BMJ Open

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055324
Article Type:	Protocol
Date Submitted by the Author:	30-Jul-2021
Complete List of Authors:	Hackert, Mariska; Santeon Ankersmid, Jet; Santeon; University of Twente, Health Technology and Services Research Engels, Noel; Santeon ; Maasstad Hospital, Internal Medicine Prick, Janine; Santeon; OLVG, Neurology Teerenstra, Steven; Radboudumc, Health Evidence, Biostatistics Siesling, Sabine; Netherlands Comprehensive Cancer Organization , Research & Development; University of Twente, Health Technology and Services Research Drossaert, Stans ; University of Twente, Psychology, Health & Technology Strobbe, Luc; Canisius Wilhelmina Hospital, Surgical Oncology Van Riet, Yvonne; Catharina Hospital, Surgical Oncology van den Dorpel, Marinus; Maasstad Hospital, Internal Medicine Bos, Willem Jan; Sint Antonius Hospital, Internal Medicine; Leiden University Medical Center, Internal Medicine van der Nat , Paul; Sint Antonius Hospital, Value-Based Healthcare; Radboudumc IQ healthcare, Radboud Institute for Health Sciences Van den Berg-Vos, RM; OLVG, Neurology; Amsterdam UMC Locatie AMC, Neurology van Schaik, Sander; OLVG, Neurology Garvelink, Mirjam; Sint Antonius Hospital, Value-Based Healthcare Van der Wees, Philip; Radboudumc IQ healthcare, Radboud Institute for Health Sciences, Rehabilitation Van Uden-Kraan, Cornelia; Santeon
Keywords:	Stroke < NEUROLOGY, Chronic renal failure < NEPHROLOGY, Breast surgery < SURGERY, MEDICAL EDUCATION & TRAINING

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Mariska QN Hackert[#1], Jet W Ankersmid[*1,2], Noel Engels[*1,3], Janine CM Prick[*1,4], Steven Teerenstra[5], Sabine Siesling[2,6], Constance HC Drossaert[7], Luc JA Strobbe[8], Yvonne EA van Riet[9], René MA van den Dorpel[3], Willem Jan W Bos[10,11], Paul B van der Nat[12,13], Renske M van den Berg-Vos[4,14], Sander M van Schaik[4], Mirjam M Garvelink[12], Philip J van der Wees[13,15], Cornelia F van Uden-Kraan[1]

On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group

[*]*Contributed equally*

[#]*Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the Netherlands. E-mail: m.hackert@santeon.nl*

1. Santeon hospital group, Utrecht, The Netherlands
2. Department of Health Technology and Services Research, Technical Medical Center, University of Twente, Enschede, The Netherlands
3. Department of Internal Medicine, Maasstad Hospital, Rotterdam, The Netherlands
4. Department of Neurology, OLVG, Amsterdam, The Netherlands
5. Radboud Institute for Health Sciences, Department for Health Evidence, section Biostatistics, Radboud University Medical Center, Nijmegen, The Netherlands
6. Department of Research and Development, Netherlands Comprehensive Cancer Organization, Utrecht, The Netherlands
7. Department of Psychology, Health and Technology, University of Twente, Enschede, The Netherlands
8. Department of Surgical Oncology, Canisius Wilhelmina Hospital, Nijmegen, The Netherlands
9. Department of Surgical Oncology, Catharina Hospital, Eindhoven, The Netherlands
10. Department of Internal Medicine, St. Antonius Hospital, Nieuwegein, The Netherlands
11. Department of Internal Medicine, Leiden University Medical Center, Leiden, The Netherlands
12. Department of Value-Based Healthcare, St. Antonius Hospital, Nieuwegein, The Netherlands
13. Radboud Institute for Health Sciences, Scientific Centre for Quality of Healthcare (IQ Healthcare), Radboud University Medical Center, Nijmegen, The Netherlands
14. Amsterdam UMC, location AMC, Department of Neurology, Amsterdam, the Netherlands
15. Radboud Institute for Health Sciences, Department of Rehabilitation, Radboud University Medical Center, Nijmegen, The Netherlands

Word count 3836

Date 08-07-2021, **Version** 1.0

ABSTRACT

Introduction Within the value-based healthcare framework, outcome data can be used to inform patients about (treatment) options, and empower them to make shared decisions with their healthcare professional. To facilitate shared decision-making (SDM) supported by outcome data, a multicomponent intervention has been designed, including patient decision aids on the organization of post-treatment surveillance (breast cancer); discharge location (stroke) and treatment modality (advanced kidney disease), and training on SDM for healthcare professionals. The SHared decision-making supported by OUTcome information (SHOUT) study will examine the effectiveness of the intervention and its implementation in clinical practice.

Methods and analysis Multiple interrupted time series will be used to stepwise implement the intervention. Patients diagnosed with either breast cancer (N = 630), stroke (N = 630) or advanced kidney disease (N = 473) will be included. Measurements will be performed at baseline, 3 (stroke), 6 and 12 (breast cancer and advanced kidney disease) months. Trends on outcomes will be measured over a period of 20 months. The primary outcome will be patients' perceived level of involvement in decision-making. Secondary outcomes regarding effectiveness will include patient-reported SDM, decisional conflict, role in decision-making, knowledge, quality of life, preferred and chosen care, satisfaction with the intervention, healthcare utilization and health outcomes. Outcomes regarding implementation will include the implementation rate and a questionnaire on the healthcare professionals' perspective on the implementation process.

Ethics and dissemination The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act does not apply to this study. Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study. The results will contribute to insight in and knowledge on the use of outcome data for SDM, and can stimulate sustainable implementation of SDM.

Registration Netherlands Trial Register NL8374, NL8375 and NL8376, registration date: February 12th 2020.

Keywords Value-based healthcare, personalized outcome data, clinical outcome data, patient-reported outcomes, patient decision aid, shared decision-making, breast cancer, stroke, advanced kidney disease

Strengths and limitations of this study

- Multiple interrupted time series are arguably the strongest quasi-experimental design as randomization is not feasible.
- All hospitals will implement and therefore benefit from the multicomponent intervention, facilitating shared decision-making supported by personalized outcome data.
- Multiple components are needed for the intervention to be effective; however, it does not allow for an individual evaluation of each component.
- By using stepwise implementation and the value-based healthcare organization structure, the hospitals can learn from each other.
- It allows the multicomponent intervention to be further refined and tested over time.

INTRODUCTION

Value-based healthcare (VBHC) is gaining momentum worldwide.[1, 2] The VBHC framework strives to maximize value for patients by achieving the best outcomes while controlling costs.[3] Per patient group, clinical and patient-reported outcomes, costs and process data are measured and compared in a structured, standardized manner. These data are used to identify variation across the care cycle to collectively enhance the value of healthcare provision on patient group level.[2] Besides the use of outcome data on group level, outcome data can also be used on the individual patient level, by integrating outcomes and value in patient communication. However, in clinical practice, the role of outcome data in patient communication is not common practice. On individual patient level, most importantly, outcome data can provide insight into benefits and harms of treatment options. Integrating outcome data in discussing treatment options between healthcare professionals and patients, is where VBHC and shared decision-making (SDM) entangle.[4, 5]

So far, SDM has shown to lead to well-informed, preference-based patient decisions, and to improve patients' relationship with their healthcare professional.[6-8] Using outcome data can further strengthen the motivation of healthcare professionals to apply SDM, and empower patients to make shared decisions with their healthcare professional. In this way, outcome data can accelerate the implementation of SDM and strengthen VBHC.[4, 5, 9, 10]

To support SDM, outcome data should be presented to patients in a meaningful way. The four-step conversational SDM model can be used for this purpose ([8]; inspired by [11]). In each step, outcome data, both on patient individual and group level (aggregated), can be incorporated (see Figure 1, based on [8, 9]).

<<INSERT Figure 1>>

The individual outcome data can be used to introduce a care decision and to determine available options for the patient *(step 1)*. Related benefits and harms of these options are explained in *step 2*. As these may differ between patients depending on clinical and personal characteristics, it is highly encouraged to display personalized outcomes ("patients-like-me data"),[9] or to use prediction models in which these characteristics can be entered to display personal estimated risks and to support personalized aftercare paths.[12] Next (*step 3*), the healthcare professional and the patient discuss the patient's preferences.

This process of value clarification can be fostered by being informed on outcome data of previous patients. In *step 4*, the healthcare professional and the patient together integrate outcome data and preferences to make a shared decision.

Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower this threshold, we developed a multicomponent intervention for three patient groups with an oncological (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as training for healthcare professionals and an accompanying implementation strategy. So far, little is known about the impact of using outcome data for SDM.[9, 10]

The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight in and knowledge on the use of personalized outcome data for SDM, and can stimulate sustainable implementation of SDM in clinical practice.

METHODS AND ANALYSIS

We used multiple interrupted time series (mITS) [13] to compare the intervention with standard care. We followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see Appendix A).[14,15] mITS will allow for initial testing and refinement of the intervention. In participating hospitals, trends on outcomes will be established through a continuous sequence of observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2). Trends in the pre-implementation phase will be 'interrupted' at planned timepoints by the stepwise implementation of the intervention in each hospital. Direct effects (level change) will be examined, as well as gradual changes over time (slope change).

<<INSERT Figure 2>>

Study setting

Seven independent large Dutch teaching hospitals, which together form the Santeon hospital group, will participate in this study. The hospitals are geographically spread across the Netherlands and account for about 11% of the Dutch hospital care volume. By using VBHC principles, comparing outcome data and collaborating in multidisciplinary improvement teams, Santeon continuously aims to improve quality of care on patient group level.[16, 17] The next step is to use the collected, real-world outcome data to better inform individual patients and healthcare professionals. Up to now, aggregated outcome data have been gathered in international studies using homogenous samples and population averages. Real-world outcomes in larger, heterogenous groups of patients provide complementary evidence.[18]

Study population

Patients diagnosed with either breast cancer, stroke or AKD, treated in Santeon hospitals, will be asked to participate in this study. These patient groups are sufficiently large and diverse to cover a relatively broad spectrum of hospital healthcare. In addition, both breast cancer and stroke are in the top-20 list of largest medical conditions in terms of national disease burden.[19]

Inclusion criteria

All participants must be aged 18 years or older, and able to understand the Dutch language in speech and writing. Inclusion criteria will be:

1) patients facing the decision for the organization of post-treatment surveillance after curative treatment for invasive non-metastasized breast cancer;
2) hospitalized patients with a (ischemic or hemorrhagic) stroke that have to decide on their discharge location and type of care after discharge from the hospital;
3) patients with AKD (i.e. CDK-KDIGO G4-$G5_{A1-3}$) that have to make a treatment modality decision (hemodialysis, peritoneal dialysis, kidney-transplantation or comprehensive conservative care).

Exclusion criteria

Patients with severe cognitive impairment or physical inability to complete a questionnaire will be excluded. Exclusion criteria per patient group are displayed in Table 1.

Table 1. Exclusion criteria per patient group.

Breast cancer	Stoke	Advanced kidney disease
• Male patients • Predisposing genetic mutations related to breast cancer • Non-invasive breast cancer • History of neoadjuvant systemic therapy or treatment for a recurrence or second primary tumor • Palliative treatment	• Reduced consciousness	• On renal replacement therapy or conservative care management

Intervention

A multicomponent intervention was developed including PtDAs, a training for healthcare professionals and an implementation strategy.

Interactive patient decision aids containing personalized outcome data

A PtDA was developed for each patient group in an iterative process of five co-creation sessions with a multidisciplinary team consisting of patients, patient representatives and healthcare professionals. A literature review and needs assessment studies among patients and healthcare professionals served as input. Development was guided by the International Patient Decision Aid Standards (IPDAS) Collaboration framework,[20] and in line with the Dutch guidelines for developing PtDAs.[21] Content was critically revised by the teams in an iterative process, and rewritten to B1 language level (Common European Framework of Reference for Languages, CEFR). Usability testing was conducted among healthcare professionals and patients that were not involved in the development process.

Each PtDA is composed of three components which contain personalized (patient-reported and clinical) outcome data, both on individual as well as aggregated level. From the transition phase onwards (Figure 2), the healthcare professional will introduce the PtDA to patients by means of a paper or digital consultation sheet *(component 1)*. Patients will receive a personal login code to access the online interactive PtDA at home or during hospital admission *(component 2)*. Each PtDA contains evidence-based information about the options and pros and cons. Information is tailored to relevant options for the patient, and presented without favoring any particular outcome. The PtDAs actively encourage patients

to weigh their options. Once patients have completed the PtDA, a summary sheet will automatically be created, containing an overview of the patient's preferences and considerations as a base for final decision-making in a consultation with their healthcare professional *(component 3)*.

Breast cancer patient decision aid

The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving curative treatment for invasive non-metastasized breast cancer. The PtDA includes the risk for locoregional recurrences estimated using the INFLUENCE nomogram [12] and a patient-reported outcome measures (PROMs) questionnaire on fear of recurrence / cancer worries (translation of the PtDAs in all patient groups was obtained for publication; see Appendix B).

Stroke patient decision aid

The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The PtDA includes an interactive "patients-like-me" model on the discharge location of comparable patients based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-being (see Appendix B).

Advanced kidney disease patient decision aid

The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive "patients-like-me" model on median survival- and mean hospitalization rates per treatment modality based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see Appendix B).

Training of healthcare professionals

Healthcare professionals will be asked to complete an e-learning on applying (personalized) outcome data to support SDM. Consequently, they will be asked to participate in a group training of one daypart. The training includes the theoretical background on SDM, reflection on audio-taped consultations, cases introduced by participants, and practicing SDM consultation skills with an actor. Upon completing the training, follow-up will be offered after one day (by offering a plasticized card or poster containing short written instructions on SDM, and by presenting a publication on using outcome data to support SDM), after one month (by offering tips, tricks, a testimonial by a colleague healthcare professional and an

instruction clip on SDM) and after two months (by offering the possibility to receive individualized feedback by sending an audio-taped consultation to the trainer).

Implementation strategy for the multicomponent intervention

The implementation strategy is based on prior successful implementation strategies for PtDAs [22] and a web-based self-management application using PROMs to monitor quality of life.[23] Core elements are listed in Table 2.

Table 2. Implementation strategy.

1. *Inform and create support for using the PtDA* by developing the PtDA by means of a participatory design approach, including both healthcare professionals and patient advocates, and by customizing the PtDA for each individual hospital (i.e. by applying the individual hospital logo).
2. *Document the current care path* in each hospital to find the best way to incorporate the PtDA. Involving both the timing of the PtDA and the healthcare professionals who will present it.
3. *Informing and involving all healthcare professionals* in the care path by means of an information meeting, and by offering the possibility to make use of an e-learning on applying outcome data in SDM.
4. *Instruction on how to introduce the PtDA* to eligible patients by means of a kick-off meeting organized in the hospitals shortly before the start of the implementation of the PtDA.
5. *Offering support in the workplace*, i.e. by providing plasticized cards containing short written instructions in line with the SDM four-step conversation model, and by stimulating implementation e.g. by distributing promotional posters. Support and technical assistance for both healthcare professionals and patients will be centralized and available through a helpdesk.
6. *Closely monitoring of progress and stimulating implementation* by local ambassador and informed by a dashboard containing usage data of the PtDA.
7. *Offering the training and the PtDA free of charge* during the study period.

Study design and procedures

The intervention will be stepwise implemented in the hospitals over a period of 20 months (see Figure 2). In each hospital, there will be 6 to 12 months in which standard care will be thoroughly assessed (pre-implementation phase), followed by a transition phase of 2 months in which healthcare professionals will be trained and the PtDA will be introduced. Finally, there will be 6 to 12 months in which the intervention will be assessed (post-implementation phase). The moment by which hospitals switch from standard care to use of the intervention will not be randomized. Internal validity will be increased, as

each hospital will act as its own historical control group and the hospitals will not switch at the same time.

Patients will be asked by their healthcare professional to participate in this study: 1) patients with breast cancer will be informed and asked to participate during the follow-up consultation on the occasion of their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision has to be made about renal replacement therapy or conservative care. When interested, patients will receive a patient information letter about the study. They will be asked for written informed consent. Patients in the post-implementation phase will receive the PtDA.

Data collection and methods

To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T_0) will be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T_1) for patients with stroke, and after 6 (T_1) and 12 (T_2) months for patients with breast cancer or AKD. Second, the consultations, in which the options are being discussed, will be audio-taped to assess patients' involvement in the decision-making process from observers' viewpoint. Also, the length of the consultations will be determined. Third, to assess the extent to which the intervention leads to changes in the utilization and outcomes of healthcare, information will be retrieved from patients' electronic health records. To evaluate the implementation, first, the estimated total number of eligible patients and the total number of patients who received the PtDA will be determined. Second, participating healthcare professionals will receive a questionnaire 6 months after start of the post implementation phase, to assess their perspective on the implementation process.

Participant timeline

The participant timeline is displayed in Figure 3.

