observed SDM level through univariable regression, a backward stepwise regression analysis was performed until all remaining variables in the model had a p-value <0.05. These would be the independent factors significantly related to the OPTION-5 score. To give a complete picture, all variables were reported in the model. This regression analysis also corrects for the expected collinearity between variables [47]. First, variables that were not part of the intervention were analysed: (1) clinical team, (2) type of clinician, (3) number of options discussed, (4) total exposure to programme implementation, (5) consultation duration. Subsequently, the components of the implementation programme were analysed. The variables recorded in the log, on which the 5 participating teams had exactly the same results were combined in the regression model: (1) completion of E-learning and reallocation of tasks; (2) use of a decision tool, adjustment of care path and appointment of coordinator; (3) having discussed feedback from consultations; (4) patient involvement; (5) participation in training; (6) participation in collaboration meetings; and (7) number of recordings submitted.

Results

Participants

Hospital teams

Five out of a total of seven approached hospitals participated in the study. Two hospitals (one teaching hospital and one general hospital) in the Amsterdam region did not accept the invitation to participate because their doctors considered the expected time investment (12–20 hours per clinician) too high in relation to the expected benefit. Therefore, two (teaching) hospitals outside the Amsterdam region were asked to participate, both of which agreed to participate. All teams performed pre- and post-intervention decision-making process measurements. Participation in the activities of the implementation programme differed per team (Table 1), e.g., one hospital only included two patients in the post-measurement.

The participating clinicians before and after the implementation were similar regarding background and education. Before implementation, 7.9% of the participants were surgeons, and after implementation, 10.4% were surgeons. For nurse specialists and medical oncologists, these percentages were 9.5% and 82.5%, respectively, before implementation, and 16.7% and 72.9%, respectively, after implementation. The practitioners who participated in the post-measurement were the same, except for one oncologist, who only participated in the pre-implementation

Table 1. Participation of hospital teams in the program.

	Participation in team training	Care pathway redesign, decision tool used, coordinator appointed	Reallocation of tasks/ e-learning	Participation clinicians in 2 collaborative meetings (N)	Patients involved	Discussed feedback from consultations (N before; N after)
Team 1	Yes	Yes	No	Yes (2)	Yes	Yes (14;15)
Team 2	Yes	No	No	No (0)	No	Yes (9;9)
Team 3	Yes	No	No	Yes (4)	Yes	Yes (9;2)
Team 4	Yes	Yes	Yes	Yes (3)	Yes	Yes (16;15)
Team 5	Yes	No	No	Yes (2)	Yes	Yes (15;8)

measurement, and three nurse practitioners who were replaced between the pre- and post-implementation measurements.

There was no registration in the logbooks of concurrent activities unrelated to the programme that might have influenced the level of SDM. Two hospital teams adapted the care process: in one hospital, the consultation with a nurse or nurse specialist now preceded the consultation with the medical oncologist (instead of afterwards), and in the other hospital, an additional consultation with the nurse or nurse specialist was offered in addition to the consultation with the medical oncologist.

Patients

A total of 112 consultations of patients with newly diagnosed breast cancer were successfully recorded: 63 consultations before and 49 after implementation. Patients' ages ranged from 25 to 86 (mean 60) years (SD: 13).

Characteristics of consultations

The options discussed were chemotherapy, hormone therapy, combined therapy (chemo/targeted therapy, chemo/hormone therapy, hormone/chemo/targeted therapy) and active surveillance. Other options related to these decisions, such as the use of cooling caps during chemotherapy, psychological support and extra diagnostic procedures, were not scored with the OPTION-5, but clinicians did receive feedback if considered relevant for applying SDM. The mean number of consultations needed to decide about systemic treatment for breast cancer was 1.75 (range 1–5) consultations per patient. No significant difference was observed between the median duration of consultations before (36:00 min:sec) and after (40:00 min:sec) the intervention ($p = 0.74$).

In total, 77.5% of the consultations were held by clinicians who participated in feedback meetings, 38.8% were held by clinicians who participated in group meetings, 98% were held by clinicians who attended a SDM training and 30.6% were held by clinicians who completed the E-learning. All but one hospital team involved a patient representative at a local level.

SDM adoption by clinicians

All five teams showed higher total OPTION-5 scores after the implementation, although the variation among teams was considerable (Table 2). The total mean OPTION-5 scores increased from 33.9 (SD 14.8) at baseline (63 patients) to 54.3 (SD 19.9) (52 patients) after implementation (MD 20.4 ($p < 0.001$, 95% CI: 13.6 to 27.2)). The three raters reached acceptable levels of inter-rater agreement over the rated consultations ($\kappa = 0.57$, $\kappa = 0.47$ and $\kappa = 0.60$).

Table 2. Consultation characteristics before and after the implementation program.

	Pre-implementation	Post-implementation	Difference (p-value) (95%CI)
1. Option-5 scores (SD) (N)			
Hospital team 1	26.4 (11.0) (14)	58.0 (17.0) (15)	+31.6 (<.001) (20.6 to 42.6)
Hospital team 2	28.9 (10.8) (9)	50.0 (12.2 (9)	+21.1 (<.001) (9.6 to 32.7)
Hospital team 3	45.6 (13.8) (9)	52.5 (3.5) (2)	+6.9 (.51) (-16.1 to 30.0)
Hospital team 4	43.8 (13.1) (16)	65.7 (21.4) (15)	+21.9 (.002) (9.0 to 34.8)
Hospital team 5	26.3 (12.9) (15)	31.3 (11.3) (8)	+5.0 (.37) (-6.3 to 16.2)
Total (N=112)	33.9 (14.8) (63)	54.3 (19.9) (49)	+20.4 (<.001) (13.6 to 27.2)
2. Total SDM-Q-9 scores			
Median (IQR) (N=74)	91.1 (82.2-100.0) (51)	88.9 (82.2-100.0) (23)	-2.2 (0.81)
3. Consultation duration			
Median min:sec (IQR) (N)	36:00 (24.0-70.0) (63)	40:00 (25.0-77.0) (49)	+04:00 (0.74)
4. Number of consultations			
1 per patient (%)	31 (49.2%)	24 (49.0%)	-0.2% (.98) (-17.8 to 18.2)
>1 per patient (%)	32 (50.8%)	25 (51.0%)	+0.2% (.98) (-17.8 to 18.2)
5. N of options offered			
1 option (%)	23.3% (14)	10.2% (5)	-13.1%
2 options (%)	60.0% (36)	53.1% (26)	-6.9%
3 options (%)	15.0% (9)	6.1% (3)	-8.9%
4 options (%)	1.7% (1)	30.6% (15)	+28.9%
Total mean	1.95% (60)	2.57% (49)	+.62% (p<.001) (.28 to .96)
6. Type of option offered			
Active surveillance	68.3% (41)	81.6% (40)	+13.3% (.11) (-3.3 to 28.4)
Chemotherapy	50.0% (30)	67.3% (33)	+17.3% (.07) (-1.2 to 34.1)
Hormone therapy	61.7% (37)	59.2% (29)	-2.5% (.79) (-20.4 to 15.4)
Chemo/targeted therapy	11.7% (7)	12.2% (6)	+0.5% (.93) (-11.8 to 14.0)
Chemo/hormone therapy	1.7% (1)	32.7% (16)	+31% (p<.001) (17.5 to 45.0)
Hormone/chemo/ targeted therapy	1.7% (1)	4.1% (2)	+2.4% (.44) (-5.4 to 12.1)
No decision yet	1.7% (1)	0.0% (0)	-1.7% (.36) (-8,9 to 5.7)
7. Chosen options			
Conservative treatment	9.8% (5)	8.2% (4)	-1.6% (.77) (-13.9 to 10.7)
Chemotherapy	29.4% (15)	28.6% (14)	-0.8% (.93) (-18.2 to 16.7)
Hormone therapy	39.2% (20)	30.6% (15)	-8.6% (.37) (-26.2 to 9.9)
Chemo/targeted therapy	13.7% (7)	8.2% (4)	-5.5% (.37) (-18.5 to 7.5)
Chemo/hormone therapy	3.9% (2)	14,3% (7)	+10.4% (.07) (-1.4 to 23.1)
Hormone/chemo/ targeted therapy	0.0% (0)	2.0% (1)	+2.0% (.31) (-5.2 to 10.7)
No decision yet	3.9% (2)	8.2% (4)	+4.3% (.37) (-6.3 to 15.6)

Percentages may not add up to 100% due to rounding

Table 3. Regression analysis of factors that are not part of the implementation program and exposure to implementation program.

Independent variables	β-coefficient* (95% CI)	p-value
1. Hospital team		
Team 1	reference	
Team 2	-4.2 (-16.8 to 8.4)	.51
Team 3	7.7 (-4.0 to 19.3)	.19
Team 4	-4.0 (-18.0 to 9.9)	.57
Team 5	-10.9 (-21.8 to .12)	.053
2. Type of clinician		
Medical oncologist	reference	
Nurse specialist	10.2 (-6.7 to 27,1)	.24
Oncology surgeon	10.4 (-6.3 to 27.0)	.22
3. Number of discussed options		
1 option	reference	
2 options	10.2 (2.7 to 17.6)	.008
>2 options	14.4 (4.2 to 24.6)	.006
4. Consultation duration		
<25 minutes	reference	
25-45 minutes	3.3 (-5.3 to 11.8)	.45
>45 minutes	6.5 (-3.7 to 16.7)	.21
5. Exposure to implementation program		
No exposure (0 activities)	reference	
Median exposure (1-5 activities)	13.1 (4.9 to 21.3)	.002
High exposure (6-10 activities)	19.6 (11.9 to 27.3)	<.001

This model explained 50% (Adjusted R2) of the variance.
* For interpretation, the Beta coefficient represents the increase in OPTION-5 score of this variable compared to the reference variable.

Perception of patients

Of the 112 included patients, 74 completed the SDM-Q-9: 51 questionnaires before and 23 after implementation (overall response rate 66.1%). Three questionnaires had to be imputed because patients left one or two items unanswered. The perceived involvement in decision-making was generally high and was not changed by the intervention: before the implementation the median score was 91.1 (IQR: 82.2–100.0) versus 88.9 (IQR:82.2–100.0) after implementation (p = 0.81) (Table 2).

Table 4. Regression analysis of components of the implementation program.

Independent variables	β-coefficient* (95% CI)	p-value
1. Completion E-learning & reallocation of tasks		
Not carried out	reference	
Carried out	11.4 (0.31 to 22.5)	.044
2. Use of decision tool, adjustment of care pathway, and appointment of a coordinator		
Not carried out	reference	
Carried out	6.0 (-5.3 to 17.3)	.30
3. Having discussed feedback from consultations		
No participation	reference	
Participation	18.7 (10.0 to 27.4)	<.001

This model explained 50% (Adjusted R2) of the variance.
* For interpretation, the Beta coefficient represents the increase in OPTION-5 score of this variable compared to the reference variable.

Correlated variables

Table 3 shows that the exposure to the implementation programme and the number of discussed options with the patients are significantly correlated to the observed level of SDM among clinicians. The Beta coefficient represents the increase in OPTION-5 score of this variable compared to the reference variable: e.g., with ’high exposure’ means that the average OPTION score increases 19.6 points when the implementation programme is (almost) fully implemented. No correlation was found for the clinical team, type of clinician and consultation duration.

Programme components (working mechanisms)

When analysing the different components of the intervention programme, (1) the completion of the e-learning and reallocation of tasks and (2) having discussed feedback from consultations were significantly correlated ($p < 0.05$) with the level of SDM (Table 4). No correlation was found for the use of a decision tool, adjustment of the care pathway, and appointment of a coordinator. The variables (1) patient involvement; (2) participation in training; (3) participation in collaboration meetings; and (4) number of recordings submitted, were removed due to collinearity.

Key consultation features: duration, discussed options and decisions made

After implementation, clinicians were significantly more likely to offer four different treatment options during the consultation than before, while there was no increase in consultation duration (Table 2). Additionally, chemo/hormone therapy was discussed significantly more often after the intervention. The type of decisions did not differ significantly between the pre- and post-intervention teams (p = 0.41).

Discussion

Discussion of results

After evaluation and adaptation, the multilevel implementation programme again led to improved patient involvement in the decision-making process [11], without a significant increase in consultation duration. No effect was demonstrated on the patients' perceived involvement in decision making as measured by the SDMQ-9.

Although implementation efforts in the field of SDM are increasing [24], these results are both promising and generalizable to other (cancer) settings: The 20-point increase in observed SDM behaviour, focusing on discussing systemic therapy in early-stage breast cancer, was relatively high [25,32]. Moreover, it occurred in five different clinical teams among team members from different clinical backgrounds (medical oncologists, oncology surgeons, nurses, nurse specialists). It implies that focusing the assessments on the interprofessional team performance, rather than the individual performance of each clinician, is meaningful because the possible improvements are then also approached as a team — or even organisational — performance. This is in line with the plea for addressing organisational characteristics as part of implementation approaches [27]. Therefore, it seems prudent to continue with systematic implementation approaches that focus on the team to strengthen the social support. At the same time, these approaches should allow customization for the different teams and even individual team members, especially to stimulate the intrinsic motivation needed for sustainable behavioural change [11,29,48]. The result from this research seems to recommend periodic individual feedback on each individual clinician's consultations, in addition to interventions aimed at the team (feedback on consultations on general issues for team learning; effective division of tasks; and facilitation with, for example, decision tools and outcome data) and the organisation (process redesign). Future research may focus on how to make multilevel implementation efforts more effective and easier to scale-up and may produce improvements that last, especially as part of a continuous improvement process.

Exposure to the implementation programme—even moderate exposure—was found to be the most strongly correlated variable for increasing observed SDM behaviour. Encouragingly, this influence is much greater than other hard-to-change variables such as the type of doctor or the length of the consultation. Within this implementation programme, the finding that the redistribution of tasks, e-training, and the discussion of feedback from consultations is associated with more application of SDM, is a breakthrough. These can be added to already proven interventions such as decision aids and training [22,31,46]. Further research is needed into the possible contribution of care pathway redesign and patient involvement, also because these variables may be less related to SDM scores as such, but rather to aspects such as consultation duration, number of consultations, and patient and practitioner satisfaction. This is especially important as both patients (representatives) and clinicians in the project indicated that having time to make decisions is an important condition for participation in SDM [25,49].

The intervention helped clinicians to discuss more options with their patients, particularly combined chemo/hormone therapy. Moreover, a trend was seen towards offering active surveillance and chemotherapy more often. Previous research also indicates that patients who use a decision aid or receive more SDM more often choose the option of active surveillance [50,51]. As there seems to be shift towards choices that are more in line with the values of patients after the use of decision aids [12], this underlines the importance of SDM implementation.

The COVID pandemic has accelerated the use of hybrid care. Phone consultations were already part of our programme so there seems no impediment to promoting the adoption of SDM also during digital consultations. An additional advantage of hybrid care is that it becomes easier to add an extra (digital) consultation in the care pathway to offer patients more reflection time. In addition, it may lower the threshold for patients to use digital means of communication and support, such as video information and better use of the electronic patient record. The implementation strategies, including financial compensation, will have to be adapted accordingly.

Strengths and limitations

A strength of this study was the active participation of clinicians from different backgrounds, and patient representatives in designing, implementing and evaluating the programme, based on a theoretical implementation framework. In addition, due to the cooperation with the contact person of each clinical team, an adequate registration of participation in the parts of the implementation programme could be obtained.

A study limitation is the before-after design without control group, especially since the programme lasted more than a year. Therefore, an effort has been made to keep accurate records of the simultaneous actions taken by teams. The fact that the patients in the pre-test were different from those in the post-test also makes it uncertain whether completely comparable groups were included, while correction for disease stage and recurrence risk for instance was not possible as these data were not collected in the study. The alternative of cluster randomization was rejected because of the much higher cost in relation to the effect as well as the possibility to scale up such an implementation programme. As the investigators had to provide relevant feedback as part of the implementation, patients, clinicians and investigators could not be blinded to the intervention and the recordings. Clinicians may have gone the extra mile to incorporate SDM in their consultations. However, previous research shows that the effect of this on the SDM-scores is limited [52,53]. In addition, raters may have been biased in scoring the consultations, as they knew that they were listening to pre-implementation or post-implementation recordings.

The required sample size was calculated for a 10-point increase in the primary outcome measure. This may mean that the size of this sample is insufficient to demonstrate significant effects of the secondary outcomes.

A limitation of the regression analysis was that some variables recorded in the logbooks for which the five participating teams had exactly the same results had to be merged in the model. Consequently, it is not clear which of the two variables ‘e-learning’ and/or ‘reallocation of tasks’ were significantly correlated. Finally, the pre-implementation scores were relatively high [32,54]. This was expected, as for breast cancer communication efforts are already relatively intensive as compared to other conditions [46], and the assessments were focused on the performance of the whole team. However, this may imply that for lower-scoring clinicians, the approach needs to be adjusted in some aspects. The lack of an obligation to offer an explicitly patient-oriented intervention as part of the implementation programme (decision aid, three good questions, etc.) could also increase the effect of the programme [12], because SDM involves the cooperation of two parties involved [55]. This was urged in the collaborative meetings and through the contact person of the teams, but the commitment to using a decision tool could not be enforced. It is worth considering to add this as a condition for participation in a programme.

Conclusions

A theory-based multilevel SDM implementation programme, co-designed with patients and clinicians, was found to result in a significant and clinically relevant improvement in SDM behaviour. Although it requires a reasonable (time) investment from clinicians, the supporting research team, and patient representatives, it is a temporary investment with no adverse effects such as increased consultation time in the long-term. Multilevel, theory-based approaches that can be tailored to both the challenges of the teams as a whole and individual clinicians seem preferable. Factors promoting the effectiveness of an implementation programme include (e-)training, discussing feedback on consultations and redistribution of tasks in the care pathway.

Supplementary materials

The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/curroncol30010019/s1. Table S1. Refined scoring definitions for the OPTION-5 manual. Table S2. Content of the multilevel implementation programme using a 4-level framework for designing an effective implementation strategy [35].

Author contributions

Conceptualization, H.v.V., M.S., E.V. and C.G.J.M.H.; methodology, H.v.V., L.J.P. and D.T.U.; software, L.J.P.; validation, H.v.V., E.v.W. and L.J.P.; formal analysis, L.J.P.; investigation, H.v.V., E.v.W., M.S. and M.P.H.; resources, H.v.V. and E.V.; data curation, H.v.V., L.J.P. and E.v.W.; writing—original draft preparation, H.v.V. and L.J.P.; writing—review and editing, H.v.V. and L.J.P., M.P.H., M.S. and D.T.U.; visualization, H.v.V.; supervision, D.T.U. and C.G.J.M.H.; project administration, H.v.V. and E.V.; funding acquisition, H.v.V., C.G.J.M.H., E.V. and M.S. coordinated patient involvement in the design of the study and the interpretation of the results. All authors have read and agreed to the published version of the manuscript.

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Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee United of Antonius Hospital (W16.019, 1 April 2016).

Informed consent statement

Written informed consent was obtained from all patients involved in the study to publish this paper.

Data availability statement

De-identified data can be requested from the corresponding author at haskevan-veenendaal@gmail.com.

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Conflicts of interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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Chapter 5

Evaluation of a multilevel implementation programme for timeout and shared decision-making in breast cancer care: a mixed methods study among 11 hospital teams

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Abstract

Objective: Evaluation of a multilevel implementation programme on shared decision-making (SDM) for breast cancer clinicians.
Methods: The programme was based on the 'Measurement Instrument for Determinants of Innovations-model' (MIDI). Key factors for effective implementation were included. Eleven breast cancer teams selected from two geographical areas participated; first six surgery teams and second five systemic therapy teams. A mixed method evaluation was carried out at the end of each period: Descriptive statistics were used for surveys and thematic content analysis for semi-structured interviews.
Results: Twenty-eight clinicians returned the questionnaire (42%). Clinicians (96%) endorse that SDM is relevant to breast cancer care. The programme supported adoption of SDM in their practice. Limited financial means, time constraints and concurrent activities were frequently reported barriers. Interviews (n = 21) showed that using a 4-step SDM model - when reinforced by practical examples, handy cards, feedback and training - helped to internalize SDM theory. Clinicians experienced positive results for their patients and themselves. Task re-assignment and flexible outpatient planning reinforce sustainable change. Patient involvement was valued.
Conclusion: Our programme supported breast cancer clinicians to adopt SDM.
Practice implications: To implement SDM, multilevel approaches are needed that reinforce intrinsic motivation by demonstrating benefits for patients and clinicians.

Highlights

- A multilevel approach is needed for effective implementation of SDM.
- SDM should be advocated as an intrinsic part of the clinician's role.
- Process redesign and professional behavioural change are key to enhancing SDM.
- Team training, feedback and a practical 4-step model boost the adoption of SDM.
- Focusing on clinician-patient interaction helps change organisational barriers to SDM.

Introduction

Shared decision-making (SDM) is a collaborative process in which patients and clinicians make decisions together, integrating patient values and preferences with clinical evidence about available options and their risks and benefits, to arrive at patient-centred decisions [1]. SDM is regarded as the pinnacle of patient-centred care [1,2], but adoption by clinicians is slow [3–5]. The application of SDM is relevant and challenging in breast cancer care as:

a. many treatment options are available [6–9];
b. patients face treatment decisions with varying short- and long-term (side) effects, affecting their quality of life [6,7]
c. different clinicians are working within a team [8,10,11]. As a result, the adoption of SDM in (breast) cancer consultations shows considerable room for improvement [6,8,12,13].

Breast cancer patients prefer sharing decisions and this has increased over time [14,15,16]. Clinicians in oncology care are generally positive towards SDM [17,18], and many national policies have been designed to enhance the implementation of SDM [19,20,21]. SDM has been advocated to be an essential part of the clinical role [21,22,23]. Several barriers to implement SDM have been reported, including: a lack of SDM-skills [24], a failure to recognize that SDM differs from current practice [22], practical problems [25,26], a lack of trust in the patient's willingness to participate in decision-making [27], and the difficulty of embedding SDM into the workflow [4,22,28].

Potentially effective strategies to enhance SDM in clinical practice involve: training clinicians and the use of patient decision tools to help patients engage in SDM [7,29–33], feedback to clinicians on performance in consultations [25,33–35]. On the organisational level, incorporating timeouts in care pathways [21,36], and the use of incentives have been proposed [4,21,22]. However, the approaches used to implement SDM in routine practice are seldom grounded in implementation theory, and often fail to anticipate the change determinants associated with a specific clinical setting [4]. Although a multilevel approach using a combination of clinician- and patient-mediated interventions is likely to be most effective [21,30,37], to date, only a few SDM implementation projects have used multilevel strategies to facilitate SDM [22,34,38–40].

We evaluated a multilevel implementation programme that was developed to enhance the adoption of SDM [40], by investigating the perceived barriers and facilitators by participating breast cancer clinicians in the programme.

Methods

The COREQ checklist was used to optimize the reporting of this study [41].

Study design

A convergent parallel mixed-method study was conducted utilizing questionnaires and semi-structured qualitative interviews. The programme was implemented twice: 1. from April 2016 till September 2017, for early-stage breast cancer (surgical) treatments and 2. from May 2018 till September 2019, for later-stage (systemic) treatments. At the end of each phase, an evaluation was carried out. The outcomes of the evaluation of phase 1 were used to adapt the programme in phase 2.

Study setting

For each phase, a different geographical area was chosen for selection of the study population from which six candidate breast cancer outpatient clinics were invited (Phase 1: Utrecht, Phase 2: around Amsterdam). Three teams declined. One team outside the region registered voluntarily in each phase, allowing us to reach the desired number of teams. All clinicians involved in the decision-making process were invited to participate, i.e. breast cancer surgeons, oncologists, and (specialized) nurses. No financial compensation for participation was offered.

In the Netherlands, fast track diagnostics is applied: patients visit the clinic in the morning for diagnostic assessments and receive the diagnosis at the end of the day [42]. This approach reduces the average diagnosis time to 3.0 workdays within 1.4 hospital visits [42]. In some clinics, breast cancer surgery is planned straight away, while in others this can take several days/consultations.

Implementation programme

The implementation programme is described in Table 1, including the adaptations made after phase 1. The programme is based on the MIDI-model (Measurement Instrument for Determinants of Innovations) containing four implementation levels [43,44]. Key factors for effective SDM-implementation were included in the programme [7,22,26,30,45–47].

Innovation (the implementation of SDM)

Evidence about the effectiveness of SDM in routine practice was incorporated, including the 4-step model for applying SDM [5]. A ‘timeout’ was defined as specified time for patients to think and reflect and was considered to be a precondition for integrating the SDM-steps into the clinical pathway [21,47]. An evidence summary of SDM in clinical practice – and handy cards with example sentences – were offered to the clinicians.

Table 1. Content of the multilevel program using a 4-level framework for designing an effective implementation strategy [42]

Level of implementation	Working mechanism	Form in Phase 1 (breast cancer surgery, 6 teams)	Timeline / months (M)	Adaptations made in Phase 2 (systemic therapy breast cancer, 5 teams)
1. Innovation (the implementation of SDM)	Discuss what SDM means and what kind of behavior is effective during a breast cancer consultation	a. A clear overview of the practical 4-step model for applying SDM was given to the clinicians. They were asked to mirror the model to their current communication behavior during consultations (sense-making). b. Background information about the theory of SDM, presentations summarizing the working sessions, etc. were also made available to the teams via a website.	M1	• We provided the teams with more concrete examples of sentences - and discussed lessons learned from Phase 1 – to enhance the implementation of SDM.
	Encourage the use of effective decision tools to support SDM in daily practice	a. Teams were provided with an overview of tools (made available via a website) that can enhance SDM, especially concerning breast cancer surgery and systemic therapy (i.e. 'Ask-3-questions' handy cards outlining the 4 SDM-steps).	M1	• We asked each team to experiment with a decision aid.
2. User (clinician and patient)	Provide individual and team feedback on actual SDM behavior (before & after implementation)	a. Each team collected audio-recordings from 15 patients pre-intervention b. Feedback was provided on the performance regarding SDM and timeout, both in a team meeting and a via a report containing feedback for the team as a whole. Individual feedback was also provided. Characteristic audio fragments were selected and listened to; these provided examples of ways in which the SDM process could be improved to discuss issues that could enhance the SDM process. c. Each team collected audio-recordings from 15 patients post-intervention	M1-4 M5-7 M12-15	• We explicitly assigned quotes to individual clinicians by color-coding quotes per clinician in the individual report.
	SDM training via team training & e-learning	a. An inter-professional team training session addressed the application of SDM and timeout in consultations, using audio fragments recorded from members of the team. The training session was tailored to the needs of the team, and the results of the pre-intervention measurement. b. A (45-minute) e-learning session explained the theory of SDM and outlined how to apply the 4-step model in practice.	M6-8 M6-8	• Actor role-play was added to the content of each training session, based on a recognizable case (extracted from the recorded consultations). • The content of the e-learning session was updated to better align with the theory and tools used in the implementation program.

Table 1. - Continued Content of the multilevel program using a 4-level framework for designing an effective implementation strategy [42]

Level of implementation	Working mechanism	Form in Phase 1 (breast cancer surgery, 6 teams)	Timeline / months (M)	Adaptations made in Phase 2 (systemic therapy breast cancer, 5 teams)
	Peer learning via collaborative working sessions for teams	a. Two or more team members were asked to participate in a total of 4 collaborative working sessions designed to facilitate the process redesign, the application of SDM, timeout, and the selection of tools for SDM. Topics: responding to barriers to and facilitators of implementation, sharing team actions, integrating the 4 steps for SDM in the care path, the use of tools and patient information, coping with implicit normativity during consultations, patient perspectives on timeout & SDM.	M1, M5, M10, M14	• The number of collaborative sessions was reduced to two sessions (and one session in between for only the team coordinator of each hospital team).
3. Organizational context	Redesign the pathway to include SDM and timeouts, using rapid cycle improvement	a. Teams were asked to include timeout & decision-tools in the pathway (support was provided). The Plan-do-check-act cycle was explained to teams and teams were encouraged to experiment with new ways of working that can better accommodate SDM and timeout. First visit: discuss test results, prognosis, treatment options, the process of SDM. Give patients information to read at home. Second visit: discuss pros and cons of options and ask patients what matters to them. Encourage patients to take extra time over the decision or schedule an extra visit to help with decision making (or, if the patient is ready, a decision can be made).	M5-14	• No major changes were made. More emphasis was placed on teamwork and on how multidisciplinary team discussions can facilitate SDM.
	Reconsider working process including SDM	a. Teams were asked to adapt multidisciplinary team consultations & reassign communication tasks (support was provided).	M5-14	• Emphasis was given to the feedback provided (in the evaluation of Phase 1), that this seems to be a promising strategy.

Table 1. - Continued Content of the multilevel program using a 4-level framework for designing an effective implementation strategy [42]

Level of implementation	Working mechanism	Form in Phase 1 (breast cancer surgery, 6 teams)	Timeline / months (M)	Adaptations made in Phase 2 (systemic therapy breast cancer, 5 teams)
4. Socio-political context	Facilitate a context that supports the implementation of SDM in daily practice	a. Commitment to invest time in the process was obtained at the start of the project. b. Barriers to and facilitators of implementation in the hospital were identified, and ways to respond to them were discussed with the team coordinator at the start of the project. c. Two team members per hospital were interviewed about experienced barriers to and facilitators of the implementation program. This information was fed back to the teams.	M0 M1 M11	• A better overview of the activities involved in the project and estimated time investment of personnel were provided before teams confirmed their participation. • From the project team, an 'account manager' was appointed for each hospital team to improve communication. • No changes were made.
	Access to implementation expertise on request	a. Expertise in the implementation of SDM, timeout, and quality improvement was offered, via telephone, face-to-face, or via an (extra) meeting with (members of) the team. Each team was visited at least once in between every collaborative working session (minimum 3 visits) and focused on: • Putting theory into practice: 4 steps of SDM • Process redesign	M1-14	• An 'account manager'/implementation expert was assigned to each hospital to facilitate communication within the team.
Added to the levels: patient involvement	Partnering with patients and collecting patient perspectives on SDM and timeout	a. We ensured that patient representation was systematically embedded, by having 3 patient representatives in the research-team, the collaborative working sessions, at least one patient representative in local team sessions and all other meetings. b. Teams were provided with the views of (ex-)breast cancer patients on the preferred number of consultations and the number of days they would like in between consultations (via website surveys). c. Each team collected the questionnaire (SDM-Q9) of 15 patients pre-intervention and 15 patients post-intervention. The scores were presented in the local team session and the written feedback report.	M1-14 M7 M1-4 and M12-15	• Additional website surveys were carried out asking about patient views about systemic treatment. Also, whether - and how - they would like to discuss the *wait & see* option.

Users of the innovation (clinicians and patients)

To support behaviour useful for clinicians to apply SDM, individual and team feedback on the audio-recorded consultations were provided, followed by a 3-hour interdisciplinary team training [31]. Recordings were made by the clinician(s) of one or more consultation(s) with the patient. Clinicians were instructed to record consultation(s) in which a decision had to be made. They were free to choose a decision process for which they wanted feedback, to stimulate intrinsic learning. The feedback was provided on paper and verbally. Individualized feedback was available for each clinician by providing the score per OPTION-item per patient [48], corresponding self-used quotes, and suggestions for improvements. Written feedback on team performance was provided, including the overall scores, a description of their team qualities, and suggestions for improving SDM. In a meeting, the team listened to, and talked about, their audio-recordings.

The team training session consisted of an explanation of theory, including the 4-step model, discussion about the relevance of SDM and examples of how to apply SDM in practice. In phase 2 of the study, role-play with an actor was included in the training and it was preceded by a 45-minute e-learning.

By suggesting the teams to use activation tools, such as Ask-Three-Questions and decision aids, patients were empowered to participate in the consultation [49]. In phase 2, the teams were provided with a booklet and an animation explaining SDM to patients.

Organisational context

Teams considered allocating time (timeouts) for SDM in their care pathways and evaluated the organisation of their multidisciplinary team meetings. They were helped by the results of a poll assessing patient opinions about the amount of time they would like to have for the decision-making process. Key moments for informing patients and timeouts in the clinical pathway were made explicit. They used the feedback from their audio-recordings to reflect on the allocation of tasks among team members. The programme was tailored to the local context: each team defined its own goals within the scope of the programme and selected tools to support SDM.

Socio-political context

As concurrent activities and external factors can influence the level of SDM, teams were asked to monitor their implementation activities via a logbook. Teams were also encouraged to involve hospital management in the project and to inform healthcare insurers, professional bodies, and other stakeholders about the programme.

Patient involvement

Patient involvement has been added to the framework and plays a role in all four levels: Participation of one patient advocate (a trained patient) and two patient representatives in the research team, and by ad hoc participation of at least one patient advocate in training sessions and meetings with the hospital teams. Results of a poll among patients and the perceived involvement in decision-making of the recorded patients (via the SDM-Q9) were fed back via the team meeting and the written feedback report.

Participants

All clinicians who actively participated in the programme were invited to complete the questionnaire (Table 2). Distribution and collection of the electronic questionnaire were done by the team coordinators to ensure anonymity. Based on previous literature, 5–6 participants per clinical group per phase is required to capture the majority of themes [50]. For the interviews (Table 3) a purposive sample was drawn from the 11 participating teams to recruit clinicians with different clinical roles. The team coordinator ((specialized) nurse) of each team was asked to participate in a semi-structured interview and to recruit one physician from the team.

Recruitment and data collection for the questionnaires and interviews were conducted from April to June 2017 (phase 1) and April to June 2019 (phase 2), immediately after the implementation programme has ended. The team coordinator was asked to send two reminders to non-responding team members, after 3 and 6 weeks.

Questionnaires and interviews

The MIDI-model describes 29 determinants that can enhance or hinder the implementation of an innovation, divided into the four levels mentioned above [44]. The validated example questions provided by the MIDI-model were rephrased in a questionnaire (Table 2) and a semi-structured interview guide (Table 3) into 25 items relevant to our programme, to be rated on a five-point Likert scale ranging from “entirely disagree” to “entirely agree” [44]. Three open questions were added to the questionnaire so respondents could list what they thought were the most prominent facilitators of and barriers to the implementation of SDM. The survey was reviewed for content and face validity by authors with expertise in the field of SDM and patient involvement (by LK, HvV, HVo, MS, EV) and tested in a previous pilot programme [51]. The face-to-face interviews were conducted by one researcher. Each interview lasted approximately 45 min and was recorded with permission from the interviewee. Two experienced researchers (HvV, HVo) trained the other researchers (LK, MS, JO, EvW) and discussed their first interview afterward, to ensure consistency between interviewers.

Table 2. Questionnaire data: clinicians' experience with the SDM implementation program

		Phase 1 (N=15)				Phase 2 (N=13)			
	Statement	Disagree*	Neutral	Agree	Average**	Disagree	Neutral	Agree	Average
Innovation (the implementation of SDM)									
1	SDM*** is easy to understand.	7%	0%	93%	3,3	0%	0%	100%	3,1
2	SDM is easy to apply in practice.	20%	7%	73%	2,8	23%	8%	69%	2,8
3	The theory of SDM is scientifically justified.	13%	7%	80%	2,7	23%	15%	62%	2,7
4	The approach corresponds to my opinion about what constitutes good health care.	0%	0%	100%	3,4	0%	0%	100%	3,4
5	The effects of SDM are clearly visible in practice.	13%	7%	80%	2,7	38%	8%	54%	2,8
6	SDM is relevant to breast cancer care.	0%	0%	100%	3,5	0%	8%	92%	3,3
7	SDM corresponds with the way I was used to working****.	7%	7%	87%	3,1	31%	8%	62%	2,8
User (clinician & patient)									
8	I possess enough knowledge about the theory of SDM to be able to properly implement it****.	7%	7%	87%	3,0	15%	23%	62%	3,1
9	Implementation of SDM has advantages for me****.	20%	7%	73%	2,7	15%	15%	69%	3,0
10	Implementation of SDM has disadvantages for me****.	53%	0%	47%	2,4	46%	15%	38%	2,6
11	Patients generally cooperate in SDM****.	7%	7%	87%	2,7	0%	15%	85%	3,1
12	Patients appreciate SDM****.	0%	0%	100%	3,1	8%	15%	77%	2,9
13	I receive sufficient support from colleagues****.	7%	7%	87%	3,0	15%	23%	62%	2,9
14	I receive sufficient support from my direct supervisor****.	27%	0%	73%	3,0	8%	31%	62%	2,9
15	My colleagues apply SDM in their way of working****.	13%	7%	80%	2,9	38%	23%	38%	2,4

Table 2. - Continued Questionnaire data: clinicians' experience with the SDM implementation program

		Phase 1 (N=15)				Phase 2 (N=13)			
	Statement	Disagree*	Neutral	Agree	Average**	Disagree	Neutral	Agree	Average
16	I apply SDM in my way of working.	13%	7%	80%	2,8	31%	23%	46%	2,6
17	I can completely implement all 4 steps of SDM during my consultations.	13%	0%	87%	3,0	54%	23%	23%	2,3
18	SDM is suitable for my role as a doctor/ nurse (practitioner).	0%	27%	73%	2,8	0%	15%	85%	3,3
Organizational & sociopolitical context									
19	Sufficient financial means are available to implement SDM.	33%	27%	40%	1,9	23%	23%	54%	2,8
20	There is enough time available.	20%	13%	67%	2,5	62%	23%	15%	2,2
21	There are enough means and facilities available****.	33%	13%	53%	2,3	54%	23%	23%	2,3
22	One or more people are designated to coordinate the implementation of SDM.	13%	7%	80%	2,9	38%	8%	54%	2,7
23	Other projects and changes are being implemented in the hospital at the same time****.	7%	7%	87%	3,1	15%	15%	69%	2,9
24	There is enough feedback for participants about the progress of the project.	27%	13%	60%	2,7	31%	0%	69%	2,7
25	Rules and laws inhibit the implementation of SDM****.	67%	7%	27%	2,1	38%	31%	31%	2,3
Support of research team									
26	Enough materials are provided by the research team.	0%	7%	93%	3,0	0%	0%	100%	3,4
27	Enough support is provided by the research team.	7%	20%	73%	2,7	0%	15%	85%	3,4
28	The meetings are helpful for the implementation of SDM.	0%	7%	93%	2,9	8%	23%	69%	3,0

Table 2. - Continued Questionnaire data: clinicians' experience with the SDM implementation program

		Phase 1 (N=15)				Phase 2 (N=13)			
	Statement	Disagree*	Neutral	Agree	Average**	Disagree	Neutral	Agree	Average
29	Easy access to information is provided by the research team.	7%	20%	73%	2,7	23%	23%	54%	2,7
30	Enough feedback has been received from the research team.	20%	7%	73%	2,8	15%	8%	77%	2,8
31	The collaboration with the research team is good.	0%	13%	87%	2,8	8%	0%	92%	2,9
32	The collaboration between participating hospitals is good.	13%	27%	60%	2,2	31%	31%	38%	2,7

* Agree is the sum of the answer categories strongly agree & agree, and disagree is the sum of strongly disagree and disagree.
** The average is calculated from 5 answer categories, range 0-5.
*** SDM = shared decision making.
**** Does not add up to 100% because of rounding.

Open questions about TO & SDM and the support you experienced from the project team:

1. According to you, what are the three most important success factors for applying TO & SDM in daily practice? And what are the three most hindering factors for applying SDM?
2. What differences did you experience in applying timeout and applying SDM? *"Is applying the one easier or more difficult than the other"?*
3. What aspect of support from the research team was most valuable for you? (e.g. the training, meetings, visits, materials, learning environment, interactions between participating teams). What suggestions do you have to improve the support provided by the research team?

Data analysis

Data analysis consisted of content analysis (surveys) and thematic analysis (interviews). All results were analysed anonymously. The data obtained from the questionnaire were exported from an Excel file in SPSS Statistics version 25 to calculate descriptive statistics. All interviews were transcribed (verbatim) using Express Scribe Transcription software (Free Version 2017) and analysed. Respondent validation was achieved by sending interviewees their transcript to approve the content. Each transcript was independently coded by two of four researchers (LK, HvV, HVo, EvW) [41]. Deductive thematic analysis was carried out on the dataset by marking text excerpts in the transcripts reflecting a 'barrier to' or a 'facilitator of' the application of SDM [52]. We used the four implementation levels and the 29 determinants of the MIDI-model as a coding scheme, supplemented with 'project support' [44]. Text fragments were charted in a table for each of the determinants and then deliberated by the coders until thematic saturation and variation were confirmed [53].

Table 3. Interview guide shared decision making (SDM)

We would like to evaluate the TO and SDM project in this interview, in order to gather your personal experiences with the project and develop an overview of the barriers to and facilitators of implementation. The information from the interviews will be used to improve the implementation program. This interview will take a maximum of 45 minutes. All responses collected will be anonymous and treated confidentially

A. Innovation

1. What do you think about the description of the four steps of SDM and the distribution of these steps over 3 visits to account for timeout? Is it clear? Complete? Feasible?
2. How does the application of SDM compare to your way of working before? In what way was it or wasn't it the same?
3. Do you believe that SDM is an effective intervention? Why? What did you expect? What was the effect you experienced?
4. Is SDM applicable to patients with breast cancer? Why?

B. User

5. What is the greatest advantage in applying SDM for you personally? And what is the greatest disadvantage?
6. Do you feel TO & SDM are relevant to your occupation? Does applying SDM affect your feelings of autonomy, responsibility? Are there conflicts between SDM and your own beliefs?
7. What influence did applying SDM have on the relationship with your patients? How do you feel about making joint decisions with your patient? How do you feel about sharing (more) responsibility with patients in making a choice?
8. What effect did the application of SDM have on your relationship with colleagues (in general, in meetings?)
9. What knowledge and skills do clinicians need to apply SDM successfully? In what way do you demonstrate this knowledge and these skills?

C. Organizational context

10. Barriers
    a. What barriers were you confronted with in the implementation of SDM (i.e. in relation to working together, planning, breaking with own patterns)?
    b. How did you or your team react to these barriers?
    c. What is your reflection afterwards on acting in this way?
11. Since the beginning of the project, what has changed in your care process? (i.e., more consultations? more time in between consultations? dosing of information, use of decision tools?)
12. Do you think there is enough information, time and resources available for you and your team to implement SDM?
13. Did it take more or less time than expected to implement SDM?
14. How often did your team give feedback to the hospital about applying SDM?

D. Socio-political context

15. Are there any laws or regulations that hindered you in the application of SDM? Which ones?
16. Did national indicators or any guidelines obstruct the implementation of SDM?

Table 3. - Continued Interview guide shared decision making (SDM)

E. Project team

17. Support of the project team
    a. What were the positive elements of the support provided by the project team (training, meetings, web portal etc.)? And why?
    b. What should be improved? Why?
    c. What kind of support did you miss?
18. What do you think about the timeframe of the project? Would you do this differently?
19. You have completed all of our questions, do you have anything else to add?

Results

Participating hospitals

Six hospitals agreed to participate in phase 1 (1 university, 2 teaching, and 3 general hospitals) and 5 agreed to participate in phase 2 (4 teaching and 1 general hospital). One hospital (phase 1) declined to participate, as they were not convinced that the implementation would further improve their level of SDM. Two hospitals (phase 2) did not want to invest the time needed to participate in the study.

Study population

Twenty-eight (42%) of the clinicians who received the questionnaire responded (phase 1: 15, phase 2: 13 clinicians) (Table 4), representing all relevant clinical professions: nurses, nurse specialists, surgeons and oncologists. Interviews were held with 21 clinicians (Table 5): the coordinator (a nurse (specialist)) and one physician of each team. In one team, only a nurse specialist was interviewed, as surgeons had delegated SDM to the nurse specialists.

Evaluation of the SDM implementation programme

Innovation

Questionnaires: Clinicians agreed with the scientific justification and relevancy of SDM and timeout for breast cancer care (Table 2). The process of SDM corresponded well with their vision of high-quality care. Moreover, 96% indicated that SDM is (highly) relevant to breast cancer care.

Interviews: Clinicians confirmed that applying SDM corresponded well with what they consider to be good healthcare and that SDM is relevant to breast cancer care (Table 5). Using a 4 step-model helped clinicians to translate the SDM-theory into practice and integrate it into their consultations. For example, video-exam-

Table 4. Study participants

	Phase 1 (breast cancer surgery)	Phase 2 (breast cancer systemic therapy)	Total (%)
Number of questionnaires	33	34	67
Number of returned questionnaires	15	13	28 (42)
Nurse	7	0	7 (25)
Nurse specialist	5	5	10 (36)
Surgeon	3	0	3 (11)
Oncologist	0	6	6 (21)
Other (project support)	0	2	2 (7)
Response rate (%)	45	38	42
Number of interviews	11	10	21
Nurse	3	0	3 (14)
Nurse specialist	3	4	7 (33)
Surgeon	5	0	5 (24)
Oncologist	0	6	6 (29)

ples (along with handy cards with example sentences and summaries of relevant theory) were provided to explain to clinicians how SDM is different from their current approach, and to help them apply it during consultations. However, a potential barrier is that some clinicians expressed that the 4 step-model did not fit with all their patients. Discussing the option of ‘watchful waiting’ as an alternative to pharmaceutical or surgical interventions was considered more complex than presenting several medically feasible options. Interviewees indicated that the effects of SDM were visible in practice, as illustrated by the following quotes:

> *“We have always been eager to learn new things and I find SDM interesting. But I did not expect the effect to be so significant.”*
>
> *“SDM is right for the times. That we approach patients as independent individuals, and they do not blindly follow what the doctor says.”*
>
> *“What I really liked, I put it on a post-it on my computer, the doctor knows everything about the treatment, but the patient knows everything about her life.”*

Users

Questionnaires: Respondents, especially clinicians involved in decisions about systemic therapy, indicated that SDM fits with their role. Responses showed that

Table 5. Experiences with SDM in breast cancer care extracted from clinician interviews

Innovation (the concept of SDM and timeout)		
Determinant	**Facilitators (& phase):**	**Barriers (& phase):**
1. Procedural clarity	• Frequent visualization of the 4 steps of SDM, explained in many ways, to understand what it entails in daily practice (examples, audio-fragments handy cards) (1,2) • Receiving concise information about SDM (Handouts) (1) • Exploitation of 4 steps of SDM for structuring consultations/pathway (2) • Gaining insight into how SDM differs from what you already do (2)	• Lack of understanding of the 4 steps of SDM by clinicians (1) • Low interest in nature of the subject or theory of SDM (1) • Lack of experienced added value of 4 steps of SDM (2) • Conflict between theory and own ideas about communication (2)
2. Correctness	• There is confidence in the theory behind the concept, especially for breast cancer (1) • Evidence for effectiveness for SDM (1)	• Doubt whether the theory applies to all patients (1) • Doubt whether the option of wait & see should be offered (1) • Doubt whether SDM leads to better care for palliative patients (2) • Doubt regarding evidence about the effectiveness of SDM and/or 4-step model (2)
3. Completeness	• Having an implementation program covering all information needed (1) • Theory fits with other actions to make care more patient-oriented (1) • Implementation program covers whole process and clinical team (2)	
4. Complexity	• Providing examples of sentences, words and questions (for value clarification) that can be used (1) • Clinicians' Perceived risk of information overload for the patient (2) • Learning how to time the steps of SDM during consultations (2)	• Experienced difficulty in translating SDM theory to daily practice (1, 2) • High number of available options (in specific situations) (1) • Disconcordance between the available number of consultations and the wish to divide steps over several consultations (1) • Conflict between applying the 4-step SDM model and customizing a consultation to an individual's situation (2) • Applying wait & see option in the consultations (2)
5. Compatibility	• Gaining understanding about how SDM is made explicit during your consultation (1) • Comparing your way of working with the way the theory of SDM ask you to work (2) • Taking time to reflect on what behavior is already supporting for SDM and how this can be better utilized (2)	• Team differences in the way of working and communicating (1) • Wanting to hold on to the 'old'/usual way of working and communicating (2) • Perceiving SDM as not applicable in all settings/situations (2)

Table 5. - Continued Experiences with SDM in breast cancer care extracted from clinician interviews

6. Observability	• Perceiving positive effects for themselves: think out loud together with the patient, asking in-depth questions, have a better eye for the patient's unique situation, planning an extra consult for the decision, better interaction with patients, ability to present options in a neutral way (1) • Perceiving positive effects for patients: more autonomy, asking more questions, increased awareness about options, more participation of patients and less anxiety (1) • Additional positive effect perceived for the organization: Creating spinoff in the team or organization regarding SDM or patient-centered care (2)	• Perceiving that SDM delivers no harsh/measurable effects but only (lower appreciated) effects on the experience of clinicians (1) • Perceiving that patient's feedback to clinicians does not change as a result of SDM (1) • Experiencing no concrete improvements of applying SDM (2) • Having other expectations from participation in the program (2)
7. Relevance for client	• Breast cancer involves several comparable treatment options (1) • Breast cancer patients are relatively information seeking (1) • Breast cancer is a relevant group for applying SDM (2) • Perceiving that SDM helps to better align treatment with an individual situation (2)	• SDM is less relevant for early-stage breast cancer patients (1) • Perceiving that SDM is not relevant for patients having only 1 legitimate option (1) • Having inadequate differentiation in patient groups/types (2) • Doubt whether all patients can/want to participate in SDM (2)
Users of the innovation (clinicians and patients)		
Determinant	**Facilitators (& phase):**	**Barriers (& phase):**
8. Personal benefits/ drawbacks	• Becoming enthusiastic about the theory of SDM (1) • Perceiving positive effects in consultations: better structured, calmer, better fit with the person, more time to decide (1) • TO helps to have all relevant diagnostic information available (1) • SDM makes it easier to discuss options for inclusion in studies (1) • Learning from colleagues, team-learning and better teamwork (2) • Perceiving more satisfaction from consultations (2) • Applying SDM fits with personal ambitions & individual learning (2) • Perceiving that patients are making more well-considered decisions (2)	• Having to give more information as more options need to be discussed (1) • Perceiving that involving critical patients lead to longer consultations (1) • Perceiving decision conflict or anxiety by patients (1) • Implementing SDM & TO demands a personal investment (2) • Change requires effort, attention, practical exercise and time (2)
9. Outcome expectations	• Patients become more aware about options, what is important to them and make well-considered decisions (1) • Patients have less regret and become more satisfied with their decision (1) • Patients will experience more control in the consultations and base decisions on facts and personal values (1) • Decision aids will support the process of reflection (1) • Patient involvement and autonomy will increase (2) • Patients will better understand the importance of taking time and use decision tools (2) • Improvement of the cost-effectiveness of breast cancer care (2)	• Having no expectations about the effect of SDM (1) • Patients do not want SDM (1) • Underestimating the time needed for applying SDM (1) • Other factors than SDM & TO are more important for the result (2) • SDM & TO will lead to process delay (2) • Having problems creating overview in the information needed for decision making (2)

Table 5. - Continued Experiences with SDM in breast cancer care extracted from clinician interviews

Users of the innovation (clinicians and patients)		
Determinant	**Facilitators (& phase):**	**Barriers (& phase):**
10. Professional obligation	• Viewing SDM as key to your clinical role (1) • Feeling the responsibility to apply SDM in consultations with patients (1) • Feeling it as an obligation to provide more than 1 option to patients, especially in case of equipoise (1) • Finding it a challenge to apply SDM tailored to each individual (2) • Perceiving that applying SDM is part of how the clinical role is changing (2) • Feeling that it is a good thing to share the responsibility for the decision (2)	• Failing to see that discussing the wait & see option is part of their role (1) • Not being positive about the concept of SDM & TO (2) • Feeling that there are many tasks for a surgeon, so also applying SDM is difficult (1)
11. Client/ patient satisfaction	• SDM and offering flexibility in surgical options makes patients more satisfied (1) • Audiotaping of consultations makes patients more satisfied (1) • More reflection on and more time for the decision makes patients more satisfied (1) • Patients are sure about their decision (2) • Patients experience equality in consultations (2) • Higher added value as SDM makes a decision process more individualized (2)	• Not giving advice to patients makes them less satisfied (1)
12. Client/ patient cooperation	• The majority of patients is suitable for SDM (1) • Breast cancer patients are assertive and want to be involved, high educated patients even more (1) • Patients want to better understand the impact of decisions (2) • Changes made in professional skills and in the approach to patients, in encouraging and preparing them to participate in SDM (2)	• Applying SDM is difficult in patients with low health literacy, lack of disease insight, from a different cultural background and emotional, anxious, passive (1) • Some patients have unrealistic expectations (1) • Too much (online) information causes uncertainty by patients (2) • Some patients do not take part in the process of SDM (have already chosen or want the doctor to choose) (2)
13. Social support	• Support for and enthusiasm for SDM in the team (1) • Changing the multidisciplinary team meetings' advice from one to more options (1) • A positive team climate that stimulates improvement and professional reflection (1) • Learning from colleagues, as a team, makes implementation successful (2) • Viewing the project as added value by the entire clinical team (2) • The project encourages the participation of the whole team and even other departments (2)	• A colleague that does not participate in the project (1) • Lack of team meetings to work on and discuss the project activities (1) • Lack of team support or room for internal professional reflection (2)

Table 5. - Continued Experiences with SDM in breast cancer care extracted from clinician interviews

14. Descriptive norm	• Team that collaborates to apply SDM (1) • Other teams that working on the implementation of SDM (1) • Integrating SDM in patient records, handovers, etc. (2) • The fact that scaling up SDM outside the own team (in the organization or on a national level) is possible (2)	• Having team members that do not apply SDM (1) • Experiencing different levels of adoption of SDM in the team (2)
15. Subjective norm	• Government, patient organizations and professional bodies support SDM (1) • SDM fits with general changes of the society (1) • SDM will become part of standard curricula medical students (2)	• Guidelines of professional bodies sometimes conflict with SDM & TO (1) • National standard that surgery is to be carried out within 5 weeks hinders the implementation of SDM (1) • Protocoled care hinders the implementation of SDM & TO (2) • Differences in interests of different stakeholders hinder the implementation of SDM (2)
16. Self-efficacy	• Experience is in communication makes applying SDM easier (1) • If more consultations are already built-in in the pathway, applying SDM is easier (1) • Trust in your skills and using visual support makes applying SDM easier (2) • Motivation to improve your performance stimulates applying SDM (2)	• If clinicians are not capable of letting go of the own opinion, applying SDM is hard (1) • Communication in breast cancer is already challenging, so applying SDM is extra hard (1) • Lack of trust in your skills makes applying SDM difficult(2) • If you do not know your patient well, applying SDM is difficult (2)
17. Knowledge & skills	• Knowledge that facilitates SDM: medical knowledge about breast cancer, treatment options with pros and cons, side-effects, risks, communication and SDM knowledge (1); knowing the 4 steps of SDM and awareness of your attitudes/opinions (2) • Skills that facilitate SDM: Listening, general communication skills, in-depth questioning, empathy, patience, explaining on different levels of understanding, reflexive behavior during consultations, involving patients who ask for advice, sensitivity for non-verbal signals, teach-back, solution-based thinking (1); tailoring to the individual, using practical examples, action-oriented behavior (trying new things), being visionary (2) • Practicing SDM skills with an actor (2)	• Confusing another opinion or feeling of a patient with the ability to understand the information (1) • Inability to recognize implicit normativity and differences in how patients process information and cope with thoughts and feelings (1) • Not being capable of coping with patients who process information slow (2) • Not letting go of old habits makes adoption of new behavior difficult (2)
18. Awareness of content of innovation	• Integrating the new theory about SDM in knowledge that is already available in the team (1) • Providing information about SDM throughout the project repeatedly (2)	• Lack of time or priority for discussion of theory and information with the team (1) • Unclear communication about involvement of team in project hindered team commitment to project (2)

Table 5. - Continued Experiences with SDM in breast cancer care extracted from clinician interviews

Organizational context		
Determinant	**Facilitators (& phase):**	**Barriers (& phase):**
19. Formal ratification by management	• Support from hospital management (1) • General promotion of SDM in hospital or nationally (2)	• Lack of cooperation and support from hospital management (2)
20. Replacement when staff leave	• Participation of a manager in the team (1) • New team members that express enthusiasm about SDM (1)	• No replacement of manager in the team after move out (1)
21. Staff capacity	• Hiring more nurse specialists (1) • Availability of surgeons and nurse specialists to offer the same clinician for each visit (1) • Splitting tasks to handle new activities (2)	• No replacement of colleagues that have left (1) • Crowded outpatient visits caused by low staff capacity (1) • High workload caused by low staff capacity hinders implementation (2)
22. Financial resources	• Applying SDM can be done with the same staff capacity (1) • Implementation via a project generates adequate resources for implementation (2)	• Extra consultations for TO and using decision tools may cost more (1)
23. Time available including redesign of care pathway and task reassignment	• Delegation of tasks to nurses (specialists) (1) • Not offering one same clinician for each visit makes planning easier (1) • Schedule an operation subject to change prevents delay (1) • Advanced planning to make the outpatient visits more flexible (1) • Regular team meetings for implementing SDM (1) • Extra time to schedule patient appointments (1) • Being realistic about medical urgency simplifies scheduling (1) • Utilize expertise to help in process redesign (1) • Allocation of adequate time for implementation (2) • Developing a smooth logistical planning process is an important requirement (2) • Saving time in the procedure is possible (2) • Awareness about the impact of everyone's role in the communication with patients (2)	• SDM takes more time, especially for complex patients (1) • More or longer consultations do not fit with current logistical process in clinic (1) • Deciding later on (through timeout) influences planning of surgery (1) • Getting the team together for discussing plans is tough (1) • Underestimating the complexity of applying the theory in practice and logistical planning process (1) • Workload in general makes it hard to make time for implementation(2) • Implementing SDM demands change in logistical planning process (2)
24. Material resources and facilities	• Organizing training session on location of the team (1) • Availability of supporting tools (handy cards, Ask-the- three-questions, educational materials) (1 & 2) • Making tools available for patients to stimulate them to be involved SDM (2)	• (long) Training session does not fit in busy schedule (1) • Lack of tools for patients to stimulate them to be involved SDM (1&2) • Malfunctioning of audio-recorders was demotivating (2)

Table 5. - Continued Experiences with SDM in breast cancer care extracted from clinician interviews

25. Coordinator	• Availability of coordinator who is allowed to schedule team meetings (1) • Use of an experienced clinician to support the implementation of SDM (1) • Availability of a team leader for the clinical team (1) • Having somebody available to include patients (audio-recordings) (2)	• Not having a team start at the beginning of a working day (hinders audio-recording) (1) • Lack of time for the coordinator of the team (1) • Lack of help for inclusion of patients (audio-recordings) (2) • Having no coordinator for the implementation (2)
26. Unsettled organization	• Flexibility to react adequately on turbulence in the organization (2)	• Lack of attention for the project caused by many other projects and studies that are carried out (1) • A merger of hospitals distracts attention for the project (1) • Too many tasks in little time hinder the implementation of SDM (2)
27. Information accessible about use of the innovation	• Availability of expert in change management and implementation (1) • Providing training that supports the application of knowledge & theory (1) • Exchanging information about the implementation with other teams (1) • (Follow-up) sessions providing examples of how to implement SDM (2) • Having meetings and providing information and decision tools (2)	• Lack of clarity about how expertise of patient advocates can be utilized (1) • Lack of concrete examples of how to apply SDM in daily practice (1) • Lack of detailed planning of the implementation project (1) • Some interventions being too experimental, lack of proven interventions (2) • Suboptimal exchange of information in collaborative team meetings (2)
28. Performance feedback	• Offering adequate personal feedback to clinicians (1, 2) • Connecting feedback on consultations with the 4 steps of SDM/theory (1) • Reflection on the feedback on consultation with the team (1) • Timing of feedback with the next steps to make in implementation (2) • Feedback that also offers insight into organizational improvements (2)	• Bad (late) timing of giving feedback on consultations (1) • Offering feedback in an unsafe setting, i.e. not giving anonymous feedback when wanted (1) • No feedback session organized in the hospital (2)
Socio-political context		
Determinant	**Facilitators (& phase):**	**Barriers (& phase):**
29. Legislation and regulations	• The ability to align the application of SDM with externally imposed rules and norms (1) • User-friendly process for administrating deviate choices of patients (1) • Hope that working on implementing SDM will have a positive impact on the policy of health care insurers (2) • SDM being important themes in society (2)	• Felt time pressure caused by imposed external guidelines of patient - and professional bodies (1) • Negative results in hospital performance scoring systems (1) • Too many demands by hospital management, health care insurers, etc. and too little time for adequate implementation (2)

SDM = shared decision making; TO = timeout they had gained enough knowledge about the theory of SDM to support implementation within their practice. A greater number of respondents involved in providing systemic therapy (54%) indicated difficulty in fully applying SDM as compared to those involved in providing surgical therapy (13%).

Interviews: Interviewees pointed out that change requires continuous (team) effort, practice, and time. They indicated that patients appreciated the application of SDM by their clinicians. Clinicians reported positive effects for themselves (better structured and less hurried consultations, better-informed decisions and more ‘person-centred’ rather than ‘patient-centred’, better-shared responsibility for the decision, and enthusiasm about the theory of SDM and timeout), for their patients (patients are more satisfied, are sure about their decision and their consultations are more at an equal level and individualized), and for the team (the feeling of teamwork increased, learning together as a team was appreciated, there was a better alignment of tasks). These advantages enhanced their intrinsic motivation. For some patients, for example palliative patients, discussing what matters to them in life may already be a natural process. However, clinicians indicated that implementing SDM with patients who are emotional, anxious, indecisive, have lower health literacy, or show an unsatisfied hunger for information, requires specific skills. Some clinicians viewed these patients as annoying, or as unmotivated/unable to share decisions. These clinicians remained doubtful as to whether all patients could — or wanted to — participate in SDM. Implementation was fostered by support from colleagues (a consequence of the team approach of the programme and observation of (new) communication skills applied by colleagues).

> *“Ultimately, you want to help patients as best as you can, that’s why you became a doctor. The advantage of SDM is that it helps to better structure the consultation. That brings more joy in your work.”*

> *“No, I always tell patients we make decisions together. Some of them are anxious to choose. They ask, ‘doctor what would you do’? Then I say: ‘I don’t have to live with it. Think about what is important in your life. We have time to think, we will work it out.”*

> *“This method helps you to get closer to patients, it puts you in a listening mode rather than a talking mode. If the patient feels you are interested, you get more information out in the open.”*

Organisational and Socio-political context

Questionnaires: Most reported barriers to the implementation of SDM included: limited (financial) means, and, to a lesser extent, a lack of time. Of the clinicians providing systemic therapy, 15% indicated that enough time is available to implement SDM and 23% felt that enough means and facilities are available. The simultaneous implementation of projects, which decreased focus and time for this project, was also perceived as a barrier (79%). Few difficulties arose from rules and laws that hamper the implementation of SDM (29%), except the criterion of the Dutch patient organisation that instructs hospitals to perform surgery within 5 weeks following diagnosis. This criterion was adjusted during the course of the project.

Interviews: Training and feedback on the recorded consultations were considered essential for gaining the skills needed to improve SDM. The interprofessional team training was thought to provide high added value: feedback was discussed, audio-recordings were used for reflection and actor role-play was used. Feedback on consultations should be as individual as possible, and connecting the feedback to the SDM-steps helped clinicians to understand how to apply SDM-theory in their practice.

The belief that SDM might cost more time (while the experience of many was that it did not cost extra time), was, at least for complex patients, felt to be a hurdle. However, interviewees reported that the duration of consultations could either be longer (e.g. with critical patients who keep asking questions and/or cannot decide) or shorter (e.g. if the care pathway has already involved several visits, better diagnostic information can save time) as a result of implementing SDM. The complexity of redesigning s care pathways to integrate SDM and timeout in consultations - and the logistical planning process required - should not be underestimated. However, if accomplished, clinicians indicated that this is a reinforcer and supported sustainable change. Implementation of SDM was facilitated by task re-assignment, especially the delegation and substitution of tasks to nurses (specialists). Clinicians indicated that their full agenda hindered them to discuss the improvements they wanted to make: ‘Many other things are going on’ in their hospital. The availability of an implementation coordinator can therefore be helpful to ensure that progress is maintained as well as offering tools to help patients engage in SDM. Clinicians did not indicate that guidelines or laws had hindered the application of SDM.

> *“Especially the feedback from the recorded conversations, you do pick out a lot of things there and then you realize how useful that is.”*
>
> *“Actually, no one can make a decision having only received information once.”*

Role of the research team

Questionnaires: Both the programme itself and the support provided by the research team was appreciated, and scores were higher in phase 2 than in phase 1. Respondents were pleased with the materials and the customized support provided by the research team. The collaborative meetings were less appreciated.