<<INSERT Figure 3>>

Outcomes

Effectiveness

The primary outcome will be patients' perceived level of involvement in decision-making. Secondary outcomes regarding effectiveness will include patient-reported SDM, decisional conflict, decision regret for patients with stroke and AKD, (preferred) role in decision-making, knowledge, quality of life, preferred and chosen care (and the role of the consultation and outcome data therein), and satisfaction with the intervention. Also, perceived risk and fear of recurrence will be measured among patients with breast cancer, and participation / functioning and caregivers' strain will be assessed among patients with stroke. An overview of the patient-reported outcomes per timepoint and patient group is presented in Table 3.

Furthermore, observer-reported SDM will be assessed by analyzing audio-recordings of encounters from clinical settings. Patients' healthcare utilization and health outcomes will be extracted from their electronic health records.

Finally, to obtain insight into moderators, we will obtain data on socio-demographic and clinical characteristics, and patients' self-reported health literacy.

Primary outcome measure

The primary outcome to assess effectiveness will be patients' perceived level of involvement in decision-making, measured with the 9-item SDM Questionnaire (SDM-Q-9).[24] (Rodenburg-Vandenbussche et al., 2015). Each item describes a different step in the SDM process, and will be scored by patients on a 6-point Likert scale. The sum of the item scores will range from 0 – 45, with higher scores indicating a greater level of perceived involvement in SDM.

Secondary outcome measures

Secondary outcomes will be patient-reported SDM, measured with the CollaboRATE; decisional conflict, measured with the Decisional Conflict Scale (DCS); decision regret for patients with stroke and AKD, measured with the Decision Regret Scale (DRS); (preferred) role in decision-making, measured with the Control Preference Scale (CPS); knowledge, measured with patient group-specific items; quality

of life, measured with the 12-item Short Form Health Survey (SF-12) for patients with breast cancer and AKD, and measured with the Patient Reported Outcomes Measurement Information System Global Health (PROMIS-10), five-dimension EuroQol five-levels questionnaire (EQ-5D-5L), and EuroQol Visual Analogue Scale (EQ-VAS) for patients with stroke; preferred and chosen care (and the role of the consultation and outcome data therein), measured with patient group-specific items; satisfaction with the intervention, measured with the Preparation for Decision Making scale (Prep-DM) and study-specific questions; perceived risk and fear of recurrence for patients with breast cancer, measured with the Cancer Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast cancer survivors (IPQ-BCS) and patient group-specific questions; and participation / functioning and caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see Table 3, also for references).

Observer-reported SDM

The Observing Patient Involvement in decision-making scale (OPTION-5) [25] will be used to analyze the audio-recordings of encounters from clinical settings. The OPTION-5 includes five core SDM steps, to which a sixth is added to assess the role of personalized outcome data *('the healthcare professional informs the patient on outcomes of different treatment options')*. The item scores will be summed and rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

Healthcare utilization and outcomes

Patients' healthcare utilization and clinical outcomes will be extracted from their electronic health records. For patients with breast cancer, the number of hospital visits, the number of mammograms and other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications during admission will be extracted. For patients with AKD, the number of visits to outpatients clinics, hospitals admissions and hospitalization days, and the rate of major treatment-related complications will be extracted.

Table 3. Overview of the patient-reported outcomes and instruments used per timepoint.

Measure	Description	Scoring range	Pre-implementation phase			Post-implementation phase		
			Baseline	T1	T2	Baseline	T1	T2
All patient groups:								
Shared decision-making								
• SDM-Q-9 [24] (primary outcome measure)	9-item, 6-point scale measures patients' perceived level of involvement in decision-making.	Range 0 – 45, higher scores indicate a greater level of perceived involvement in decision-making.	X			X		
• CollaboRATE [31]	3-item, 10-point scale measures patient-reported SDM.	Range 0 – 100, higher scores indicate a higher patient-reported SDM.	X			X		
Decisional conflict								
• DCS [32]	16-item, 5-point scale measures personal perceptions of a) uncertainty in choosing options, b) modifiable factors contributing to uncertainty and c) effective decision-making.	Range 0 – 100, higher scores indicate greater decisional conflict.	X			X		
Decision regret								
Stoke and advanced kidney disease:	5-item, 5-point scale measures distress or remorse after a healthcare decision.	Range 0 – 100, higher scores indicate greater regret.		X	X		X	X
• DRS [33]								
(Preferred) role in decision-making								
• CPS [34]	1-item with 5 response options to assess the patient's preferred or perceived degree of control when decisions about treatment are being made.		X			X		
Knowledge (patient group-specific items)								
Breast cancer:	10 items with 3 response options.		X			X		
Stroke:	7 items with 3 – 7 response options.		X			X		
Advanced kidney disease:	7 items with 3 – 5 response options.		X			X		
Quality of life								
Breast cancer and advanced kidney disease:	12-items with 2 – 6 response options on quality of life.	Mental and physical component score based on the US population scoring system, higher scores indicate greater quality of life.	X	X	X	X	X	X
• SF-12 [35,36]								
Stroke:								
• PROMIS Global-10 [37]	10 items with 5 – 11 response options on quality of life.	Physical and mental health summary scores based on the US population scoring system, higher scores indicate greater quality of life.		X			X	
• EQ-5D-5L [38,39]	5 items, 5-point scale measures patients' health-related quality of life.	Range -0.446 – 1 based on the Dutch population tariff, higher scores indicate greater health-related quality of life.		X			X	
• EQ-VAS [38]	Visual analogue scale measures patients' health-related quality of life.	Range 0 – 100, higher scores indicate greater health-related quality of life.		X			X	

Preferred and chosen care (and the role of the consultation and outcome data therein) (patient group-specific items)								
Breast cancer: *Stroke:* *Advanced kidney disease*	48 items with 3 – 10 response options / open-ended. 6 items with 3 – 8 response options / open-ended. 9 items with 2 – 9 response options / open-ended.		X X X			X X X		
Satisfaction with the intervention								
• Prep-DM [40]	10-item, 5-point scale measures patients' perception of how useful the PtDA is in preparing them to communicate with their healthcare professional during consultations, and for making a healthcare decision.	Range 0 – 100, higher scores indicate higher perceived level of preparation for decision-making.				X		
• Study-specific items	24 items with 2 – 8 response options / open-ended to assess a) the way in which the PtDA has been presented to the patient, b) the experience of the patient with using the PtDA, and c) the extent to which the PtDA is of value to the patient.					X		
Breast cancer:								
Perceived risk and fear of recurrence								
• CWS [41]	6-item, 4-point scale measures concerns about cancer recurrence and the impact of these concerns on daily functioning.	Range 6 – 24, higher scores indicate greater worrying.	X	X	X	X	X	X
• IPQ-BCS (cure and personal control subscale) [42]	2x 4-item, 5-point scale measures a) patients' cure beliefs and b) personal control over the risk for recurrences.		X	X	X	X	X	X
• Patient group-specific items based on CRHWS [43], FCR7 [44] and FoP-Q [45]	9 items with 4 – 6 response options to assess patients' feelings about imaging during follow-up and worry about cancer recurrence, and to assesses patients' perceived (absolute and comparative) risk of recurrence.		X	X	X	X	X	X
Stroke:								
Participation / functioning								
• Simplified mRS [46]	5-item, 2-point scale measures the degree of dependence of patients with stroke.	Range 0 – 5, higher scores indicate greater dependence.		X			X	
• USER-P restriction subscale [47]	11-item, 5-point scale measures experienced restrictions on 11 domains of participation.			X			X	
Caregivers' strain								
• CSI [48]	13-item, 2-point scale measures strain related to care provision.	Range 0 – 13, ≥ 7 indicates a higher level of strain.		X			X	

9-item Shared Decision Making Questionnaire, SDM-Q-9; Decisional Conflict Scale, DCS; Decision Regret Scale, DRS; Control Preference Scale, CPS; 12-item Short Form Health Survey , SF-12; Patient Reported Outcomes Measurement Information System, PROMIS; five-dimension EuroQol five-levels questionnaire, EQ-5D-5L; Preparation for Decision Making scale, Prep-DM; Cancer Worry Scale, CWS; modified version of the Revised Illness Perception Questionnaire for breast cancer survivors, IPQ-BCS; cancer-related health worries scale, CRHWS; seven-item Fears of Cancer Recurrence, FCR7; Fear of Progression Questionnaire, FoP-Q; modified Ranking Scale, mRS; USER-P, Utrecht Scale for Evaluation of Rehabilitation-Participation; CSI, Caregiver Strain Index.

Moderators

Socio-demographic characteristics

In the baseline questionnaire, patients' sex, birth year, marital status, occupation, and education level will be asked.

Clinical characteristics

Relevant medical characteristics will be extracted from the baseline questionnaire and the electronic health records. For patients with breast cancer, tumor and treatment characteristics will be extracted. For patients with stroke, etiology of stroke, and whether or not the patient has been treated with reperfusion therapy will be extracted. For patients with AKD, renal function, etiology and duration of kidney failure, whether or not these patients have had other treatment modalities for kidney failure in the past, comorbidity and definite treatment modality will be extracted.

Health literacy

Patients' health literacy will be assessed in the baseline questionnaire by the Set of Brief Screening Questions (SBSQ).[26] The mean score on the three items will be calculated, with higher scores reflecting higher health literacy skills.

Implementation

To evaluate the implementation of the intervention, outcomes will include the implementation rate and a questionnaire on implementation for healthcare professionals.

Implementation rate

The implementation rate will be calculated as the proportion of patients who received the PtDA compared to the estimated total number of eligible patients during the period of 6 to 12 months in which the PtDA will be handed out.

Healthcare professionals' view on the implementation process and use of the patient decision aid

Determinants of implementing an innovation

Healthcare professionals will fill out a questionnaire based on the Measurement Instrument for Determinants of Innovations (MIDI).[27] The MIDI assesses barriers and facilitators of implementation at the level of innovation (PtDA), the user (healthcare professionals) and the organization (hospital).

Physicians' willingness to incorporate shared decision-making

Healthcare professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[28]

Sample size

The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary outcome measure with the statistical significance level set at alpha = 0.05 (two-sided). The size of the expected effect of the intervention on the SDM-Q-9 was set to be small to moderate (Cohen's d = 0.3-0.4) as relatively high scores on the SDM-Q-9 are common in the Netherlands.[29] The mITS with seven clusters (i.e. hospitals) had 18 measurement periods (excluding the transition phase, see Figure 2). A non-large Intraclass Correlation Coefficient (ICC = 0.05) was assumed. The correlation between monthly measurements was expected to be high (0.7 – 0.9) throughout a period of 18 months, although correlations between months farther apart could be lower than for month closer by. A normal autoregressive correlation structure turned out too conservative and a compound symmetry correlation structure too optimistic for this purpose. Therefore, power calculations were primarily based on the linear exponent autoregressive correlation structure [30] that sits in between both and can be characterized by the correlation between subsequent months and the correlation between the first and the last month. Correlation between months decreases by distance between months from the highest value (for consecutive months) to the lowest value (for largest distance, i.e. between the first and last month). For patients with breast cancer and stroke, we assumed a high correlation between two consecutive months (at least r = 0.9) and a moderate correlation between the first and final month (r = 0.7). Five patients per hospital per month was considered feasible, and with a 25% loss to follow-up, this results in a monthly inclusion rate of four patients. This yields more than 80% power and amounts to a study population of N = 504 – 630.

For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals. Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting a Cohen's d = 0.4 assuming a correlation between subsequent months of at least 0.8 and a correlation between the first and last month of at least 0.6. This amounts to a study population of N = 378 – 473.

Statistical methods

An overview of the demographic and clinical characteristics will be provided using descriptive statistics. Continuous data will be expressed as a mean with the standard deviation (SD), or as the median (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless stated otherwise.

Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented regression will be employed, with the period before and after the introduction of the intervention as segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time series to exhibit different levels and trends. Correlation between repeated measurements in each time series will be accounted for by modelling the error structure. The effect of the intervention will be examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using the following model:

$$Y(T) = \beta 0 + \beta 1 \cdot T + \beta 2 \cdot I + \beta 3 \cdot I \cdot t$$

where $\beta 0$ will represent the baseline level at $T = 0$, $\beta 1$ will be interpreted as the change in outcomes associated with a time unit increase (representing the underlying trend in the pre-implementation phase), $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, $\beta 2$ will be the level change in the post-implementation phase and $\beta 3$ will indicate the slope change following the implementation phase (using the interaction between time t since the intervention started and the indicator for being in the intervention: I). A change in $\beta 2$ will constitute an immediate effect, while a change in $\beta 3$ will imply an effect that was experienced over time (which also allows us to measure the sustainability of the impact). Moreover, segmented regression will enable us to control for other variables, that can cause a change in level or trend of the outcomes of interest.

Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation techniques or sensitivity analyses will be used to assess their impact on the trial results.

To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis across all patient groups and hospitals will be performed.

ETHICS AND DISSEMINATION

The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference numbers METC 2019-075, -076 and -077).

The study will be conducted in accordance with local laws and regulations. Eligible patients will fully be informed about the study and asked to participate. They will receive a patient information letter and will be informed by telephone about the implications of participation. Patients will have sufficient opportunity to ask questions and to consider the implications before providing written informed consent. They will be allowed to withdraw from the study without giving a reason, at any time.

The SHOUT study is part of a larger Santeon program on using outcome data for SDM (‘Experiment Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals, (inter)national conferences, workshops webinars, and newsletters and social media.

ACKNOWLEDGEMENTS

We thank all patients, patient representatives and health care professionals for their contribution to designing the multi-component intervention and execution the SHOUT study. The SHOUT study is part of a larger program on using outcome data for SDM ('Experiment Uitkomstindicatoren Santeon'), which is part of the Outcome-based Healthcare program initiated by the Dutch Ministry of Health, Welfare and Sports. We would like to thank ZonMw for funding this project.

FOOTNOTES

Availability of data and materials

Data will be collected and recorded in CASTOR EDC, a cloud-based electronic data capture platform. This platform is fully compliant with GCP, 21 CFR part 11, GDPR, HIPAA, ISO27001 and ISO 9001. All data will be coded and password protected. Study participants will be assigned a participant identification number (PIN). A digital, password protected identifying list relating medical information of participants to their PIN numbers will be kept on a secured server in the Santeon hospitals. All data and study documents will deleted and discarded after 15 years. The datasets used and / or analyzed during the SHOUT study are available from JWA (breast cancer), NE (AKD) and JCMP (stroke) on reasonable request. The (intellectual) property rights with regard to the generated data will reside at Santeon, Utrecht, The Netherlands. Interested parties can request a non-exclusive license for research and educational purposes. The non-exclusive license may be requested only after the completion of the theses to be written reserving the generated data.

Competing interests

None declared.

Funding

This research project is funded by ZonMw as part of the 'Experiment Uitkomstindicatoren Santeon'. This funding had no involvement in collection, management, analysis, and interpretation of the data; writing this manuscript or the decision to submit the article for publication.

Authors' contributions

JWA, NE, JCMP, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, SMvS, and CFvU-K developed the multicomponent intervention. MQNH, ST, PBvdN, PJvdW and CFvU-K contributed to the design of the study. JWA, NE, JCMP are conducting this study in fulfillment of a PhD and will be responsible for data collection. JWA, NE, JCMP and ST will be responsible for data analysis. All authors will be responsible for interpretating the data. The present manuscript was drafted by MQNH and CFvU-K. JWA, NE, JCMP, ST, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, PBvdN, RMvdB-V, SMvS, MMG and PJvdW critically revised this manuscript. All authors have read and approved the final manuscript.

Patient and public involvement

Santeon supports that patients with 'lived experiences' become members of a research team. Since the very beginning (composing the grant application), we have engaged a core group of patients and patient representatives of the patient associations involved. We designed the multicomponent intervention in collaboration with patients and healthcare professionals (see the Methods and Analysis). In addition, patient representatives were involved in the development of the study. Our collaboration with the patient associations will continue throughout the study. Study findings about the potential benefits of the multicomponent intervention will be disseminated by means of our project website.

ABBREVIATIONS

AKD, advanced kidney disease

mITS, multiple interrupted time series

PROM, patient-reported outcome measure

PtDA, patient decision aid

SDM, shared decision-making

VBHC, value-based healthcare

REFERENCES

1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health outcomes measurement and organizational readiness support quality improvement: a systematic review. BMC Health *Serv Res* 2018;18:1005. https://doi.org/10.1186/s12913-018-3828-9.

2 Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med* 2016;374:504-6. https://doi.org/10.1056/NEJMp1511701.

3 Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477-81. https://doi.org/10.1056/NEJMp1011024.

4 Steinmann G, van de Bovenkamp H, de Bont A, Delnoij D. Redefining value: a discourse analysis on value-based health care. *BMC Health Ser Res* 2020;20:862. https://doi.org/10.1186/s12913-020-05614-7.

5 Van der Nat PB. The new strategic agenda for value transformation. *Health Serv Manage Res* 2021;0(0):1-5. https://doi.org/10.1177/09514848211011739.

6 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Sys Rev* 2017;4:CD001431. https://doi.org/10.1002/14651858.CD001431.pub5.

7 Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci* 2016;11:114. https://doi.org/10.1186/s13012-016-0480-9.

8 Stiggelbout AM, Pieterse AH, de Haes JCJM. Shared decision making: concepts, evidence and practice. *Patient Educ Couns* 2015;98(10):1172-9. https://doi.org/10.1016/j.pec.2015.06.022.

9 Damman OC, Jani A, de Jong BA, et al. The use of PROMs and shared decision-making in medical encounters with patients: an opportunity to deliver value-based health care to patients. *J Eval Clin Pract* 2020;26:524-40. https://doi.org/10.1111/jep.13321.

10 La Grouw Y, Kee K, Ybema S, Taverne H, Boonen L. *Samen Beslissen in de praktijk: praktijkonderzoek i.o.v. het Zorginstituut Nederland.* Equalis / VU, 2019. https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen-beslissen-in-de-praktijk

11 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-7. https://doi.org/10.1007/s11606-012-2077-6.

12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36. https://doi.org/10.1007/s10549-015-3490-4.

13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community intervention research. *Prev Sci* 2000;1:31-49. https://doi.org/10.1023/A:1010024016308.

14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013a;158:200-7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583.

15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013b;346:e7586. https://doi.org/10.1136/bmj.e7586.

16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director: Gregory Katz). 2020.

17 Santeon. www.santeon.nl 2021; 22 June.

18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. https://doi.org/10.1200/JCO.19.02035.

19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's).* 2018. https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys.

20 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710. https://doi.org/10.1177/0272989X13501721.

21 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een keuzehulp bij een richtlijn?* Den Haag, The Netherlands, 2018.

22 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J* 2020;26(2):1194-207. https://doi.org/10.1177/1460458219873528.

23 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a web-based self-management application "Oncokompas" in routine cancer care: a national pilot study. *Support Care Cancer* 2019;27:2911-20. https://doi.org/10.1007/s00520-018-4591-5.

24 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care. *PloS ONE* 2015;10(7):e0132158. https://doi.org/10.1371/journal.pone.0132158.

25 Elwyn G, Grande SW, Barr P. *Observer OPTION^5 manual. Measuring shared decision making by assessing recordings or transcripts of encounters from clinical settings.* The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, USA, 2018.

26 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6. https://doi.org/10.1007/s11606-008-0520-5.

27 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10. https://doi.org/10.1093/intqhc/mzu060.

28 Berkowitz J, Martinez-Camblor P, Stevens G, Elwyn G. The development of incorpoRATE: a measure of physicians' willingness to incorporate shared decision making into practice. *Patient Educ Couns* 2021; Feb 25:S0738-3991(21)00140-3. https://doi.org/10.1016/j.pec.2021.02.040.

29 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke besluitvorming.* Utrecht: Nivel, 2021.

30 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of correlation structures. *Stat Med* 2010;29(17):1825-38. https://doi.org/10.1002/sim.3928.

31 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93(1):102-7. http://doi.org/10.1016/j.pec.2013.05.009.

32 O'Connor AM. *User Manual – Decisional Conflict Scale.* OHRI. 1993 (modified 2010);1:1-16.

33 O'Connor AM. *User Manual – Decision Regret Scale.* Ottawa, Ottawa Hospital Research Institute; 1996 (modified 2003).

34 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-43.

35 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33. https://doi.org/10.1097/00005650-199603000-00003.

36 Ware JE, Kosinski MA, Keller SD. SF-12: *How to score the SF-12 Physical and Mental Health Summary Scales.* The Health Institute, New England Medical Center, Boston Massachusetts, 1995.

37 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res* 2009;18:873-80. https://doi.org/10.1007/s11136-009-9496-9.

38 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. https://doi.org/10.1007/s11136-011-9903-x.

39 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52. https://doi.org/10.1016/j.jval.2016.01.003.

40 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale.* Ottawa, Ottawa Hospital Research Institute, 1995 (modified 2010).

41 Lerman C, Daly M, Masny A, Balshem A. Attitudes about genetic testing for breast-ovarian cancer susceptibility. *J Clin Oncol* 1994;12(4):843-50. https://doi.org/10.1200/JCO.1994.12.4.843.

42 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58. https://doi.org/10.1080/08870446.2016.1275629.

43 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol* 2006;15(4):306-20. https://doi.org/10.1002/pon.955.

44 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out* 2018;16:30. https://doi.org/10.1186/s12955-018-0850-x.

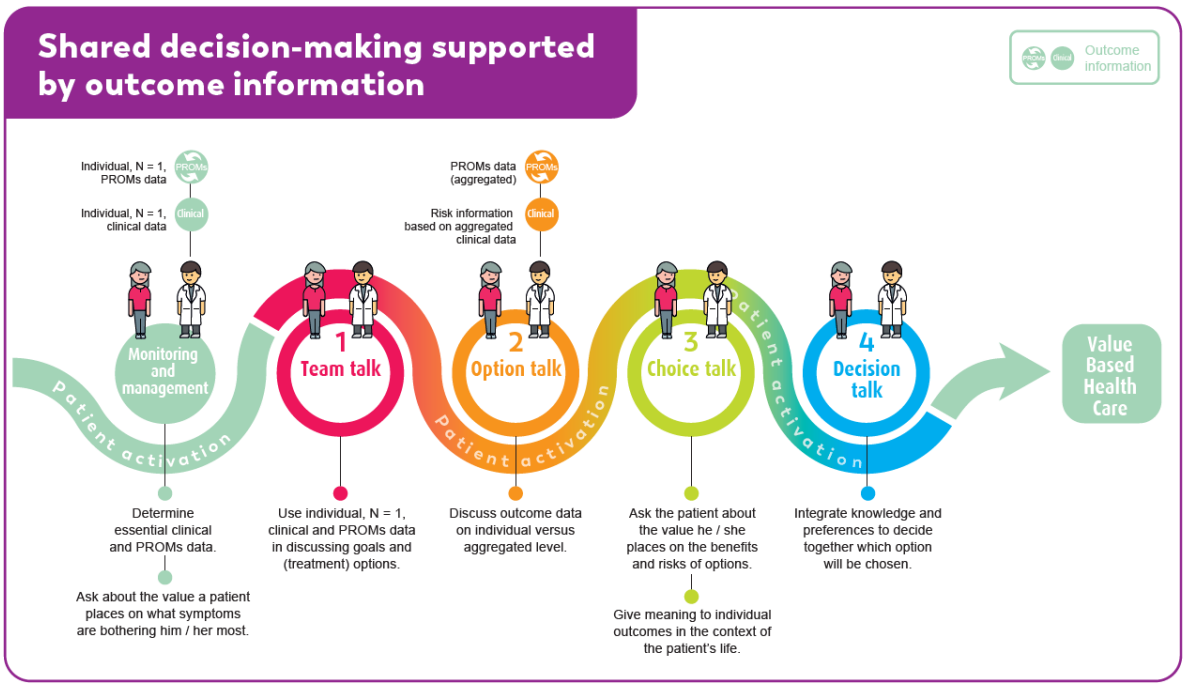
45 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11. https://doi.org/10.1016/j.jpsychores.2005.02.007.

46 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke* 2011;42(8):2276-9. https://doi.org/10.1161/STROKEAHA.111.613273.

47 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB. Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil* 2012;34(6): 478-85. https://doi.org/10.3109/09638288.2011.608148.

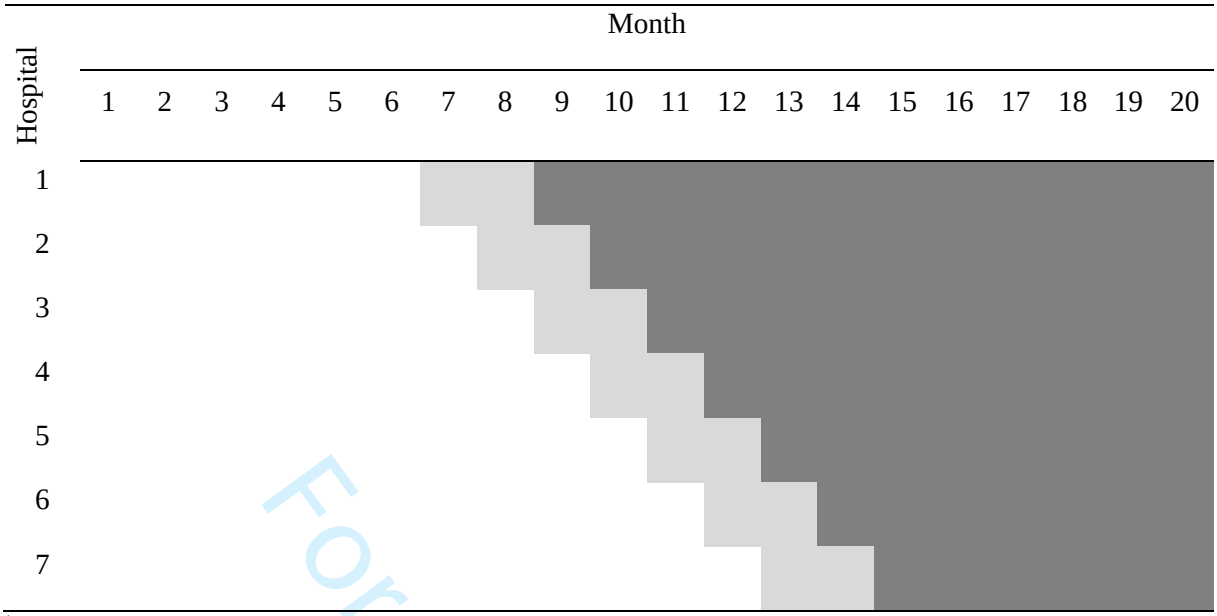
48 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8. https://doi.org/10.1093/geronj/38.3.344.

49 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.



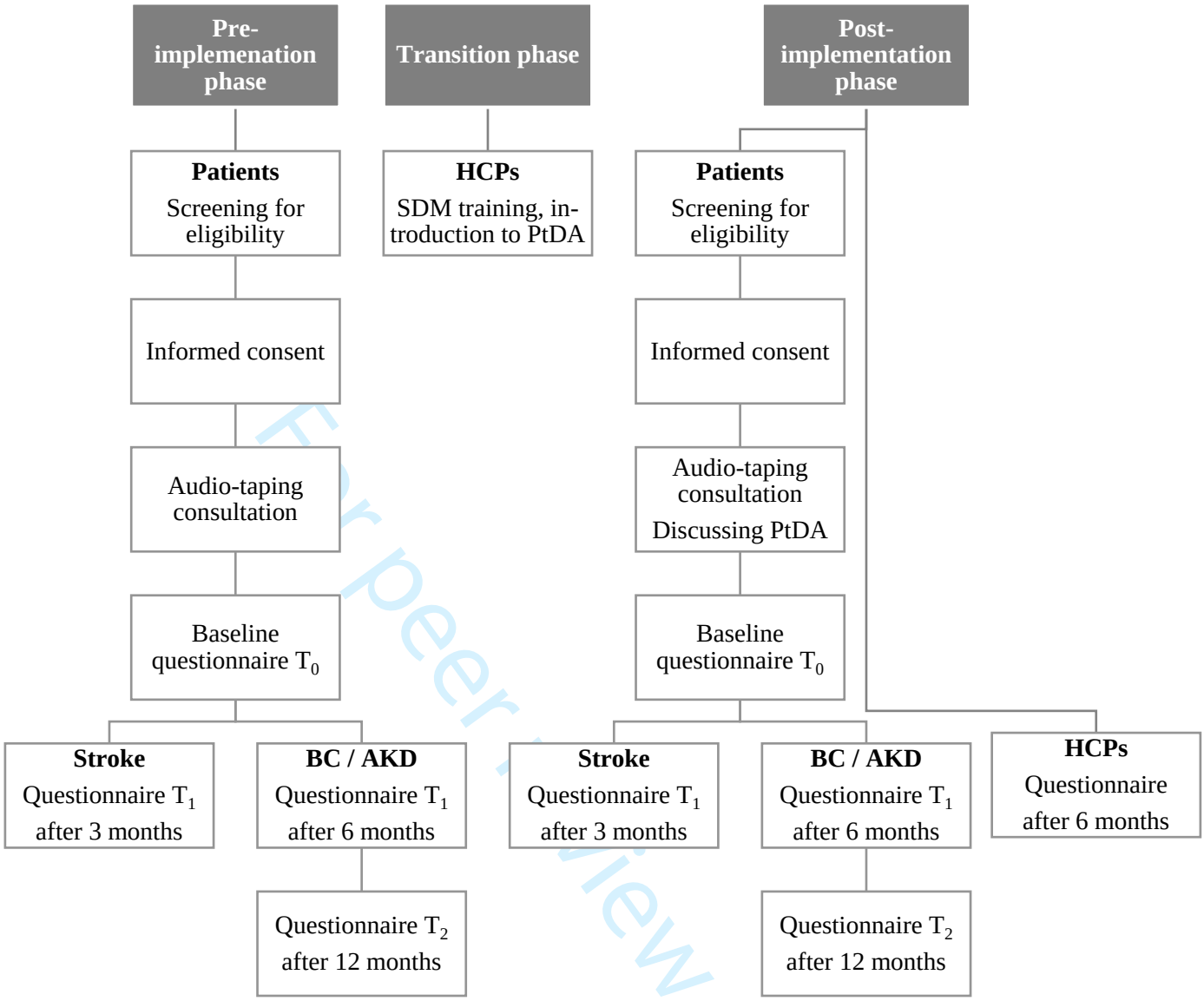
PROMs, patient-reported outcome measures.

Figure 1. How to use outcome data in the four-step conversational SDM model.



* White blocks: pre-implementation phase; light grey blocks: transition phase, dark grey blocks: post-implementation phase.

Figure 2. Time schedule of the multiple interrupted time series.*



HCPs, healthcare professionals; SDM, shared decision-making; PtDA, patient decision aid; BC, breast cancer; AKD, advanced kidney disease.

Figure 3. Participant timeline.

BMJ Open

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

APPENDIX A

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, 19
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3 – 4

	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 – 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6 – 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10 – 15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15 – 16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8, 14 – 15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8 – 9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8 – 9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16 – 17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17 – 18
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

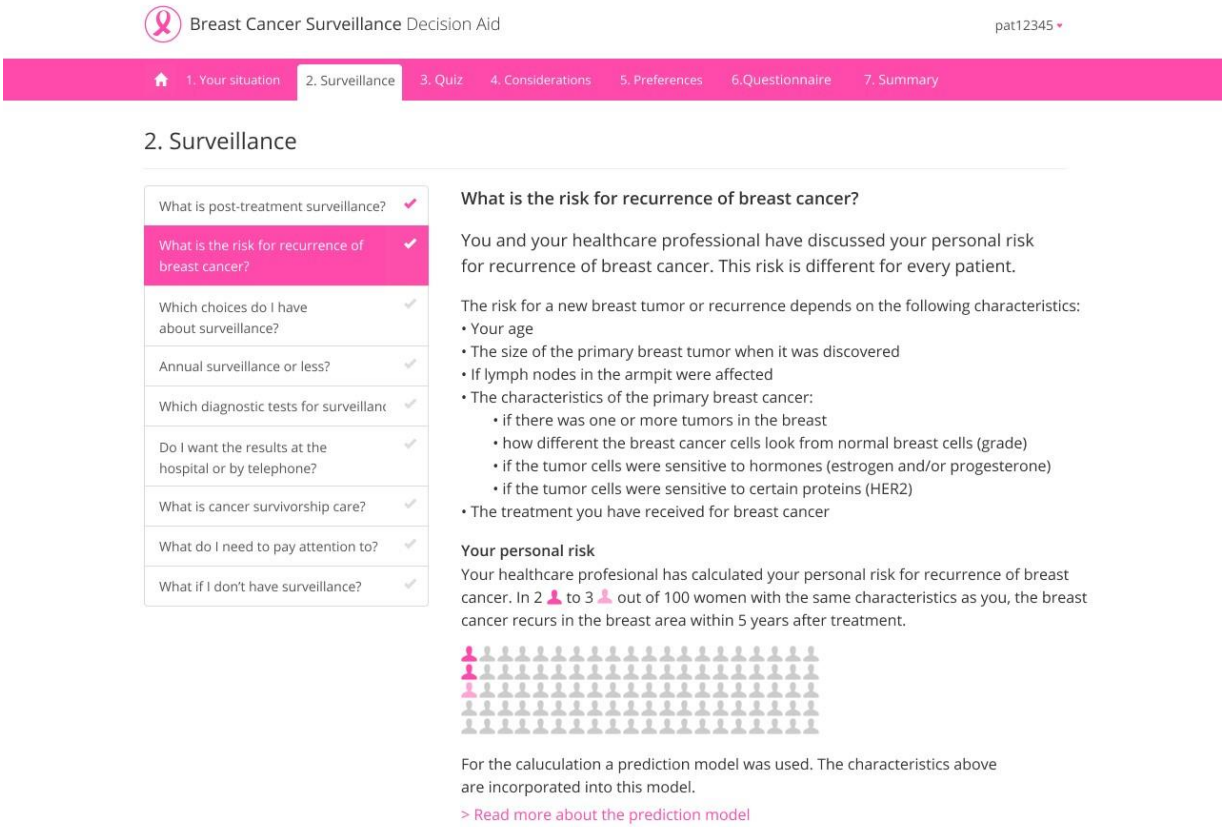
*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