Interviews: Appreciation for the programme and the research team was high. In particular, the accessibility of the team, the practical examples provided, the feedback, and the training that included actor role-play were appreciated. Interviewees were also positive about the involvement of patient (representatives) in the programme.

Adaptations to the implementation programme

The programme was adjusted based on the feedback provided by participating clinicians in phase 1 (Table A.1). The major adaptations to the programme were: fewer collaborative meetings (in response to clinicians' busy schedules), personalization of the feedback provided to clinicians (achieved by individually marking consultation quotes), the addition of role-play as part of the training, and improvement of the tailored support provided by the research team. This included the provision of information about the project for both clinicians and patients, but also the appointment of an account manager per team who offered customized support to the team (coordinator) to help overcome any local barriers and practical problems.

Discussion and conclusion

Discussion

In this study, we evaluated how clinicians involved in breast cancer care perceived a multilevel implementation programme to accelerate the adoption of SDM. Clinicians rated the programme as feasible and valuable. They appreciated that the programme: (1) covered an important topic (SDM) of benefit to themselves and patients, (2) contained feedback and training that was both theory-based and practical, (3) included a focus on the team and care pathway, and (4) involved patients in the programme.

The programme was feasible to implement in routine breast cancer care, despite the generally high workload of clinicians. Our study participants consider SDM very relevant to breast cancer care, and feel that SDM is compatible with their views on what constitutes good healthcare. Aside from the personal investment and the extra time needed for critical, indecisive, or low health literate patients, clinicians experienced positive benefits of SDM for their patients, for their teamwork and their conversational skills. Clinicians' positive attitudes towards SDM are increasingly being reported [7,18], but our study adds knowledge on how this can be reinforced. This offers opportunities for future implementation.

Team training, individual and team feedback, combined with a theory-based 4-step model to structure consultations and the provision of practical examples [5], supports the translation of theory into practice. Clinicians perceived that this led to better-structured and more person-oriented consultations, and a more comprehensive communication approach of the team as a whole. It was considered important that the theory is reinforced by feedback and training. Clinicians were positive about the modern learning principles applied in the programme: Clinicians appreciated that individual feedback is given, and is shared with the team both in writing and face-to-face. They confirm that repetition of training, feedback and (team) reflection will be needed even when SDM has become part of routine care, in line with other findings [21,25,33–35,54,55]. The challenge appears to be to strengthen intrinsic motivation by inviting clinicians to embrace SDM as an essential part of their clinical role [21,56].

The integration of SDM and the inclusion of timeouts as part of their care pathway was also valued and requires that the team aligns the logistical processes and team tasks accordingly. This demands the cooperation of many colleagues, and management, and involves the reallocation of tasks and financial resources. They appreciated that the implementation approach focused on the multidisciplinary team: it is fun to learn about and work on SDM together, and involving management helps to overcome financial or organisational (i.e. logistical planning) problems, or counterproductive incentives. These findings are important for the design of SDM implementation programmes as they have been recommended – but they have hardly been put into practice [4,11,19,21,22,40,47,57,58].

Clinicians indicated that co-creation with patients helps to focus on enhancing SDM as part of the patient-clinician interaction, utilizes patient knowledge and ensures that what matters most to their life is taken into account. Patient involvement as part of implementation activities has been advocated before [21,31]. From our evaluation, it must be considered as a key implementation strategy.

Strengths and limitations

A strength of this study was the active participation of clinicians from different backgrounds, and patient representatives in designing, testing and evaluating the programme, based on theoretical implementation framework. The evaluation was carried out shortly after the intervention, which lowered the risk of recall bias. However, the limited response rate of the questionnaires might have led to sampling bias. Moreover, 13 of the 21 interviews were not conducted by an independent researcher but by members of the research team. This might have influenced the responses but may also have helped to collect more in-depth information. Another limitation is that the participants were more motivated to implement SDM than clinicians in general or that barriers or facilitators were missed due to the limited number of interviewees. The study results might therefore reflect the views of early adopters in this field. Nevertheless, this is valuable as it will help to attract the next group of followers and accelerate the implementation of SDM.

Conclusions

In this study, an implementation programme for SDM in breast cancer care was evaluated favourably. Our multilevel approach helped to reinforce clinicians' intrinsic motivation to apply SDM. Highly valued aspects of the programme design were: the provision of feedback on consultations, interprofessional training incorporating actor role play, the team-focus, and the process of redesign to create time for SDM. Patient involvement should be an essential part of any SDM implementation effort. Finally, clinical teams benefit from a co-creating and accessible research team in overcoming practical barriers and supporting change at different levels in the organisation.

Practice implications

Key elements for implementing SDM in clinical practice are process redesign and improving conversational skills as part of professional behaviour. By taking the clinician-patient interaction as the starting point for the design of the care process, clinicians can be intrinsically motivated to adopt SDM and barriers related to the multidisciplinary context of the workplace and the workload can be overcome. Standardization of the programme lowers costs for the clinical and/or research (support) team and makes this approach scalable.

Ethics approval and consent to participate

Approval for the study was obtained from the medical ethics review board (W16.019) and informed consent from the interviewees was received for making audio-recordings.

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CRediT authorship contribution statement

Two investigators (HvV, CH) designed the study. HvV, CH and EV obtained funding. HvV coordinated the research activities: selection of the study participants and study design, data collection, data analysis, data interpretation, and writing of the manuscript. LK, HVo, JO, EvW conducted interviews and collected questionnaires. HvV, HVo, LK, EvW and HvV performed the data analysis. JO, EV and MS coordinated patient involvement in the design of the study and the interpretation of the results. All authors contributed to the interpretation of the data and had full access to all of the data (including notes from interviews, questionnaires and tables), and can take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to the concept versions of this manuscript and approved the final version for publication. HvV is the guarantor.

Data sharing

De-identified data can be requested from the corresponding author at haskevanveenendaal@gmail.com.

Transparency

The corresponding author (HvV) affirms that the manuscript is honest, accurate, and a transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

Conflict of interests

The views presented in this publication are solely the responsibility of the authors. The funders of the study were informed about the study progress during the course of the project and approved the study concept and the final results of the study. The funders were not allowed to propose participants for the interviews or questionnaires.

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Chapter 6

Shared decision-making and the effect on the duration of medical consultations: A systematic review

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Abstract

Objective: 1) determine whether increased levels of shared decision-making (SDM) affect consultation duration, 2) investigate the intervention characteristics involved.
Methods: MEDLINE, EMBASE, CINAHL and Cochrane library were systematically searched for experimental and cross-sectional studies up to December 2021. A best-evidence synthesis was performed, and characteristics of interventions that increased at least one SDM-outcome, were pooled and descriptively analysed.
Results: Sixty-three studies were selected: 28 randomized clinical trials, 8 quasi-experimental studies, and 27 cross-sectional studies. Overall pooling was not possible due to substantial heterogeneity. No difference in consultation duration was found more often than increased durations. Consultation times (minutes; seconds) were significantly increased among interventions that: 1) targeted clinicians only (Mean Difference [MD] 1;30, 95% Confidence Interval [CI] 0;24 – 2;37), 2) were performed in primary care settings (MD 2;05, 95%CI 0;11 – 3;59) 3) used a group format (MD 2;25, 95%CI 0;45 – 4;05), and 4) were not theory-based (MD 4;01, 95%CI 0;38–7;23).
Conclusion: Applying SDM does not necessarily require longer consultation durations. Theory-based, multilevel implementation approaches possibly lower the risk of increasing consultation durations.
Practice implications: The commonly heard concern that time hinders SDM implementation can be contradicted, but implementation demands multifaceted approaches and space for training and adapting work processes.

Highlights

- Introducing SDM does not necessarily lead to a prolonged consultation length
- Multilevel theory-based approaches seem important to avoid longer consultations
- Clinicians initially need time for training SDM skills and adapting work processes
- It is important to train and facilitate clinicians to work with decision tools
- Even if SDM increases consultation time, this is so limited that it justifies the effect

Introduction

Encouraging implementation of shared decision-making (SDM) is essential as SDM is considered to be the crux of patient-centred, high-quality healthcare [1–3]. SDM refers to a process of deliberate decision-making, involving both the patient and clinician in an equal manner, and applying the best available evidence in line with patients' personal values and preferences [4]. SDM will help patients play a more active role in the decision-making process and transform the patient-clinician relationship from the paternalistic model into a shared approach, especially in the context of preference-sensitive decisions [5,6]. Despite the evidence on the benefits of SDM, the extent to which physicians apply it in daily practice remains low [7–10]. Multiple barriers to SDM implementation have been identified. A limited consultation duration or the clinicians' concern that SDM may result in a prolonged consultation duration is perceived to be one of the biggest barriers [11–16].

Studies evaluating the effects of SDM have mainly addressed patient- and clinician-reported outcomes focusing on their views and experiences with SDM. The impact of SDM, or patient decision aids used during clinical encounters, on consultation length received less attention. One review showed no significant difference in consultation duration when a decision aid was used in 9 out of 13 included trials [17]. Another review, examining pre-encounter and encounter-based decision aids, found that outpatient consultations were not prolonged in 8 out of 10 studies [18,19]. However, as not all interventions succeeded in improving the level of SDM in routine clinical practice, no conclusions can be drawn from these reviews as to whether increased or decreased consultation time is related to the level of SDM in practice, or with applying the SDM intervention itself.

Therefore, the aim of this study was to determine whether an increase in the level of SDM in routine medical practice affects consultation duration and, if so, which intervention characteristics are involved. As many implementation approaches have been investigated, it is important to know which type of interventions contribute to SDM in an efficient way. Resolving this query could help clinicians acknowledge and overcome the perceived time barrier and, consequently, contribute to better SDM implementation in daily medical practice.

Methods

The Preferred Reporting Items for Systematic Reviews and MetaAnalyses (PRISMA) checklist was applied to ensure transparent and complete description of the methods used [20].

Eligibility criteria

Study eligibility was based on the following inclusion criteria: 1) experimental study design, evaluating the implementation of one or multiple SDM-intervention(s), or non-experimental, measuring the extent to which SDM is applied in clinical practice and providing data on its correlation with consultation duration; 2) study population of patients aged 18 years or older, facing decisions in regard to screening, diagnosis or treatment for themselves, their child, partner or other mentally or physically incompetent family member; 3) for experimental study designs the intervention should be designed to facilitate constructive encounters and collaborative discussions between patients and clinicians, aiming to involve patients in the decision-making process; 4) control group(s) receiving usual care or an alternative intervention; 5) the study should assess (the level of) SDM using at least two of the following SDM-related outcomes: observed level of SDM (i.e. OPTION-score), patient/clinician-perceived level of SDM (i.e. SDM-Q-9, Collaborate), patient knowledge, decisional conflict, accuracy of patient risk perceptions, patient/clinician satisfaction with the decision-making process; 6) providing consultation duration and data regarding its possible association with SDM (for experimental studies: measurements of SDM and consultation duration in both intervention and control groups; for non-experimental studies: statistical assessment of the correlation between the level of SDM-related outcomes and consultation duration). Only peer reviewed studies were eligible.

Experimental studies that did not result in any statistically significant improvement in at least one of the abovementioned SDM-related outcomes favouring the intervention, were excluded. The objective and patient perceived level of SDM possibly represent a more valid outcome for the occurrence of SDM. Therefore, the studies that scored at least positive on one of these 2 outcomes were also analysed.

Articles were also excluded if they strictly focused on describing patient preferences regarding different approaches to patient-clinician communication (e.g. passive, autonomous or shared patient role). Systematic reviews were excluded after screening their reference lists. Abstracts in absence of available full text, letters, correspondences, editorials, and commentaries were excluded too.

Consultation duration was defined as the time patients personally spent with the clinician(s), either with or without using a SDM support tool, to discuss possible screening, diagnostic or therapeutic options in order to make a decision. Additional time spent by patients or clinician to review SDM support tools prior to, or after the patient-clinician encounter was not accounted for as a part of 'consultation duration'.

Information sources and search strategy

Multiple search strategies were developed by a trained clinical librarian to avoid bias from narrow searches and to widen the range of studies beyond those already identified in previously published literature reviews. Databases were searched from their inception to December 2021 employing MEDLINE (Ovid), EMBASE (Ovid), CINAHL (Ebsco) and Cochrane Library (Wiley). No language or publication time restrictions were imposed. Search strategies included a variety of subject headings and text words associated with 'shared decision-making' and 'consultation time'. Full versions of search strategies used in this review can be found in Supplementary file 1.

Selection process

After elimination of duplicate publications, two review team members (EC and HvV or CB) screened titles and abstracts of all identified references, independently deciding on which papers to retrieve for full text evaluation. Full texts of potentially relevant articles were then independently assessed for eligibility by two reviewers (EC and HvV). Reference lists of identified systematic reviews and articles selected for full-text review were manually screened for relevant citations. Discrepancies in study selection between the researchers were resolved through discussion.

Data collection process

Standardized data collection sheets were used to extract data on participants, SDM interventions, control conditions, follow-up intervals and relevant outcomes. Data were independently extracted by two of the review team members (GC and HvV or CB), blinded to each other's evaluation, and cross-checked by the first authors (GC, HvV). If studies failed to report mean differences, p-values, or confidence intervals, either the study authors were asked via email to provide these values, or these metrics were calculated as means and standard deviations, whenever possible. Extended versions of the data tables can be found in Supplementary File 2.

Risk of bias assessment

Risk of bias assessment was performed by the reviewers (GC and HvV or CB) and cross-checked. In cases of uncertainty or disagreement, reviewers conferred until consensus was reached. The selected RCTs and quasi-experimental studies were analysed using the Cochrane Collaboration's tool for risk of bias assessment [21]. Seven domains were scored as low risk of bias/positive (+), high risk of bias/negative (-), or unclear risk of bias (?). Blinding of participants and personnel was not taken into account in the quality assessment as it was considered impossible in studies that evaluate SDM interventions. Therefore, a positive score on the remaining six key domains were considered were considered high-quality studies [22].

For cross-sectional studies, the Centre for Evidence-Based Medicine (CEBM) checklist for critical appraisal was used [23]. The checklist consists of 12 appraisal questions, receiving a score (Yes, Can't tell, No). For the assessment, a slightly higher cut-off value (75%) was used than in similar studies [24,25] to have a value more in line with that of the RCTs: When 9 or more questions were answered with yes, studies were considered to be of "high quality". Below this threshold they were considered as "low quality".

Data items, effect measures and synthesis methods

Intervention characteristics and consultation time

The Template for Intervention Description and Replication (TIDieR) checklist was used to describe the details of the SDM interventions in the selected studies [26]. The presence of all characteristics in each intervention was independently reported by three researchers (GC, CB, HvV). Differences in extracted data between the researchers were resolved through discussion. The following intervention characteristics were documented: 1) theory-based (yes, no); 2) multifaceted (yes, no); 3) target (patients only, clinicians only, or both clinicians and patients); 4) care setting (primary care, secondary/tertiary care, other); 5) format (individual, group); 6) intervention mode (face-to-face, paper-based, digital, telecommunication); 7) Intervention content (includes patient information, patient coaching, patient/personal risk assessment, clinician training); 8) timing (pre-encounter, during encounters, both pre- & during encounters); 9) frequency (once, more than once).

As primary outcome, the mean differences (MD) in consultation times (in minutes: seconds) between before and after the SDM-intervention were used. Standardized mean differences (SMD) were used when consultation durations were operationalized in different ways. Continuous variable scales, e.g. of the level of SDM, were standardized to a scale of 0–100. If outcome data could not be retrieved from authors, standard deviations were derived from standard errors or confidence intervals [27].

To arrive at a percentage of studies showing no increased consultation time when introducing a SDM-intervention with the specified intervention characteristic, the number of studies that did not report a significant increase in consultation time are divided by total number of studies that investigated this specific intervention characteristic, and reported a statistically significant outcome in favour of the SDM-intervention group. A high percentage indicates that this intervention characteristic does not take more consultation time.

Best evidence synthesis

As we expected high level of heterogeneity in the (subgroup) analyses, a best evidence synthesis was carried out to explore the impact of SDM interventions on consultation length [28]. For the appraised RCT's and Quasi-experimental studies four levels of evidence were defined [29]: Strong evidence (consistent results among two or more high-quality studies), Moderate evidence (results from one high-quality study and/or consistent results among two or more lower-quality studies), Limited evidence (one lower-quality study) and Conflicting evidence (inconsistent results among two or more studies). Outcomes were considered consistent if at least 75% of the studies reported the same positive or negative finding [22]. If there were two or more high-quality studies, the lower-quality studies were ignored in the best evidence synthesis.

For the selected cross-sectional studies, the quality of individual studies was assessed, but no best evidence synthesis was performed.

Meta-analysis

Review Manager Software (version 5.4.1) was used for pooling consultation duration across studies, if reported in three or more studies in order to have sufficient data for pooling. We refrained from pooling if the studies showed large clinical heterogeneity, e.g., due to differences in patient populations, care processes, interventions, or reported outcomes including consultation duration. Statistical heterogeneity across studies was determined using the I^2 statistic. An I^2 value above 50% was interpreted as substantial heterogeneity [31]. If pooling was meaningful, meta-analysis was conducted using DerSimonian and Laird's random effects model for continuous outcomes with 95% confidence intervals (CI) [30].

Results

Study selection

After removing duplicates, the literature search identified 5319 publications. After screening titles and abstracts, 159 full-text articles were retrieved for a detailed eligibility assessment. Eventually, a total of 63 studies met the inclusion criteria: 28 randomized clinical trials [32–59], 7 quasi-experimental studies [60–66], and 28 cross-sectional studies [15,67–93]. The flow of study inclusion and reasons for exclusion are presented in Fig. 1.

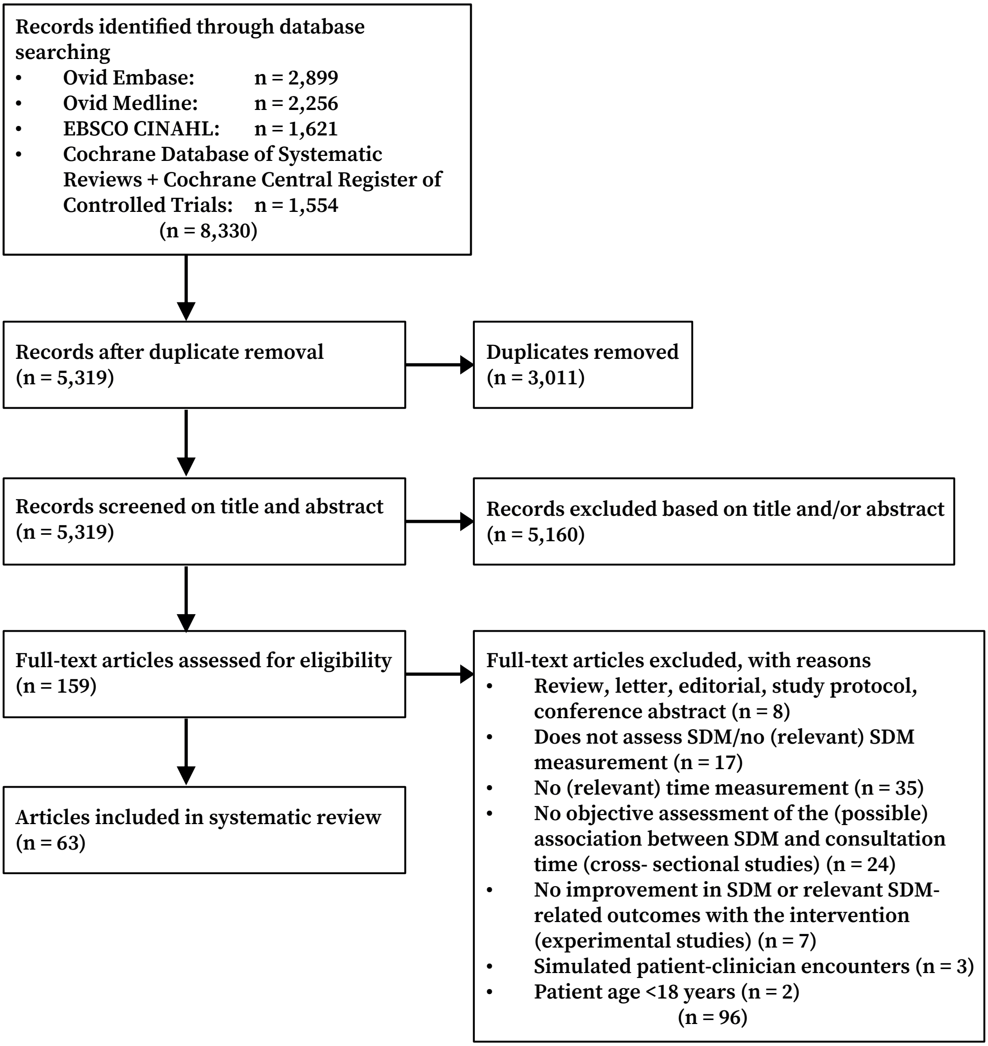


Figure 1. Inclusion procedure.

Study characteristics

Study participants

An overview of characteristics of the included studies is presented in Table 1 (experimental studies) and Table 2 (cross-sectional studies). A total of 14,469 patients (range 18–3453) participated in the studies. The selected studies reported on a broad variety of conditions: oncology [33,35,45,47,49,64–66,69,86,90,91], musculoskeletal disorders [34,40,42,44,48,50,55,81,84,87], cardiovascular disease [36,51–53,70,78,93,94], general practice consultations [68,71,73,75,80,83,95], mental disorders [32,39,41,60,61,82], diabetes mellitus type II [37,43,46], elective otolaryngologic surgery [72,88,92], asthma [57,67], palliative care [58,77], and other [15,38,56,62,63,74,76,79,85,89].

SDM interventions

The characteristics of the included interventions are described in Table 3 [26]. Overall, the included interventions could be divided in three groups: SDM support tools for use during face-to-face patient-clinician encounters (mainly paper-based decision aids), support tools designed for patient and/or clinician review prior to patient-clinician encounters (e.g., digital patient decision aids, websites), and clinician training to enhance SDM implementation skills. The majority of the included quasi-experimental and cross-sectional studies (17 of 35) evaluated a decision aid, ten combined decision aids with additional training or instruction for clinicians, four studies investigated training without a decision aid and four interventions had a multifaceted design (i.e. a combination of at least 2 interventions, whereby training is not limited to instruction of the decision tool). Four studies examined the effect of clinician training only.

Control groups received placebo or no intervention (usual care). In the control groups, usual care or an alternative information intervention was provided, such as patient pamphlets, brochures [43,47,50], or written evidence-based guidelines [52]. One crossover study randomized clinicians to receive training in SDM skills or the use of risk communication aids [95]. The quasi-experimental studies used a baseline measurement as control situation [61–63,66].

Follow-up intervals, outcomes and measurement of consultation duration

Follow-up intervals of most studies were short; only three studies had a follow-up of approximately a year [56,66,96]. Normally, studies collected their data during or directly after the intervention. Consultation duration was measured in different ways across studies. Mostly, consultation time was defined as the moment patients enter and exit the clinicians' office, so including history taking and physical examination. Consultation time in 22 randomized and quasi-experimental studies was retrieved from audio- or video- recordings of the consultations

Table 1. Overview of the included studies

Randomized Controlled Trials									
	Participants	Intervention	Control condition	Outcome		Score	Study quality	Observed SDM level	Patient perception
				Measurement method	Mean difference between groups [95%CI]				
Aoki (2019)	Depressive disorder (n = 68) Bipolar disorder (n = 20)	7-day multifaceted SDM program for patients	Passive	Documented by an observer	-1.78 [-7.77, 4.21]	NS	Low	X	↑
Berger-Höger (2019)	Breast cancer (n = 64)	DA, nurse-led SDM patient coaching	Passive	Video-recordings	-11.50 [-14.68, -8.32]	↓	Low	↑	NS
Bozic (2013)	Osteoarthritis of hip and knee (n = 123)	DA's (2x) and SCOPED question-listing intervention	Active	Audio-recordings	0.0 [-2.47, 2.47]	NS	Low	X	X
Coylewright (2016)	Stable coronary artery disease (n = 124)	DA	Passive	Video-recordings	0.00 [-7.82, 7.82]	NS	Low	NS	X
Elwyn (2004)	Atrial fibrillation, prostatism, menorrhagia or menopausal symptoms (n = 352)	Workshops for clinicians	Active	Audio-recordings	-	NS	High	↑	X
Elwyn (2016)	Osteoarthritis of the knee (n = 72)	DA	Passive	Audio-recordings	-1.70 [-6.17, 2.77]	NS	High	↑	X
Geiger (2017)	Various medical contexts (n = 152)	Training module for clinicians	Active	Video-recordings	0.65 [-4.70, 6.00]	NS	Low	↑	↑
George (2021)	Asthma (n = 77))	Clinician-led semi-scripted discussion using motivational interviewing	Active	Retrieved from the audio-recordings of the consultations	-2.50 [-5.24, 0.24]	NS	High	X	↑

Table 1. - Continued Overview of the included studies

Randomized Controlled Trials									
	Participants	Intervention	Control condition	Outcome		Score	Study quality	Observed SDM level	Patient perception
				Measurement method	Mean difference between groups [95%CI]				
Henselmans (2020)	Palliative systemic treatment (n = 187)	Skills training for clinicians, DA	Passive	Retrieved from the audio-recordings of the consultations	0.94 [-3.24 -5,71]	NS	Low	↑	↑
Hess (2016)	Low risk chest pain (n = 898)	Risk assessment web-tool, corresponding DA	Passive	Video-recordings	1.30 [1.25, 1.35]	↑	Low	↑	X
Jajakumar (2021)	Osteoarthritis of the knee (n = 129)	Artificial Intelligence-enabled DA	Active	Personalized outcome estimations within the DA (using patient-reported measurements)	2.20 [-2.02, 6.42]	NS	Low	X	↑
Krist (2007)	Prostate cancer screening (n = 497)	DA (2 versions)	Passive	Reported by the patient directly after the consultation (estimate) Reported by the clinician directly after the consultation (estimate)	-	NS ↓	Low	X	↑
Kunneman (2020)	Atrial fibrillation (n = 922)	DA including individualized risk assessment	Passive	Registration by observer/researcher	1.00 [-1.18, 3.18]	NS	Low	↑	X
Kunneman (2021)	Diabetes mellitus type 2 (n = 350)	DA, clinician training on the use of the DA	Active	Retrieved from the audio-recordings of the consultations	-2.00 [-14.50, 10.50]	NS	Low	↑	X
Kushner (2021)	Ventral hernia (n = 18)	DA	Passive	Timed by observer/researcher	10.90 [5.20, 16.60]	↑	Low	↑	X

Table 1. - Continued Overview of the included studies

Randomized Controlled Trials									
	Participants	Intervention	Control condition	Outcome		Score	Study quality	Observed SDM level	Patient percep-tion
				Measurement method	Mean differ-ence between groups [95%CI]				
LeBlanc (2015, D)	Mild depression (n = 297)	DA	Passive	Video-recordings	-4.00 [-13.99, 5.99]	NS	Low	↑	X
LeBlanc (2015, O)	Osteoporosis (n = 77)	DA	Passive	Video-recordings	-4.10 [-12.57, 4.37]	NS	Low	↑	X
Loh (2007)	Depression (n = 287)	Multifaceted SDM program including physician training, printed patient information and a DA	Passive	Documented by the clinician	2.50 [-1.04, 6.04]	NS	Low	X	↑
Montori (2011)	Osteoporosis (n = 100)	DA including risk assessment cal-culator (FRAX)	Active	Video-recordings	0.00 [-6.51, 6.51]	↑	High	↑	X
Nannenga (2009)	Type 2 diabetes (n = 98)	DA	Active	Video-recordings	13.60 [6.33, 20.87]	NS	High	↑	X
Ozanne (2007)	Breast cancer prevention (n = 30)	DA, clinician training on the use of the DA	Passive	Documented by the clinician	2.40 [-3.34, 8.14]	NS	Low	X	X
Pereste-lo-Perez (2016)	Type 2 diabetes (n = 168)	DA	Passive	Documented by the clinician	-1.55 [-5.26, 2.16]	NS	Low	X	X
Politi (2019)	Breast recon-structions (n = 120)	DA including risk assessment tool	Active	Documented by the clinician	-0.10 [-34.91, 34.71]	NS	Low	NS	NS
Sanders (2017)	Lower back pain (n = 172)	Training sessions for clinicians (2x),	Passive	Audio-recordings	2.70 [0.88, 4.52]	↑	High	↑	X

Table 1. - Continued Overview of the included studies

Randomized Controlled Trials									
	Participants	Intervention	Control condition	Outcome		Score	Study quality	Observed SDM level	Patient perception
				Measurement method	Mean difference between groups [95%CI]				
Stubenrouch (2022)	Abdominal Aortic Aneurism (n = 87) Intermittent Claudication (n = 143) Varicose Veins (n = 112)	DA's, consultation cards, decision cards, clinician training	Passive	Obtained from the audio-recordings or reported by participating surgeon/center	2.10 [0.91, 3.29]	↑	Low	↑	NS
Thomson (2007)	Atrial fibrillation (n = 136)	DA including risk assessment	Active	Video-recordings	7.33 [2.01, 12.65]	↑	High	X	X
Whelan (2003)	Lymph node-negative breast cancer (n = 175)	DA	Active	Documented by the clinician	2.60 [-5.48, 10.68]	NS	Low	X	NS
Wilkens (2019)	Trapezio-metacarpal arthritis (n = 90)	DA	Active	Documented by the clinician	0.00 [-0.38, 0.38]	NS	Low	X	X
Quasi-experimental studies									
Abousheishaa (2021)	Major depressive disorder (n = 378)	DA	Passive	Post-encounter clinician report	-1	NS	Low	X	↑
Brinkman (2013)	Attention-deficit hyperactivity disorder (n = 54)	Printed patient information, DA, physician training	Passive	Video-recordings	0.6 (-3.4, 4.8)	NS	Low	↑	X
Fay (2016)	Neonatal circumcision (n = 32)	DA, physician training	Passive	Video-recordings	0.5	NS	Low	↑	X
Kim (2005)	Family planning (n = 83)	DA, physician training	Passive	Video-recordings	4	↑	Low	↑	X

Table 1. - Continued Overview of the included studies

Randomized Controlled Trials									
	Participants	Intervention	Control condition	Outcome		Score	Study quality	Observed SDM level	Patient perception
				Measurement method	Mean difference between groups [95%CI]				
Lowenstein (2020)	Lung cancer screening (n = 51)	DA, in person decision coaching for patients (guided by nurses/APPs), clinician training	Passive	Audio-recordings	2.1	NS	Low	X	↑
Søndergaard (2021)	Breast cancer, lung cancer (n = 261)	2 DA's, clinician training on the use of SDM and DA's	Active	Documented by an observer	1.18 (-1.33, 5,72)	NS	Low	↑	X
Veenendaal, van (2021)	Breast cancer (n = 139)	Multifaceted program including physician training, feedback, and DA's	Passive	Audio-recordings	2.3 (-4.,1, 8.8)	NS	Low	↑	NS

NS = Not significant; ↑ = Significant increase; X = Not measured in this study

Table 2. Overview of the included cross-sectional studies

Study	Participants/ clinical context	SDM provider/ type healthcare professional	Clinical setting	Follow-up interval/ timing measurements	Method/scale used to assess SDM	Method used to assess consultation duration	Study quality	Score
Adams (2001)	Asthma (n = 128)	Pulmonologists	Pulmonology (tertiary care)	12 months (data gathered at the end of the 12-months follow-up)	Patient-perceived involvement	Reported by the patient (estimate)	Low	↑
Burton (2010)	Heart disease (n = 85)	Cardiologists	Cardiology	During the consultation	Observed level of SDM (OPTION-12) Patient-perceived involvement (SDMQ-9)	Documented by the observer	Low	NS
Coutu (2015)	Persistent (>12 weeks) pain (n = 37)	Occupational therapists	Work rehabilitation programs/ clinics	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Driever (2021)	Hospital care (n = 727)	18 different specialties	Mixed conditions, hospital	During the consultation (video-recorded)	Observed level of SDM (OPTION-5)	Video recordings	Low	↑
Dubenske (2021)	Breast cancer screening (n = 53)	DA including risk assessment tool	Primary care	During the consultation (audio-recorded	Observed level of SDM (OPTION-5)	Audio recordings	Low	↑
Evong (2019)	Elective otolaryngologic surgery (n = 117)	Otolaryngologists	Pediatric Otolaryngology	During the consultation (video-recorded)	Observed level of SDM (OPTION-12)	Video recordings	Low	↑
Gagnon (2010)	Prenatal screening for Down syndrome (n = 128)	Family physicians	Family care practice	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Geesink (2018)	Oncologic surgery (n = 80)	Oncologic surgeons	Oncology	During the consultation (audio-recorded)	Observed level of SDM (OPTION-5, OPTION-12, MAPPINSDM)	Audio recordings	Low	↑
Gotler (2000)	GP consultations (n = 3453)	General practitioners	General practice	During the consultation	Observed level of SDM (Davis Observation Code/DOC)	Documented by the observer	Low	↑