APPENDIX B

Breast cancer patient decision aid

Component 1: consultation sheet

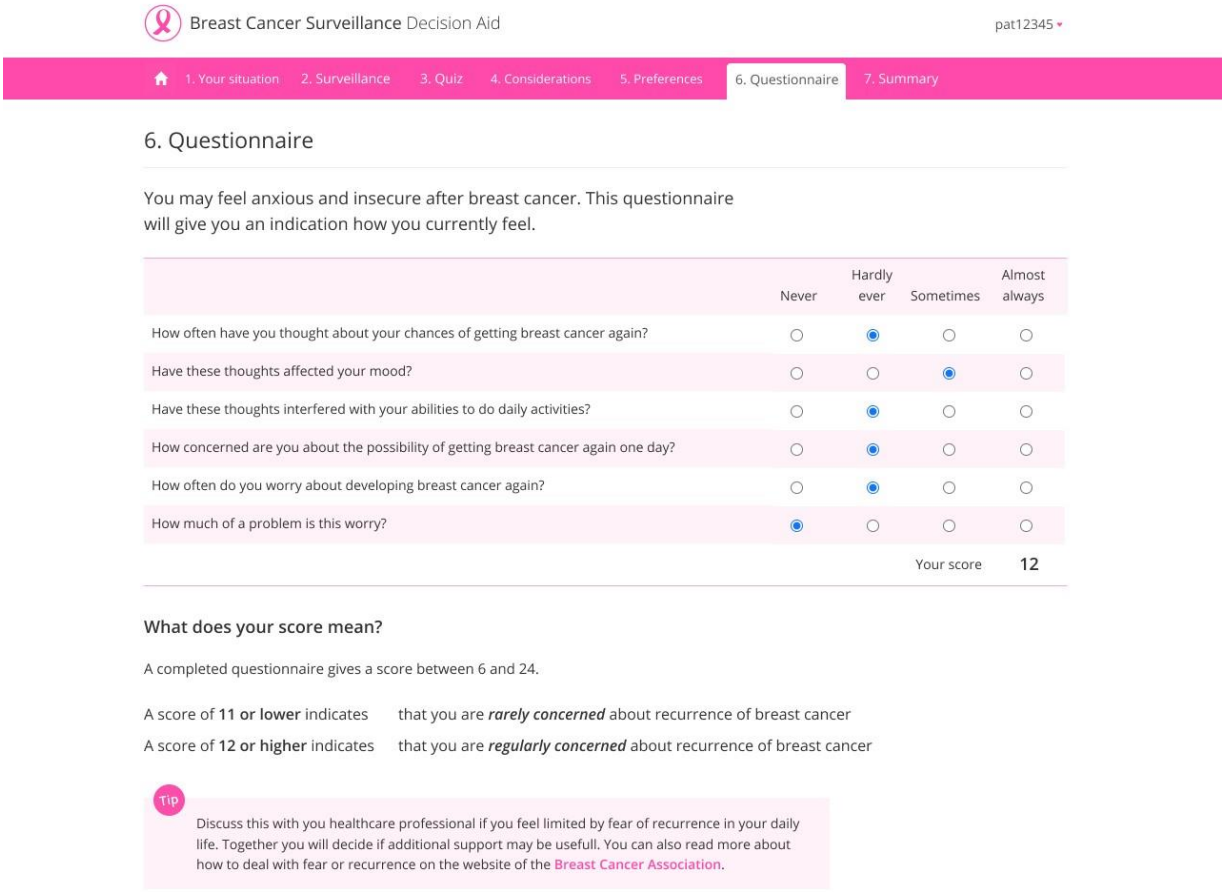
The consultation sheet (printed or digital) contains a visualization of a risk estimation of the personalized risk for breast cancer recurrence (local regional recurrences and secondary primary breast tumors), combined with a display of available options for post-treatment surveillance (e.g. frequency, imaging and duration). The personalized risk is estimated based on individual patient, tumor, and treatment characteristics, using the web-based INFLUENCE-nomogram. The nomogram was validated based on a large set of outcome data from the Netherlands Cancer Registry and shows a good predictive ability in the Dutch population.[12]



Component 2: online interactive PtDA

The online interactive PtDA contains information about SDM, post-treatment surveillance, available options and a clarification of the risk estimation. Interactive elements include a knowledge quiz, and value-clarification exercises. As part of using the PtDA, patients are asked to complete a patient-reported

outcome on fear of recurrence.[49] Data is processed in real-time and linked to tailored feedback on individual outcomes including comprehensive self-care advice (tips and tools).



Component 3: summary sheet

A summary sheet (printed or digital), to be used in the clinical consultation, containing women's preferences, personal considerations, and the individual outcomes on fear of recurrence.

Breast Cancer Surveillance Decision Aid pat12345

Your summary

This is the summary of your situation and preferences. Bring summary to your next consultation with your healthcare professional. Together you decide what surveillance options suit you best.

My situation

My personal risk	**2.3 %**
Surveillance for a maximum duration of	**5 years**
Options for diagnostic tests	**Mammography, physical examination**

My preferences about surveillance

How often?	**Every year**
How many years?	**5 years**
Which diagnostic tests?	**Mammography, physical examination**
Results at the hospital or by phone?	**Consultation at the hospital**
My remarks	**- Argument**
My role in decision making	**I prefer that my healthcare professional and I make the decision together**
My questions	**- Question**

My considerations

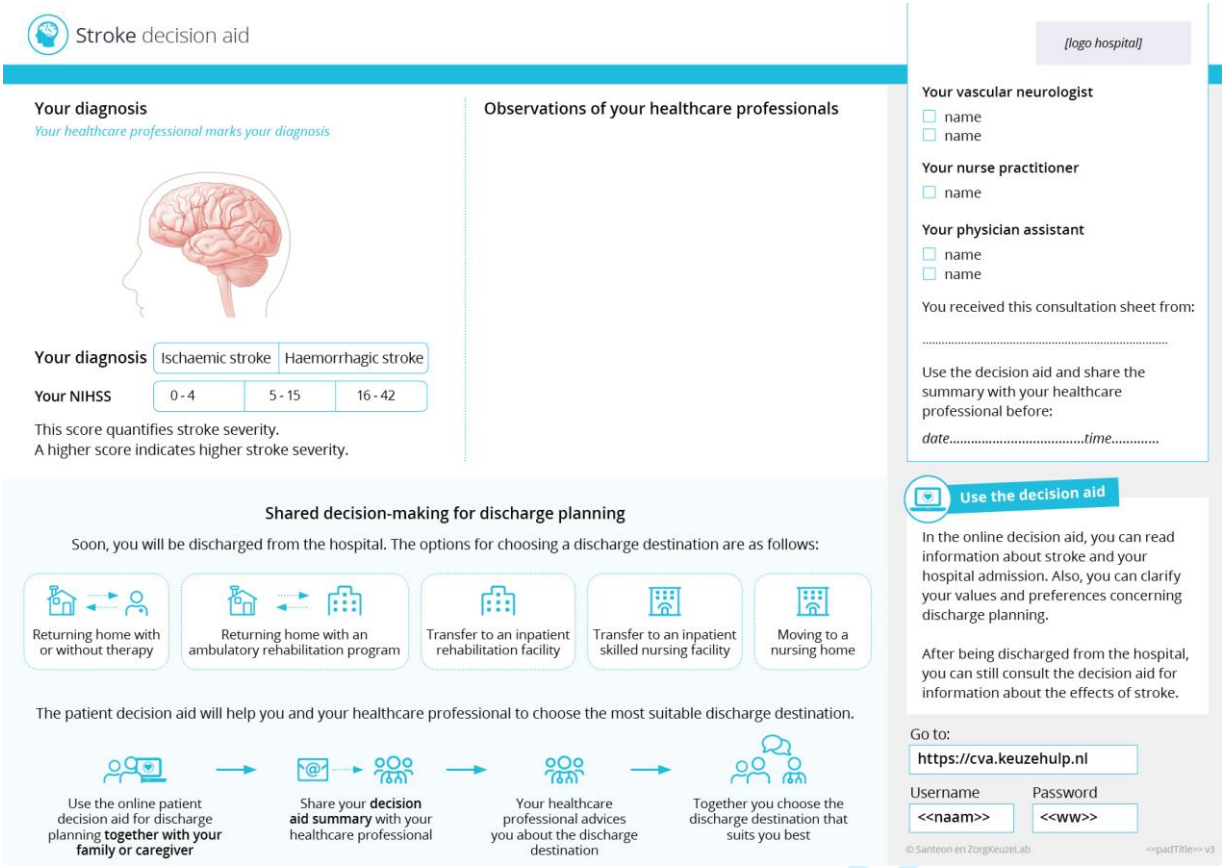
I don't mind going to the hospital for surveillance		I don't want to go to the hospital for surveillance
I want to go for surveillance, even though it makes me restless		I want as little surveillance as possible to avoid stress and unrest
Periodical surveillance makes me feel safe and reassured		I only want surveillance when I feel it is necessary
I want to have periodical surveillance, even if it takes time and effort		I prefer to spend as little time and effort as possible on surveillance
I want surveillance in the hospital, regardless of the costs		I don't want surveillance in the hospital, because of the costs
My loved ones thinks it is important that I have periodical surveillance		My loved ones understand if I don't have periodical surveillance
My score on the fear of recurrence questionnaire	12	

santeon ZorgKeuzeLab

Stroke patient decision aid

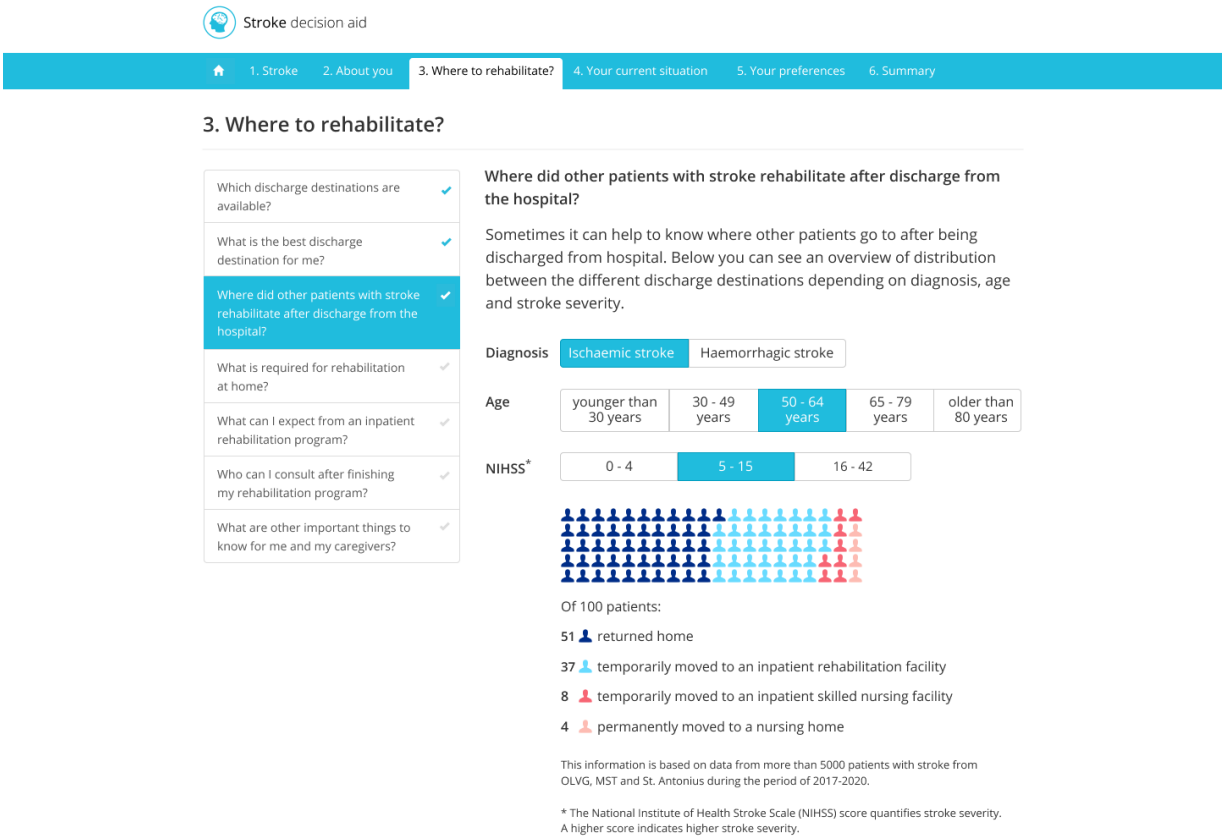
Component 1: consultation sheet

The consultation sheet contains basic information about the diagnosis (i.e. a visual representation of the brain to use as a topic starter on stroke and associated consequences), the type of stroke (i.e. ischemic or hemorrhagic), the individual stroke severity score as measured by the National Institutes of Health Stroke Scale (NIHSS), and options eligible for discharge locations.



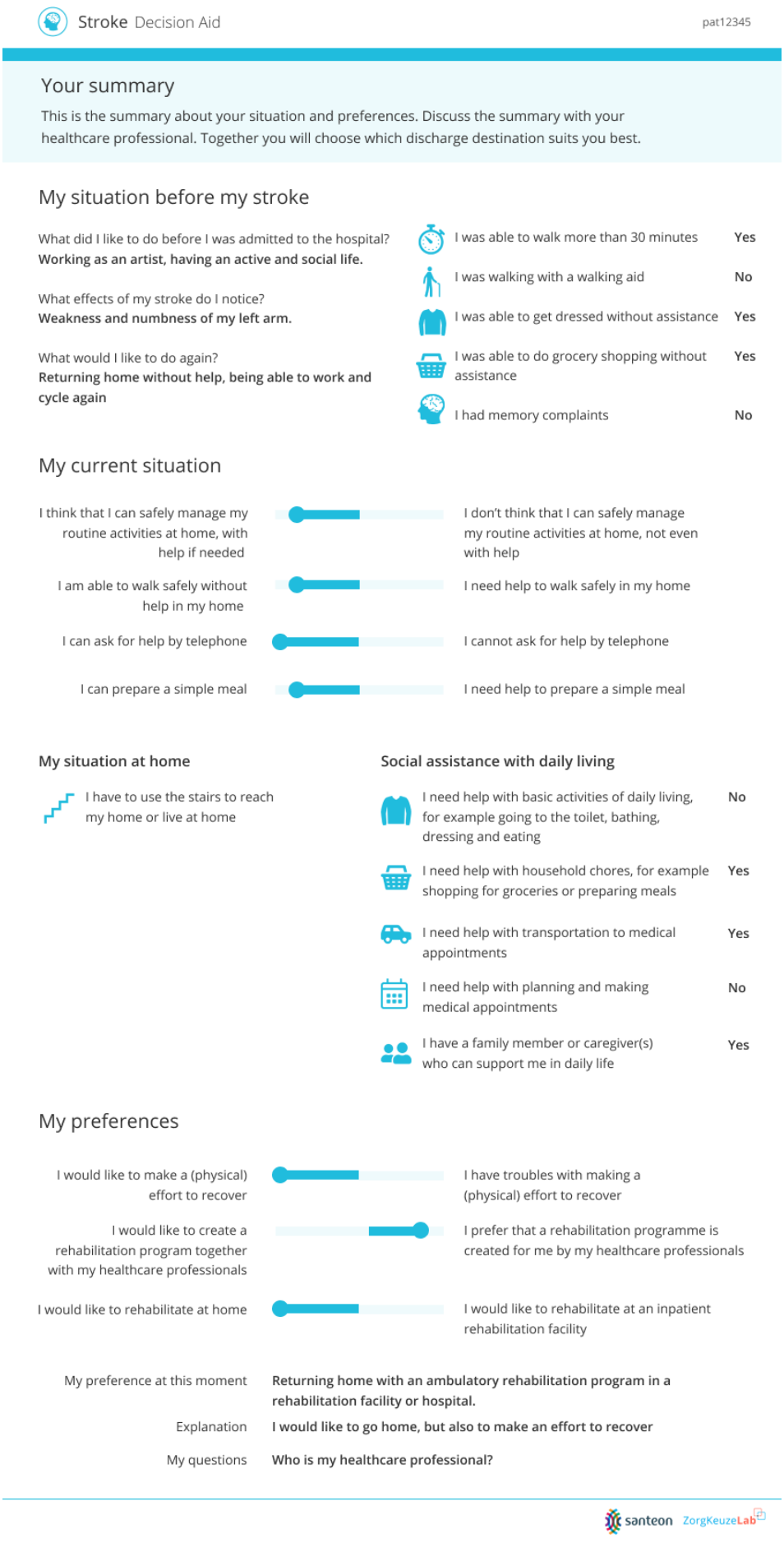
Component 2: online interactive PtDA

The online interactive PtDA contains information about the etiology and impact of stroke, prognosis and discharge planning. As part of the PtDA, patients are asked to complete PROM questionnaires on their physical and mental condition and to elaborate on their situation prior to admission to the hospital, as well as to indicate personal treatment goals. Also, the process of SDM is explained and value clarification exercises are included. The PtDA contains an interactive "patients-like-me" model: patients can enter their type of stroke, stroke severity and age in the model, which then shows the discharge location of comparable patients based on historical Santeon data (N > 4000).



Component 3: summary sheet

A digital summary sheet containing patients' values, preferences concerning discharge planning, and individual PROM scores to be used in the doctor-patient consultation.



Stroke Decision Aid

pat12345

Your summary

This is the summary about your situation and preferences. Discuss the summary with your healthcare professional. Together you will choose which discharge destination suits you best.

My situation before my stroke

What did I like to do before I was admitted to the hospital?
Working as an artist, having an active and social life.

What effects of my stroke do I notice?
Weakness and numbness of my left arm.

What would I like to do again?
Returning home without help, being able to work and cycle again

I was able to walk more than 30 minutes	**Yes**
I was walking with a walking aid	**No**
I was able to get dressed without assistance	**Yes**
I was able to do grocery shopping without assistance	**Yes**
I had memory complaints	**No**

My current situation

I think that I can safely manage my routine activities at home, with help if needed	I don't think that I can safely manage my routine activities at home, not even with help
I am able to walk safely without help in my home	I need help to walk safely in my home
I can ask for help by telephone	I cannot ask for help by telephone
I can prepare a simple meal	I need help to prepare a simple meal

My situation at home

I have to use the stairs to reach my home or live at home

Social assistance with daily living

I need help with basic activities of daily living, for example going to the toilet, bathing, dressing and eating	**No**
I need help with household chores, for example shopping for groceries or preparing meals	**Yes**
I need help with transportation to medical appointments	**Yes**
I need help with planning and making medical appointments	**No**
I have a family member or caregiver(s) who can support me in daily life	**Yes**

My preferences

I would like to make a (physical) effort to recover	I have troubles with making a (physical) effort to recover
I would like to create a rehabilitation program together with my healthcare professionals	I prefer that a rehabilitation programme is created for me by my healthcare professionals
I would like to rehabilitate at home	I would like to rehabilitate at an inpatient rehabilitation facility

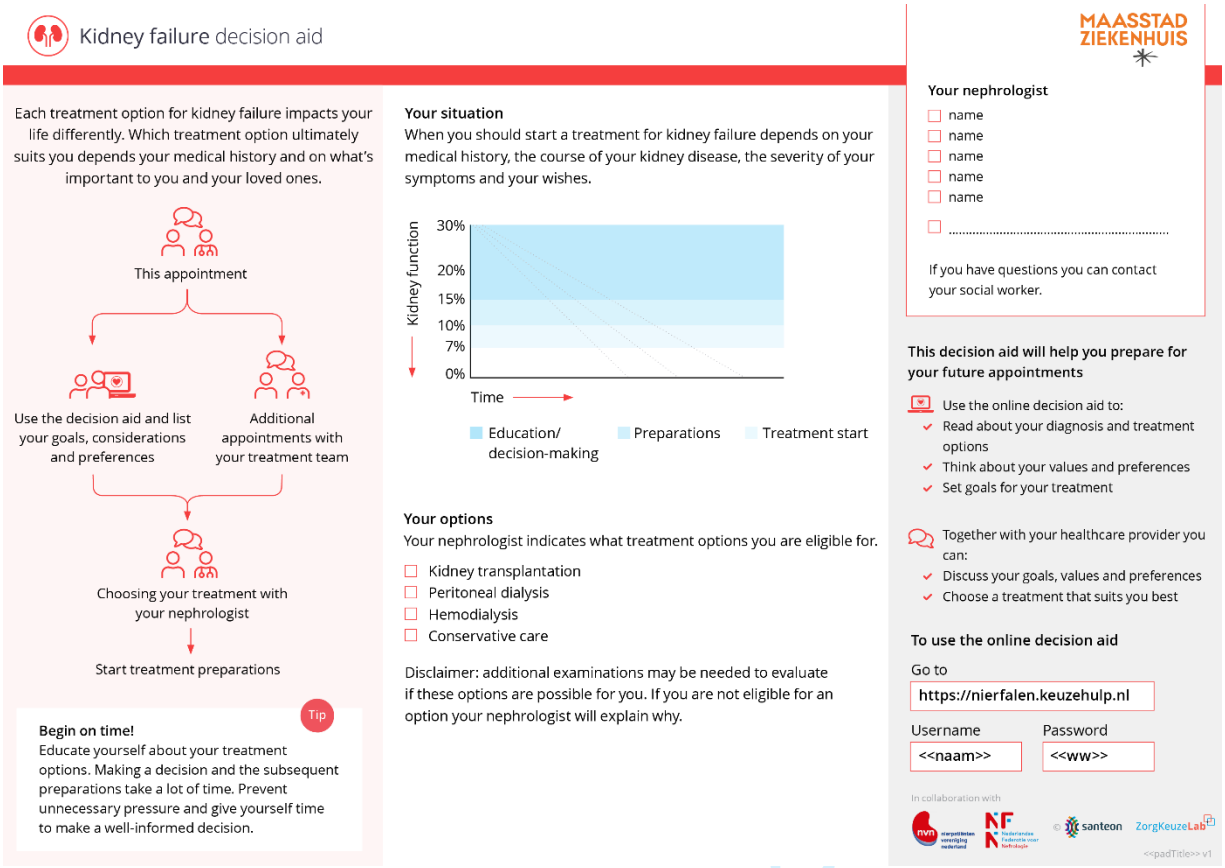
My preference at this moment	**Returning home with an ambulatory rehabilitation program in a rehabilitation facility or hospital.**
Explanation	**I would like to go home, but also to make an effort to recover**
My questions	**Who is my healthcare professional?**

santeon ZorgKeuzeLab

Advanced kidney disease patient decision aid

Component 1: consultation sheet

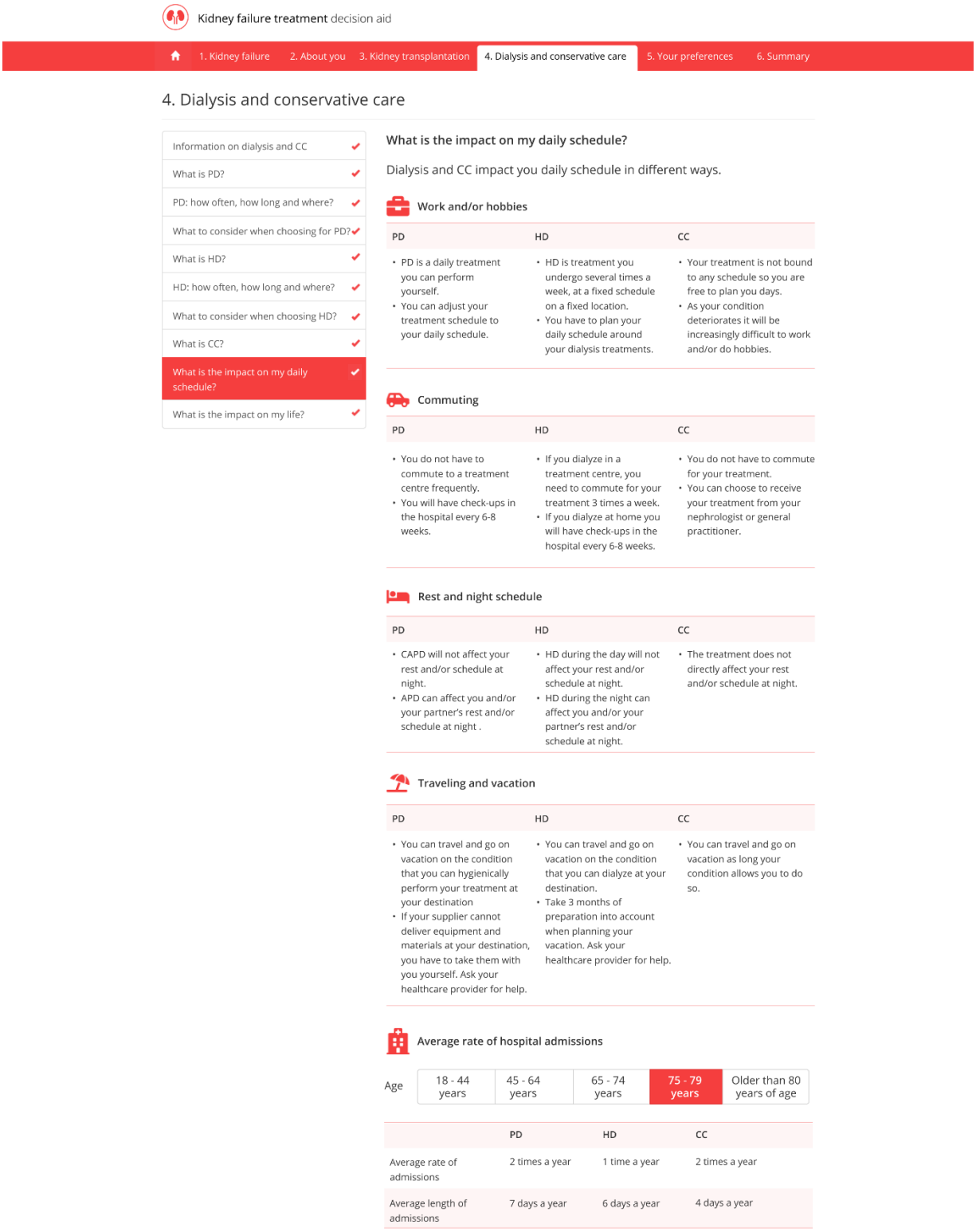
The consultation sheet (printed or digital) contains a flowchart of the kidney failure care path, a graph that healthcare professionals can use to draw the patient's individual eGFR decline, and a table that healthcare professionals can use to mark eligible treatment modalities.



Component 2: online interactive PtDA

The online interactive PtDA contains information on SDM, kidney failure and treatment modalities (hemodialysis, peritoneal dialysis, kidney-transplantation and comprehensive conservative care). Written information is supplemented with videos of patients' experiences. As part of the PtDA, patients are asked to complete PROMs questionnaires on their physical condition and on whether they consider life as completed. Additionally, patients are asked to complete value-clarification exercises regarding kidney transplantation (when applicable), dialysis and conservative care management. The PtDA contains an interactive "patients-like-me" model: patients can enter their age in the model, which then

shows the median survival- and mean hospitalization rates per treatment modality based on both Santeon and national data.



Component 3: summary sheet

A printed or digital summary sheet to be used in a clinical consultation, containing patients' values, preferences concerning discharge planning, and individual PROM scores.

Kidney Failure treatment Decision Aid pat12345

Your summary

This is the summary of your situation and preferences. You can use this summary at your next appointment to help you and your doctor make a treatment decision that suits you best.

About me

What do I enjoy doing in my daily life?
I enjoy working at my garage with my two sons and nephew. I would give anything to keep working for a couple of more years so one of them can mature and take over my responsibilities.

Who plays an important role in making this decision?
My wife and I are real team players. She's my personal consultant.

Can you continuously walk for 30 minutes or more? **Yes**

Can you dress yourself? **Yes**

Do you do groceries by yourself? **No**

What symptoms are currently bothering you the most?
The nausea and breathlessness.

Tell us what you think

There are things I still want to do with my life — I feel fulfilled with my life

I want a treatment that primarily focuses on extending my life — I want a treatment that primarily focuses on my quality of my life

Kidney transplantation

Do you have moral objections to receiving a kidney from a living donor?
No

Did you talk about living donation kidney transplantation with anyone you know?
I talked about it with my wife, but I don't want to put this burden on my kids.

Has anyone offered to donate you a kidney?
[Not yet]

Do you have any questions or comments about kidney donation?
Am I also eligible for a kidney from a deceased donor?

Dialysis at home or in a hospital?

At home — In a hospital

I don't mind doing dialysis at home — I don't want to feel like a patient at home

I don't want to be in the hospital on a weekly basis — I don't mind being in the hospital on a weekly basis

I want to be flexible and plan my dialysis according to schedule — I don't mind being in the hospital according to a fixed schedule

I feel confident that I can perform dialysis on my own at home — I would rather have a healthcare professionals help me with my dialysis

Comments: **I would prefer doing PD treatment at home**

Dialysis during the day or night?

During the day — During the night

I want to sleep without having to deal with my dialysis — I accept that the quality of my sleep may worsen due to my dialysis

I can free time during the day to make time for my dialysis — I want to remain flexible during the day

Comments: **I would prefer doing my PD at night so I can freely manage my garage during the day!**

My preference

My preference at this moment: **Kidney transplantation from a deceased donor or APD**

What goals do I want to achieve with this treatment? **Extending my life while remaining flexible. I want to spend my golden years with my wife after making my sons owners of my garage. They still have a lot to learn though!**

What do I absolutely not want? **CC**

My questions **no additional questions**

santeon ZorgKeuzeLab

BMJ Open

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055324.R1
Article Type:	Protocol
Date Submitted by the Author:	30-Mar-2022
Complete List of Authors:	Hackert, Mariska; Santeon Ankersmid, Jet; Santeon; University of Twente, Health Technology and Services Research Engels, Noel; Santeon ; Maasstad Hospital, Internal Medicine Prick, Janine; Santeon; OLVG, Neurology Teerenstra, Steven; Radboudumc, Health Evidence, Biostatistics Siesling, Sabine; Netherlands Comprehensive Cancer Organization , Research & Development; University of Twente, Health Technology and Services Research Drossaert, Stans ; University of Twente, Psychology, Health & Technology Strobbe, Luc; Canisius Wilhelmina Hospital, Surgical Oncology Van Riet, Yvonne; Catharina Hospital, Surgical Oncology van den Dorpel, Marinus; Maasstad Hospital, Internal Medicine Bos, Willem Jan; Sint Antonius Hospital, Internal Medicine; Leiden University Medical Center, Internal Medicine van der Nat , Paul; Sint Antonius Hospital, Value-Based Healthcare; Radboudumc IQ healthcare, Radboud Institute for Health Sciences Van den Berg-Vos, RM; OLVG, Neurology; Amsterdam UMC Locatie AMC, Neurology van Schaik, Sander; OLVG, Neurology Garvelink, Mirjam; Sint Antonius Hospital, Value-Based Healthcare Van der Wees, Philip; Radboudumc IQ healthcare, Radboud Institute for Health Sciences, Rehabilitation Van Uden-Kraan, Cornelia; Santeon
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research
Keywords:	Stroke < NEUROLOGY, Chronic renal failure < NEPHROLOGY, Breast surgery < SURGERY, MEDICAL EDUCATION & TRAINING

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Mariska QN Hackert[#1], Jet W Ankersmid[*1,2], Noel Engels[*1,3], Janine CM Prick[*1,4], Steven Teerenstra[5], Sabine Siesling[2,6], Constance HC Drossaert[7], Luc JA Strobbe[8], Yvonne EA van Riet[9], René MA van den Dorpel[3], Willem Jan W Bos[10,11], Paul B van der Nat[12,13], Renske M van den Berg-Vos[4,14], Sander M van Schaik[4], Mirjam M Garvelink[12], Philip J van der Wees[13,15], Cornelia F van Uden-Kraan[1]

On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group

[*]*Contributed equally*

[#]*Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the Netherlands. E-mail: m.hackert@santeon.nl*

1. Santeon hospital group, Utrecht, The Netherlands
2. Department of Health Technology and Services Research, Technical Medical Center, University of Twente, Enschede, The Netherlands
3. Department of Internal Medicine, Maasstad Hospital, Rotterdam, The Netherlands
4. Department of Neurology, OLVG, Amsterdam, The Netherlands
5. Radboud Institute for Health Sciences, Department for Health Evidence, section Biostatistics, Radboud University Medical Center, Nijmegen, The Netherlands
6. Department of Research and Development, Netherlands Comprehensive Cancer Organization, Utrecht, The Netherlands
7. Department of Psychology, Health and Technology, University of Twente, Enschede, The Netherlands
8. Department of Surgical Oncology, Canisius Wilhelmina Hospital, Nijmegen, The Netherlands
9. Department of Surgical Oncology, Catharina Hospital, Eindhoven, The Netherlands
10. Department of Internal Medicine, St. Antonius Hospital, Nieuwegein, The Netherlands
11. Department of Internal Medicine, Leiden University Medical Center, Leiden, The Netherlands
12. Department of Value-Based Health Care, St. Antonius Hospital, Nieuwegein, The Netherlands
13. Radboud Institute for Health Sciences, Scientific Centre for Quality of Healthcare (IQ Healthcare), Radboud University Medical Center, Nijmegen, The Netherlands
14. Amsterdam UMC, location AMC, Department of Neurology, Amsterdam, the Netherlands
15. Radboud Institute for Health Sciences, Department of Rehabilitation, Radboud University Medical Center, Nijmegen, The Netherlands

Word count 4412

Date 28-03-2022, **Version** 2.0

ABSTRACT

Introduction Within the value-based health care framework, outcome data can be used to inform patients about (treatment) options, and empower them to make shared decisions with their health care professional. To facilitate shared decision-making (SDM) supported by outcome data, a multicomponent intervention has been designed, including patient decision aids on the organization of post-treatment surveillance (breast cancer); discharge location (stroke) and treatment modality (advanced kidney disease), and training on SDM for health care professionals. The SHared decision-making supported by OUTcome information (SHOUT) study will examine the effectiveness of the intervention and its implementation in clinical practice.