Table 2. - **Continued** Overview of the included cross-sectional studies

Study	Participants/ clinical context	SDM provider/ type healthcare professional	Clinical setting	Follow-up interval/ timing measurements	Method/scale used to assess SDM	Method used to assess consultation duration	Study quality	Score
Holmes-Rovner (2015)	Localized prostate cancer (n = 252)	Urologists	Oncology (Veteran Affairs Medical Centers)	During the consultation (audio-recorded)	Observed level of SDM (IDM score)	Audio recordings	Low	↑
Hong (2016)	Adeontonsillectomy or tympanostomy tube insertion (n = 126)	Pediatric otolaryngologists	Pediatric otolaryngology (tertiary)	During the consultation (video-recorded)	Patient-perceived involvement (SDMQ-9)	Video recordings	Low	NS
Hoorn, van (2021)	Hand surgery (n = 123)	Trauma surgeons & Plastic surgeons	Hand surgery (secondary & tertiary)	During the consultation (audio-recorded)	Observed level of SDM (OPTION-5)	Audio recordings	Low	↑
Jackson (2020)	Hypertension (n = 105)	Primary care physicians	Primary care	During the consultation (audio-recorded)	Observed level of SDM (OPTION-5)	Audio recordings	Low	NS
Labrie (2015)	GP consultations (n = 70)	General practitioners	General practice	During the consultation (video-recorded)	Observed level of SDM (OPTION-12)	Video recordings	Low	NS
Lam (2014)	Breast cancer (n = 283)	Breast surgeons and breast surgery trainees	Breast surgery	During the consultation (video-recorded)	Observed level of SDM (modified DAS-O score)	Video recordings	Low	↑
Langseth (2012)	Cardiac arrythmia (n = 49)	Cardiologists	Cardiology	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	NS
Lee (2020)	Primary care consultations, various conditions (n = 199)	Primary care physicians	Primary care	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Mathijssen (2019)	Rheumatoid arthritis (n = 168)	Rheumatologists	Rheumatology centers	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑

Table 2. - Continued Overview of the included cross-sectional studies

Study	Participants/ clinical context	SDM provider/ type healthcare professional	Clinical setting	Follow-up interval/ timing measurements	Method/scale used to assess SDM	Method used to assess consultation duration	Study quality	Score
Melong (2019)	Elective pediatric otolaryngologic surgery (n = 81)	Pediatric otolaryngologists (surgeons)	Pediatric otolaryngology	During the consultation (video-recorded)	Observed level of SDM (OPTION-12)	Video recordings	Low	↑
Menear (2018)	GP consultations (n = 114)	Primary care physicians	Primary care practices	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Milte (2015)	Geriatric transition care focusing on returning home from the ICU (n = 59)	Geriatricians	Post-acute residential care facility which provided transition care	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Pellerin (2011)	GP consultations (n = 152)	General practice residents	Primary care	During the consultation (video-recorded)	Observed level of SDM (OPTION-12)	Video recordings	High	↑
Pietrolongo (2013)	Multiple sclerosis (n = 88)	Primary care physicians, neurologists, neurology residents	MS care clinics	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Roodbeen (2021)	Palliative care consultations in patients with low health literacy	Oncologists, oncologic radiologists, pulmonologists, palliative care clinicians	Oncology, oncologic radiology, pulmonology	During the consultation (video-recorded)	Observed level of SDM (OPTION-5)	Video recordings	Low	↑
Stubenrouch (2017)	Elective surgery for which three anesthesia techniques were feasible (n = 80)	Anesthesiologists, anesthesia assistants	Anesthesiology	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	High	↑

Table 2. - Continued Overview of the included cross-sectional studies

Study	Participants/ clinical context	SDM provider/ type healthcare professional	Clinical setting	Follow-up interval/ timing measurements	Method/scale used to assess SDM	Method used to assess consultation duration	Study quality	Score
Vaillancourt (2012)	Nutrition/diet-related health care (n = 19)	Dietitians	Nutrition/ diet-related health care	During the consultation (audio-recorded)	Observed level of SDM (OPTION-12)	Audio recordings	Low	↑
Valverde Bolivar (2016)	GP consultations (n = 436)	Primary care residents and tutors	Primary care practice	During the consultation (video-recorded)	Observed level of SDM (CICCAA evaluation)	Video recordings	High	↑
Verwijmeren (2018)	Bipolar disorder (n = 78)	Psychiatrists, nurse practitioners	Psychiatry	During the consultation and directly after	Observed level of SDM (OPTION-12) Patient-perceived involvement (SDMQ-9)	Documented by the observer	Low	↑ NS

Table 3. Presence of all characteristics in each SDM intervention, percentage of SDM interventions with a particular intervention characteristic and success rates of intervention characteristics

	Theory-based		Multi-faceted		Target		Care setting			Format		Mode				Content				Timing		Frequency	
	Yes	No	Yes	No	Patient	Clinician	GP	Secondary/ tertiary	Other	Indi-vidual	Group	Face-to-face	Paper-based	Digital	Telecom	Patient infor-mation	Patient coaching	Risk assess-ment	Clinician training	Pre-en-counter	During the encounter	Once	More than once
Randomized controlled trials																							
Aoki (2019)	x		x		x	x		x		x		x	x		x	x	x		x	x	x		x
Berger-Hoger (2019)	x		x		x			x		x		x	x			x	x		x	x	x		x
Bozic (2013)	x		x		x			x		x		x	x	x	x	x	x			x			x
Coylewright (2016)	x			x	x	x		x		x			x			x			x	x			x
Elwyn (2016)	x			x	x	x			x	x			x			x					x	x	
Elwyn (2004)	x			x		x	x				x	x							x	x			x
Geiger (2017)	x			x		x	x	x		x		x	x	x					x	x			x
George (2020)	x			x	x			x		x		x	x	x			x				x	x	
Henselmans (2020)	x		x		x	x		x		x	x	x	x	x		x	x		x	x	x	x	x
Hess (2016)	x			x	x			x		x		x		x		x		x		x		x	
Jajakumar (2021)		x	x		x			x		x		x		x		x	x	x		x	x	x	
Krist (2007)		X		x	x		x			x			x	x		x				x		x	
Kushner (2021)	x			x	x			x		x		x	x			x	x	x			x	x	
Kunneman (2020)	x			x	x	x		x		x		x		x		x		x			x	x	
Kunneman (2021)	x			x		x	x			x		x	x			x					x	x	
LeBlanc (2015, D)	x			x	x		x			x		x	x			x			x		x	x	

Table 3. - Continued Presence of all characteristics in each SDM intervention, percentage of SDM interventions with a particular intervention characteristic and success rates of intervention characteristics

	Theory-based		Multi-faceted		Target		Care setting			Format		Mode				Content				Timing		Frequency	
	Yes	No	Yes	No	Patient	Clinician	GP	Secondary/ tertiary	Other	Indi-vidual	Group	Face-to-face	Paper-based	Digital	Telecom	Patient infor-mation	Patient coaching	Risk assess-ment	Clinician training	Pre-en-counter	During the encounter	Once	More than once
LeBlanc (2015, O)	x			x	x		x			x		x	x			x		x			x	X	
Loh (2007)	x		x		x	x	x			x		x	x	x		x			x	x	x		x
Montori (2011)	x			x	x		x			x		x	x			x		x			x	x	
Nannenga (2009)	x			x	x			x		x		x	x			x		x			x	x	
Ozanne (2007)	x		x		x	x		x		x		x		x		x		x	x	x	x		x
Perestre-lo-Perez (2016)	x			x	x			x		x		x	x			x		x			x	x	
Politi (2019)	x			x	x			x		x			x	x		x		x		x		x	
Sanders (2017)	x		x			x	x			x	x	x	x	x		x		x	x	x	x		x
Stuben-rouch (2022)	x			x	x	x		x		x	x	x	x			x			x	x	x		x
Thomson (2007)		X		x	x		x			x		x	x	x		x		x			x	X	
Whelan (2003)		X		x	x			x		x		x	x			x	x	x			x	x	
Wilkens (2019)	x			x	x			x		x				x		x	x			x		x	
% included*	85.7	14.3	28.6	71.4	85.7	42.3	35.7	64.3	3.6	96.4	14.3	82.1	78.6	50.0	9.1	89.3	32.1	46.4	39.3	57.1	71.4	64.3	39.3
Success rates**	19/24	3/4	7/8	15/20	19/24	10/12	7/10	15/18	1/1	21/27	2/4	17/23	17/22	11/14	2/2	19/25	8/9	8/13	9/11	13/16	15/20	14/18	9/11

Table 3. - Continued Presence of all characteristics in each SDM intervention, percentage of SDM interventions with a particular intervention characteristic and success rates of intervention characteristics

	Theory-based		Multi-faceted		Target		Care setting			Format		Mode				Content				Timing		Frequency	
	Yes	No	Yes	No	Patient	Clinician	GP	Secondary/ tertiary	Other	Indi-vidual	Group	Face-to-face	Paper-based	Digital	Telecom	Patient infor-mation	Patient coaching	Risk assess-ment	Clinician training	Pre-en-counter	During the encounter	Once	More than once
Quasi-experimental studies																							
Aboushe-ishaa (2021)	x			x	x			x		x		x	x			x					x	x	
Brinkman (2013)	x			x	x			x		x		x	x			x	x		x	x	x	x	
Fay (2016)	x			x	x	x		x		x		x	x	x		x			x		x	x	
Kim (2005)		x		x	x	x	x		x	x		x	x			x			x		x	x	
Lowenstein (2020)	x		x		x			x		x		x		x		x	x			x		x	
Sondergaard (2021)	x		x		x	x		x		x	x	x	x			x			x	x	x	x	
Veenendaal, van (2021)	x		x			x		x		x	x	x	x	x					x	x			x
% included*	85.7	14.3	42.9	57.1	85.7	57.1	14.3	85.7	14.3	100	28.6	100	85.7	42.9	0	85.7	28.6	0	71.4	57.1	71.4	85.7	14.3
Success rates**	6/6	0/1	3/3	3/4	5/6	3/4	0/1	6/6	0/1	6/7	2/2	6/7	5/6	3/3	0/0	5/6	2/2	0/0	4/5	4/4	4/5	5/6	1/1
Randomized controlled trials + quasi-experimental studies																							
% included*	85.7	14.3	31.4	68.6	85.7	45.7	31.4	68.6	5.7	97.1	17.1	85.7	80.0	48.6	5.7	88.6	31.4	37.1	45.7	57.1	71.4	68.6	34.3
Success rates** %	25/30 83.3	3/5 60.0	10/11 90.9	18/24 75.0	24/30 80.0	13/16 81.3	7/11 63.6	21/24 87.5	1/2 50.0	27/34 79.4	4/6 66.7	23/30 76.7	22/28 78.6	14/17 82.4	2/2 100	24/31 77.4	10/11 90.9	8/13 61.5	13/16 81.3	17/20 85.0	19/25 76.0	19/24 79.7	10/12 83.3

Inclusions: Of the total of 28 RCT's and 8 quasi-experimental studies, 27 RCT's + 8 quasi-experimental were included in the table. One study was excluded as the intervention characteristics were not available yet.
* % included: The number of studies that investigated an intervention with this intervention characteristic divided by the total number of studies.
** success rate: The number of studies that did not report a significant increase in consultation time divided by the total amount of studies that investigated this specific intervention characteristic.

(n = 22) [33,37,39,40,42–44,48,51-53,55-59,61–64,66,95]. In eight studies the patient or professional reported the duration after the consultation [35,41,45–47,50,60,96], four studies used a third observer (e.g. nurses on the ward) [32,36,38,65], and one study used personalized outcome estimations [34].

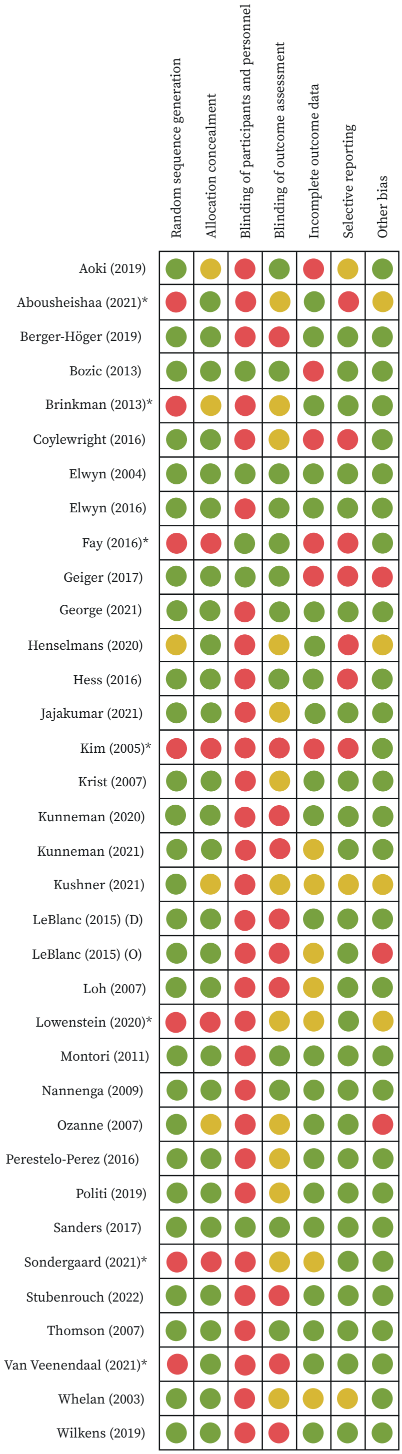
Risk of bias assessment

The risk of bias assessment is summarized in Fig. 2. Seven RCTs had positive scores on the six selected key domains and were considered high-quality studies [33,42,48,52,55,57,95].

Study results

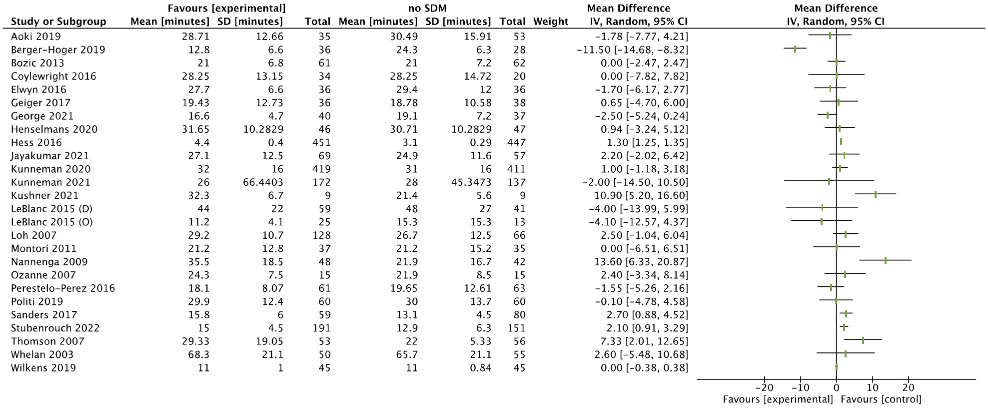
Consultation duration

Only the identified RCTs were selected for meta-analysis, as the quasi-experimental and cross-sectional studies did not report the necessary data. Two studies (RCTs) were excluded from the meta-analysis, as data on consultation duration were missing and/or could not be retrieved [35,95]. For one study that performed two measurements after the intervention, the first measurement was included [56], and for a study with four parallel arms, the combined intervention was inserted [58]. The included studies showed substantial clinical heterogeneity (Fig. 3), so an overall meta-analysis was not meaningful (I^2 =84%). After the SDM interventions, changes in mean consultation durations ranged between 11:30 min:sec shorter to 13:36 min:sec longer than before the intervention. In 24 of the 26 included RCTs (88%) and 6 of the 7 quasi-experimental studies (86%) this difference in consultation duration was less than 3 min, while before the intervention the mean consultation time in the control groups was 24:13 min:sec (range 3:06–84:00). Reduced consultation durations (2 studies) or no difference (26 studies) was found more



	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Aoki (2019)	🟢	🟡	🔴	🟢	🔴	🟡	🟢
Abousheishaa (2021)*	🔴	🟢	🔴	🟡	🟢	🔴	🟡
Berger-Höger (2019)	🟢	🟢	🔴	🔴	🟢	🟢	🟢
Bozic (2013)	🟢	🟢	🟢	🟢	🔴	🟢	🟢
Brinkman (2013)*	🔴	🟡	🔴	🟡	🟢	🟢	🟢
Coylewright (2016)	🟢	🟢	🔴	🟡	🔴	🔴	🟢
Elwyn (2004)	🟢	🟢	🟢	🟢	🟢	🟢	🟢
Elwyn (2016)	🟢	🟢	🔴	🟢	🟢	🟢	🟢
Fay (2016)*	🔴	🔴	🟢	🟢	🔴	🔴	🟢
Geiger (2017)	🟢	🟢	🟢	🟢	🔴	🔴	🔴
George (2021)	🟢	🟢	🔴	🟢	🟢	🟢	🟢
Henselmans (2020)	🟡	🟢	🔴	🟡	🟢	🔴	🟡
Hess (2016)	🟢	🟢	🔴	🟢	🟢	🔴	🟢
Jajakumar (2021)	🟢	🟢	🔴	🟡	🟢	🟢	🟢
Kim (2005)*	🔴	🔴	🔴	🔴	🔴	🔴	🟢
Krist (2007)	🟢	🟢	🔴	🟡	🟢	🟢	🟢
Kunneman (2020)	🟢	🟢	🔴	🔴	🟢	🟢	🟢
Kunneman (2021)	🟢	🟢	🔴	🔴	🟡	🟢	🟢
Kushner (2021)	🟢	🟡	🔴	🟡	🟡	🟡	🟡
LeBlanc (2015) (D)	🟢	🟢	🔴	🔴	🟢	🟢	🟢
LeBlanc (2015) (O)	🟢	🟢	🔴	🔴	🟡	🟢	🔴
Loh (2007)	🟢	🟢	🔴	🔴	🟡	🟢	🟢
Lowenstein (2020)*	🔴	🔴	🔴	🟡	🟡	🟢	🟡
Montori (2011)	🟢	🟢	🔴	🟢	🟢	🟢	🟢
Nannenga (2009)	🟢	🟢	🔴	🟢	🟢	🟢	🟢
Ozanne (2007)	🟢	🟡	🔴	🟡	🟢	🟢	🔴
Perestelo-Perez (2016)	🟢	🟢	🔴	🟡	🟢	🟢	🟢
Politi (2019)	🟢	🟢	🔴	🟡	🟢	🟢	🟢
Sanders (2017)	🟢	🟢	🟢	🟢	🟢	🟢	🟢
Sondergaard (2021)*	🔴	🔴	🔴	🟡	🟡	🟢	🟢
Stubenrouch (2022)	🟢	🟢	🔴	🔴	🟢	🟢	🟢
Thomson (2007)	🟢	🟢	🔴	🟢	🟢	🟢	🟢
Van Veenendaal (2021)*	🔴	🟢	🔴	🔴	🟢	🟢	🟢
Whelan (2003)	🟢	🟢	🔴	🟡	🟡	🟡	🟢
Wilkens (2019)	🟢	🟢	🔴	🔴	🟢	🟢	🟢

Figure 2. Cochrane risk of bias assessment.



Study or Subgroup	Favours [experimental] Mean [minutes]	SD [minutes]	Total	no SDM Mean [minutes]	SD [minutes]	Total	Weight	Mean Difference IV, Random, 95% CI
Aoki 2019	28.71	12.66	35	30.49	15.91	53		−1.78 [−7.77, 4.21]
Berger−Hoger 2019	12.8	6.6	36	24.3	6.3	28		−11.50 [−14.68, −8.32]
Bozic 2013	21	6.8	61	21	7.2	62		0.00 [−2.47, 2.47]
Coylewright 2016	28.25	13.15	34	28.25	14.72	20		0.00 [−7.82, 7.82]
Elwyn 2016	27.7	6.6	36	29.4	12	36		−1.70 [−6.17, 2.77]
Geiger 2017	19.43	12.73	36	18.78	10.58	38		0.65 [−4.70, 6.00]
George 2021	16.6	4.7	40	19.1	7.2	37		−2.50 [−5.24, 0.24]
Henselmans 2020	31.65	10.2829	46	30.71	10.2829	47		0.94 [−3.24, 5.12]
Hess 2016	4.4	0.4	451	3.1	0.29	447		1.30 [1.25, 1.35]
Jayakumar 2021	27.1	12.5	69	24.9	11.6	57		2.20 [−2.02, 6.42]
Kunneman 2020	32	16	419	31	16	411		1.00 [−1.18, 3.18]
Kunneman 2021	26	66.4403	172	28	45.3473	137		−2.00 [−14.50, 10.50]
Kushner 2021	32.3	6.7	9	21.4	5.6	9		10.90 [5.20, 16.60]
LeBlanc 2015 (D)	44	22	59	48	27	41		−4.00 [−13.99, 5.99]
LeBlanc 2015 (O)	11.2	4.1	25	15.3	15.3	13		−4.10 [−12.57, 4.37]
Loh 2007	29.2	10.7	128	26.7	12.5	66		2.50 [−1.04, 6.04]
Montori 2011	21.2	12.8	37	21.2	15.2	35		0.00 [−6.51, 6.51]
Nannenga 2009	35.5	18.5	48	21.9	16.7	42		13.60 [6.33, 20.87]
Ozanne 2007	24.3	7.5	15	21.9	8.5	15		2.40 [−3.34, 8.14]
Perestelo−Perez 2016	18.1	8.07	61	19.65	12.61	63		−1.55 [−5.26, 2.16]
Politi 2019	29.9	12.4	60	30	13.7	60		−0.10 [−4.78, 4.58]
Sanders 2017	15.8	6	59	13.1	4.5	80		2.70 [0.88, 4.52]
Stubenrouch 2022	15	4.5	191	12.9	6.3	151		2.10 [0.91, 3.29]
Thomson 2007	29.33	19.05	53	22	5.33	56		7.33 [2.01, 12.65]
Whelan 2003	68.3	21.1	50	65.7	21.1	55		2.60 [−5.48, 10.68]
Wilkens 2019	11	1	45	11	0.84	45		0.00 [−0.38, 0.38]

Figure 3. Forest plot 1.1 - all studies.

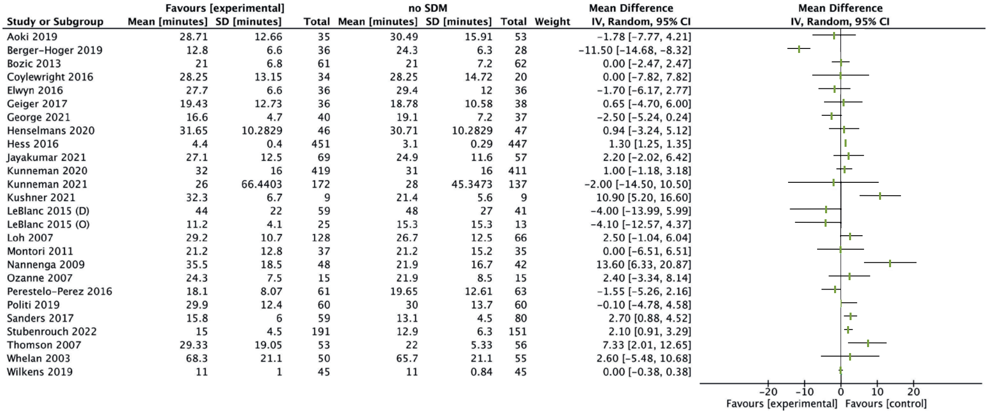
often than increased durations (7 studies). Selecting studies with only a positive outcome on either the objective or patient-perceived level of SDM, eight studies would be excluded (Table 1). Also then, heterogeneity was too high to conduct a meta-analysis. Of the remaining 27 experimental studies, 18 reported no significant change in duration, 2 showed a reduction and 6 an increase in consultation time.

Effects of intervention characteristics on consultation duration

In the analysis of intervention subtypes, study homogeneity was found for 5 out of 23 types of intervention characteristics: interventions that targeted clinicians only, used telecom (phone) as intervention mode, were applied in primary care settings, used a group format, or were not theory-based (see Fig. 4). Interventions that used telecom as intervention mode (MD − 0:16 min:sec, 95%CI − 2:33–2:02, I^2 =0%) did not lead to significant changes in consultation duration. Interventions that targeted clinicians only (MD 1:30 min:sec, 95%CI 0:24–2:37, I^2 =0%), were performed in primary care settings (MD 2:05 min:sec, 95% CI 0:11–3:59, I^2 =19%), used a group format (MD 2:25 min:sec, 95%CI 0:45–4:05, I^2 =0%) and were not theory-based (MD 4:01 min:sec, 95% CI 0:38–7:23, I^2 =14%), resulted in a significant increase in consultation time, after the level of SDM had improved according to at least one of the selected SDM outcomes. If the subgroup analysis is limited to studies with a positive outcome on either the objective or patient perceived SDM level, increased durations were found for digital interventions (MD 1:13 min:sec, 95%CI 0:17–2:09, I^2 =33%).

Best evidence synthesis

Seven high-quality and 28 lower-quality randomized clinical and quasi-experimental studies that reported an increased application of SDM in routine medical



	Favours [experimental]			no SDM				Mean Difference
Study or Subgroup	Mean [minutes]	SD [minutes]	Total	Mean [minutes]	SD [minutes]	Total	Weight	IV, Random, 95% CI
Aoki 2019	28.71	12.66	35	30.49	15.91	53		−1.78 [−7.77, 4.21]
Berger–Hoger 2019	12.8	6.6	36	24.3	6.3	28		−11.50 [−14.68, −8.32]
Bozic 2013	21	6.8	61	21	7.2	62		0.00 [−2.47, 2.47]
Coylewright 2016	28.25	13.15	34	28.25	14.72	20		0.00 [−7.82, 7.82]
Elwyn 2016	27.7	6.6	36	29.4	12	36		−1.70 [−6.17, 2.77]
Geiger 2017	19.43	12.73	36	18.78	10.58	38		0.65 [−4.70, 6.00]
George 2021	16.6	4.7	40	19.1	7.2	37		−2.50 [−5.24, 0.24]
Henselmans 2020	31.65	10.2829	46	30.71	10.2829	47		0.94 [−3.24, 5.12]
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Jayakumar 2021	27.1	12.5	69	24.9	11.6	57		2.20 [−2.02, 6.42]
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LeBlanc 2015 (D)	44	22	59	48	27	41		−4.00 [−13.99, 5.99]
LeBlanc 2015 (O)	11.2	4.1	25	15.3	15.3	13		−4.10 [−12.57, 4.37]
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Montori 2011	21.2	12.8	37	21.2	15.2	35		0.00 [−6.51, 6.51]
Nannenga 2009	35.5	18.5	48	21.9	16.7	42		13.60 [6.33, 20.87]
Ozanne 2007	24.3	7.5	15	21.9	8.5	15		2.40 [−3.34, 8.14]
Perestelo–Perez 2016	18.1	8.07	61	19.65	12.61	63		−1.55 [−5.26, 2.16]
Politi 2019	29.9	12.4	60	30	13.7	60		−0.10 [−4.78, 4.58]
Sanders 2017	15.8	6	59	13.1	4.5	80		2.70 [0.88, 4.52]
Stubenrouch 2022	15	4.5	191	12.9	6.3	151		2.10 [0.91, 3.29]
Thomson 2007	29.33	19.05	53	22	5.33	56		7.33 [2.01, 12.65]
Whelan 2003	68.3	21.1	50	65.7	21.1	55		2.60 [−5.48, 10.68]
Wilkens 2019	11	1	45	11	0.84	45		0.00 [−0.38, 0.38]

Figure 4. Meta-analysis of intervention subtypes.

practice were included in the best-evidence synthesis. These showed conflicting evidence as to the effect of these SDM-interventions on consultation duration: From the seven high-quality RCTs included [33,42,48,52,55,57,95], three showed a significant increase in consultation duration [42,48,52], while four showed no significant change (Table 1) [43,55,57,95]. Of the 28 included lower-quality studies, four showed significant increases [38,59,63,86], one a significant decrease [33], and 23 showed no significant change in consultation duration in the intervention group compared to control. No synthesis of the high-quality cross-sectional studies was performed; 23 out of the 28 studies reported positive associations between the SDM level and consultation length and five showed no association [68,70,78,92,93].

Success rates

For each intervention characteristic of the investigated interventions in the selected RCTs and quasi-experimental studies, the percentage of studies reporting with no increased (i.e. not significant or decreased) consultation duration are presented (Table 3). Intervention characteristics that appeared to have a low risk (success rate>80%) of increasing consultation duration were: interventions that used telecom (100%, but only 2 studies), included patient coaching (90.9%), were multifaceted (90.9%), took place in secondary or tertiary care (87,5%), were provided before the encounter (85.0%), were offered more than once (83.3%), were theory-based (83.3%), were digital (82.4%), targeted clinicians (81.3%) and included training (81.3%) (Table 3). On the other hand, interventions that took place in an 'other care setting' (50%, but only 2 studies), were not theory-based (60%), were carried out in primary care (63.6%), or included risk assessment (61.51%), might carry a higher risk of lengthening consultations.

Discussion

Discussion

This study shows that SDM-promoting interventions in general do not necessarily lead to prolonged consultation durations. Overall, the number of studies showing shorter or similar consultation durations was higher than the number of studies reporting increased durations. These conclusions did not change when we limited our analysis to only studies reporting a positive outcome on patient perceived or observer reported SDM level. The effect on consultation duration varied with the types of SDM interventions. SDM interventions targeting clinicians only, in primary care settings, using a group format or having no theoretical basis, appear to lead to longer consultation durations. This may occur when interventions make insufficient use of theory that promotes the application of SDM, e.g. in clinician-only interventions [14,75,97]. The finding that consultation duration tends to increase when introducing SDM in primary care and when SDM interventions focus on groups, requires further research, especially since healthcare is more and more provided through multidisciplinary teams, which confounds the implementation of SDM in clinical practice. So far, the integration of SDM-interventions, for example through time-outs, into multidisciplinary care processes, has been investigated only in breast cancer care [33,66]. Here, it seems possible to lower the physicians' consultation time by adding a consultation with a (specialized) nurse in the clinical pathway [33], while preserving the level of SDM.

Research has repeatedly highlighted the importance of training clinicians as an effective means to promote SDM [11,98-101]. Only one study explicitly looked at a possible training effect over time [56], indicating that consultation duration may increase initially while training SDM skills, but decreases after the clinician has acquired these skills and conducts a more efficient and structured consultation gearing towards SDM. Clinicians' concerns about an increase in consultation duration, possible information overload, and patients' disinterest in being involved in the process of SDM, may resolve after a basic training and a short period of practicing SDM in daily practice [102]. This coincides with current medical learning theory, such as deliberate practice, that proposes to involve opportunities for repeated performance to refine behaviour [103,104]. Future research should focus on repeated forms of training SDM over longer time periods, and look for possibilities to provide immediate feedback [56,66], and time for problem-solving and evaluation, to investigate and pass through this learning curve over time. This is quite similar to the learning curves when new surgical techniques are introduced, e.g., robot surgery [105].

Providing patient information (e.g. patient decision aids) as an intervention to enhance SDM is theoretically likely to reduce consultation duration, as patients are better informed when entering the consultation room. This may explain our finding that consultation time increases after clinician-only SDM interventions. However, training might have a more substantial effect than providing patient information [58]. Therefore, it seems pivotal to properly train and facilitate clinicians (as well as patients) to work with decision tools [58]. This will also counteract the limited implementation of decision tools [18,106].