Methods and analysis Multiple interrupted time series will be used to stepwise implement the intervention. Patients diagnosed with either breast cancer (N = 630), stroke (N = 630) or advanced kidney disease (N = 473) will be included. Measurements will be performed at baseline, 3 (stroke), 6 and 12 (breast cancer and advanced kidney disease) months. Trends on outcomes will be measured over a period of 20 months. The primary outcome will be patients' perceived level of involvement in decision-making. Secondary outcomes regarding effectiveness will include patient-reported SDM, decisional conflict, role in decision-making, knowledge, quality of life, preferred and chosen care, satisfaction with the intervention, health care utilization and health outcomes. Outcomes regarding implementation will include the implementation rate and a questionnaire on the health care professionals' perspective on the implementation process.

Ethics and dissemination The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act does not apply to this study. Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study. The results will contribute to insight in and knowledge on the use of outcome data for SDM, and can stimulate sustainable implementation of SDM.

Registration Netherlands Trial Register NL8374, NL8375 and NL8376, registration date: February 12th 2020.

Keywords Value-based health care; personalized outcome data; clinical outcome data; patient-reported outcomes; patient decision aid; shared decision-making; breast cancer; stroke; advanced kidney disease

Strengths and limitations of this study

- All hospitals will implement and therefore benefit from the multicomponent intervention, facilitating shared decision-making supported by personalized outcome data.
- Multiple components are needed for the intervention to be effective; however, it does not allow for an individual evaluation of each component.
- By using stepwise implementation and the value-based health care organization structure, the hospitals can learn from each other.
- It allows the multicomponent intervention to be further refined and tested over time.
- It is unclear whether the effect size aimed to achieve, constitutes a clinically meaningful difference.

INTRODUCTION

Value-based health care (VBHC) is gaining momentum worldwide.[1, 2] The VBHC framework strives to maximize value for patients by achieving the best outcomes while controlling costs.[3] Per patient group, clinical and patient-reported outcomes, costs and process data are measured and compared in a structured, standardized manner. These data are used to identify variation across the care cycle to collectively enhance the value of health care provision on patient group level.[2] Besides the use of outcome data on group level, outcome data can also be used on the individual patient level, by integrating outcomes and value in patient communication. However, in clinical practice, the role of outcome data in patient communication is not common practice. On individual patient level, most importantly, outcome data can provide insight into benefits and harms of treatment options. Integrating outcome data in discussing treatment options between health care professionals and patients, is where VBHC and shared decision-making (SDM) entangle.[4, 5]

SDM is the process in which patients and health care professionals make well-informed, collaborative choices by combining the best available evidence and patients' values and preferences.[6, 7] So far, SDM has shown to lead to well-informed, preference-based patient decisions, and to improve patients' relationship with their health care professional.[6, 8, 9] Using outcome data can further strengthen the motivation of health care professionals to apply SDM and empower patients to make shared decisions with their health care professional. In this way, outcome data can accelerate the implementation of SDM and strengthen VBHC.[4, 5, 10, 11]

To support SDM, outcome data should be presented to patients in a meaningful way. The four-step conversational SDM model can be used for this purpose ([6]; inspired by [7]). In each step, outcome data, both on patient individual and group level (aggregated), can be incorporated (see Figure 1, based on [6, 9]).

<<INSERT Figure 1>>

The individual outcome data can be used to introduce a care decision and to determine available options for the patient *(step 1)*. Related benefits and harms of these options are explained in *step 2*. As these may differ between patients depending on clinical and personal characteristics, it is highly encouraged to display personalized outcomes ("patients-like-me data"),[10] or to use prediction models in which these

characteristics can be entered to display personal estimated risks and to support personalized aftercare paths.[12] Next (*step 3*), the health care professional and the patient discuss the patient's preferences. This process of value clarification can be fostered by being informed on outcome data of previous patients. In *step 4*, the health care professional and the patient together integrate outcome data and preferences to make a shared decision.

Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower this threshold, we developed a multicomponent intervention for three patient groups with an oncological (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as training for health care professionals and an accompanying implementation strategy. So far, little is known about the impact of using outcome data for SDM.[10, 11]

The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight in and knowledge on the use of personalized outcome data for SDM, and can stimulate sustainable implementation of SDM in clinical practice.

METHODS AND ANALYSIS

We use multiple interrupted time series (mITS) [13] to compare the intervention with standard care. We follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see Appendix A).[14, 15] mITS will allow for initial testing and refinement of the intervention. In participating hospitals, trends on outcomes will be evaluated through a continuous sequence of observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2). Trends in the pre-implementation phase will be 'interrupted' at planned timepoints by the stepwise implementation of the intervention in each hospital. Direct effects (level change) will be examined, as well as gradual changes over time (slope change).

<<INSERT Figure 2>>

Study setting

Seven independent large Dutch teaching hospitals, which together form the Santeon hospital group, will participate in this study. The hospitals are geographically spread across the Netherlands and account for about 11% of the Dutch hospital care volume. By using VBHC principles, comparing outcome data, collaborating in multidisciplinary improvement teams, and by focusing on SDM supported by personalized outcome data as part of the Experiment Outcome Indicators, Santeon continuously aims to improve quality of care on patient group level.[16, 17] The next step is to use the collected, real-world outcome data to better inform individual patients and health care professionals. Up to now, aggregated outcome data have been gathered in international studies using homogenous samples and population averages. Real-world outcomes in larger, heterogenous groups of patients provide complementary evidence.[18]

Study population

Patients diagnosed with either breast cancer, stroke or AKD, treated in Santeon hospitals, will be asked to participate in this study. These patient groups are sufficiently large and diverse to cover a relatively broad spectrum of hospital health care. In addition, both breast cancer and stroke are in the top-20 list of largest medical conditions in terms of national disease burden.[19]

Inclusion criteria

All participants must be aged 18 years or older, and able to understand the Dutch language in speech and writing. Inclusion criteria will be:

1) patients facing the decision for the organization of post-treatment surveillance after curative treatment for invasive non-metastasized breast cancer;
2) hospitalized patients with a (ischemic or hemorrhagic) stroke that have to decide on their discharge location and type of care after discharge from the hospital;
3) patients with AKD (i.e. CDK-KDIGO G4-$G5_{A1-3}$) that have to make a treatment modality decision (hemodialysis, peritoneal dialysis, kidney-transplantation or comprehensive conservative care).

Exclusion criteria

Patients with severe cognitive impairment or physical inability to complete a questionnaire will be excluded. Exclusion criteria per patient group are displayed in Table 1.

Table 1. Exclusion criteria per patient group.

Breast cancer	Stoke	Advanced kidney disease
• Male patients • Predisposing genetic mutations related to breast cancer • Non-invasive breast cancer • History of neoadjuvant systemic therapy or treatment for a recurrence or second primary tumor • Palliative treatment	• Reduced consciousness	• On kidney replacement therapy or conservative care management

Intervention

A multicomponent intervention was developed including PtDAs and a training for health care professionals. Because the implementation of SDM is not only a matter of introducing PtDAs, nor that it is achieved by providing personalized outcome data, we designed an implementation strategy focusing on awareness, willingness and behavior of both health care professionals and patients.

Interactive patient decision aids containing personalized outcome data

A PtDA was developed for each patient group in an iterative process of five co-creation sessions with a multidisciplinary team consisting of patients, patient representatives and health care professionals. A literature review and needs assessment studies among patients and health care professionals served as input.[20] Development was guided by the International Patient Decision Aid Standards (IPDAS) Collaboration framework,[21] and in line with the Dutch guidelines for developing PtDAs.[22] Content was critically revised by the teams in an iterative process and rewritten to B1 language level (Common European Framework of Reference for Languages, CEFR). Usability testing consisted of going through the PtDA, combined with think-aloud sessions with patients, an online survey (stroke) and/or interviews

by telephone (breast cancer, stroke, and advanced kidney disease) among health care professionals. Detailed results of the developmental process of the PtDAs will be published.

Each PtDA is composed of three components which contain personalized (patient-reported and clinical) outcome data, both on individual as well as aggregated level. Personalized data is entered into the PtDA by both health care professionals and patients. From the transition phase onwards (Figure 2), the health care professional will introduce the PtDA to patients by means of a paper or digital consultation sheet *(component 1)*. Health care professionals provide personalized clinical data (e.g., for patients with stroke: type of stroke, NIHSS score) when introducing the PtDA. Next, patients will receive a personal login code to access the online interactive PtDA at home or during hospital admission *(component 2)*. Each PtDA contains evidence-based information about the options and pros and cons. Information is tailored to relevant options for the patient and presented without favoring any particular outcome. Patients enter patient-reported data, by means of PROMs, into the PtDA during use (e.g., for patients with advanced kidney disease: physical condition, treatment goals). The PtDAs actively encourage patients to weigh their options. Once patients have completed the PtDA, a summary sheet will automatically be created, containing an overview of patient-reported personalized data and patient's preferences and considerations, which can be used as a base for final decision-making in a consultation with their health care professional *(component 3)*.

Breast cancer patient decision aid

The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving curative treatment for invasive non-metastasized breast cancer. The PtDA includes patients' personal risks for locoregional recurrences estimated using the INFLUENCE-nomogram [12], a validated prediction model with which the five-year risk for locoregional recurrences can be estimated, and a patient-reported outcome measure (PROM) questionnaire on fear of cancer recurrence (sections of the PtDAs were translated for publication; see Appendix B).

Stroke patient decision aid

The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The PtDA includes an interactive "patients-like-me" model on the discharge location of comparable patients

based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-being (see Appendix B).

Advanced kidney disease patient decision aid

The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive "patients-like-me" model on median survival- and mean hospitalization rates per treatment modality based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see Appendix B).

Training of health care professionals

Health care professionals will be asked to complete an e-learning on applying (personalized) outcome data to support SDM. Consequently, they will be asked to participate in a group training of one daypart. The e-learning is focused on providing theoretical background and practical tips and tricks on applying outcome information in the four steps of SDM in clinical consultations (including text, videos and self-assessment tests). Completion of the e-learning takes approximately one hour. The group training includes theoretical background information on SDM, reflection on audio-taped consultations (provided by participating health care professionals as part of the data collection for the study), cases introduced by participants, and practicing SDM conversational skills with an actor. By offering the e-learning before the group training sessions, we reduce the time spent on theoretical background in the training, leaving more time to practice on SDM conversational skills. Upon completion of the group training, follow-up will be offered after one day (by offering a plasticized card or poster containing short written instructions on SDM, and by presenting a publication on using outcome data to support SDM), after one month (by offering tips, tricks, a testimonial by a colleague health care professional and an instruction clip on SDM) and after two months (by offering the possibility to receive individualized feedback by sending an audio-taped consultation to the trainer).

Implementation strategy for the multicomponent intervention

The implementation strategy is based on prior successful implementation strategies for PtDAs [23] and a web-based self-management application using PROMs to monitor quality of life and focuses on awareness, willingness and behavior of both health care professionals and patients.[24] Core elements are listed in Table 2.

Table 2. Implementation strategy.

1. *Inform and create support for using the PtDA* by deciding on the key moment for introducing a PtDA for these three patient groups, developing the PtDA by means of a participatory design approach, including both health care professionals and patient advocates, and by customizing the PtDA for each individual hospital (i.e. by applying the individual hospital logo).
2. *Document the current care path* in each hospital to find the best way to incorporate the PtDA. Involving both the timing of the PtDA and the health care professionals who will present it.
3. *Remove organizational barriers* that represent obstacles to the process of implementing the PtDA, such as reorganizations, or the simultaneous implementation of different innovations, by asking hospitals when it is most convenient for them to proceed with the implementation.
4. *Informing and involving all (health care) professionals* in the care path by means of an information meeting, and by offering the possibility to make use of an e-learning for these professionals also on applying outcome data in SDM.
5. *Instruction on how to introduce the PtDA* to eligible patients by means of a kick-off meeting organized in the hospitals shortly before the start of the implementation of the PtDA.
6. *Offering support in the workplace*, i.e. by providing plasticized cards containing short written instructions in line with the SDM four-step conversation model, and by stimulating implementation e.g. by distributing promotional posters and informative video's for patients on SDM with personalized outcome data. Support and technical assistance for both health care professionals and patients will be centralized and available through a helpdesk.
7. *Closely monitoring of progress and stimulating implementation* by local ambassador and informed by a dashboard containing usage data of the PtDA.
8. *Offering the training and the PtDA free of charge* during the study period.

Study design and procedures

The intervention will be stepwise implemented in the hospitals over a period of 20 months (see Figure 2). In each hospital, there will be 6 to 12 months in which standard care will be thoroughly assessed (pre-implementation phase), followed by a transition phase of 2 months in which health care professionals will be trained and the PtDA will be introduced. Finally, there will be 6 to 12 months in which the intervention will be assessed (post-implementation phase). Data collection is ongoing. The moment by which hospitals switch from standard care to use of the intervention will not be randomized. To promote that PtDAs will become successfully implemented into routine clinical settings, we will ask involved health care professionals when it will be most convenient for them to proceed with implementation.

Internal validity will be increased, as each hospital will act as its own historical control group and the hospitals will not switch at the same time.

Patients will be asked by their health care professional to participate in this study: 1) patients with breast cancer will be informed and asked to participate during the follow-up consultation on the occasion of their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision has to be made about renal replacement therapy or conservative care. When interested, patients will receive a patient information letter about the study. They will be asked for written informed consent. In the post-implementation phase, patients that decline participation in the SHOUT-study will still be offered the SDM supported by outcome information as the standard form of care.

Data collection and methods

To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T0) will be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T1) for patients with stroke, and after 6 (T1) and 12 (T2) months for patients with breast cancer or AKD. The time it takes to complete the questionnaires differs per measurement moment. The T0 questionnaire takes about 30 to 45 minutes to complete and the T1 and T2 questionnaires take 15 to 20 minutes. The timing of follow-up questionnaires differs between the three conditions due to the course and nature of and the care pathways for the three conditions. Furthermore, some outcome measures are disease-specific and will therefore only be assessed in the patient groups for which they are suitable.

Second, the consultations, in which the options are being discussed, will be audio-taped to assess patients' involvement in the decision-making process from observers' viewpoint. Also, the length of the consultations will be determined. Third, to assess the extent to which the intervention leads to changes in the utilization and outcomes of health care, information will be retrieved from patients' electronic health records.

To evaluate the implementation, first, the estimated total number of eligible patients and the total number of patients who received the PtDA will be determined. Second, participating health care professionals

will receive a questionnaire 6 months after start of the post implementation phase, to assess their perspective on the implementation process.

Participant timeline

The participant timeline is displayed in Figure 3.

<<INSERT Figure 3>>

Outcomes

Effectiveness

Primary outcome measure

The primary outcome to assess effectiveness will be patients' perceived level of involvement in decision-making, measured with the 9-item SDM Questionnaire (SDM-Q-9). [25, 26] Each item describes a different step in the SDM process and will be scored by patients on a 6-point Likert scale. The sum of the item scores will range from 0 – 45, with higher scores indicating a greater level of perceived involvement in SDM.

Secondary outcome measures

Secondary outcomes will be: 1) patient-reported SDM, measured with the CollaboRATE; 2) decisional conflict, measured with the Decisional Conflict Scale (DCS); 3) decision regret for patients with stroke and AKD, measured with the Decision Regret Scale (DRS); 4) preferred and perceived role in decision-making, measured with the Control Preference Scale (CPS); 5) patients' knowledge regarding their disease and treatment options, measured with patient group-specific items; 6) quality of life, measured with the 12-item Short Form Health Survey (SF-12) for patients with breast cancer and AKD, and measured with the Patient Reported Outcomes Measurement Information System Global Health (PROMIS-10), five-dimension EuroQol five-levels questionnaire (EQ-5D-5L), and EuroQol Visual Analogue Scale (EQ-VAS) for patients with stroke; 7) preferred and chosen care (and the role of the consultation and outcome data therein), measured with patient group-specific items; 8) satisfaction with the intervention, measured with the Preparation for Decision Making scale (Prep-DM) and study-specific

questions; 9) perceived risk and fear of recurrence for patients with breast cancer, measured with the Cancer Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast cancer survivors (IPQ-BCS) and patient group-specific questions; and 10) participation / functioning and caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see Table 3, also for references).

Observer-reported SDM

We will combine the SDM-measurement tools, with a more objective score of SDM, as this score may differ from the patients' subjective interpretation [27]. The Observing Patient Involvement in decision-making scale (OPTION-5) [28] will be used to analyze the audio-recordings of encounters from clinical settings. All audio-recordings will be double coded by two raters who have been trained on rating the OPTION-5. In case of disagreement, a third rater will be consulted. The OPTION-5 includes five core SDM steps, to which a sixth is added to assess the role of personalized outcome data *('the health care professional informs the patient on outcomes of different treatment options')*. The item scores will be summed and rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

Health care utilization and outcomes

Patients' health care utilization and clinical outcomes will be extracted from their electronic health records. For patients with breast cancer, the number of hospital visits, the number of mammograms and other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications during admission will be extracted. For patients with AKD, the number of visits to outpatient clinics, hospital admissions and hospitalization days, and the rate of major treatment-related complications will be extracted.

Table 3. Overview of the patient-reported outcomes and instruments used per timepoint.

Measure	Description	Scoring range	Pre-implementation phase			Post-implementation phase		
			Baseline	T1	T2	Baseline	T1	T2
All patient groups:								
Shared decision-making								
• SDM-Q-9 [25, 26] (primary outcome measure)	9-item, 6-point scale measures patients' perceived level of involvement in decision-making.	Range 0 – 45, higher scores indicate a greater level of perceived involvement in decision-making.	X			X		
• CollaboRATE [29]	3-item, 10-point scale measures patient-reported SDM.	Range 0 – 100, higher scores indicate a higher patient-reported SDM.	X			X		
Decisional conflict								
• DCS [30]	16-item, 5-point scale measures personal perceptions of a) uncertainty in choosing options, b) modifiable factors contributing to uncertainty and c) effective decision-making.	Range 0 – 100, higher scores indicate greater decisional conflict.	X			X		
Decision regret								
Stoke and advanced kidney disease: • DRS [31]	5-item, 5-point scale measures distress or remorse after a health care decision.	Range 0 – 100, higher scores indicate greater regret.		X	X		X	X
(Preferred) role in decision-making								
• CPS [32]	1-item with 5 response options to assess the patient's preferred or perceived degree of control when decisions about treatment are being made.		X			X		
Patients' knowledge regarding their disease and treatment options (patient group-specific items)								
Breast cancer:	10 items with 3 response options.		X			X		
Stroke:	7 items with 3 – 7 response options.		X			X		
Advanced kidney disease:	7 items with 3 – 5 response options.		X			X		
Quality of life								
Breast cancer and advanced kidney disease: • SF-12 [33, 34]	12-items with 2 – 6 response options on quality of life.	Mental and physical component score based on the US population scoring system, higher scores indicate greater quality of life.	X	X	X	X	X	X
Stroke:								
• PROMIS Global-10 [35]	10 items with 5 – 11 response options on quality of life.	Physical and mental health summary scores based on the US population scoring system, higher scores indicate greater quality of life.		X			X	
• EQ-5D-5L [36, 37]	5 items, 5-point scale measures patients' health-related quality of life.	Range -0.446 – 1 based on the Dutch population tariff, higher scores indicate greater health-related quality of life.		X			X	
• EQ-VAS [36]				X			X	

	Visual analogue scale measures patients' health-related quality of life.	Range 0 – 100, higher scores indicate greater health-related quality of life.						
Preferred and chosen care (and the role of the consultation and outcome data therein) (patient group-specific items)								
Breast cancer:	48 items with 3 – 10 response options / open-ended.		X			X		
Stroke:	6 items with 3 – 8 response options / open-ended.		X			X		
Advanced kidney disease	9 items with 2 – 9 response options / open-ended.		X			X		
Satisfaction with the intervention								
• Prep-DM [38]	10-item, 5-point scale measures patients' perception of how useful the PtDA is in preparing them to communicate with their health care professional during consultations, and for making a health care decision.	Range 0 – 100, higher scores indicate higher perceived level of preparation for decision-making.				X		
• Study-specific items	24 items with 2 – 8 response options / open-ended to assess a) the way in which the PtDA has been presented to the patient, b) the experience of the patient with using the PtDA, and c) the extent to which the PtDA is of value to the patient.					X		
Breast cancer:								
Perceived risk and fear of recurrence								
• CWS [39]	6-item, 4-point scale measures concerns about cancer recurrence and the impact of these concerns on daily functioning.	Range 6 – 24, higher scores indicate greater worrying.	X	X	X	X	X	X
• IPQ-BCS (cure and personal control subscale) [40]	2x 4-item, 5-point scale measures a) patients' cure beliefs and b) personal control over the risk for recurrences.		X	X	X	X	X	X
• Patient group-specific items based on CRHWS [41], FCR7 [42] and FoP-Q [43]	9 items with 4 – 6 response options to assess patients' feelings about imaging during follow-up and worry about cancer recurrence, and to assess patients' perceived (absolute and comparative) risk of recurrence.		X	X	X	X	X	X
Stroke:								
Participation / functioning								
• Simplified mRS [44]	5-item, 2-point scale measures the degree of dependence of patients with stroke.	Range 0 – 5, higher scores indicate greater dependence.		X			X	
• USER-P restriction subscale [45]	11-item, 5-point scale measures experienced restrictions on 11 domains of participation.			X			X	
Caregivers' strain								
• CSI [46]	13-item, 2-point scale measures strain related to care provision.	Range 0 – 13, ≥ 7 indicates a higher level of strain.		X			X	

9-item Shared Decision Making Questionnaire, SDM-Q-9; Decisional Conflict Scale, DCS; Decision Regret Scale, DRS; Control Preference Scale, CPS; 12-item Short Form Health Survey , SF-12; Patient Reported Outcomes Measurement Information System, PROMIS; five-dimension EuroQol five-levels questionnaire, EQ-5D-5L; Preparation for Decision Making scale, Prep-DM; Cancer Worry Scale, CWS; modified version of the Revised Illness Perception Questionnaire for breast cancer survivors, IPQ-BCS; cancer-related health worries scale, CRHWS; seven-item Fears of Cancer Recurrence, FCR7; Fear of Progression Questionnaire, FoP-Q; modified Ranking Scale, mRS; USER-P, Utrecht Scale for Evaluation of Rehabilitation-Participation; CSI, Caregiver Strain Index.

Moderators

Socio-demographic characteristics

In the baseline questionnaire, patients' sex, birth year, marital status, occupation, and education level will be asked.

Clinical characteristics

Relevant medical characteristics will be extracted from the baseline questionnaire and the electronic health records. For patients with breast cancer, tumor and treatment characteristics will be extracted. For patients with stroke, etiology of stroke, and whether or not the patient has been treated with reperfusion therapy will be extracted. For patients with AKD, renal function, etiology and duration of kidney failure, whether these patients have had other treatment modalities for kidney failure in the past, comorbidity and definite treatment modality will be extracted.

Health literacy

Patients' health literacy will be assessed in the baseline questionnaire by the Set of Brief Screening Questions (SBSQ).[47] The mean score on the three items will be calculated, with higher scores reflecting higher health literacy skills.

Implementation

Implementation rate

The implementation rate will be calculated as the proportion of patients who received the PtDA compared to the estimated total number of eligible patients during the period of 6 to 12 months in which the PtDA will be handed out.

Health care professionals' view on the implementation process and use of the patient decision aid

Determinants of implementing an innovation

Health care professionals will fill out a questionnaire based on the Measurement Instrument for Determinants of Innovations (MIDI).[48] The MIDI assesses barriers and facilitators of implementation at the level of innovation (PtDA), the user (health care professionals) and the organization (hospital).

Physicians' willingness to incorporate shared decision-making

Health care professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[49]

Sample size

The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary outcome measure with the statistical significance level set at alpha = 0.05 (two-sided). Since there is no agreement on what constitutes a clinically meaningful difference on the SDM-Q-9, we estimated the size of the expected effect on previous studies using the SDM-Q-9. The size of the expected effect of the intervention on the SDM-Q-9 was set to be small to moderate (Cohen's d = 0.3-0.4) as relatively high scores on the SDM-Q-9 are common in the Netherlands.[50] The mITS with seven clusters (i.e. hospitals) had 18 measurement periods (excluding the transition phase, see Figure 2). For patients with breast cancer and stroke, a non-large Intraclass Correlation Coefficient (ICC = 0.05) was assumed. The correlation between monthly measurements was expected to be high (0.7 – 0.9) throughout a period of 18 months, although correlations between months farther apart could be lower than for months closer by. A correlation structure where the correlation decreases exponentially with the distance between months (autoregressive correlation structure) turned out too conservative and a correlation structure where the correlation between months is the same regardless of the distance between them (compound symmetry correlation structure) was too optimistic and not realistic for this purpose. Therefore, power calculations were primarily based on assuming that the correlation between months decreases from 0.9, for subsequent months, to 0.7, for months that are the farthest apart (i.e. the first and last month). To be precise, the correlation decreases linearly on the log scale from log(0.9) to log(0.7) (linear exponent autoregressive correlation structure).[51] Five patients per hospital per month was considered feasible, and with a 25% loss to follow-up, this results in a monthly inclusion rate of four patients. This yields more than 80% power and amounts to a study population of N = 504 – 630.

For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals. Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting

a Cohen's d = 0.4 assuming a correlation between subsequent months of at least 0.8 and a correlation between the first and last month of at least 0.6. This amounts to a study population of N = 378 – 473.

Statistical methods

An overview of the demographic and clinical characteristics will be provided using descriptive statistics. Continuous data will be expressed as a mean with the standard deviation (SD), or as the median (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless stated otherwise.

Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented regression will be employed, with the period before and after the introduction of the intervention as segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time series to exhibit different levels and trends. Correlation between repeated measurements in each time series will be accounted for by modelling the error structure. The effect of the intervention will be examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using the following model:

$$Y(T) = \beta 0 + \beta 1 \cdot T + \beta 2 \cdot I + \beta 3 \cdot I \cdot t$$

where $\beta 0$ will represent the baseline level at $T = 0$, $\beta 1$ will be interpreted as the change in outcomes associated with a time unit increase (representing the underlying trend in the pre-implementation phase), $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, $\beta 2$ will be the level change in the post-implementation phase and $\beta 3$ will indicate the slope change following the implementation phase (using the interaction between time t since the intervention started and the indicator for being in the intervention: I). A change in $\beta 2$ will constitute an immediate effect, while a change in $\beta 3$ will imply an effect that was experienced over time (which also allows us to measure the sustainability of the impact). Moreover, segmented regression will enable us to control for other variables, that can cause a change in level or trend of the outcomes of interest.

Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation techniques or sensitivity analyses will be used to assess their impact on the trial results.

To correct for multiple testing and the risk of type-1 errors a Bonferroni-Holm procedure will be applied across the set of primary and secondary endpoints.

To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis across all patient groups and hospitals will be performed. Finally, implementation across all patient groups will be investigated by using several the same outcome measures at a similar points in time.

Patient and public involvement

Santeon supports that patients with 'lived experiences' become members of a research team. Since the very beginning (composing the grant application), we have engaged a core group of patients and patient representatives of the patient associations involved. We designed the multicomponent intervention in collaboration with patients and health care professionals (see the Methods and Analysis). In addition, patient representatives were involved in the development of the study. Our collaboration with the patient associations will continue throughout the study. Study findings about the potential benefits of the multicomponent intervention will be disseminated by means of our project website.

ETHICS AND DISSEMINATION

The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference numbers METC 2019-075, -076 and -077).

The study will be conducted in accordance with local laws and regulations. Eligible patients will fully be informed about the study and asked to participate. They will receive a patient information letter and will be informed by telephone about the implications of participation. Patients will have sufficient opportunity to ask questions and to consider the implications before providing written informed consent. They will be allowed to withdraw from the study without giving a reason, at any time.

The SHOUT study is part of a larger Santeon program on using outcome data for SDM ('Experiment Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and

patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals, (inter)national conferences, workshops webinars, and newsletters and social media.

ACKNOWLEDGEMENTS

We thank all patients, patient representatives and health care professionals for their contribution to designing the multi-component intervention and execution the SHOUT study. The SHOUT study is part of a larger program on using outcome data for SDM ('Experiment Uitkomstindicatoren Santeon'), which is part of the Outcome-based Health care program initiated by the Dutch Ministry of Health, Welfare and Sports. We would like to thank ZonMw for funding this project.

FOOTNOTES

Availability of data and materials

Data will be collected and recorded in CASTOR EDC, a cloud-based electronic data capture platform. This platform is fully compliant with GCP, 21 CFR part 11, GDPR, HIPAA, ISO27001 and ISO 9001. All data will be coded and password protected. Study participants will be assigned a participant identification number (PIN). A digital, password protected identifying list relating medical information of participants to their PIN numbers will be kept on a secured server in the Santeon hospitals. All data and study documents will deleted and discarded after 15 years. The datasets used and / or analyzed during the SHOUT study are available from JWA (breast cancer), NE (AKD) and JCMP (stroke) on reasonable request. The (intellectual) property rights with regard to the generated data will reside at Santeon, Utrecht, The Netherlands. Interested parties can request a non-exclusive license for research and educational purposes. The non-exclusive license may be requested only after the completion of the theses to be written reserving the generated data.

Competing interests

None declared.

Funding

This research project is funded by ZonMw as part of the 'Experiment Uitkomstindicatoren Santeon'. This funding had no involvement in collection, management, analysis, and interpretation of the data; writing this manuscript or the decision to submit the article for publication.

Authors' contributions

JWA, NE, JCMP, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, SMvS, and CFvU-K developed the multicomponent intervention. MQNH, ST, PBvdN, PJvdW and CFvU-K contributed to the design of the study. JWA, NE, JCMP are conducting this study in fulfillment of a PhD and will be responsible for data collection. JWA, NE, JCMP and ST will be responsible for data analysis. All authors will be responsible for interpretating the data. The present manuscript was drafted by MQNH and CFvU-K. JWA, NE, JCMP, ST, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, PBvdN, RMvdB-V, SMvS, MMG and PJvdW critically revised this manuscript. All authors have read and approved the final manuscript.

ABBREVIATIONS

AKD, advanced kidney disease

mITS, multiple interrupted time series

PROM, patient-reported outcome measure

PtDA, patient decision aid

SDM, shared decision-making

VBHC, value-based health care

REFERENCES

1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health outcomes measurement and organizational readiness support quality improvement: a systematic review. BMC Health *Serv Res* 2018;18:1005. https://doi.org/10.1186/s12913-018-3828-9.

2 Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med* 2016;374:504-6. https://doi.org/10.1056/NEJMp1511701.

3 Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477-81. https://doi.org/10.1056/NEJMp1011024.

4 Steinmann G, van de Bovenkamp H, de Bont A, Delnoij D. Redefining value: a discourse analysis on value-based health care. *BMC Health Ser Res* 2020;20:862. https://doi.org/10.1186/s12913-020-05614-7.

5 Van der Nat PB. The new strategic agenda for value transformation. *Health Serv Manage Res* 2021;0(0):1-5. https://doi.org/10.1177/09514848211011739.

6 Stiggelbout AM, Pieterse AH, de Haes JCJM. Shared decision making: concepts, evidence and practice. *Patient Educ Couns* 2015;98(10):1172-9. https://doi.org/10.1016/j.pec.2015.06.022.

7 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-7. https://doi.org/10.1007/s11606-012-2077-6.

8 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Sys Rev* 2017;4:CD001431. https://doi.org/10.1002/14651858.CD001431.pub5.

9 Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci* 2016;11:114. https://doi.org/10.1186/s13012-016-0480-9.

10 Damman OC, Jani A, de Jong BA, et al. The use of PROMs and shared decision-making in medical encounters with patients: an opportunity to deliver value-based health care to patients. *J Eval Clin Pract* 2020;26:524-40. https://doi.org/10.1111/jep.13321.

11 La Grouw Y, Kee K, Ybema S, Taverne H, Boonen L. *Samen Beslissen in de praktijk: praktijkonderzoek i.o.v. het Zorginstituut Nederland.* Equalis / VU, 2019. https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen-beslissen-in-de-praktijk

12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36. https://doi.org/10.1007/s10549-015-3490-4.

13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community intervention research. *Prev Sci* 2000;1:31-49. https://doi.org/10.1023/A:1010024016308.

14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013a;158:200-7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583.

15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013b;346:e7586. https://doi.org/10.1136/bmj.e7586.

16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director: Gregory Katz). 2020.

17 Santeon. www.santeon.nl 2021; 22 June.

18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. https://doi.org/10.1200/JCO.19.02035.

19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's).* 2018. https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys.

20 Ankersmid JW, Drossaert CHC, van Riet YEA, et al. Needs and preferences of breast cancer survivors regarding outcome-based shared decision-making about personalised post-treatment surveillance. J Cancer Surviv 2022; https://doi.org/10.1007/s11764-022-01178-z.

21 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710. https://doi.org/10.1177/0272989X13501721.

22 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een keuzehulp bij een richtlijn?* Den Haag, The Netherlands, 2018.

23 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J* 2020;26(2):1194-207. https://doi.org/10.1177/1460458219873528.

24 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a web-based self-management application "Oncokompas" in routine cancer care: a national pilot study. *Support Care Cancer* 2019;27:2911-20. https://doi.org/10.1007/s00520-018-4591-5.

25 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care. *PloS ONE* 2015;10(7):e0132158. https://doi.org/10.1371/journal.pone.0132158.

26 Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010 Jul;80(1):94-9. doi: 10.1016/j.pec.2009.09.034.