Cross-sectional studies suggest a positive correlation between increased SDM levels and consultation duration. However, as cross-sectional studies are unsuited to differentiate between cause and effect, this does not mean that applying SDM prolongs consultation duration. No intervention was offered in these studies and clinicians were not trained in SDM. A longer encounter could facilitate clinicians to adapt a more comprehensive approach to medical consultation, exploring patients' perspectives and values, suggesting higher SDM levels [8].

Strengths and limitations of this study.

A strength of this review is its focus on consultation duration in studies using interventions that actually improved SDM, and the inclusion of many studies that used an objective, observer-based assessment of the level of SDM [66]. Second, we were able to perform some quantitative meta-analyses. Furthermore, several non-observer-based SDM-related outcomes provided a comprehensive overview and added value in taking the patient's perspective into account.

On the other hand, this literature review has several limitations. Assessing the duration of a consultation varied across studies and may have been influenced by other factors than the introduction of SDM-interventions. Second, the Cochrane Collaboration's tool for assessing risk of bias assesses internal validity, but it does not account for insufficient statistical power [97]. It is conceivable that included studies were not sufficiently powered to show a true effect. Lastly, the inclusion of non-randomized studies resulted in a higher risk of bias and, thus, a lower quality of evidence.

Conclusion

Implementation of SDM in clinical practice does not necessarily require longer consultation durations. Consultations were not prolonged in the majority of studies reviewing the effects of SDM interventions. Theory-based multilevel implementation approaches seem to have a higher impact on observed SDM behaviour, while at the same time reducing the risk of increased consultation durations [13,66]. Training clinicians' SDM skills allows for feedback and a learning curve over time.

Adapting the context of clinicians, such as the introduction of time-outs in the clinical pathway, redesign of the collaboration within multidisciplinary teams and diffusion of team tasks, might be crucial for substantial integration of SDM in routine medical practice and for its maintained usage over time. Research should investigate how decision tools can be better integrated in clinical pathways and at the same time reduce consultation duration [107–109]. Nevertheless, the increase in consultation duration in the studies reporting this appears to be so limited, that it may be justified by the improved SDM application and its associated quality improvement.

Practice implications

Clinicians' concerns that SDM may result in prolonged consultation durations, being a major implementation barrier, can be best prevented by implementing SDM thoughtfully. Results of this review reinforce the idea that concerted efforts are needed for effective implementation of SDM in routine medical practice, especially by multifaceted approaches that include improving the diffusion of tasks in the clinical team, thus dividing the time pressure and the workload. Finding space in the busy agenda of clinicians is vital, as it is likely that training SDM skills and adapting working processes will initially need a time investment, but may save time eventually. Promising actions to enhance SDM include training clinicians' SDM skills, the use of decision aids, option-grids, and time-outs to match the number and timing of consultations to the pace that patients need to participate in the process of SDM. To secure an effective approach and support of clinicians, learning principles that strengthen intrinsic motivation and proper facilitation of process redesign are vital.

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Ethical approval

No approval for the study was needed from the medical ethics review board.

CRediT authorship contribution statement

Haske van Veenendaal: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Visualization, Project administration. Genya Chernova: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – review & editing, Project administration. Carlijn MB Bouman: Investigation, Formal analysis. Faridi S. van Etten – Jamaludin: Methodology, Data curation, Investigation, Formal analysis. Susan van Dieren: Methodology, Validation, Investigation. Dirk T. Ubbink: Conceptualization, Methodology, Supervision.

Declaration of Competing Interest

The authors declare that there is no conflict of interest. The views presented in this publication are solely the responsibility of the authors.

Data Availability

De-identified data can be requested from the corresponding author at vanveenendaal@eshpm.eur.nl.

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Transparency

The corresponding author (HvV) affirms that the manuscript is honest, accurate, and a transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned and registered have been explained.

Appendix

Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2022.11.003.

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Chapter 7

Shared decision-making in cancer treatment: A Dutch national survey on patients' preferences and perceptions

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Abstract

Objective: Shared decision-making (SDM) for cancer treatment yields positive results. However, it appears that discussing essential topics for SDM is not fully integrated into treatment decision making yet. Therefore, we aim to explore to what extent discussion of therapy options, treatment consequences, and personal priorities is preferred and perceived by (former) cancer patients.

Methods: An online questionnaire was distributed by the Dutch Federation of Cancer Patient Organisations among (former) cancer patients in 2018.

Results: Among 3785 (former) cancer patients, 3254 patients (86%) had discussed treatments with their health care provider (HCP) and were included for analysis. Mean age was 62.1 ± 11.5; 55% were female. Discussing the option to choose no (further) treatment was rated by 2751 (84.5%) as very important (median score 9/10—IQR 8–10). Its occurrence was perceived by 28% (N = 899), and short- and long-term treatment consequences were discussed in 81% (N = 2626) and 53% (N = 1727), respectively. An unmet wish to discuss short- and long-term consequences was reported by 22% and 26%, respectively. Less than half of the (former) cancer patients perceived that personal priorities (44%) and future plans (34%) were discussed.

Conclusion: In the perception of (former) cancer patients, several essential elements for effective SDM are insufficiently discussed during cancer treatment decision making.

Introduction

Over the last decades, health care has shifted away from its former paternalistic attitude towards a more patient-centred approach [1]. Shared decision-making (SDM) is a key component of patient-centred care [1,2]. SDM is 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" [3]. It requires active participation from both health care provider (HCP) and patient, as they collaboratively weigh different treatment options in the light of priorities and values of the patient. The process of SDM is dynamic and complex but essentially consists of four key steps: (1) raising awareness of the fact that patients have a choice, (2) talking through the different options and discussing consequences of each option, including their probabilities, (3) discussing a patient's values, and — after some time for deliberation, supported by their HCP — (4) taking a decision based on informed preferences [4].

There are multiple reasons why, especially in the field of oncology, there is great value in SDM. First, an increasing variety of cancer treatments is being developed and multiple treatment options are suitable with side-effects that may significantly affect the patients "quality of life" [5-7]. Second, the process of SDM ensures the discussion of treatment consequences and their probabilities [5,8,9]. This is important since — as a result of rising survival rates — an increasing number of former cancer patients are living with long-term consequences of their treatment [10]. Thirdly, the fact that HCPs are insufficiently able to accurately predict patients' values underlines the importance of discussing patients' values (SDM step 3) [11-13]. Finally, SDM in cancer care, compared to the traditional style of communication, is associated with a higher perceived satisfaction with, and confidence in, treatment decisions [5], greater levels of treatment adherence [14], perceived quality of life [15] and mental health [16].

Despite the need for SDM and its positive effects, it has been reported that SDM is not yet fully integrated into the decision-making process for cancer treatment [17-19], especially concerning steps 2 and 3 of SDM. For instance, observations of consultations in multiple cancer care settings show that HCPs regularly steer towards active treatment while the option to choose no (further) treatment is left underexposed [20,21]. Furthermore, the amount of information provided to cancer patients during treatment decision processes may be insufficient [22]. Observations also suggest that patients' values (SDM step 3) may be underexposed, since essential elements such as exploring a patient's expectations and concerns are only discussed in half of patients [23,24]. In order to improve the integration of SDM in daily practice, it is important to know which elements of SDM are currently lacking in the cancer treatment decision-making process.

Therefore, we aim to explore to what extent (1) therapy options, (2) their consequences and (3) personal preferences are discussed during the SDM process, as perceived by (former) cancer patients and what patients would have wished to discuss regarding these topics.

Methods

In 2018, an online questionnaire on how cancer patients perceived their decision-making process was developed and distributed by the Dutch Federation of Cancer Patient Organisations (NFK in Dutch) among their network of (former) cancer patients. NFK is an umbrella organisation in the Netherlands representing 19 cancer patient organisations. Annually, they develop and send out several questionnaires to explore cancer patients' needs and experiences.

Questionnaire development and content

The questionnaire (Appendix) was developed by NFK, together with representatives of affiliated cancer patient organisations. Preferences and perceptions of (former) cancer patients regarding their treatment decision process were assessed with numeric, multiple-choice questions and open-ended questions. Conditional logic was applied. First, a validation question was asked to confirm that respondents have (had) cancer. Of the (former) cancer patients, patients who reported that they did not discuss one or more treatments were excluded from further analysis. Respondents were able to quit the questionnaire at any time. Responses were only included if respondents finished all demographic questions in addition to at least one decision-making related question.

Basic demographic information was collected: type of cancer, time since the last cancer treatment decision was made, and time since the last treatment. Then, using the structure of the key steps of SDM [4], questions were asked to explore the extent to which patients perceived that SDM took place during their treatment process. SDM step 2 was explored with use of questions 9, 12–19, and 22 and 23; SDM step 3 was explored with use of questions 20 and 21. This included discussing the option to choose no (further) treatment and its perceived importance rated on a scale of 1 to 10 (1 = not important, 10 = very important). It also included exploring to which extent patients perceived that short- and long-term consequences were discussed, and if not, should preferably have been discussed in retrospect. Finally, respondents were asked to rate to which extent—in their perception—the topics "what is important to patients in daily life" and "their future plans," were discussed during their decision-making process.

The survey was reviewed for content and face validity by co-authors with expertise in the field of SDM and patient involvement, through a continuous process of reflection within the team, resulting in an iterative version of the questionnaire.

Distribution and data collection

The questionnaire was distributed by NFK in October 2018 among members and followers of affiliated cancer patient organisations, by email, newsletter and/or website. NFK also posted a direct link to the questionnaire on their website and all their social media channels, and asked affiliated organisations to post the questionnaire. Furthermore, a group of cancer patients who volunteered to participate in NFK's questionnaire panel received an invitation via email to fill out the questionnaire. Recipients were given 2 weeks to complete the survey. Data were collected anonymously with the use of the online tool "Survey Monkey."

Data analysis

IBM SPSS Statistics version 25 was used for all analyses. Categorical variables are presented as numbers and percentages, continuous variables are presented as mean and standard deviation if normally distributed and otherwise as the median and interquartile range (IQR). Percentages were calculated by consistently using the total of patients included in our study as a denominator. Descriptive analyses were performed to explore differences for subgroups of our population, based on cancer type.

Results

Study population

A total of 3785 (former) cancer patients filled out the questionnaire. Of these respondents, 3254 (86.0%) patients discussed one or multiple treatments with their HCP and were included. Patient characteristics are presented in Table 1. The mean age was 62.1 (±11.5) and 55.1% of participants were female. The most prevalent cancer types were breast (27.2%), haematological (17.8%), and colon (17.3%) cancer. A majority of patients (88.1%; N = 2867) expressed a preference for SDM regarding their cancer treatment.

Table 1. Characteristics of the study population (N = 3254).

Age, years (SD)	62.1	(11.5)
Sex, female (%)		
≤ 60 years old	1,054	(77.3)
> 60 years old	738	(39.0)
Diagnosis, (%)		
Breast cancer	886	(27.2)
Hematological cancer	579	(17.8)
Colon cancer	563	(17.3)
Prostate cancer	400	(12.3)
Bladder cancer	195	(6.0)
Melanoma/skin cancer	120	(3.7)
Gynaecological cancer	118	(3.6)
Lung cancer	77	(2.4)
Other	316	(9.7)
Median time since last treatment (IQR)	2	(0-5)
Median time since last treatment decision (IQR)	2	(0-5)
Hospital type where patients were treated (%)		
Academic (or specialised in cancer-care)	1,013	(31.1)
'Top-clinical'	1,277	(39.2)
General	917	(28.2)
Other	47	(1.4)
Median number of healthcare professionals involved (IQR)	1	(1-2)

Abbreviations: HCPs, health care providers; IQR, interquartile range; SD, standard deviation.

SDM step 2: Discussing the different treatment options and their consequences

Forty-two per cent of patients (N = 1352) reported that only one treatment was discussed during the decision-making process. The importance of discussing the option to choose no (further) treatment was rated by 2751 (84.5%) patients, with a median score of 9 out of 10 (IQR 8–10). Twenty-eight per cent of patients (N = 899) reported that the option to choose no (further) treatment was discussed. Of all included patients, 80.7% (N = 2626) reported that short-term consequences of their treatment had been discussed (Table 2) and 53.1% (N = 1727) reported the discussion of long-term consequences. The short- and long-term consequences discussed are presented in Table 2.

Table 2. Discussion of short- and long-term consequences in SDM process: perceptions (SDM step 2)

Discussion of short-term consequences % (N)	80.7 (2,626)	
Discussion of long-term consequences % (N)	**53.1 (1,727)**	
	Discussion of short-term consequences % (N)	**Discussion of long-term consequences % (N)**
Fatigue	47.8 (1,557)	25.1 (816)
Diminished physical capacity	38.5 (1,254)	18.7 (610)
Sexual dysfunction	NA	15.8 (515)
Nausea/vomiting	28.9 (940)	NA
Gastrointestinal complaints	24.6 (802)	10.0 (324)
Osteoporosis	NA	9.0 (293)
Hair loss	24.0 (780)	NA
Weight shift/problems eating or drinking	21.4 (696)	6.8 (220)
Pain	19.6 (637)	6.7 (219)
Neuropathy	18.2 (592)	10.9 (354)
Cardiological problems	NA	5.9 (191)
Hormonal dysfunction	16.2 (527)	9.0 (293)
Oral/dental problems	15.6 (507)	4.4 (143)
Mental focus problems	13.2 (428)	8.2 (266)
Incontinence	11.2 (364)	7.9 (257)
Lymphedema	9.9 (321)	6.0 (196)
Memory problems	8.8 (286)	5.9 (191)
Depressive symptoms	8.8 (285)	5.3 (174)
Fertility problems	NA	4.9 (160)
Secondary tumors	NA	4.0 (130)
Dyspnea/shortness of breath	6.1 (199)	NA
Stress	5.9 (192)	3.0 (99)
Anxiety	5.4 (176)	3.3 (107)

Note: Higher means or medians indicate more discussion.
Abbreviations: NA, not applicable; SDM, shared decision making.

When asked "Are there any short-term consequences that were left undiscussed, which you would have preferred to have discussed" patients answered "yes" in 22.4% of cases (N = 728) (Table 3). Most reported short-term consequences that patients would like to have discussed, but were not, were fatigue (6.8%), diminished physical capacity (6.6%), and concentration problems (5.4%).

Table 3. Preferred but not perceived discussion of consequences (SDM step 2)

	Breast cancer		Haematological cancer		Colon cancer		Prostate cancer		Other cancer types	
Total	N = 886		N = 579		N = 563		N = 400		N = 826	
	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term	Short-term	Long-term
Preferred but not perceived discussion consequences†	26.7 (273)	36.2 (321)	20.4 (118)	25.6 (148)	17.4 (98)	17.6 (99)	13.3 (53)	17.0 (68)	22.5 (186)	23.8 (197)
Fatigue†	10.3 (91)	16.4 (145)	5.5 (32)	10.2 (59)	4.6 (26)	7.1 (40)	3.3 (13)	4,0 (16)	7.0 (58)	9.6 (79)
Diminished physical capacity†	10.2 (90)	13.3 (118)	4.3 (25)	7.4 (43)	5.3 (30)	5.0 (28)	3,0 (12)	4.3 (17)	7.0 (58)	7.6 (63)
Sexual dysfunction†	NA	9.8 (87)	NA	4.5 (26)	NA	6.9 (39)	NA	6.5 (26)	NA	5.2 (43)
Gastrointestinal complaints†	3.3 (29)	3.0 (27)	4.1 (24)	3.3 (19)	3.7 (21)	2.3 (13)	2.5 (10)	2.8 (11)	3.8 (31)	3.6 (30)
Osteoporosis†	NA	7.8 (69)	NA	2.9 (17)	NA	1.8 (10)	NA	2.5 (10)	NA	2.8 (23)
Weight shift/ problems eating or drinking†	5.8 (51)	6.7 (59)	2.8 (16)	2.1 (12)	3.2 (18)	2.3 (13)	1.0 (4)	1.0 (4)	3.0 (25)	3.5 (29)
Pain†	6.5 (58)	10.2 (90)	2.6 (15)	2.9 (17)	2.3 (13)	1.8 (10)	2.0 (8)	1.5 (6)	4.0 (33)	4.1 (34)
Neuropathy†	8.1 (72)	11.5 (102)	5.2 (30)	7.4 (43)	2.1 (12)	3.7 (21)	0.3 (1)	0.8 (3)	3.3 (27)	3.9 (32)
Cardiological problems†	NA	7.1 (63)	NA	4.1 (24)	NA	0.9 (5)	NA	0.8 (3)	NA	1.7 (14)
Hormonal dysfunction†	6.5 (58)	10.2 (90)	1.9 (11)	1.2 (7)	0.9 (5)	1.2 (7)	2.5 (10)	2.0 (8)	1.5 (12)	2.1 (17)
Oral/dental problems†	8.0 (71)	9.0 (80)	2.6 (15)	3.6 (21)	1.2 (7)	0.9 (5)	1.3 (5)	1.3 (5)	2.1 (17)	3.0 (25)

Table 3. - **Continued** Preferred but not perceived discussion of consequences (SDM step 2)

	Breast cancer		Haematological cancer		Colon cancer		Prostate cancer		Other cancer types	
Total	N = 886		N = 579		N = 563		N = 400		N = 826	
Mental focus problems†	9.1 (81)	15.3 (136)	5.5 (32)	8.5 (49)	3.0 (17)	3.2 (18)	1.0 (4)	1.3 (5)	5.2 (43)	6.9 (57)
Lymphedema†	6.8 (60)	9.1 (81)	0.7 (4)	0.3 (2)	0.5 (3)	0.5 (3)	1.5 (6)	1.5 (6)	1.5 (18)	3.9 (32)
Memory problems†	8.8 (78)	14.2 (126)	4.8 (28)	7.8 (45)	2.7 (15)	2.3 (13)	1.0 (4)	1.5 (6)	4.4 (36)	6.1 (50)
Depressive symptoms†	8.8 (78)	9.1 (81)	3.3 (19)	4.7 (27)	2.5 (14)	2.3 (13)	2.3 (9)	4.0 (16)	5.8 (48)	6.1 (50)
Secondary tumors†	NA	3.2 (28)	NA	2.8 (16)	NA	1.1 (6)	NA	1.3 (5)	NA	1.7 (14)
Stress†	5.3 (47)	4.6 (41)	2.6 (15)	2.9 (17)	1.1 (6)	2.1 (12)	1.5 (6)	0.8 (3)	2.8 (23)	4.2 (35)
Anxiety†	5.3 (47)	6.8 (60)	3.5 (20)	2.6 (15)	3.2 (18)	2.3 (13)	1.0 (4)	2.3 (9)	4.7 (39)	5.1 (42)
Dyspnea/shortness of breath†	4.7 (42)	NA	1.7 (10)	NA	0.7 (4)	NA	0.5 (2)	NA	1.7 (14)	NA

The following treatment consequences were reported by less than 2% of the study population and are not presented in this table: nausea, hair loss, incontinence and fertility problems. SDM Shared decision making NA not applicable. † results presented as % (N).

Table 4. Perceived discussion of patient's preferences (SDM step 3).

	All included patients	Breast cancer	Haema-tological cancer	Colon cancer	Prostate cancer	Melanoma/ skin cancer	Other cancer types
Total	N = 3,254	N = 866	N = 579	N = 563	N = 400	N = 120	N = 706
Perceived discussion of what is important in daily life % (N)	44.1 (1,434)	40.4 (350)	42.3 (245)	46.0 (259)	50.0 (200)	30.0 (36)	48.7 (344)
Perceived discussion of future plans % (N)	33.6 (1,093)	27.0 (234)	34.0 (197)	35.9 (202)	41.5 (166)	25.0 (30)	37.4 (264)

Abbreviation: SDM Shared decision making.

Of all included patients, 25.6% (N = 833) reported the preference to talk about long-term consequences that were left undiscussed. The most reported long-term consequences which were preferred but were left undiscussed again included fatigue (10.4%), diminished physical capacity (8.3%), and concentration problems (8.1%).

SDM step 3: Discussing patient's values

Forty-four per cent of patients (N = 1434) reported that their HCP discussed with them what they consider important in daily life (Table 4). The discussion of future plans was reported by 33.6% of patients (N = 1093).

Discussion

Our study explores to what extent (1) therapy options, (2) their short- and long-term consequences, and (3) patients' personal preferences are part of the SDM process in cancer treatment decision-making. Our results suggest that essential topics — such as the option to choose no (further) treatment or long-term consequences of treatment — are insufficiently discussed during the cancer treatment decision-making process.

Of the patients who discussed their treatments with their HCP, less than half reported discussing only one treatment. Only a quarter reported discussing the option to choose no (further) treatment, even though patients rated this option as very important to discuss. An unmet wish to have short- and long-term consequences discussed was reported by one in four and one in five patients, respectively. Less than half of the respondents perceived that personal priorities (44%) and future plans (34%) were discussed. These findings suggest that there is room for improvement in the extent to which essential elements of the SDM process are part of the conversation(s) between cancer patients and their HCPs. Our finding that the option to choose no (further) treatment is currently underexposed is especially worrisome for patients with palliative cancer, as we assume that the discussion of this option is even more relevant to them, compared to patients with curative cancer.

Unfortunately, we were unable to stratify our results based on prognosis (i.e., curative or palliative treatment), since this information was not collected in the questionnaire. Our results are supported by previous research in which consultations concerning preference-sensitive neo-adjuvant treatment decisions in breast and rectal cancer patients were audiotaped. In none of the 100 consultations, the option to choose no (further) treatment was the topic of conversation [18]. This was confirmed in an observational study among patients with advanced cancer [20]. Discussing and presenting the option of choosing no (further) treatment with cancer patients seems warranted, particularly since discussing this option was rated as very important by patients.

Our data also demonstrate that patients perceive more frequently that they are informed about short-term consequences (81%) than about long-term consequences (53%). In hindsight, the most frequently omitted consequences that patients preferred to talk about were; fatigue, diminished physical capacity and concentration problems. Kunneman, Marijnen, Rozema, et al. [25], who studied radiotherapy decisions for rectal cancer, showed comparable proportions in which short- and long-term consequences were discussed. In their study, short- and long-term consequences of treatment were discussed in 65% and 70% of consultations, respectively. The slight difference in results may be due to the different study methods, treatment options and study populations.

Discussion of what is important to patients in their daily life and their future plans was experienced by less than half of patients. Similar results were found in rectal cancer treatment decisions: patient's values were considered in only one in five consultations [26]. Additionally, a study in cancer patients with a median life expectancy of less than 1 year showed that values were discussed in only 48% of consultations [27]. This lack of discussion of patients' values is also reported in other specialties. In a study performed on 35 patients with an abdominal aortic aneurysm, patient's priorities were discussed in only 18%–31% of consultations, depending on the size of the aneurysm [28].

A recent systematic review showed that patients often prefer, but not experience a shared decisional role for cancer treatment [29]. Our study provides direct clues on how to improve patient involvement in SDM. In short, our findings are in line with observations from previous studies, and support the idea that vital steps (2 and 3) of the SDM process may be improved by increasing the extent to which both short and long-term treatment consequences and personal priorities are discussed with cancer patients. Some promising interventions were developed in an attempt to improve the extent to which essential elements are discussed. One of these interventions is the "time out consultation," where patients take time to discuss their situation with their own family physician before they proceed with the cancer treatment-decision with their medical specialist [30]. Other promising interventions that have been reported recently are training and feedback on consultations [31,32], and the coaching of patients (by a nurse or other health care provider) in developing skills necessary for SDM, such as using medical information, raising questions and clarifying values [33]. These interventions may help close the gap between the preferred and actual level of SDM implementation in cancer care.

Strengths and limitations

A major strength of this study is its large sample size and the variation of cancer types within the study population. Even though this supports generalisability and reliability of findings for our study domain and offers insight into differences between cancer types, the approach used in our study also has limitations, which must be taken into consideration when interpreting our results. The questionnaire was distributed by NFK and affiliated cancer patient organisations. This convenience sampling may lead to selective participation. First, because members and followers of these patient organisations may have different (i.e., more informed or critical) opinions than the average cancer patient. Since participation in the study is voluntary, it may be possible that people who were very satisfied or very unsatisfied concerning their decision-making process are overrepresented. The response rate would therefore be relevant, but cannot be estimated: the number of patients that were reached with the request to participate is unknown as—in addition to other routes—social media were used to distribute the questionnaire.

Second, the types of cancers represented by the organisations affiliated with NFK are not a direct reflection of the incidence of cancer types in the Netherlands [34]. For example, due to the participation of a large haematological cancer patient organisation, patients with haematological cancers are overrepresented in our study population. This selective participation should be taken into account when generalising our findings. Another limitation is potential recall bias. It has been reported that patients' memory for medical information is far from optimal, especially in case of the emotional stress following a diagnosis of cancer [35-37]. Our results are based on patients' perceptions of a situation that sometimes occurred several years ago (median time since treatment was 2 years, IQR 0–5). Therefore, patients may underestimate the extent to which the elemental SDM topics were actually discussed. Previous studies have shown that patients only recall about half of the information provided in cancer consultations [35,36]. Also, when cancer patients were asked how many adverse effects of treatment were discussed, they recalled a median of two adverse effects while a median of eight was discussed [38]. Additionally, some patients may have perceived adverse effects of their treatment, possibly affecting the preferences regarding discussed issues during their treatment decision-making process. Given the fact that our study provides a hindsight view, our findings should be interpreted as the extent to which patients remember discussing elemental SDM topics.

Finally, we restricted our study population solely to (former) cancer patients who reported that one or multiple treatments had been discussed, since we assumed that if treatment had not been discussed, treatment consequences and corresponding patient values would also be left undiscussed. Therefore, 14% (N = 531) of patients who did not recall a treatment to be discussed were excluded. The finding that one in seven patients did not recall discussing treatments at all is worrisome, particularly given the need for "choice awareness" in the SDM process [18]. Since we did not include this 14% of patients in our results, our results possibly overestimate the extent to which essential elements of SDM are implemented in cancer treatment decision making.

Our study suggests that essential elements in the SDM process are insufficiently experienced in cancer treatment decision making. This includes the perception of a treatment choice, awareness of treatment options and their consequences, and weighing options in the light of personal values. Particularly, in the perception of patients, the option to choose no (further) treatment and long-term consequences for daily life is insufficiently discussed. Consequently, cancer patients may currently be insufficiently equipped to make the important treatment decisions that they must face. The HCPs guiding these patients may need to improve the way in which they actively accompany and lead cancer patients through the steps required to attain an informed and shared cancer treatment decision.

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Conflict of interest

The views presented in this research are the sole responsibility of the authors. The subsidiser of the study was informed regularly about the study during the course of the project and approved the study concept and the final results of the study. The subsidy provider was not allowed to propose participants for the questionnaires or to comment on the content of the study.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Appendix

Questionnaire (originally in Dutch)

1. This questionnaire is meant for people who were diagnosed with cancer. Does this apply to you?
☐ Yes, I’ve had a cancer diagnosis
☐ No → *end of questionnaire*

2. What is your sex?
☐ Male
☐ Female

3. What is your year of birth?

4. What type of cancer were you diagnosed with? In case of multiple diagnoses, please fill out the most recent one.
5. How long ago was your most recent treatment?

6. How long ago was your most recent treatment decision?

7. In what hospital were you a patient when this last treatment decision was made?

8. Do you feel a need for shared decision-making regarding your cancer treatment?
☐ Yes
☐ No
☐ Do not know/not applicable

9. Did a care provider discus one or multiple treatment options with you? (during your most recent treatment decision process)?
☐ Yes, one treatment option
☐ Yes, multiple treatment options
☐ No, no treatment options were discussed → *skip to question 20*
☐ Do not know/not applicable → *skip to question 20*

10. Who discussed one or multiple treatment options with you (during your most recent treatment decision process)? (multiple answers possible)
☐ Oncologist/internist
☐ Surgeon
☐ Urologist
☐ Gynaecologist
☐ Haematologist
☐ Radiotherapist
☐ Other doctor in hospital
☐ Specialised nurse/nurse practitioner
☐ Other nurse in hospital
☐ General practitioner
☐ Do not know/not applicable
☐ Other, namely …

11. In what way were you informed about one or multiple treatment options with you (during your most recent treatment decision process)? (multiple answers possible)
☐ Orally (e.g., during consultation with your care provider)
☐ Written (e.g., in brochures)

☐ Digitally (e.g., via websites)
☐ Through a printed decision aid
☐ Through a digital decision aid
☐ Do not know/not applicable
☐ Other, namely ...

12. Were short-term consequences of treatments discussed with your care provider (during your most recent treatment decision process)?
☐ Yes
☐ No → *skip to question 14*
☐ Do not know/not applicable → *skip to question 16*

13. Which short-term consequences of treatments were discussed with your care provider (during your most recent treatment decision process)?
☐ Fatigue
☐ Pain
☐ Concentration problems
☐ Memory problems
☐ Incontinence
☐ Diminished physical capacity
☐ Neuropathy (nerve pain)
☐ Depressive symptoms
☐ Anxiety
☐ Stress
☐ Hormonal dysfunction
☐ Nausea/vomiting
☐ Hair loss
☐ Gastrointestinal complaints
☐ Oral/dental problems
☐ Lymphedema
☐ Dyspnoea
☐ Weight change/problems eating or drinking
☐ Do not know/not applicable
☐ Other, namely ...

14. Are there short-term consequences of treatments that were not discussed, but you wish they would have been discussed?
☐ Yes
☐ No → *skip to question 16*
☐ Do not know/not applicable -> *skip to question 16*

15. Which short-term consequences of treatments that were not discussed do you wish would have been discussed?

☐ Fatigue
☐ Pain
☐ Concentration problems
☐ Memory problems
☐ Incontinence
☐ Diminished physical capacity
☐ Neuropathy (nerve pain)
☐ Depressive symptoms
☐ Anxiety
☐ Stress
☐ Hormonal dysfunction
☐ Nausea/vomiting
☐ Hair loss
☐ Gastrointestinal complaints
☐ Oral/dental problems
☐ Lymphedema
☐ Dyspnoea
☐ Weight change/problems eating or drinking
☐ Do not know/not applicable
☐ Other, namely ...

16. Were long-term consequences of treatments discussed by your care provider (during your most recent treatment decision process)?

☐ Yes
☐ No → *skip to question 18*
☐ Do not know/not applicable → *skip to question 20*

17. Which long-term consequences of treatments were discussed by your care provider (during your most recent treatment decision process)?

☐ Fatigue
☐ Memory problems
☐ Concentration problems
☐ Sexual problems
☐ Incontinence
☐ Diminished physical capacity
☐ Neuropathy (nerve pain)
☐ Depressive symptoms
☐ Anxiety

☐ Stress
☐ Hormonal dysfunction
☐ Osteoporosis
☐ Cardiological problems
☐ Oral/dental problems
☐ Lymphedema
☐ Pain
☐ Fertility problems
☐ Secondary tumours
☐ Gastrointestinal problems
☐ Weight change/problems eating or drinking
☐ Do not know/not applicable
☐ Other, namely …

18. Are there long-term consequences of treatments that were not discussed, but you wish they would have been discussed?
☐ Yes
☐ No → *skip to question 20*
☐ Do not know/not applicable → *skip to question 20*

19. Which long-term consequences of treatments that were not discussed do you wish they would have been discussed?
☐ Fatigue
☐ Memory problems
☐ Concentration problems
☐ Sexual problems
☐ Incontinence
☐ Diminished physical capacity
☐ Neuropathy (nerve pain)
☐ Depressive symptoms
☐ Anxiety
☐ Stress
☐ Hormonal dysfunction
☐ Osteoporosis
☐ Cardiological problems
☐ Oral/dental problems
☐ Lymphedema
☐ Pain
☐ Fertility problems
☐ Secondary tumours

☐ Gastrointestinal problems
☐ Weight change/problems eating or drinking
☐ Do not know/not applicable
☐ Other, namely

20. Cancer treatment can influence your daily life. Therefore, we feel that it is important for your care provider to know what is important to you in your daily life, so that this can be taken into account during the treatment decision process. Did a care provider talk to you about what is important to you in daily life (during your most recent treatment decision process)?
☐ Yes
☐ No
☐ Do not know/not applicable

21. Cancer treatment can have long-term consequences. Therefore, we feel that it is important for your care provider to know what is important to you in your future, so that this can be taken into account during the treatment decision process. Did a care provider talk to you about your future plans or wishes (during your most recent treatment decision process)?
☐ Yes
☐ No
☐ Do not know/not applicable

22. Choosing no (further) cancer treatment can be an option too, for example if the advantages of treatment do not outweigh the disadvantages of treatment. Or if patients do not wish (further) treatment. Did a care provider talk to you about the option to choose no (further) cancer treatment (during your most recent treatment decision process)?
☐ Yes
☐ No
☐ Do not know/not applicable

23. How important do you think it is that a care provider discusses the option to choose no (further) treatment? Please give a score between 1 and 10. (1 = not important at all, 10 = very important).

24. Who eventually took the treatment decision?
☐ Me
☐ My loved ones
☐ My care provider(s)

☐ Me, together with my loved ones
☐ Me, together with my care provider(s)
☐ My loved ones, together with my care provider(s)
☐ Me, together with my loved ones and care provider(s)
☐ Do not know/not applicable
☐ Other, namely …

25. How content are you with the support you received from your care provider during your most recent treatment decision process? Please give a score between 1 and 10. (1 = not content at all, 10 = very content).

26. How important do you think it is to receive support from your care provider during a treatment decision process? Please give a score between 1 and 10. (1 = not important at all, 10 = very important).

27. How much time for deliberation was given to you by your care provider, before a final decision was made (in you most recent treatment decision process)?
☐ No time for deliberation
☐ Less than 1 day
☐ 1–3 days
☐ 4–6 days
☐ 1–2 weeks
☐ More than 2 weeks
☐ Do not know/not applicable

28. Retrospectively, how do you feel about the time for deliberation that was given to you by your care provider, before a final decision was made (in you most recent treatment decision process)?
☐ Precisely enough time
☐ I would have wanted more time
☐ I would have wanted less time
☐ Time for deliberation was not possible in my situation
☐ Do not know/not applicable

29. This is the final question of this questionnaire. If something you would like to tell us about shared decision-making that has not been addressed in this questionnaire, please leave a comment.

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Chapter 8

Effectiveness of individual feedback and coaching on shared decision-making consultations in oncology care: Protocol for a randomized clinical trial

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Abstract

Background: Shared decision-making (SDM) is particularly important in oncology as many treatments involve serious side effects, and treatment decisions involve a trade-off between benefits and risks. However, the implementation of SDM in oncology care is challenging, and clinicians state that it is difficult to apply SDM in their actual workplace. Training clinicians is known to be an effective means of improving SDM but is considered time consuming.

Objective: This study aims to address the effectiveness of an individual SDM training programme using the concept of deliberate practice.

Methods: This multicentre, single-blinded randomized clinical trial will be performed at 12 Dutch hospitals. Clinicians involved in decisions with oncology patients will be invited to participate in the study and allocated to the control or intervention group. All clinicians will record 3 decision-making processes with 3 different oncology patients. Clinicians in the intervention group will receive the following SDM intervention: completing e-learning, reflecting on feedback reports, performing a self-assessment and defining 1 to 3 personal learning questions, and participating in face-to-face coaching. Clinicians in the control group will not receive the SDM intervention until the end of the study. The primary outcome will be the extent to which clinicians involve their patients in the decision-making process, as scored using the Observing Patient Involvement–5 instrument. As secondary outcomes, patients will rate their perceived involvement in decision-making, and the duration of the consultations will be registered. All participating clinicians and their patients will receive information about the study and complete an informed consent form beforehand.

Results: This trial was retrospectively registered on August 03, 2021. Approval for the study was obtained from the ethical review board (medical research ethics committee Delft and Leiden, the Netherlands [N20.170]). Recruitment and data collection procedures are ongoing and are expected to be completed by July 2022; we plan to complete data analyses by December 2022. As of February 2022, a total of 12 hospitals have been recruited to participate in the study, and 30 clinicians have started the SDM training programme.

Conclusions: This theory-based and blended approach will increase our knowledge of effective and feasible training methods for clinicians in the field of SDM. The intervention will be tailored to the context of individual clinicians and will target the knowledge, attitude, and skills of clinicians. The patients will also be involved in the design and implementation of the study.

Trial registration: Netherlands Trial Registry NL9647; https://www.trialregister.nl/trial/9647.

Introduction

Background

Shared decision-making (SDM) has been promoted to support patients in making informed decisions that best fit their personal preferences, circumstances, and concerns [1,2]. This is particularly important in oncology as many treatments involve serious side effects, and treatment decisions involve a trade-off between benefits and risks [3,4]. Approximately 110,000 Dutch patients are diagnosed with cancer each year [5]. Surgery, radiation, and systemic treatment options are available for most patients with cancer. The made treatment decisions determine crucial aspects of the lives of all patients and their families. Being diagnosed with cancer brings emotional stress, which affects patients' information recall and the decision-making process [6-8].

However, SDM implementation in oncology is challenging [9-12]. There is a relatively high level of uncertainty in cancer care regarding the treatment benefits and risks [10,12,13]. Fighting cancer is paramount in the focus of both clinicians and patients, which may impede the process of considering multiple treatment options and weighing their short- and long-term consequences [14-16]. Moreover, different clinicians within a team must coordinate the decision-making process over an extended period and for several decisions, which makes it difficult to guarantee continuity in the decision-making process [4]. Interventions tailored to specific local contexts have been proposed to stimulate the integration of SDM in usual care [17-21].

In addition, clinicians underline the importance of communication with their patients but feel that it is difficult to apply SDM in their actual workplace and believe that applying SDM does not differ much from their current practice [22-24]. Training clinicians as part of the implementation of SDM is generally seen as vital to overcome these hurdles [22,25-29]. Training involves theory and skills but is more effective when it also accounts for peer pressure, individual attitudes, and learning objectives [30]. It has been suggested that elements such as reflection and real time feedback be added to a clinician's actual SDM performance [31]. Recent efforts that incorporate feedback from observations of consultations to improve SDM competencies are promising [23,29,32].

SDM behaviour is complex as it comprises interacting elements that are also influenced by contextual factors [32-34]. Medical professionals are expected to continuously improve their knowledge, skills, and behaviours, which requires the development and use of reflective practice skills [35,36]. Regarding medical performance, it has been stated that additional experience will not improve once it reaches the level of automaticity and effortless execution [37]. Deliberate practice involves the provision of immediate feedback, time for problem-solving and evaluation, and opportunities for repeated performance to refine behaviour [37,38]. As deliberate practice supports teaching that is more focused on the motivation and self-directed learning of the clinician, coaching is being increasingly recognized as a method of enhancing technical and nontechnical clinical performance [39-42]. Effective coaching on complex communication skills, including those involved in SDM, requires direct observation or review of audio- or video-recorded health care encounters, followed by constructive feedback from the coach and the processing of this feedback into developmental actions by the coachee [43,44]. As training clinicians — face to face, individually, or in a team — is time consuming and challenging for a busy health care team [26,45], training approaches that improve SDM behaviours should be both effective and feasible. The effects of deliberate practice have not been evaluated in the design of effective SDM education but coincide with clinicians' own views that feedback and reflection, tailored to their own learning needs and firmly embedded in the daily working context, are considered vital to effectively learn communication skills [46].

Objective

The aim of this randomized clinical trial is to examine whether an individual SDM training programme for oncology clinicians grounded in the theory of deliberate practice [37], as compared with their standard clinical practice, improves SDM behaviour. The programme comprises audiotaping the consultation or consultations of a single patient and conducting an SDM e-learning programme containing both theory and a role-play example, followed by self-assessments, individual feedback reports, and coaching facilitated by an individual action-planning template.

Methods

Trial design

This multicentre, single-blinded randomized clinical trial was designed and will be reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) guidelines [47]. The trial addresses the effect of SDM interventions in real-life clinician-patient consultations on the extent to which clinicians involve their patients in the decision-making process. The design is unpaired, meaning that patients are only audiotaped once, either before or after the intervention. In the control group, the clinicians will not receive the SDM intervention until the trial period has finished. The trial will include different oncology clinicians, diagnoses, hospitals, and decisions to investigate applications in a range of oncological diagnoses, including patients in palliative care.

Study conduct

When joining the study, clinicians will complete a short questionnaire asking about their number of years of experience, former participation in SDM skills training (yes or no) during medical school or as part of continuous medical education, residency, profession, age, and gender. The diagnosis, gender, and age of the patients will be recorded by the clinician to gather the basic demographic data of the study sample.

A measurement involves recording ≥1 consultation relevant to a decision-making process of 1 patient only, with a questionnaire that measures patients' perceived involvement in the decision-making process. The physicians and patients will be aware that consultations are being recorded. Each clinician will record the decision-making process for 3 different patients. By recording 2 consultations after the SDM intervention, with a time interval of 3 to 4 weeks between the recordings, the effectiveness of the SDM intervention for clinicians can be measured over time. The duration of the consultations and coaching sessions will be noted by the researcher (HvV) directly from the recordings. Clinicians will be instructed not to participate in educational activities related to patient-centred communication during the study. In addition, clinicians in the intervention group will be asked not to discuss the training contents or study-related information with participants in the control group. Once the final consultation is recorded, clinicians in the control group will receive the equivalent communication training. The period between each measurement will be 3 to 4 weeks, summing up to a total participation of approximately 8 weeks per clinician.

Participants

A total of 12 hospitals in the Netherlands will be included in this study (n=3, 25% universities; n=5, 42% general teaching; and n=4, 33% district hospitals). The recruitment of consecutive clinicians, who will discuss treatment decisions with their patients, will take place from April 2021 to July 2022.

All clinicians from the 12 hospitals involved in the decision-making process with patients of oncology regarding treatments will be invited to participate in the study. Clinicians in training (residents) are also eligible as, in the Dutch situation, they work under supervision but communicate with patients independently. Clinicians who have already received individual feedback on consultations or participated in SDM training within the past 3 years will be excluded. The inclusion criterion is that clinicians should be conducting consultations in which a decision is to be made with a patient who is capable and willing to participate. In addition, choices may relate not only directly to the final treatment decisions but also to other aspects of the care process. Consultations with patients who are palliatively treated with no prospect of cure, for whom decisions are to be made regarding the quality of life, are also eligible.

Intervention

Overview To clarify what SDM entails when applied in daily practice, we will invite clinicians to reflect on their own communication behaviour during ≥1 consultation in which a treatment decision is made in relation to the following four steps for applying SDM: (1) creating option awareness, (2) discussing the options and their pros and cons, (3) exploring patients' values, and (4) agreeing on a decision that fits best with the patients' personal preferences [48]. All participants receive a crib sheet, a pocket-sized card to be used during or in between consultations that shows the 4 SDM steps with example phrases. These 4 steps are also key elements in the educational components of our intervention.

To support the adoption of SDM behaviour by clinicians in daily practice, we will use the following four implementation levels of the Meetinstrument Determinanten van Innovaties model and their change determinants for our implementation approach [21]: (1) innovation (the implementation of SDM), (2) users of the innovation (clinicians and patients), (3) organisational context, and (4) socio-political context. To take the social context into account, oncology clinicians will be asked to participate as teams to enhance implementation success. By asking for a fee for participation in the training, we also ensure financial commitment from the hospitals to increase legitimacy and adherence to the trial.

Next, we will use the principles of deliberate practice as the basis for the educational approach. The best training situations focus on activities of short duration with opportunities for immediate feedback, reflection, and corrections [37]. In addition, additional reinforcing principles of medical coaching and action learning have been added [49-55].

The full SDM intervention takes <2.5 hours and comprises 4 parts, as described in the following sections.

- e-Learning (45 Minutes) An e-learning programme was developed to comprehensively explain the principles and theoretical background of SDM. It addresses knowledge (ie, definition, rationale, effect, and the 4 steps for applying SDM); attitude (ie, reported barriers, own beliefs, and providing evidence on frequent misconceptions about SDM) [52]; and, to a lesser extent, self-efficacy illustrated with a video example of a consultation following the 4 steps of SDM. In e-learning, information is given about patients' perspectives on SDM based on internet polls among (former) patients. A total of 7 questions will be asked during the 45-minute e-learning programme to stimulate reflection and memory. e-Learning was used and evaluated in a former implementation project on breast cancer [23,32]. The completion of basic SDM e-learning will be mandatory. Additional e-learning may be completed on a voluntary basis.

- Reflection on Feedback Report (15 Minutes) Participants will receive a personal feedback report from a communication researcher based on the Observing Patient Involvement–5 (OPTION-5) scores of their own consultation or consultations recording of a decision process with a patient [30]. This individual report will contain a score (0-4) per OPTION-5 item, as well as illustrative quotes and behaviours during the encounter that contributed most to a score and comprises 1 to 2 pages of ≥1 consultation per patient. The report was tested in 11 teams comprising patients with breast cancer during former implementation projects [23,32]. The direct observation of clinical encounters followed by structured feedback and coaching is educationally valuable [30] and seems promising for improving SDM behaviours [29,56,57]. By recording an actual clinical consultation in which a decision with a patient is made, feedback can be provided, and the recording can be stopped at critical points to reflect on and discuss appropriate goals with the coach. We put emphasis on quotes and non-judgmental feedback rather than using a summative assessment form, as clinicians might feel this may reduce communication skills to behavioural components and may perceive this as impeding the improvement of their communication skills [46].
- Self-assessment and Defining 1 to 3 Personal Learning Questions (30 to 45 Minutes) This feedback will be aligned with the learner's ambition by giving clinicians a short version of the OPTION-5 checklist to complete a self-assessment of their recording. Next, we strive to provide feedback as individualized as possible and as close to their clinical reality by using quotes and linking the quotes to a practical 4-step model that can be used in the consultation. In addition, clinicians will then be asked to write down 1 to 3 learning questions, which will help reflect on their own performance. In addition, defining a personal ambition stimulates intrinsic behavioural changes. Participants will use e-learning, self-assessment, and personal feedback reports to reflect on what would help them improve the adoption of SDM in their daily practice the most. Writing down learning questions is the first part of the action-planning template, which is provided to serve as a checklist for the coaching session, self-reflection, and follow-up of planned actions.

- Face-to-face Coaching: 15 to 30 Minutes Clinicians will discuss the feedback with an experienced communication coach (HvV, Maaike Schuurman, or Esther van Weele) using both the participants' learning question or questions and the feedback report. To support reflexive and action learning, all participants will be provided with an action-planning template [50]. A model for effective coaching [40] will be used that involves four step$^{\text{s: (1}}$) establishing principles of the relationship, (2) conducting an assessment, (3) developing and implementing an action plan, and (4) assessing the results of action plans and revising them accordingly. After the coaching session, each clinician will complete the action-planning template to force them to reflect on their SDM behaviour, consider goals, and decide which strategies and skills will help them attain those goals. The coaching model is explained in Table 1, and the study design is presented in Figure 1. A professor of clinical medical education (PB) was consulted to finalize the form of coaching. In addition, an evaluation of the coaching will take place after 3 and 10 coaching sessions. After the coaching, the following characteristics of the coaching session will be noted: the content of the session; action planning; duration of the session; whether the clinicians prepared the learning objectives, relistened their own consultation, and read the feedback report beforehand; and the number of e-learnings completed.

Comparator

The time schedule for participants randomized to the control group is shown in Figure 1. They will first be asked to complete the recording of the decision-making process of 2 different patients before they are offered the intervention (including recording a third decision-making process). This will enable a comparison of their SDM behaviour with participants who are exposed to the intervention. By offering the intervention to participants in the control group after the trial period, we will ensure that all participants in this trial have the opportunity to develop themselves in the field of SDM. To keep similar trial circumstances, the interval between these 3 recordings (3-4 weeks) will be similar to that of the intervention group.

Outcomes

The primary outcome is the OPTION-5 instrument to rate the clinicians' behaviour in the decision-making process objectively, which will be performed by 2 of the 3 researchers (HvV and Maaike Schuurman and Esther van Weele) independently [30]. Each of the 5 items will be rated on a scale ranging from 0 (no effort made) to 4 (exemplary effort made).

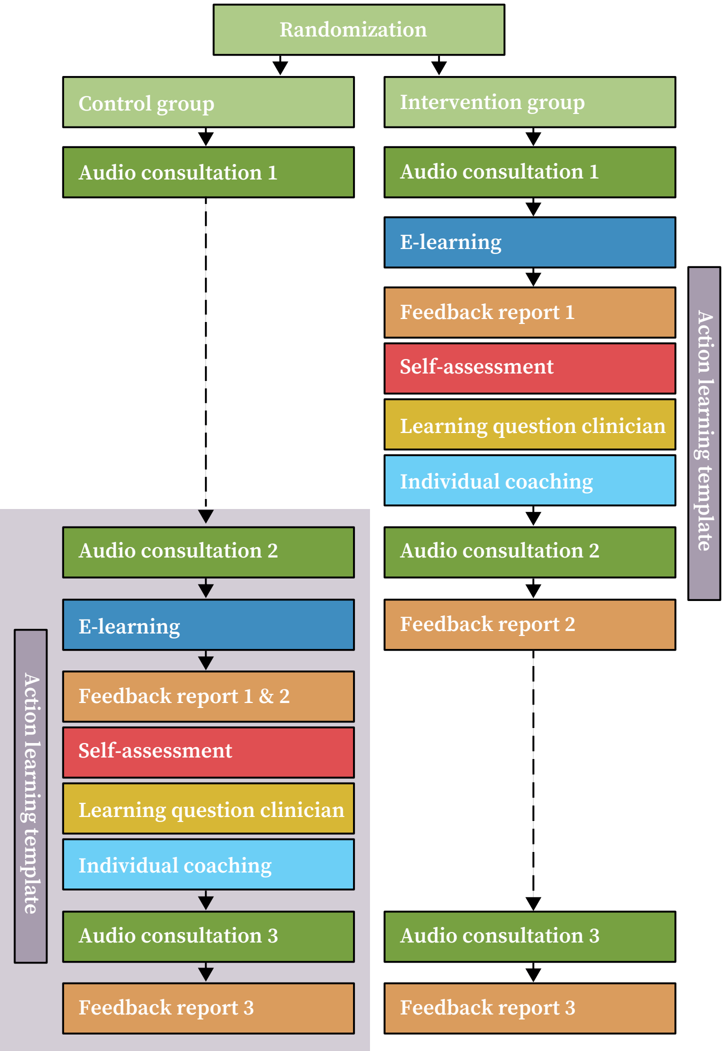

Figure 1. Design of the study.

As secondary outcomes, we will use subjective measures of SDM scored by the patients: the iSHARE, Control Preferences Scale (CPS), and the SDM Questionnaire–9 (SDM-Q-9) questionnaires.

The 15-item iSHARE questionnaire measures the perceived level of SDM during medical consultation or consultations; it was recently developed and has shown adequate content validity and comprehensibility [55]. It covers the entire SDM process rather than a single consultation and involves both clinician and patient

Table 1. Elements and working constructs of effective coaching

Element for effective coaching [40]	Working construct	Translation to our coaching approach [39, 43, 64]
Establishing principles of the relationship	Establish goals and parameters of the relationship, as well as ethical considerations, including confidentiality and boundary issues	• Express roles: The learner sets goals and designs the actions that help to apply SDM; the coach makes suggestions and encourages the learner to define actions to realize ambitions • Downplay the coaches' role: Position the coach as a learner, not an expert in order to establish a non-hierarchical relationship that contributes to creating a safe space and to co-construct meaning and knowledge rather than to dictate it. Emphasize that interdependence is basis of valuable interaction • Facilitate honest discussion about strengths and challenges regarding SDM; Help clinicians to shift the focus from performance to learning • Make room for discussing areas for improvement of applying SDM in daily practice • Ask about the positive consequences the learner expects to accomplish with applying new SDM behaviour
Conducting an assessment: self-assessment and assessment by a communication-coach	In order to facilitate a feedback process to begin self-monitoring and encourage learners gaining reflective skills to help them set goals for their program, personal (to foster discovering the students' learning or interpersonal management style) and systemic assessments (assessments provided by the learner's program)	• In general: active and appreciative listening, asking questions. Stimulate reflection: capable of being introspective and to learn from yourself • Ask about the importance of SDM for the learners' professional role and development • Provide written feedback, after permission, of audio recorded consultation(s) of the learner with one patient in which a decision is made • A self-assessment is performed by listening back his or her own consultation and use a shortened OPTION-5 measurement tool • Ask the learner to draw up 1-3 personal learning questions for the coaching session based on personal ambition and feedback • Review together the written feedback that was provided: was it recognizable? to promote self-reflection and goal-setting as the foundation of self-regulated learning [43] • Discuss theory of SDM: what does it intend? What insights and/or questions come out from the e-learning? • Use the 4-step model as a mirror for reflection on the feedback and the goals • Uses practical examples from 'best practices', including prompts, of potential areas of struggle to help learners to identify challenges

Table 1. - Continued Elements and working constructs of effective coaching

Element for effective coaching [40]	Working construct	Translation to our coaching approach [39, 43, 64]
Developing and implementing an action plan	This step determining new and revised actions that will lead to goal attainment. The learner reflects on what is working and what is not working, relate these to learning style, and identifies learning opportunities that build knowledge and/or skills, or initiates actions that demonstrates the learner's progress toward competence	• Focus discussion to areas of 'dilemmas' and/or 'best cases' in order to create action ideas. Ask the learner what he or she needs in order to accomplish expressed ambitions regarding SDM • If clinicians express the wish to gain knowledge about SDM (i.e. evidence for the use of teach back, decision aids, background information about SDM measurement tools or theory about elicitation values and preferences), we provide handy cards, decision tools, support (i.e. decision tools, tips to apply SDM as a team) or written information to read • Facilitate the transition from self-assessment and feedback to intervention: collaboratively crafting an action plan to implement appropriate intervention strategies [50, 51] • Encourage the learner 'set one to three goals' to be attempted in a next consultation, establish a short 'action planning template' • Ask questions to make goals ISMART (important, specific, measurable, accountable, realistic, timeline) • Ask the learner about possible barriers or facilitators to achieve the express goals and discuss possible ways to cope with them to increase clinicians' level of confidence in achieving the planned actions and how to cope with the feelings of failure
Assessing the results of action plans and revising accordingly	The coach and learner review and evaluate the learners' progression according to the action plan and whether features of the plan should be revised	• The action planning template ends with identifying at least 2 goals for their clinical practice over the ensuing weeks • After the coaching session, clinicians received feedback on their aspired goals, integrated as part of the feedback on their consultation • Evaluate the session and ask if there are any issues left to discuss • If a next meeting is appreciated, plan meeting date and agenda for next meeting • Finally, residents completed a brief evaluation, with Likert scale response options, that addressed the acceptability and usefulness of coaching

behaviours. It is especially meant for the oncology setting, as definitions of SDM differ between health care settings [58]. The CPS has proven to be a clinically relevant, easily administered, valid, and reliable measure of preferred or experienced roles in decision-making among people with life-threatening illnesses [59].

The CPS comprises 1 question with 5 possible statements indicating the role of the clinician and patient in the decision-making process. The SDM-Q-9 comprises 9 statements. For each statement, patients rate the extent to which they completely disagree (0) to completely agree (5) on a 6-point Likert-type scale. The scores are added, multiplied by 20, and divided by 9 to provide a percentage of the maximum score, ranging from 0 (no SDM) to 100 (maximum level of SDM). If needed, a maximum of 2 missing items will be imputed with the mean of the items that are scored [60]. The duration and number of consultations are registered for each physician directly from the audiotaped consultation or consultations.

Sample size

The primary outcome of this trial will be the extent to which clinicians involve their patients in the decision-making process, as scored using the OPTION-5 instrument [30,61]. A ≥10-point improvement in the OPTION-5 score is considered clinically relevant and significant, given the relatively limited time investment of the participants. For instance, a >10-point OPTION-5 score indicates 2 out of 5 items improving from moderate effort (2 points) to skilled effort (3 points) or 1 item improving from minimal effort (1 point) to skilled effort (3 points).

A preintervention mean score of 38 is assumed for our sample, which was measured in a former implementation project involving 6 outpatient breast cancer teams [32]. This is a high baseline score compared with other studies in general [56] and for oncology [9,11,57]. A total sample size in a 2-sided Z test for 2 means of 72 patients will be calculated based on an increase in the OPTION-5 score from 38 before implementation to 48 after implementation, with an SD of 13 in both groups, achieving a 90.38% power at the 5% significance level [13,32,56]. We will expand the sample size to 100 clinicians to account for possible failed recordings and dropouts of clinicians. A sub analysis will be performed to evaluate whether the results for palliative decisions, that is, patients who are palliatively treated (both tumour targeted and non–tumour targeted), are similar to those for the group with curative treatment intentions.

Randomization and blinding

Randomization (Figure 1) will be conducted by allocating each clinician agreeing to participate in the study to either the intervention arm or the control arm (1:1) based on randomly mixed block sizes (2, 4, or 6) using Castor EDC (Castor Company) [62].

This type of randomization is common in multicentre studies that include approximately 100 participants to reduce the predictability of allocation [63]. All patients and raters will be blinded, whereas clinicians cannot be blinded to their allocation. The allocation sequence, enrolment, and assignment of participants to interventions will be conducted by a coordinator (LP) not involved in rating consultations and coaching of the participants.

Statistical methods

All raters will use the OPTION-5 coding scheme, which has been refined for patients of oncology and vascular surgery [61,64]. The manual will be adjusted to be relevant to the oncology setting to increase raters' agreement in scoring the audio recordings. All audio recordings will be scored independently by 2 raters blinded to the intervention using the OPTION-5 instrument. After the first 10 audio recordings, these scores will be compared, and the coding rules will be discussed to reach an agreement over the final score. Moreover, the personal feedback and coaching sessions with the first 10 clinicians will be discussed by the project team in which patients are involved, and the unweighted Cohen κ values will be calculated as a measure of the interrater agreement [65]. The OPTION-5 score will be converted from a 0- to 20-point scale into a 0% to 100% scale.

Descriptive statistics will be presented as percentages or means with SDs. Differences will be expressed as mean differences with 95% CIs. The Pearson chi-square statistic will be used to analyse the differences between categorical variables at $P<.05$. We will check whether previous training in communication skills, professional background, disease, duration of the consultation or consultations, hospital, age, and number of consultations are equally distributed between the study arms. If they are not equally distributed, they will be included in the regression model for the OPTION-5 score. We will also perform a sub analysis for palliative decisions to evaluate whether the effectiveness of the SDM intervention for these consultations is comparable with that for the entire group. Statistical analyses will be performed using SPSS Statistics (version 25; IBM Corporation).

Patient involvement

To guarantee that the patient's perspective is sufficiently included in the design of the SDM intervention, 2 patient representatives (Maaike Schuurman and Ella Visserman) and 1 (former) patient with breast cancer (Lisanne de Groot) have been involved in the study. The 2 patient representatives have been involved from the start of setting up the research project (including determining research questions and outcome measures) as part of the research team in recruiting clinicians for the study and are also committed to disseminating the study results and methodology in oncology care. A patient representative (Maaike Schuurman) is involved as a researcher in rating consultations with the OPTION-5 instrument and providing coaching to clinicians (Maaike Schuurman), and all three (Maaike Schuurman, Ella Visserman, and Lisanne de Groot) will give feedback on specific parts of the training programme, such as the content of the coaching sessions and feedback reports.

Ethics approval and informed consent

All participating clinicians will receive information about the study and will be asked to give verbal consent for participation in the study: providing contact details, selecting a patient, and recording a consultation will be considered as their verbal consent. Their patients will complete a written consent form as consultations will be audio recorded, and patient characteristics will be collected. Non–Dutch-speaking patients will be excluded unless they are accompanied by a person who speaks Dutch sufficiently. Approval for the study has been obtained from the medical ethics review board of Leiden Den Haag Delft, located at Leiden University Medical Centre, the Netherlands (reference N20.170/ML/ml). Each participating hospital provided local approval for this study.

Data management

All sensitive data will be stored in encrypted password-protected databases (EUR Document Vault and Codific Document Vault [to save audio recordings during the study period]). Data will be entered by the study coordinator (LJP).

Results

Ethical approval for the study was obtained in December 2020, and thereafter, until December 2021, each of the 12 participating hospitals obtained local approval for this study. The first clinician started with the individual SDM training programme in May 2021. As of February 2022, we enrolled 30 clinicians, of whom 5 (17%) have completed the training programme. The pace of participant inclusion in the study is increasing; therefore, study recruitment is planned to be finalized around July 2022. We plan to complete data analyses by December 2022.

A mixed cofunding was obtained from the participating clinicians themselves (voluntary contribution), from the Dutch OncoZon-Citrienfonds (a professional oncology network), CZ Health Care Insurer, and DSW-Phoenix Health Care Insurer.

The study results will be disseminated to partnering organisations, study participants, and organisations involved in the development of clinician education. The findings will be submitted to a peer-reviewed journal and presented at academic conferences.

Discussion

Principal findings

We hypothesize that clinicians exposed to this intervention are more likely to adopt SDM behaviour than clinicians who do not, resulting in decisions that better match the preferences and values of oncology patients. We expect that clinicians in the intervention group will increase their observed level of SDM after each part of the intervention. We also believe that the effect of the training programme will be at least as large as the average increase that other interventions have shown [56]. Another possible effect is that patients may perceive greater involvement in the decision-making process and thereby experience a higher level of autonomy.

Comparison with prior work

We have previously worked on designing effective interventions, including training, to help clinicians adopt SDM in daily practice [23,31,32]. The theory-based and blended approach builds on previous research and includes different types of clinicians, diagnoses, hospitals, and oncology decisions to stimulate generalizability [29]. This approach is grounded in the theory of deliberate practice [37]. Moreover, patient involvement is guaranteed in the design and implementation of this study. Therefore, the study is perceived to have global value and should engender considerable interest in the academic and clinical education fields.

Strengths and limitations

A strength of our approach is that it will be tailored to the context of individual clinicians and that it targets attitudes, knowledge, and skills of clinicians. The possible limitation of this protocol could be that participating clinicians may already have an inclination toward SDM, which can lead to selection bias. Therefore, we will try to invite clinical teams rather than individuals to participate in this study to include a group of clinicians with a wide range of SDM interests and skills. Another limitation is that the clinicians cannot be blinded to the intervention. This might encourage them to practice SDM apart from the intervention itself.

Future directions

This trial takes the next step in the pursuit of developing effective training methods for clinicians in the field of SDM. It will increase our knowledge about how effective and feasible the direct observation of audio-recorded health care encounters, followed by constructive feedback from a coach, can be. Principles of deliberate practice are used as the basis for the educational approach, which enables effective learning [37], and the intervention is substantiated by implementation theory (Meetinstrument Determinanten van Innovaties model) and a 4-step model for applying SDM during clinical consultations [21,48].

Our intervention incorporates important elements from the theory of deliberate practice, such as having a well-defined goal, motivation to improve, and providing feedback on real-life situations [37]. Nevertheless, in our delineated intervention, it is difficult to meet the hallmark of providing opportunities for repetition and gradual refinement of performance over time. Therefore, future studies should address this challenge.

Conclusions

For most patients with cancer, multiple treatment options exist, and SDM is crucial to support them in making informed decisions that best fit their personal preferences. Clinicians play an important role in enhancing SDM implementation; however, SDM implementation remains challenging. This study will examine the effectiveness of an individual SDM training programme for physicians. The results of this study will be disseminated through publication in an open-access journal to enable the uptake of this deliberate practice study in other fields of interest and through presentations. In the Netherlands, patient organisations, professional bodies, and health care insurers are involved in the project and are committed to using valuable results for daily practice. Although our educational intervention is a mixed set of interventions with several elements over a 10-week period, it is relatively short and labour intensive, with one-on-one feedback and coaching. For implementation, it is important to take this into account and continue to look for interventions that are applicable in daily (oncological) care as well as support a continuous learning process for clinicians.

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Abbreviations

CONSORT	Consolidated Standards of Reporting Trials
CPS	Control Preferences Scale
OPTION-5	Observing Patient Involvement–5
SDM	shared decision-making
SDM-Q-9	Shared Decision-Making Questionnaire–9

Footnotes

Authors' contributions: The authors contributed to the work in accordance with the recommendations of the International Committee of Medical Journal Editors. All authors provided feedback on the concept of the work and the acquisition, analysis, and interpretation of data. HvV coordinated the design and preparation of this trial and drafted the protocol with primary support from LJP, FES, DTU, AMS, PLPB, and GV. HvV, LJP, DTU, and CGJMH were involved in the acquisition of funding and the recruitment of clinicians. HvV, LJP, and PLPB were involved in preparing the coaching interventions. All authors contributed to the final version of the manuscript and agreed to be accountable for all aspects of this work.

Conflicts of interest

None declared.

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Chapter 9

Discussion

'The patient is the centre of the medical universe
around which all our works revolve and
towards which all our efforts tend'.

(John Benjamin Murphy, surgeon (1857–1916)[1]*)*

Lessons learned on implementing shared decision-making: Towards equity and equality in healthcare

The studies conducted in this thesis have led to five insights regarding SDM implementation:

Multilevel implementation is effective and feasible

A systematic implementation approach, starting with an analysis of what would help in the local context, stimulates clinicians to better adopt SDM in daily practice (chapter 3 and 4) [2,3]. It will lead to a multilevel design of implementation strategies that include the use of tools to introduce patients and clinicians in SDM theory, accompanied by the learning of new skills and an effective response to barriers and accelerators in the organisation and in the broader context of how care is organised [4,5,6]. SDM is potentially rewarding for clinicians: clinicians perceive SDM as highly relevant to quality of care, and they report significant benefits for themselves, their patients and their team that reinforces their intrinsic motivation (chapter 5) [7].

By team-based SDM learning, the satisfaction of learning and team development can be utilized and aspects that transcend the individual clinician can be tackled, such as the division of tasks between physician and nurse (specialist), the provision of information to the patient, and the organisation of multidisciplinary team consultations. Motivating clinicians to record consultations as a team is easier than by approaching individual clinicians. And the team approach strengthens peer support, for example by observing (new) communication skills applied by colleagues [7].

Building reflection time (time-out) into care pathways so that patients have time to make well-considered decisions within the limits of delay leading to a significantly worse prognosis (*‘fast diagnosis, slow decision’*), should not be missing in a multilevel approach. Adjustment of outpatient schedules and division of tasks between clinicians may be indicated. This also proved to be feasible in various clinical (oncological) contexts, without extending the consultation time [2,3].

Organisational and socio-political factors that may drive SDM implementation, must also be considered. SDM deserves an explicit place in the vision and policy of the government, care organisations, health insurers, and professional and patient organisations, including investments to give clinicians room to participate in SDM-activities. When it comes to time, this remains one of the barriers most felt or feared by clinicians (chapter 2) [6,7,8,9]. However, we found that SDM-promoting interventions do not necessarily lead to increased consultation times (chapter 6) [10].

Durations can be longer or shorter, depending on the type of decision, the patient, and the trajectory [7]. Yet, it is crucial to take clinicians' concerns seriously: the feared risk of longer consultation time can be minimized by offering a tailored, theory-based implementation approach [10], and by limiting this investment.

Training, training, training

Training is important for implementing SDM [6,7,12,13], without training the effect of using decision aids may even be threatened [14]. Clinicians particularly value actor role-play based on their own patient cases [7]. Both individual and team feedback on consultations appears to be effective [2,3] and is also perceived as very valuable [7], especially if their SDM behaviour and the possibility on how improve therein is recognized by individual clinicians. Clinicians indicate that training is necessary to transform old routines into new ones: *'I have to go off autopilot'*, a nurse specialist sighed during one of the SDM training sessions. A surgeon responded to the feedback that was presented to him on a taped consultation: *'Did I say this to her?* (silence, reads further in the feedback) ... *Yes, I guess this is what I said.'* We therefore call for interprofessional workplace learning with minimal distance to the clinicians' daily reality and focused on repeated performance to refine behaviour [15].

Learning is more important than (only) measuring

Being the pinnacle of patient-centred care and value-based healthcare [16,17], SDM should be at the heart of continuous quality improvement, in which it is common that multidisciplinary teams work in a structured manner on improvement goals [18]. In our studies, principles applied in quality improvement collaboratives and implementation theory were used to underpin our implementation efforts [19]. Essential is that (the core of) teams remain intact and collect data to show clinicians and managers the benefit to their patients and to clinical practice [6,19,20].

Clinicians participating in our studies reported different benefits for themselves and their patients, and for each clinician the benefit that motivated them could differ [7]. However, too strong a focus on collecting (reliable) data can threaten learning and improvement [6]. Regarding SDM, there is much to be learned from mapping SDM effects through qualitative rather than quantitative evaluation, and this also appears to be more motivating [6].

Hence, the purpose of observing consultations needs a shift to learning rather than measurement primarily for research or accountability. Implementation experts in the SDM field are advised to adopt a learning attitude in the sense that they need to know a lot about the theory but work from day-to-day practice to co-design and apply the right improvements in the local context: 'All teach, all learn' as motto for the support (research/expert) team [21].

Patients and clinicians are merely humans

Patients use a variety of old and new sources of information (medical professionals, websites, friends, family, and social media) to gain health knowledge [22,23]. Clinicians have been the most valued source of information, consistent with the trust people place in them [24]. To sustain this trust, patients' confidence that their best interests are taken into account is essential and can be enhanced through patient-centred communication [24,25]. In SDM, a doctor and a patient meet. But it is also an encounter between two human beings (**equality**): Both are uncertain about the treatment benefits [26]. The clinician has dreams and ambitions in exercising the chosen profession. Dreams and ambitions of the patient are affected by the diagnosis. In their conversation, both 'take themselves with them': each time, their knowledge, skills, and values must be aligned to be able to decide on the care that fits the patient best (**equity**). A personal barrier for clinicians arises when a SDM process culminates in a decision that they themselves consider suboptimal for the patient. This barrier can be overcome if the clinician verifies that the patient has understood all the pros and cons of the choice — and when the physician truly understands the values and preferences that make this decision the right one for this patient (chapter 7) [27]. This is both challenging and valuable: SDM is rewarding for clinicians because they will find they bond better with their patients, share rather than carry responsibility for decisions, and feel patients are more engaged, satisfied, and equal [7]. Working as a team to improve SDM encourages them to reconsider their team collaboration. In times of increasing demand for healthcare and high rates of burnout, depressive symptoms, and suicide risk among clinicians, the positive effect of human connection offers great potential for making healthcare more sustainable [28].

Do not forget the system

While the ethical necessity of SDM is compelling, and it makes sense to give SDM a key role in a value-driven economic sector such as healthcare, more is needed to make SDM the norm [4,29]. It is precisely the daily interaction between clinicians and patients that can be the promising starting point for modernizing our healthcare system: a high-quality decision-making process then forms the basis for designing care pathways, establishing supportive health information, adjusting financial incentives, and delivering only care with added value [7,8]. If one has the patience for a long-term perspective on SDM, the contextual barriers and facilitators involved emerge, and can be influenced to improve SDM adoption [4].

A potentially valuable development in this is the call for the use of patient-reported outcome information (PROMs) as it can depict relevant outcomes and consequences of decisions to the patient [30]. Little is yet known about the use of PROMs as part of SDM in the medical encounter [31]. However, it is essential that PROMs be used to strengthen the SDM process, especially the use of patient values, rather than falling into the trap of providing (too) complete numerical information while not knowing what really matters to the patient.

Five years after the recommendations of frontrunners on accelerating SDM adoption were published [8], we follow up on this: (1) For organisations or teams that are (still) showing little SDM adoption, small, flexible teams, experienced in working with an SDM implementation toolbox, can be deployed to provide a tailored boost to practice with temporary additional support. (2) In addition, proven interventions should be embedded by default, as part of training, education, and collaboration of (teams of) clinicians. (3) Finally, government, health insurers, patient and professional organizations must monitor progress and continually remove barriers to achieving a system of care that is both patient-centred and sustainable.

Some critical comments

We have tried to do our research work as close as possible to daily reality, because that is where SDM takes place and when its application can be improved. This choice also has cons. We relied on observations using the OPTION-instrument, which has a limited number of categories and is sensitive to the interpretation of the rater [32]. Second, our measurements were not blinded, relatively highly motivated clinicians were included, and we waived a control group. Third, we did not measure nonverbal behaviour, even though this is important in communication [33]. In addition, it meant less focus on how patients and clinicians could improve decision-making activities outside of clinical encounters. Fourth, it was disappointing that measuring improvements in patient-perceived involvement in SDM appeared difficult [2,3], although others had similar experiences.

Both educational principles and implementation theory were used [15,19]. This made our approach systematic. On the other hand, working with the MIDI-framework might suggest that all implementation levels (1. the concept of SDM, 2. clinician and/or patient, 3. organisational context and 4. socio-political context) and taking into account all 29 identified factors that affect implementation seem (equally) important [19]. However, in the context of a predominantly behavioural innovation such as SDM, very different from a technically driven innovation such as a new drug, the user perspective may dominate the other levels of implementation.

With an inclusive approach to everyone who wanted to promote SDM, and by actively transferring our research findings and tools, we tried to maximize our reach: we included teams from 20 hospitals (>25% of Dutch hospitals). Mostly, however, we worked with a single team and we (and the effects?) were there as long as the project lasted. The question remains how to accelerate the scaling up? And how to guarantee sufficient depth in that scaling up: SDM must not become a passing creed, but a lasting need: it is an art of performing that requires optimal conditions at all levels of implementation. This also requires patience.

Implications for future research

Even though knowledge about, and experience with the implementation of SDM has increased considerably in the past ten years, several knowledge gaps remain in this area.

A first poignant question is how a (Dutch) healthcare system can adapt more quickly and adequately to the changes that appear necessary for greater adoption of SDM in daily practice. For example: SDM causes shifts in work between professional groups and care domains [7,34,35], between a surgeon and nurse, or between general practitioners and the hospital. Incidentally, these are shifts that policymakers are welcoming, as exemplified by the latest 'integral care agreement' ('Passende zorg') as issued by the Dutch healthcare stakeholders [36].

Further research is also needed into the sustainability of improvements in SDM application. In our studies, we were able to extend the interval between intervention and measurement of SDM behaviour to 4-6 months. However, little is known about which factors help make these results sustainable in the long term and how they interact. For example, adjusting care pathways can play an important role. How can this be supported efficiently, while healthcare is more and more provided through multidisciplinary teams? And how to empower patients, especially the less health-literate groups who may need extra or different support? How sustainable is the effect of repeated blended training, including providing immediate feedback, over longer time periods [2,37]?

Another area of research relevant to scaling up SDM is the relationship between time and SDM. Several aspects are relevant: Do well-trained clinicians gain long-term (consultation) time after adopting SDM skills (chapter 8) [38]? And does a time investment in patient communication reduce time later in the process? Next, little research has been done on when and why patients need time to reflect on difficult decisions, such as through time-outs. Since time is precious to both parties and the question arises how this preciousness can be met to result in maximum added value to the patient's life, evidence is needed on how patients and clinicians spend time on decision-making activities outside of clinical encounters [39].

The last area needing further exploration is the perspective of clinicians on their own professional role and the place of SDM in it. Clinicians reported having difficulty "letting go of their patient" when approaching a decision they consider sub-optimal for him or her. To make healthcare effective and sustainable, it is essential to build an attractive and rewarding workplace by ensuring that well-trained clinicians can align with their motivations. SDM offers opportunities for this [28]. We also found interesting leads in that direction [7], but still little is known about how this potential can be fully exploited.

To conclude: a prediction

In the Dutch context, substantial work has been done as to the implementation of SDM [40]. It is to be applauded that since the mid-2010s, the Dutch Ministry of Health has made SDM a policy priority and has allocated significant resources to promote implementation. Patient organisations and an increasing number of clinicians and healthcare insurers are supporting the culture change needed to make SDM the norm for decision-making. In 2020, SDM has been legally anchored in the updated Medical Treatment Contracts Act (WGBO) [41].

At its core, research has shown that effective design of an implementation process for applying SDM is theory-based, multilevel, and adaptable to the challenges of both teams as a whole and individual clinicians. It is now essential that SDM implementation remains an inclusive process that binds clinicians and patients by addressing them in terms of intrinsic motivation and allowing them to personally experience the added value of SDM [35]. SDM must maintain 'depth': it is a valuable and fragile process that requires equal input from both people who want to reach a decision together, with maximum added value for the patient. Also, SDM is not about who takes the decision, but the process of arriving at this decision [42]. At the same time, we need to further expand the indication for application of SDM - further away from application only to medically equivalent decisions (equipoise), like monitoring cancer recurrence as a suitable situation for SDM [46]. Investments will be needed to address SDM challenges, such as tailoring it to intercultural changes in society and vulnerable groups ("precision SDM" [45]).

This is not easy. It seems that the SDM implementation and our healthcare system imprison each other: the system hinders the routine upscaling of SDM and the incomplete implementation of SDM is obstructing the necessary evolution of the healthcare system. The Dutch government itself has concluded that in the public sector there is too much complexity in legislation and regulations, in the way processes are organised, in the accumulation of policies and in IT systems [46]. Employees report a lack of space for professional leadership to work on adding social value, too many rules, and a poor learning climate [47]. At a time when the labour shortage becomes visible, and absenteeism is high, precious time must be spent optimally and reimbursement must support SDM rather than interventions.

To do so, strengthening clinical leadership is essential. A prerequisite for this is that clinicians are given room for ensuring stronger relationships with clients, for peer learning and for deliberation. We invest up to 12 years in the education of clinicians, and then overload them with (partly meaningless [44]) work that leaves no time for learning and development. Consequently, time for learning is shifting to outside working hours or to conferences that function as a refuge for colleagues who are in the same boat. The signal being sent is that investing time in improving communication, the part of the job that requires evolving expertise most to achieve customized care and to handle changes due to social and technological developments, is not important. On the contrary, career-long learning at local, regional, and national levels is desperately needed. Let us restore trust in clinicians and patients by asking them to be accountable (horizontally) to each other rather than (vertically) to managers and policy makers who are far away from the daily delivery of care and the process of SDM. In return, clinicians have to take responsibility in embedding SDM: in their daily work, guidelines [48], and training [49].

Imagine!

Let us decide together that SDM is challenging, but fun, and normal. Our future healthcare will then be based on effective, well-organised and patient-driven decisions. In the medical universe, supported by an interprofessional team, the patient is really at the centre. Because SDM potentially leads to sustainable care in which patients experience greater autonomy, their emotions and rationality can be better balanced, but sincere attention is also needed when they are vulnerable. The paradox here is that we need to take time to gain time: by making it the norm to discover together how intrinsic motivation leads to better outcomes. It then appears that more care is not always better. As positive side effects, clinicians become happier, and the healthcare system becomes less complex and less based on distrust. With the added bonus, not to be confused with a motive for efficiency gains, of a 10-20% lower demand for care [34,50,51]. All we need to do is to work towards **equity** and **equality** as pillars for strengthening the autonomy of those affected by disease and those who have made it their mission to help them: **equity** to respond to the differences between people and especially those who are particularly vulnerable. And **equality** to cherish that a decision-making process will only lead to high-quality care if two people, each with their own expertise, are able to authentically meet each other.

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Chapter 10

Summary

Chapter 1: Introduction; SDM needs implementation

Although in current practice a certain degree of shared decision-making (SDM) already takes place, there is general agreement that it is good to apply more from an ethical and quality perspective. Applying SDM requires the understanding that every patient is different and needs a tailored approach based on an individuals' circumstances to achieve the desired level of SDM ('**equity**'). It is important to realize that people are vulnerable when confronted with an (oncological) disease. This might hinder an equal cooperation of clinician and patient, meaning that individuals are considered equal as people regardless of their circumstances ('**equality**').

In practice, several challenges arise in the application of SDM. Knowing that SDM is an effective way of making decisions together with patients does not mean that it is automatically applied in clinical practice. To enhance the application of SDM, **implementation** science can be used, an effective and organised effort to strengthen the day-to-day application.

SDM can be particularly valuable in the oncology setting as the diagnosis of cancer brings emotional distress. This affects the patient's information recall and decision-making process. Moreover, treatment choices and cancer mortality rates vary significantly by educational level. Given that positive effects of SDM are also reported in oncology, and observations of consultations in multiple cancer care settings show considerable room for improvement, the aim of this thesis is to investigate promising implementation approaches to boost the uptake of SDM in healthcare.

The following question is central to this thesis: ***what are contributing factors to a wider adoption of (a process of) shared decision-making in healthcare?***

Chapter 2: National approach to SDM implementation

In a qualitative investigation 43 interviews with frontrunners in the application of SDM were organised to elicit perceived barriers to and facilitators of a national SDM implementation agenda. The selected frontrunners were patients, clinicians, policy makers from different healthcare sectors. The interviews were followed-up by focus group discussions to prioritize strategies to implement SDM in daily practice. Determinants for change were addressed at four implementation levels: (1) the concept of SDM, (2) clinician and/or patient, (3) organisational context and (4) socio-political context.

Four strategies were proposed to scale up SDM: 1) stimulating intrinsic motivation among clinicians via an integrated programmatic approach, 2) training and implementation in routine practice, 3) stimulating the empowerment of patients, 4) creating an enabling socio-political context.

Interesting to note was that clinicians argued that applying SDM potentially makes their job more rewarding. They suggested to redesign daily practice ground-up to allow for alignment with each clinical context. This also makes it possible to integrate the different steps of SDM in their clinical pathways in a way that is supportive to better explore patient values and offer time to reflect on what is important to them. This also demands a team-oriented approach in which the organisation and the socio-political context are helpful. Fragmented but promising initiatives need to be coordinated to inspire the next group of followers.

Chapter 3: Implementation programme breast cancer

Six breast cancer teams from hospitals in the Utrecht Region participated in a multilevel implementation programme that supported them to apply SDM with newly diagnosed breast cancer patients that face or neoadjuvant systemic treatment or surgical treatment: lumpectomy (normally with radiation) or mastectomy (normally without radiation). The study evaluated whether the implementation programme enhanced the level of SDM behaviour of clinicians observed in consultations.

In a before–after design, 139 audio recordings of consultations were made (80 before and 59 after implementation) and analysed using the five-item Observing Patient Involvement in Decision-Making (OPTION-5) instrument to assess whether clinicians adopted new behaviour needed for applying SDM.

The mean OPTION-5 scores, increased from 38.3 at baseline to 53.2 year after implementation on a 0–100 scale, (mean difference (MD) 14.9). Patients perceived level of SDM, measured with the nine-item Shared Decision-Making Questionnaire (SDM-Q-9) were high and showed no significant changes (91.3 versus 87.6). It did not lead to an increase in either consultation time or mean number of consultations. The implementation design was tailored to each team's needs to evoke social support within the team to improve one another's behaviour, as well as the intrinsic encouragement needed for sustainable behavioural change. Providing time-out for patients was an explicit element of the implementation programme.

The multilevel implementation programme appeared effective and useful in the context of daily care, as five of the six hospital teams involved were able to participate fully in the programme while continuing their regular clinical care.

Chapter 4: Working mechanisms of the implementation programme in breast cancer

Five breast cancer teams that offer systemic treatment to breast cancer patients participated in the adapted multilevel SDM implementation programme that was tested in six other teams for the surgical phase (chapter 3).

Breast cancer patients qualifying for (neo)adjuvant systemic treatment were included in a multicentre before–after study. Consultations were audio recorded between June 2018 and July 2019 and analysed using the five-item Observing Patient Involvement in Decision-Making (OPTION-5) instrument to score SDM application by clinicians. The Shared Decision-Making Questionnaire (SDM-Q-9) was used to rate patients' perceived SDM level. Consultation duration, decision types, number of options discussed and consultations per patient were monitored. Regression analysis was used to investigate the correlated variables and programme components.

The mean OPTION-5 scores increased from 33.9 ($n = 63$) before implementation to 54.3 ($n = 49$) after implementation ($p < 0.001$). The SDM-Q-9 scores did not change: 91.1 ($n = 51$) at baseline versus 88.9 ($n = 23$) after implementation ($p = 0.81$). Without increasing consultation time, clinicians discussed more options after implementation. The regression analysis showed that exposure to the implementation programme, redistribution of tasks and discussing feedback from consultations was associated with a higher level of SDM.

The multilevel programme helped clinicians achieve clinically relevant improvement in SDM, especially when it is tailored to (individuals in) teams and includes (e-)training, discussing feedback on consultations and redistribution of tasks.

Chapter 5: Clinicians' perceptions regarding implementation programme

The multilevel implementation programme that was applied to 11 hospital teams in two projects (6 teams: surgical phase breast cancer and 5 teams: systemic treatment), was evaluated among the participating clinicians. Key factors for effective implementation were included in the programme for which the 'Measurement Instrument for Determinants of Innovations-model' (MIDI) was used as a theoretical framework programme. In a mixed-method design, descriptive statistics were used for surveys and thematic content analysis for semi-structured interviews.

Twenty-eight clinicians participated in the questionnaire (response 42%). These clinicians reported that the programme supported adoption of SDM in their practice and that they perceive SDM as very relevant to breast cancer care. Limited financial means, time constraints and concurrent activities were frequently reported barriers.

The 21 clinicians who were interviewed indicated that they very much appreciate the use of a 4-step SDM model having a fixed structure to fall back on during consultations, especially when it is reinforced by practical examples, handy cards, feedback, and training. This enabled them to internalize SDM theory in the sense that it helped them to translate the theory into their own situation, using existing skills and testing new skills. Clinicians experienced positive results for their patients and themselves (e.g., better structured and more interesting consultations). Task re-assignment in the team and flexible outpatient planning to allow for reflection time for patients, reinforce sustainable change. Patient involvement was valued.

Chapter 6: SDM and consultation time

Clinicians perceive a limited consultation duration or their concern that SDM may result in a prolonged consultation duration, as an important barrier to applying SDM. This systematic review and meta-analysis describe whether increased levels of SDM affect consultation duration and investigated which intervention characteristics involved.

Studies up to December 2021 were systematically searched in MEDLINE, EMBASE, CINAHL and the Cochrane library. Sixty-three studies were selected of interventions that increased at least one SDM-outcome, and measured consultation time: 28 randomized clinical trials, 8 quasi-experimental studies, and 27 cross-sectional studies.

Overall pooling was not possible due to substantial heterogeneity. After the SDM interventions, changes in mean consultation durations ranged between 11:30 (min:sec) shorter to 13:36 longer than before the intervention. In 24 of the 26 included RCT's (88%) and 6 of the 7 quasi-experimental studies (86%) this difference in consultation duration was less than 3 minutes (total mean was 24;13). Reduced consultation times (2 studies) or no difference (26 studies) was found more often than increased durations (7 studies). Significant increased consultation times were observed among interventions that: 1) targeted clinicians only, 2) were performed in primary care settings, 3) used a group format, and 4) were not theory-based. Follow-up intervals were short, and only one study reported about indications for a training effect on consultation time.

There is no evidence that applying SDM increases consultation duration. Theory-based multilevel implementation is advised as it is possibly associated with reduced consultation times.

Chapter 7: Perceptions of cancer patients about SDM

This study aimed to find out to what extent (former) cancer patients receive SDM and what they preferred while making decisions with their clinician. The internet questionnaire asked respondents about whether or not essential SDM topics were discussed, such as talking about therapy options, treatment consequences, and personal priorities, and what they would have wanted.

The Dutch Federation of Cancer Patient Organisations distributed an online questionnaire in 2018 that was filled in by 3254 (former) cancer patients. Their mean age was 62.1 ± 11.5; 55% were female. Discussing the option to choose no (further) treatment was rated by 2751 (84.5%) as very important. Its occurrence was perceived by 28% (N = 899), and short- and long-term treatment consequences were discussed in 81% (N = 2626) and 53% (N = 1727) of the patients, respectively. An unmet wish to discuss short- and long-term consequences was reported by 22% and 26%, respectively. Less than half of the (former) cancer patients perceived that personal priorities (44%) and future plans (34%) were discussed.

Despite methodological limitations of the study, this study suggested that essential elements in the SDM process are insufficiently experienced in cancer treatment decision making. This includes the perception of a treatment choice, awareness of treatment options and their consequences, and weighing options in the light of personal values. Particularly, in the perception of patients, the option to choose no (further) treatment and long-term consequences for daily life is insufficiently discussed.

Chapter 8: Trial protocol for an individual SDM training programme

As the implementation of SDM in oncology care is challenging and training clinicians is known to be an effective means of improving SDM, a training programme is developed. In this study protocol, the design of this individual digital SDM training programme is described, using the concept of deliberate practice, to allow for the provision of immediate feedback, time for problem-solving and evaluation, and opportunities for repeated performance to refine behaviour. Recent efforts (see chapter 2, 3 and 5) indicate that feedback from observations of consultations is promising to improve SDM competencies. As deliberate practice supports teaching that is focused on the motivation and self-directed learning, digital coaching and constructive feedback is added to the programme.

In this multicentre, single-blinded randomized clinical trial oncology clinicians of 12 Dutch hospitals participate. They record 3 decision-making processes with 3 different oncology patients. Clinicians in the intervention group receive: e-learning, feedback reports, a self-assessment and defining 1 to 3 personal learning questions, and face-to-face coaching. Clinicians in the control group do not receive the intervention until the end of the study. The primary outcome is the extent to which clinicians involve their patients in the decision-making process, as scored using the Observing Patient Involvement–5 instrument. As secondary outcomes, patients will rate their perceived involvement in decision-making, and the duration of the consultations will be registered. Patients are involved in the design and implementation of the study.

Registration was obtained on August 03, 2021. The ethical review board provided approval. Recruitment and data collection are expected to be completed by July 2023.

Chapter 9: Discussion

This dissertation contributed to the body of knowledge on the implementation of SDM in daily practice. Promising multilevel programs, co-designed with clinicians and patients and using implementation theory, were found to increase the level of SDM, yield positive experiences among participants, and do not lead to a significant increase in consultation time. It led to five insights regarding SDM implementation:

1. Multilevel implementation is effective and feasible.
2. Training, training, training.
3. Learning is more important than (only) measuring.
4. Patients and clinicians are merely humans.
5. Do not forget the system.

This thesis did not answer all implementation questions. We need to gain more knowledge on how healthcare systems can adapt better to the changes necessary for SDM adoption. The sustainability of improvements and patient empowerment in the less health-literate, intercultural and vulnerable groups need further attention, to nurture the process of equity.

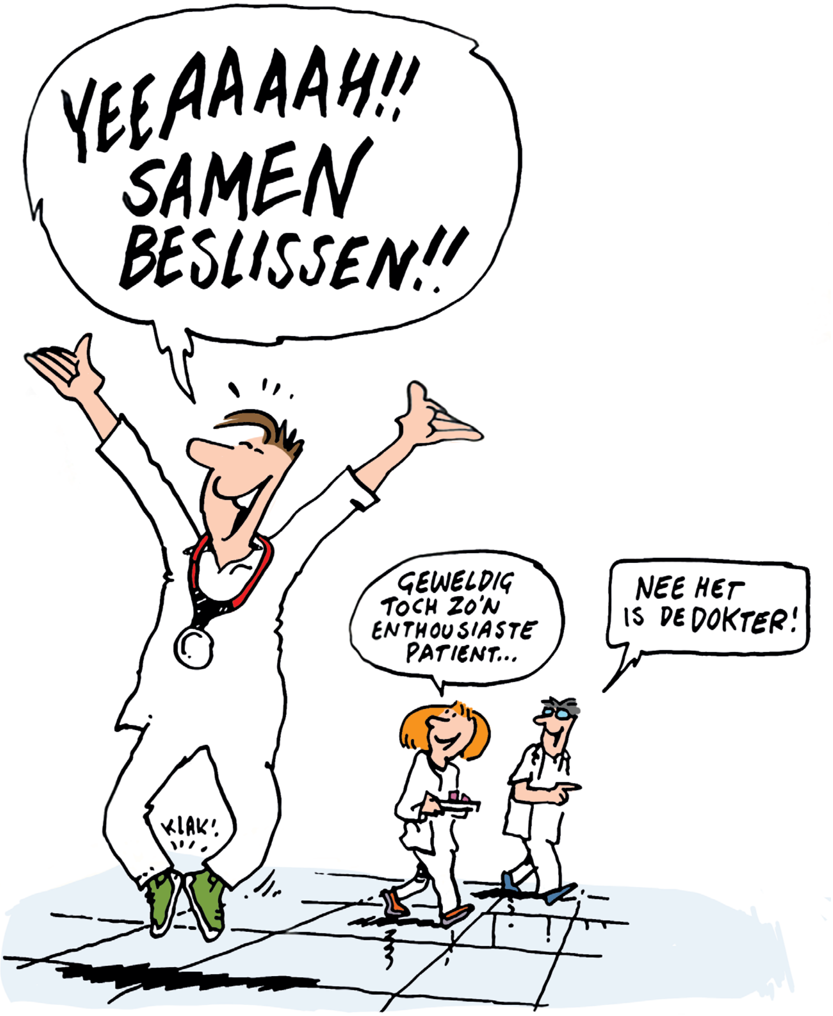
Clinicians must take the lead in integrating SDM into daily care: giving them room for ensuring stronger relationships with clients, peer learning and deliberation, is essential. Let us decide together that SDM is challenging, fun, and normal. By making it the norm that clinical teams and patients and family discover together the decisions that fit best. Clinicians become happier, and the healthcare system becomes less complex and less based on distrust. All we need to do is to work towards **equity** and **equality** as pillars for strengthening the autonomy of those affected by disease and those who have made it their mission to help them: ***equity*** to respond to the differences between people and those who are particularly vulnerable. And ***equality*** to cherish that a decision-making process will only lead to high-quality care if two people, each with their own expertise, are able to authentically meet each other.

Chapter 11

Nederlandse samenvatting

Speak only if it improves upon the silence

(Mahatma Gandhi, politician (1869-1948))



Hoofdstuk 1: Introductie; Samen beslissen vereist implementatie

Hoewel er in de huidige praktijk een zekere mate van samen beslissen (SB) plaatsvindt, is er overeenstemming dat het vanuit ethisch en kwaliteitsperspectief nuttig is om het meer toe te passen. Dit vereist het begrip dat elke patiënt anders is en een aangepaste benadering nodig heeft op basis van individuele kenmerken om het gewenste niveau van SB te bereiken (‘**equity**’). Mensen zijn kwetsbaar wanneer ze geconfronteerd worden met een (oncologische) ziekte. Dit kan een gelijkwaardig partnerschap tussen clinicus en patiënten - dat individuen als mensen als gelijk worden beschouwd ongeacht hun omstandigheden (’**equality**’) - in de weg staan.

In de praktijk doen zich verschillende uitdagingen voor bij de toepassing van SB. De wetenschap dat SB een effectieve manier is om samen met patiënten beslissingen te nemen, betekent niet dat het automatisch wordt toegepast. Om dit te verbeteren, kan implementatiewetenschap worden gebruikt: een effectieve en planmatige inspanning om de dagelijkse toepassing van een vernieuwing te versnellen.

SB kan vooral waardevol zijn in de oncologische zorg omdat de diagnose kanker (veel) emoties met zich mee kan brengen. Dit beïnvloedt de mate waarin de patiënt informatie kan verwerken en ook het besluitvormingsproces. Bovendien verschillen de behandelkeuzes voor kanker en de sterftecijfers aanzienlijk per opleidingsniveau. Aangezien positieve effecten van SB ook worden gerapporteerd in de oncologie, en observaties van consulten voor verschillende soorten kanker significante ruimte voor verbetering laten zien, is het doel van dit proefschrift om kansrijke implementatiebenaderingen te verkennen om zo de adoptie van SB in de zorg te stimuleren.

De volgende vraag staat centraal in dit proefschrift: ***wat zijn bevorderende factoren voor bredere adoptie van (een proces van) samen beslissen in de gezondheidszorg?***

Hoofdstuk 2: Landelijk implementatie aanpak

Een kwalitatief onderzoek werd uitgevoerd, waarin 43 voorlopers in de toepassing van SB werden geïnterviewd om belemmeringen en bevorderende factoren van een nationale aanpak voor de implementatie van SB te ontwikkelen. De voorlopers waren patiënten, zorgverleners en beleidsmakers uit diverse zorgsectoren. Na de interviews werden via focusgroepen prioriteiten voor het bevorderen van de toepassing van SB in de dagelijkse praktijk, bepaald.

Factoren die de verandering kunnen beïnvloeden, kwamen aan de orde op vier implementatieniveaus: (1) het concept van SB, (2) gedrag van de zorgverlener en/of patiënt, (3) de organisatorische context en (4) de sociaal-politieke context. Er werden vier strategieën voorgesteld om SB op te schalen: 1) het stimuleren van intrinsieke motivatie bij zorgverleners via een programmatische aanpak, 2) uitvoeren van training en implementatie in de dagelijkse praktijk, 3) het stimuleren van de empowerment van patiënten, 4) het creëren van een stimulerende sociaal-politieke context.

Interessant was dat zorgverleners ervaarden dat toepassing van SB hun werk meer (be)lonend maakt. Ze stelden voor om hun werk vanaf de basis op te bouwen met SB als belangrijk onderdeel. Zo kunnen ze SB inbouwen in de eigen werkwijze, door de 4 stappen van SB een plek te geven in de klinische paden die teams gebruiken: Er kan plaats gemaakt worden om de waarden en voorkeuren van patiënten beter te bespreken en tijd te bieden om na te denken over wat voor hen belangrijk is. Dit vraagt om een team-aanpak waarbij de organisatie en de sociaal-politieke context vooral moeten kijken hoe ze helpend kunnen zijn aan de praktijk. Het advies is ook om veelbelovende maar gefragmenteerde initiatieven te coördineren om de volgende groep volgers te inspireren.

Hoofdstuk 3: Helpt een implementatieprogramma borstkanker om te komen tot meer samen beslissen

Zes borstkankerteams van ziekenhuizen in de regio Utrecht namen deel aan een implementatieprogramma. Dit was bedoeld om hen te ondersteunen om SB in de praktijk (meer) toe te passen bij vrouwen met borstkanker die een keuze moeten maken tussen systemische behandeling voor een borstoperatie, een borstsparende operatie met bestraling of borstamputatie (normaal zonder bestraling). Het bieden van time-out (bedenktijd) aan patiënten was een expliciet onderdeel van het programma en de aanpak kon op maat voor elk team worden ingericht.

In de studie werd geëvalueerd of SB tijdens consulten meer werd toegepast na de implementatie. In een voor-na-studie werden 139 audio-opnames van consultaties gemaakt (80 voor en 59 na implementatie) en geanalyseerd met het Observing Patient Involvement in Decision-Making (OPTION-5) instrument om te beoordelen of clinici gewenst gedrag op het gebied van SB tijdens hun consulten toepasten.

De gemiddelde OPTION-5-score, steeg van 38,3 voor tot 53,2 na implementatie op een schaal van 0-100 (gemiddeld verschil (MD) 14,9). Het door de patiënten ervaren niveau van SDM, gemeten met de Shared Decision-Making Questionnaire (SDM-Q-9) was hoog en vertoonde geen significante verbetering (91,3 versus 87,6). Ook de duur van en het aantal consulten in de nameting toonde geen significant verschil.

Het implementatieprogramma bleek effectief en uitvoerbaar in de context van de dagelijkse zorg, aangezien vijf van de zes betrokken ziekenhuisteams volledig konden deelnemen aan het programma terwijl ze hun reguliere klinische zorg bleven uitvoeren.

Hoofdstuk 4: Welk onderdeel van het implementatieprogramma helpt het meest?

In deze studie werd het effect van het in hoofdstuk 3 besproken multilevel SDM-implementatieprogramma opnieuw onderzocht in een multicenter voor-na studie met 5 ziekenhuisteams, nu nadat aanpassingen waren aangebracht op basis van een (tussen)evaluatie (zie hoofdstuk 5).

Consulten van borstkankerpatiënten die in aanmerking kwamen voor systemische behandeling werden tussen juni 2018 en juli 2019 opgenomen via audio en geanalyseerd met het Observing Patient Involvement in Decision-Making (OPTION-5) instrument om de mate van SDM-toepassing door clinici te scoren. De Shared Decision-Making Questionnaire (SDM-Q-9) werd gebruikt om het door patiënten ervaren SDM-niveau te beoordelen. Consultduur, soorten beslissingen, aantal besproken opties en consulten per patiënt werden gemonitord. Regressieanalyse werd gebruikt om te kijken welke programmaonderdelen de grootste rol speelden.

De gemiddelde OPTION-5-score nam toe van 33,9 (n=63) vóór implementatie tot 54,3 (n=49) na de implementatie (p<0,001). De SDM-Q-9-scores veranderden niet: 91,1 (n=51) voor versus 88,9 (n=23) na implementatie (p=0,81). Zonder dat de consulttijd toenam, bespraken clinici meer opties na implementatie. De regressieanalyse liet zien dat de mate van meedoen aan het programma, herverdeling van taken en het bespreken van feedback uit opgenomen consulten samengingen met het meer toepassen van SDM.

Het programma hielp clinici om relevante verbeteringen in SDM te bereiken, vooral wanneer het is toegesneden op (individuen in) teams en (e-)training, het bespreken van feedback op consulten en herverdeling van taken omvat.

Hoofdstuk 5: Percepties van clinici over het implementatieprogramma

Het implementatieprogramma dat werd doorlopen met 11 ziekenhuisteams in twee projecten (6 teams chirurgische fase borstkanker en 5 teams systemische behandeling), werd geëvalueerd onder de deelnemende clinici. Als theoretisch kader werd het 'Meetinstrument voor determinanten van innovaties-model' (MIDI) gebruikt. Er werden beschrijvende statistieken gebruikt voor de interpretatie van enquêtes en thematische inhoudsanalyse voor verwerking van semigestructureerde interviews.

Achtentwintig clinici vulden de vragenlijst in (respons 42%). Deze clinici meldden dat het programma de toepassing van SB in hun praktijk ondersteunde en dat zij SB als zeer relevant beschouwen voor de zorg aan mensen met borstkanker. Beperkte financiële middelen, tijdsdruk en andere gelijktijdige activiteiten waren vaak gemelde belemmeringen.

De 21 clinici die zijn geïnterviewd gaven aan dat het gebruik van een 4-stappen SB-model hen een vaste structuur bood om op terug te vallen tijdens consulten, zeker als dit wordt versterkt door praktijkvoorbeelden, handige 'spiekkaartjes', feedback en training. Dit stelde hen in staat om de SB-theorie te internaliseren: het hielp hen de theorie te vertalen naar hun eigen situatie, bestaande vaardigheden te gebruiken en nieuwe vaardigheden te testen.

Clinici ervaren voordelen van SB voor hun patiënten en zichzelf (bijvoorbeeld beter gestructureerde en interessantere consulten). Taakherschikking in het team en flexibele poliplanning om patiënten bedenktijd te kunnen aanbieden, versterken duurzame toepassing van SB. Betrokkenheid van patiënten in het implementatieprogramma werd gewaardeerd.

Hoofdstuk 6: SDM en duur van consulten

Bezorgdheid van clinici dat SB leidt tot langere consultduren, zijn belemmerend voor het toepassen ervan. In deze meta-analyse en systematische review is onderzocht of de consultduur verandert indien er meer SB plaatsvindt en wat kenmerken zijn van interventies die hierbij toegepast zijn.

Er werd systematisch gezocht naar experimentele en cross-sectionele studies tot december 2021 in MEDLINE, EMBASE, CINAHL en de Cochrane-bibliotheek.

Drieënzestig studies waarin de consultduur werd gemeten én de interventie(s) ten minste op één SB-uitkomst voor een verbetering zorgden, werden geselecteerd: 28 gerandomiseerde studies (RCT's), 8 quasi-experimentele studies en 27 cross-sectionele studies.

Door de verschillen in de opzet van de studies was het niet mogelijk om met een meta-analyse te bepalen of de consultduur door SB veranderd was. Na de interventie bleek de gemiddelde consultduur 11:30 (min:sec) korter tot 13:36 langer te zijn. In 24 van de 26 gerandomiseerde studies (RCT's) (88%) en in 6 van de 7 quasi-experimentele onderzoeken (86%) was het verschil minder dan 3 minuten (op gemiddeld 24;13). Een verkorte consultduur (2 studies) of geen significant verschil (26 studies) kwam vaker voor dan een langere consulttijd (7 studies). Interventies die: 1) alleen op clinici waren gericht, 2) werden uitgevoerd in de 1elijn, 3) op een groep gericht waren en 4) niet theoretisch waren onderbouwd, leidden tot significant langere consulttijden. De follow-up duur in de studies was kort, en slechts één studie liet een tijdelijk effect op de consulttijd van training zien.

Er is geen bewijs dat SB toepassen de consultduur verlengt. Op theorie gebaseerde multilevel implementatie, die ook ruimte maakt voor training en de aanpassing van werkprocessen verlaagt het risico op hogere consultatietijden.

Hoofdstuk 7: Percepties van kankerpatiënten over SB

Dit onderzoek was bedoeld om erachter te komen in welke mate (ex-)kankerpatienten SB ervaren bij het nemen van beslissingen met hun zorgverlener en welke wensen ze daarin hebben. In een internetenquête werd respondenten gevraagd of essentiële SB-onderwerpen al dan niet werden besproken, zoals het praten over therapie-opties, behandelconsequenties en persoonlijke wensen, en wat ze zouden hebben gewild.

De Nederlandse Federatie van Kankerpatiëntenorganisaties (NFK) heeft in 2018 een online vragenlijst verspreid die is ingevuld door 3254 (ex-)kankerpatiënten. Hun gemiddelde leeftijd was 62,1 ± 11,5 jaar; 55% was vrouw. Het bespreken van de mogelijkheid om geen (verdere) behandeling te kiezen werd door 2751 (84,5%) als (zeer) belangrijk beoordeeld. De ervaring dat dit heeft plaatsgevonden werd door 28% bevestigd (N=899). De gevolgen van de behandeling op korte en lange termijn werden besproken in respectievelijk 81% (N=2626) en 53% (N=1727) van de patiënten. Een onvervulde wens om de gevolgen van de keuzes op korte en lange termijn te bespreken werd gemeld door respectievelijk 22% en 26%. Minder dan de helft van de (ex-) kankerpatiënten vond dat persoonlijke prioriteiten (44%) en toekomstplannen (34%) werden besproken.

Ondanks methodologische beperkingen van de studie, lijken essentiële elementen bij het nemen van beslissingen in het SB-proces door (ex-)patiënten onvoldoende ervaren te zijn. Denk hierbij aan of patiënten zich bewust zijn van het feit dat er behandelkeuze is, de korte en lange termijn consequenties daarvan, en afwegingen in het licht van persoonlijke waarden. Volgens patiënten mag er meer worden ingegaan op de mogelijkheid om geen (verdere) behandeling te kiezen en op lange termijn gevolgen voor het dagelijks leven

Hoofdstuk 8: Studie protocol voor een individueel SB-trainingsprogramma

Omdat het trainen van clinici een effectief middel is in de uitdaging om implementatie van SB in de oncologische zorg te realiseren, is een trainingsprogramma ontwikkeld. Recent onderzoek (zie hoofdstuk 2, 3 en 5) geeft aan dat feedback op observaties van consulten veelbelovend is om SB-vaardigheden te verbeteren. In dit studieprotocol wordt het ontwerp van deze individuele digitale SB-training beschreven, volgens het concept van 'Deliberate practice': Het bieden van een leerproces met directe feedback, oplossingen bedenken en testen, evaluatie, en herhaalde toepassing hiervan om gedrag te verfijnen. Omdat 'Deliberate practice' motivatie en zelfgestuurd leren ondersteunt, zijn digitale coaching en feedback in het trainingsprogramma toegevoegd.

In deze multicenter, enkelblinde gerandomiseerde klinische trial, nemen clinici van 12 ziekenhuizen deel. Elke deelnemer neemt consult(en) op van 3 SB-processen met 3 patiënten. Clinici in de interventiegroep ontvangen een e-learning, schriftelijke feedback en persoonlijke coaching, doen een zelfevaluatie en definiëren 1-3 persoonlijke leervragen. Clinici in de controlegroep krijgen dezelfde interventie aan het einde van het onderzoek. De primaire uitkomstmaat is de mate waarin clinici patiënten in SDM betrekken, gescoord met het Observing Patient Involvement–5 (OPTION-5) instrument. Secondaire uitkomstmaten zijn de door de patient ervaren betrokkenheid in besluitvorming (SDMQ-9), en consultduur.

Deze studie werd retrospectief geregistreerd op 3 augustus 2021. Medisch ethische goedkeuring werd verkregen. Patiënten(vertegenwoordigers) zijn betrokken in het ontwerp en de uitvoering van de studie. De inclusie van deelnemers loopt naar verwachting tot juli 2023.

Hoofdstuk 9: Discussie

Dit proefschrift heeft bijgedragen aan de kennis over de implementatie van SB in de dagelijkse praktijk. Veelbelovende multilevel programma's, ontworpen met clinici en patiënten met gebruik van implementatietheorie, bleken het niveau van SB te verhogen, positieve ervaringen onder deelnemers op te leveren en niet te leiden tot een significante toename in consulttijd. Het leidde tot vijf inzichten over SB-implementatie:

1. Multilevel implementatie is effectief en haalbaar.
2. Training, training, training.
3. Leren is belangrijker dan (alleen) meten.
4. Patiënten en clinici zijn ook maar mensen.
5. Vergeet het systeem niet.

Dit proefschrift heeft niet alle implementatievragen beantwoord. Meer kennis is nodig over hoe zorgsystemen zich beter kunnen aanpassen aan de veranderingen die nodig zijn om SB te implementeren. De borging van verbeteringen en empowerment van patiënten in minder gezondheidsvaardige, interculturele en kwetsbare groepen hebben meer aandacht nodig om het proces van equity te versterken.

Clinici moeten de leiding nemen om SB te integreren in de dagelijkse zorg: het is essentieel dat zij de ruimte krijgen om sterke relaties met cliënten op te bouwen, te leren van elkaar en voor reflectie. Laten we samen besluiten dat SB uitdagend, leuk en normaal is. Door het de norm te maken dat klinische teams en patiënten en hun families samen beslissingen ontdekken die het beste passen. Clinici worden gelukkiger en de gezondheidszorg minder complex en minder gebaseerd op wantrouwen. Het enige wat we moeten doen is werken aan **equity** en **equality** als pijlers voor het versterken van de autonomie van degenen die getroffen zijn door ziekte en degenen die het tot hun missie hebben gemaakt om hen te helpen: ***equity*** om rekening te houden met de verschillen tussen mensen en degenen die bijzonder kwetsbaar zijn. En ***equality*** om te koesteren dat een besluitvormingsproces alleen zal leiden tot zorg van hoge kwaliteit als twee mensen, elk met hun eigen expertise, elkaar op authentieke wijze kunnen ontmoeten.

Chapter 12

Completion

Dankwoord
Portfolio
About the author

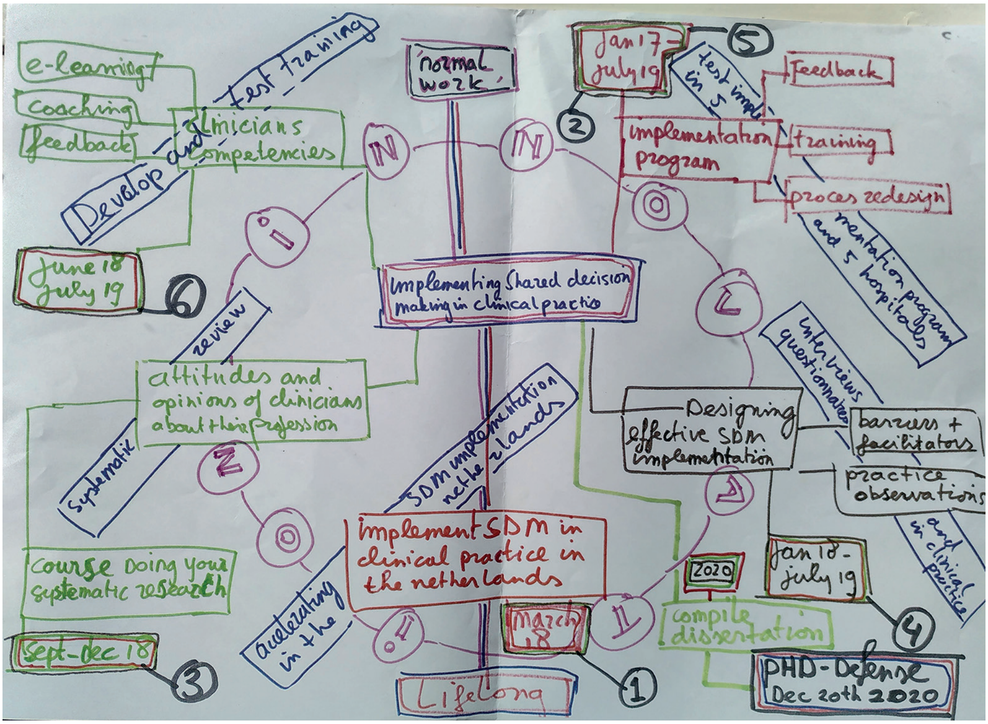
The slow one now
Will later be fast
As the present now
Will later be past
The order is rapidly fadin'
And the first one now
Will later be last
For the times they are a-changin'

(From The Times They Are A-Changin', Bob Dylan)

Dankwoord

Dit proefschrift is de uitkomst van een interessant proces, in ieder geval voor mijzelf. In de loop van twintig jaar werken in de praktijk (waarover later meer), groeide langzaam de behoefte om onderzoek in, met en voor die praktijk doen. Dat plan nestelde zich in mijn hoofd en in 2015 raakte ik aan de praat met Carina Hilders en Dirk Ubbink, die er beiden direct een uitdaging in zagen om mij te begeleiden. Het werd een onderzoek naar het versnellen van de toepassing van 'samen beslissen', waar ik uiteindelijk in 2016 mee kon beginnen en waarvan het resultaat hier nu voor je ligt. Tijdens de training 'How to survive my PhD?' in 2017 kreeg ik de opdracht om mijn gedachten op papier te zetten en een concreet beeld en planning te maken van het promotietraject (zie figuur 1).

De inspiratiebron voor mijn onderzoek was en is de praktijk. Daar is het telkens een gezamenlijke zoektocht van degenen die getroffen zijn door ziekte en degenen die het tot hun missie hebben gemaakt om hen te helpen, om samen die afslag te kiezen die past bij wat belangrijk is in het leven. Mijn oorspronkelijke idee



Figuur 1. Het beoogde promotietraject op één a4 (2017).

over wat nodig is om ‘samen beslissen’ verder te brengen is overeind gebleven en gedurende het promotietraject verdiept en verbreed. In het onderzoek en bij de totstandkoming van dit proefschrift zijn vele mensen belangrijk geweest. Als ik probeer volledig te zijn en iedereen zou willen bedanken, zou ik ongetwijfeld mensen vergeten. Daarom wil ik in de eerste plaats mijn oprechte dank uitspreken aan alle bevlogen mensen die ik heb mogen ontmoeten. Dank voor jullie hulp bij het ontdekken van hoe ‘samen beslissen’ kan bijdragen aan een meer gelijkwaardige en rechtvaardige zorg.

In mijn onderzoek vallen veel puzzelstukjes van mijn (werkzame) leven in elkaar: bij Spierziekten Nederland mocht ik leren denken en werken vanuit het perspectief van de mens met een spierziekte. Bij het CBO leerde ik dat kwaliteit in de kern gaat over wat die patiënt nodig heeft en hoe je daarin met zorgprofessionals en stakeholders elke dag beter kan worden. Dank aan alle inspirerende collega’s die mij daarin hielpen de passie te vinden om betekenisvol werk te doen. Nadat deze werkomgevingen mij in sterke mate hadden gevormd, heb ik tijdens mijn onderzoek met vele andere mensen en organisaties aan een betere kwaliteit van zorg gewerkt en dan met name meer ‘samen beslissen’: onder wie alle collega’s en partners die ik heb mogen ontmoeten bij Borstkankervereniging Nederland, de Nederlandse Federatie Kankerpatiëntenorganisaties, Longkanker Nederland, de VSOP en de Patiëntenfederatie Nederland, Aveleijn, Santeon, de Stichting Topklinische Ziekenhuizen, de Nederlandse Vereniging voor Toezichthouders in de Zorg, de Academie Medisch Specialisten, de Federatie Medisch Specialisten, Oncozon, Qruxx-Kwaliteit in Zorg en ZonMw. Jullie wil ik bedanken voor fijne en verrijkende samenwerking.

Mijn bijzondere dank gaat uit naar mijn promotoren: Carina, ik kon altijd een beroep op je doen. Ik kijk met bewondering naar hoe je onvermoeibaar positieve feedback geeft en naar je gevoel voor timing om op belangrijke momenten net dat duwtje te geven zodat dingen voort kunnen gaan. Daarbij zijn je enthousiasme voor ‘samen beslissen’ en je nieuwsgierigheid naar wat het de dagelijkse praktijk oplevert, erg motiverend. Dat helpt om te zorgen dat ‘samen beslissen’ ook tot de kern van het professionele vakmanschap behoort. Dirk, je bent een wetenschapper met een open blik die zelf voortdurend verdieping zoekt en mij bovendien op een prettige manier uitdaagt om mijn wetenschappelijke vaardigheden uit te breiden. Een ogenschijnlijke onschuldige vraag van jou, bijvoorbeeld waarom er bij de regressieanalyse een Beta coëfficiënt gerapporteerd wordt en geen odds ratio, betekende soms een week uitpluiswerk. Ik heb dat zeer gewaardeerd. Het maakt me trots dat ik nu met jullie een high five kan slaan en dan wel eentje met 7 vingers (één voor elke publicatie)!

Mijn erkentelijkheid gaat uit naar Ellen Smets, Marie-Jeanne Vrancken Peeters en Kees Ahaus voor het beoordelen van mijn proefschrift. Ik stel het bijzonder op prijs dat jullie hier prioriteit aan hebben gegeven. Ook veel dank aan de overige commissieleden Anne Stiggelbout, Tijn Kool en Arwen Pieterse. We hebben de afgelopen jaren met elkaar en op de schouders van andere reuzen in het land van 'samen beslissen', dit belangrijke thema steeds beter op de agenda kunnen zetten. Dat juist jullie in de beoordelingscommissie wilden plaatsnemen, maakt dat daarmee verleden, heden en toekomst (we zijn er nog niet) voor mij sterk met elkaar verbonden raken.

Het promotieonderzoek mocht ik doen bij de Erasmus School of Health Policy & Management (ESHPM) van de Erasmus Universiteit te Rotterdam. De ontvangst van zowel de staf als mede-promovendi was altijd hartelijk en behulpzaam. Kees, dat ik bij jou mocht landen om in deze werkfase wederom met elkaar op te trekken, was erg fijn. De uitnodiging om studenten te mogen begeleiden en met projecten mee te denken, waardeer ik zeer. Ik hoop in de toekomst ook van betekenis voor het ESHPM te kunnen zijn.

Uiteraard is ook de bijdrage van de diverse sponsors die aan mijn onderzoek hebben bijgedragen van groot belang voor het mogelijk maken van dit werk. Sponsors zijn essentieel voor het vergroten van de zichtbaarheid van 'samen beslissen' en een legitimering van noodzakelijke investeringen in dit thema.

Ik prijs me gelukkig dat ik met vele goede co-auteurs aan de artikelen heb mogen werken en vele collega-onderzoekers in het veld hebben mij direct of indirect (en altijd hartelijk) geholpen in het denken over hoe we tot een hoger niveau van 'samen beslissen' konden komen. Ook de zorgprofessionals hebben mij enorm gemotiveerd: jullie agenda's zijn tjokvol, maar jullie maakten wel enthousiast ruimte voor (nog) een avondtraining. Velen hebben zich opengesteld door geluidsopnames van consulten beschikbaar te stellen en door nieuw gedrag te oefenen tijdens bijeenkomsten en trainingen. Veel van wat wij gebruiken als tips en tops is van jullie zelf afkomstig.
Ella, Maaike, Loes, Esther, Helene, Jannie en Gijs, jullie zijn het avontuur aangegaan om het 'samen beslissen' voor te gaan leven en telkens te ontdekken waarmee patiënten en zorgprofessionals geholpen zouden kunnen zijn. Wat een mooi plan om nu met onze School voor Samen Beslissen de lessen aan anderen over te dragen. Ook de samenwerking met 'mijn' acteurs en hun enthousiasme hierin waardeer ik enorm.

Niet elke slag is een homerun en daarom is voor mij het vinden van een veilig en vertrouwd rustpunt een noodzaak. Mijn gesprekken, weekenden weg, diners en andere activiteiten met mijn fijne vrienden – vele nog uit de Maastrichtse tijd – zijn mij erg dierbaar. Marieke, Nicole, Tuk-tuk, Pascale, Jacco, Joris, Karin, Lodewien, Rob, Marius, Jo, Judy, beste Wils- én Van Veenendaal-familie, buren en loop- en voetbalvrienden, ik hoop dat ik nog vaak samen met jullie op honk mag staan.

Mijn familie is mijn thuishonk van waaruit ik telkens vertrek en weer terugkeer. Als je zeven jaar aan een proefschrift werkt en hebt bedacht dat dat best naast je bestaande werk moet kunnen, ben je gebaat bij een thuisomgeving die je niet in de weg zit maar zeker niet onverschillig is. Daaf en Rietje, dank dat jullie mij hebben aangemoedigd om mijn eigen(-)aardige zelf te zijn en het nieuwe met de nodige naïviteit tegemoet te durven treden. Het is geen toeval dat de titel van dit proefschrift ook de kernwaarden zijn die jullie me hebben meegegeven: gelijkheid en rechtvaardigheid. Rietje, Derke, Jelt, Ellen en Marja, het is meer dan fijn om jullie als moeder, broers en schoonzussen te hebben. Door jullie nuchterheid, humor en onvoorwaardelijkheid voel ik me telkens geaard als ik bij jullie ben. Arthur, Fia, Maartje en Ward: wat is het fijn om regelmatig met jullie te vertragen in een vaak vogelrijke omgeving met heuvels, lekker eten en een goed gesprek.

Kasper en Jop, als vader doe ik mijn uiterste best om ook jullie die onvoorwaardelijkheid te bieden. Mijn ijdele hoop was dat jullie eeuwig mijn kleine oogappels zouden blijven. Ik besef nu dat het puur geluk is om naast jullie te staan en jullie te zien groeien. Voor mij is er niets fijner dan dat juist jullie op de ceremonie achter me staan. En dan mijn Barrie: voor het ultieme gevoel van thuis prijs ik mij gelukkig dat ik jou heb mogen ontmoeten. Het was en is bijzonder om te ervaren dat ik mijn beste maatje gevonden heb om het leven te vieren: onvoorwaardelijk en gelijkwaardig. Je haalt de goede eigen-wijsheid in mij naar boven en biedt me daarin een verdiepend reflectief. Bij jou is zelfs het vertrekken van het honk fijn, omdat ik immers direct na vertrek voel dat ik weer op weg ben naar thuis. Inmiddels ben ik zo ver om te stellen dat je een minstens zo goede fikkiestoker bent als ik. Denk jij dat een volgende doelstelling kan zijn om in het hier en nu te leven?

Portfolio

Name:	Haske van Veenendaal
Department:	Erasmus School of Health Policy & Management (ESHPM)
PhD period:	2016-2022
Promotors:	Prof.dr. Carina Hilders Prof.dr. Dirk Ubbink

Courses

• How to search, find and evaluate scholarly information (1 CETS)	2017
• Brush up your research design (1 CETS)	2017
• Action Oriented Research Methodology (AORM) education (1 CETS)	2017
• How to survive your PhD (2.5 CETS)	2018
• Comparing nations in quantitative studies (2.5 CETS)	2018
• SPSS skills (1 CETS)	2019
• Dilemma Game (1 CETS)	2022

Relevant presentations

• 35^{e} Oncologiedagen. Gedeelde besluitvorming bij Borstkanker	2016
• European Breast Cancer Congress (EBCC): Patient participation for better Shared Decision Making	2016
• Stamppottenborrel Reinier de Graaf. What is Shared decision-making; And how do you do it?	2017
• ISPO 16th World Congress: Shared decision making in stroke rehabilitation	2017
• ISDM-congress: Implementing shared decision-making & time-out for breast cancer patients in six Dutch Hospitals	2017
• International Forum on Quality and Safety in Healthcare: 10 steps to Shared Decision Making	2017
• Zorginstituut Nederland, Ministerie van VWS: Shared decision-making; facilitating without forcing	2017
• ISDM-congress: Design of an implementation program for shared decision-making & time-out for breast cancer patients	2019
• ISDM-congress: Results of an implementation program for shared decision-making in breast cancer	2019
• ISDM-congress: Co creation for integrating patients perspectives	2019
• ISDM-congress: Educating clinicians in shared decision-making	2019
• Oncozon: Shared decision-making in practice: struggle and overcome	2019

• NVCO 6th Dutch Breast Surgeons Course: Implementing Shared-decision Making and time-out	2020
• Oncozon: Shared decision-making for a tailormade treatment plan	2021
• ISDM-seminar: Implementation of SDM in the Netherlands: State of the art	2022
• ISDM-congress: Interim results of randomized clinical trial for a novel learning intervention in oncology	2022
• ISDM-congress: Results of a systematic review about the relation between SDM and consultation duration	2022
• NVMO-congres: Mini-symposium Samen Beslissen	2023
• Masterclass Genootschap Gepersonaliseerde Zorg: Embedding Shared decision-making in the workflow	2023
• Landelijke werkbijeenkomst: Samen beslissen – zo doe je dat!: Training clinicians in shared decision-making: how do you do it?	2023

Relevant teaching activities

• Supervising 5 master theses	2018-2022
• Shared Decision-Making is better. Master Advanced Nursing Practice Rotterdam	2016-2022
• Various (train-the-trainer) training courses on Shared Decision-Making (Heliomare, Hogeschool Rotterdam, Trimbos Radboudumc, Geriant, Antonius, Meander Medical Center, Vie Curi Medical Center, Basalt, Tergooi).	2016-2023
• Various training courses on healthcare improvement for the Dutch Association of Healthcare Supervisors (NVTZ) and the Academy of Medical Specialists	2016-2023

Additional activities

• Peer reviewer BMJ-open, BMC, Patient Education and counseling, Digital Health, BMJ Evidence-Based Medicine	2016-2023
• Member of the supervisory board of various organizations such as the patient organization VSOP, and mytylschool St. Gabriel	2016-2023
• Member of the editorial board of internet journal Qruxx	2016-2023

Relevant international publications (in addition to this thesis)

1. van den Berg, van Veenendaal H, de Vos M, Laout-Kole F, Blink M. Barriers and Facilitators for Implementing Shared Decision Making in Pediatric Intensive Care: a qualitative interview study of healthcare professionals' perspectives. (submitted to Pediatric Critical Care Medicine).
2. van Veenendaal H, Peters LJ, van Weele E, Hendriks MP, Schuurman M, Visserman E, Hilders CGJM, Ubbink DT. Effects and Working Mechanisms of a Multilevel Implementation Program for Applying Shared Decision-Making while Discussing Systemic Treatment in Breast Cancer. Curr Oncol. 2022 Dec 23;30(1):236-249. *doi: 10.3390/curroncol30010019*.
3. van der Weijden T, van der Kraan J, Brand PLP, van Veenendaal H, Drenthen T, Schoon Y, Tuyn E, van der Weele G, Stalmeier P, Damman OC, Stiggelbout A. Shared decision-making in the Netherlands: Progress is made, but not for all. Time to become inclusive to patients. Z Evid Fortbild Qual Gesundhwes. 2022 Jun;171:98-104. *doi: 10.1016/j.zefq.2022.04.029*.
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About the author

Haske van Veenendaal was born in Son en Breugel on December 20, 1970. He studied Health Sciences at Maastricht University. He worked as a policy maker, advisor and trainer for various organizations including the patient organization Spierziekten Nederland and the Dutch Institute for Healthcare Improvement CBO. In the course of his professional career, he developed into an expert in Shared decision-making (SDM) and quality of care. He was one of the founders of the Shared decision-making Platform.

Since 2015, Haske is self-employed and PhD candidate at Erasmus School of Health Policy & Management (ESHPM) on the implementation of SDM in daily (oncology) practice. He has advised organizations such as Aveleijn on the design of their quality system. He has also led several national implementation projects for organizations including the Dutch Federation of Cancer Patient Organizations (NFK), the Foundation for Top Clinical Hospitals (STZ) and the Academic Medical Center (AMC).

Haske has been a trainer for over 10 years for various organizations such as the Academy of Medical Specialists, Erasmus University and the Supervisors in Care and Welfare (NVTZ). He has given many trainings and lectures on SDM in hospital-, rehabilitation-, mental health-, primary-, youth- and elderly care. He has been involved in the development of training programs for e.g. Santeon and educational materials such as the handbook ‘Training Healthcare Professionals in SDM’ and various e-learnings. Since 2020, Haske has been working part-time at Zorgonderzoek Nederland (ZonMw) as an implementation specialist.

In 2023, Haske founded the School for SDM (School voor Samen Beslissen), a network organization of SDM-professionals driving the ambition that SDM is self-evident and needs to be applied nationwide in healthcare organizations and by healthcare professionals. Finally, Haske has been an supervisor at Mytylschool St Gabriël in Den Bosch since 2020.

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