27 Ubbink DT, van Asbeck EV, Aarts JWM, et al. Comparison of the CollaboRATE and SDM-Q-9 questionnaires to appreciate the patient-reported level of shared decision-making. Patient Educ Couns, available online 10 March 2022 https://doi.org/10.1016/j.pec.2022.03.007

28 Elwyn G, Grande SW, Barr P. *Observer OPTION^5 manual. Measuring shared decision making by assessing recordings or transcripts of encounters from clinical settings.* The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, USA, 2018.

29 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93(1):102-7. http://doi.org/10.1016/j.pec.2013.05.009.

30 O'Connor AM. *User Manual – Decisional Conflict Scale.* OHRI. 1993 (modified 2010);1:1-16.

31 O'Connor AM. *User Manual – Decision Regret Scale.* Ottawa, Ottawa Hospital Research Institute; 1996 (modified 2003).

32 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-43.

33 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33. https://doi.org/10.1097/00005650-199603000-00003.

34 Ware JE, Kosinski MA, Keller SD. SF-12: *How to score the SF-12 Physical and Mental Health Summary Scales*. The Health Institute, New England Medical Center, Boston Massachusetts, 1995.

35 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res* 2009;18:873-80. https://doi.org/10.1007/s11136-009-9496-9.

36 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. https://doi.org/10.1007/s11136-011-9903-x.

37 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52. https://doi.org/10.1016/j.jval.2016.01.003.

38 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale.* Ottawa, Ottawa Hospital Research Institute, 1995 (modified 2010).

39 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.

40 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58. https://doi.org/10.1080/08870446.2016.1275629.

41 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol* 2006;15(4):306-20. https://doi.org/10.1002/pon.955.

42 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out* 2018;16:30. https://doi.org/10.1186/s12955-018-0850-x.

43 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11. https://doi.org/10.1016/j.jpsychores.2005.02.007.

44 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke* 2011;42(8):2276-9. https://doi.org/10.1161/STROKEAHA.111.613273.

45 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB. Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil* 2012;34(6): 478-85. https://doi.org/10.3109/09638288.2011.608148.

46 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8. https://doi.org/10.1093/geronj/38.3.344.

47 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6. https://doi.org/10.1007/s11606-008-0520-5.

48 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10. https://doi.org/10.1093/intqhc/mzu060.

49 Berkowitz J, Martinez-Camblor P, Stevens G, Elwyn G. The development of incorpoRATE: a measure of physicians' willingness to incorporate shared decision making into practice. *Patient Educ Couns* 2021; Feb 25:S0738-3991(21)00140-3. https://doi.org/10.1016/j.pec.2021.02.040.

50 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke besluitvorming.* Utrecht: Nivel, 2021.

51 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of correlation structures. *Stat Med* 2010;29(17):1825-38. https://doi.org/10.1002/sim.3928.

Figure legend

- **Figure 1:** How to use outcome data in the four-step conversational SDM model. *PROMs = patient-reported outcome measures.*

- **Figure 2:** Time schedule of the multiple interrupted time series. *White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.*
- **Figure 3:** Participant timeline. *HCPs; healthcare professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.*

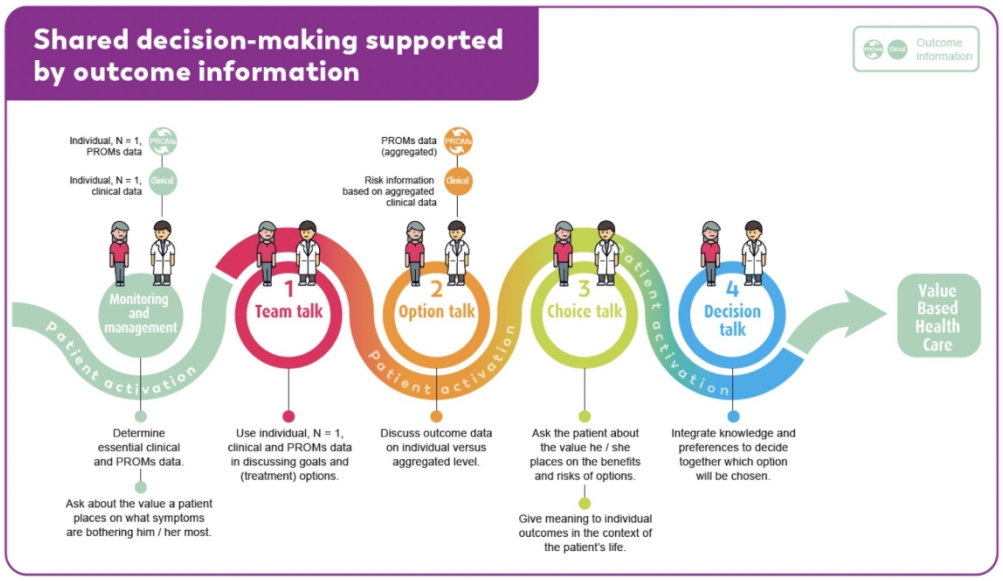


Figure 1: How to use outcome data in the four-step conversational SDM model. / PROMs = patient-reported outcome measures.

361x207mm (300 x 300 DPI)

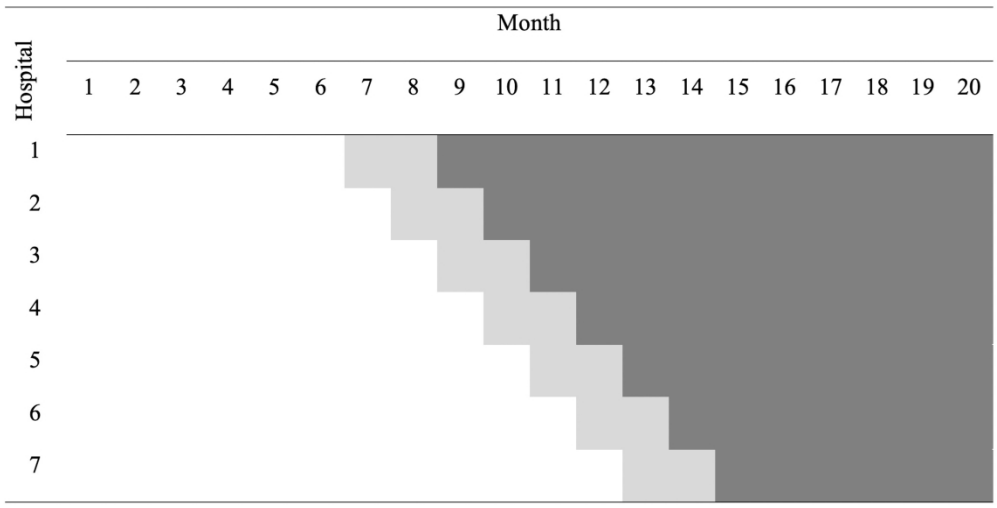


Figure 2: Time schedule of the multiple interrupted time series. / White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.

373x187mm (300 x 300 DPI)

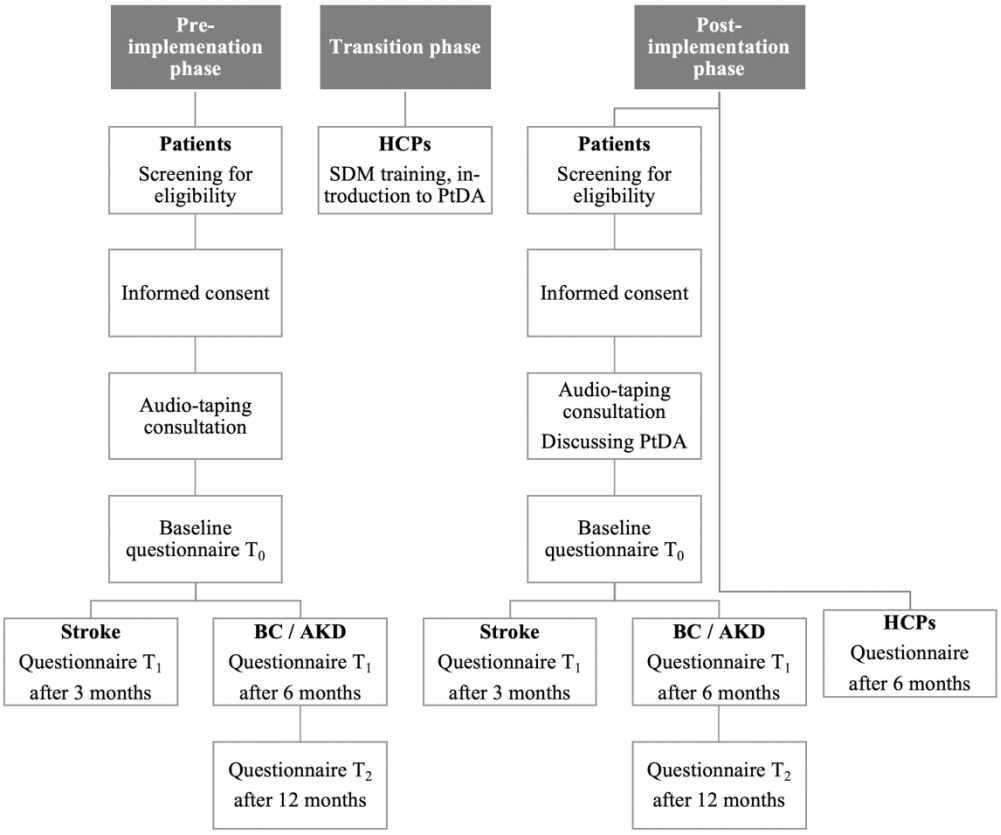


Figure 3: Participant timeline. / HCPs; healthcare professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.

423x352mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

APPENDIX A

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, 19
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3 – 4

	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 – 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6 – 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10 – 15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15 – 16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8, 14 – 15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8 – 9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8 – 9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16 – 17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17 – 18
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

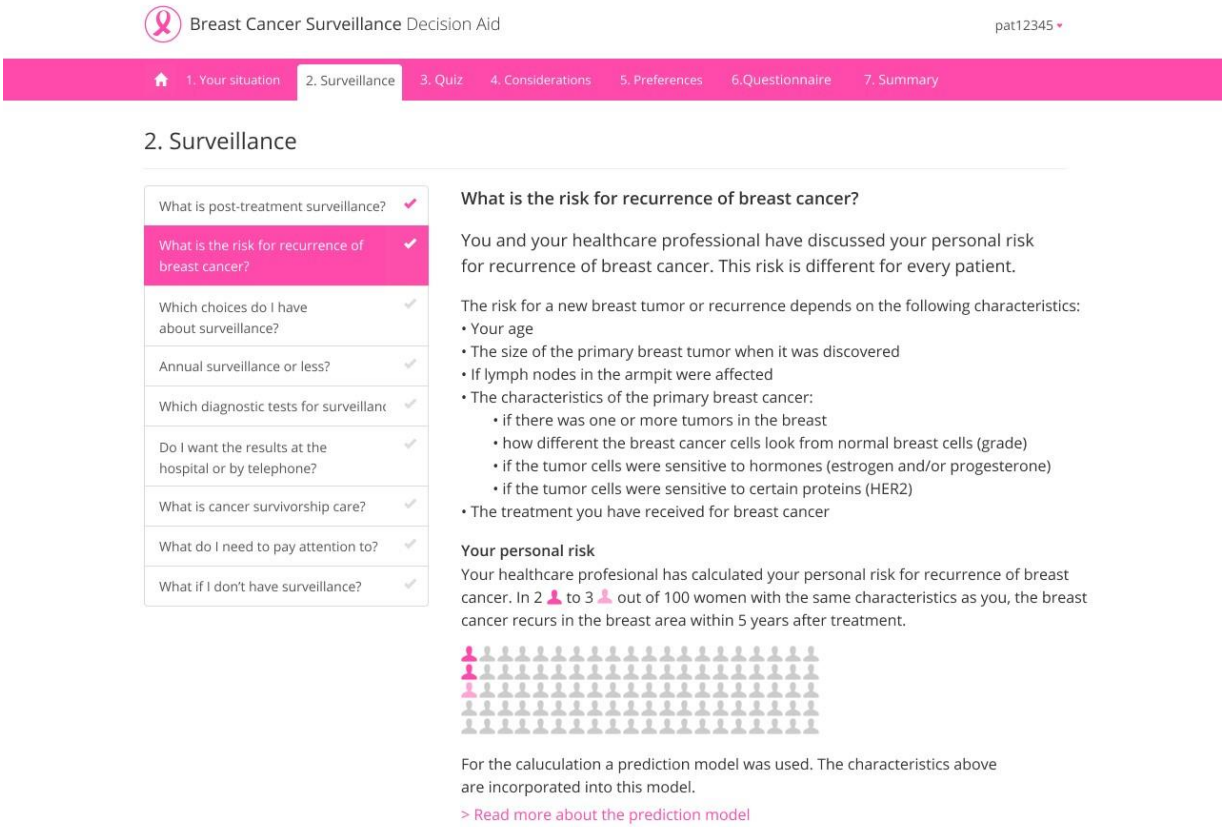
*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

APPENDIX B

Breast cancer patient decision aid

Component 1: consultation sheet

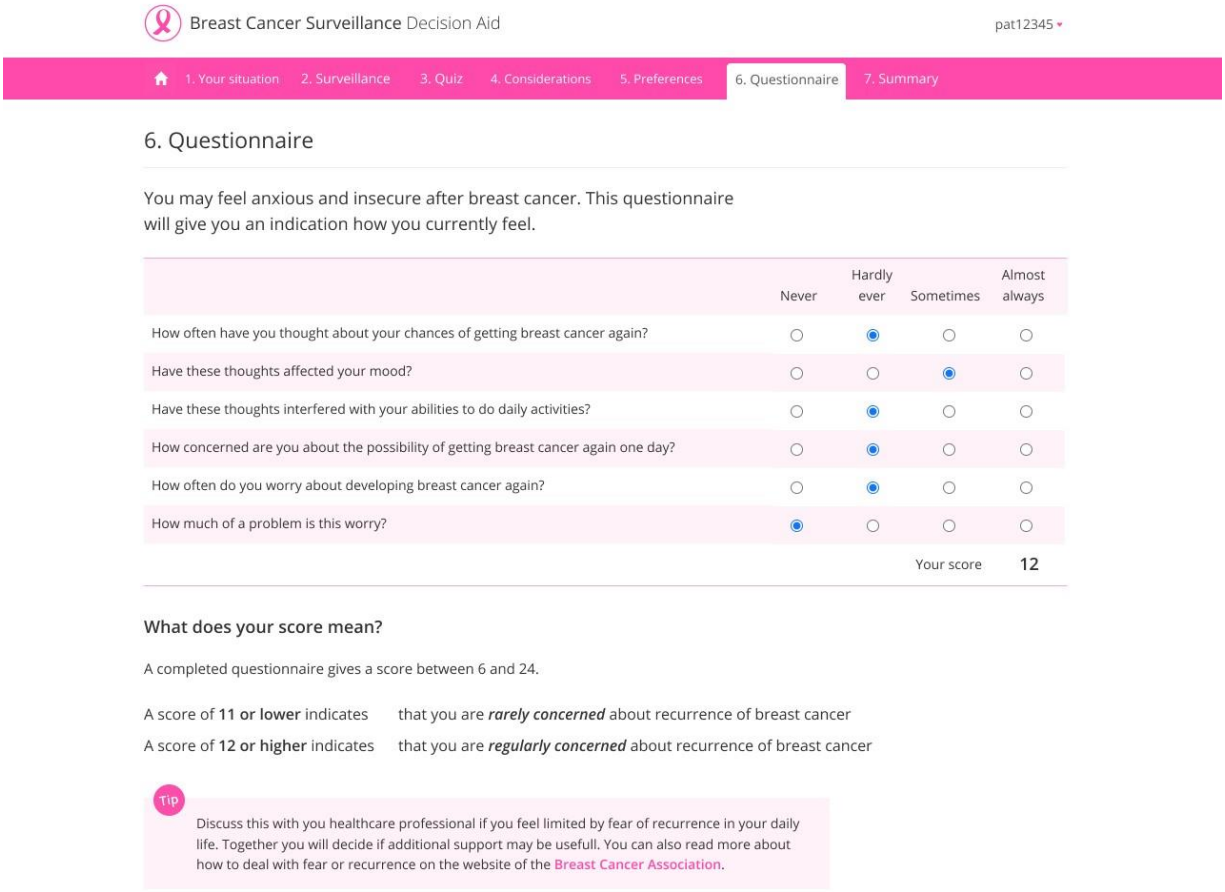
The consultation sheet (printed or digital) contains a visualization of a risk estimation of the personalized risk for breast cancer recurrence (local regional recurrences and secondary primary breast tumors), combined with a display of available options for post-treatment surveillance (e.g. frequency, imaging and duration). The personalized risk is estimated based on individual patient, tumor, and treatment characteristics, using the web-based INFLUENCE-nomogram. The nomogram was validated based on a large set of outcome data from the Netherlands Cancer Registry and shows a good predictive ability in the Dutch population.[12]



Component 2: online interactive PtDA

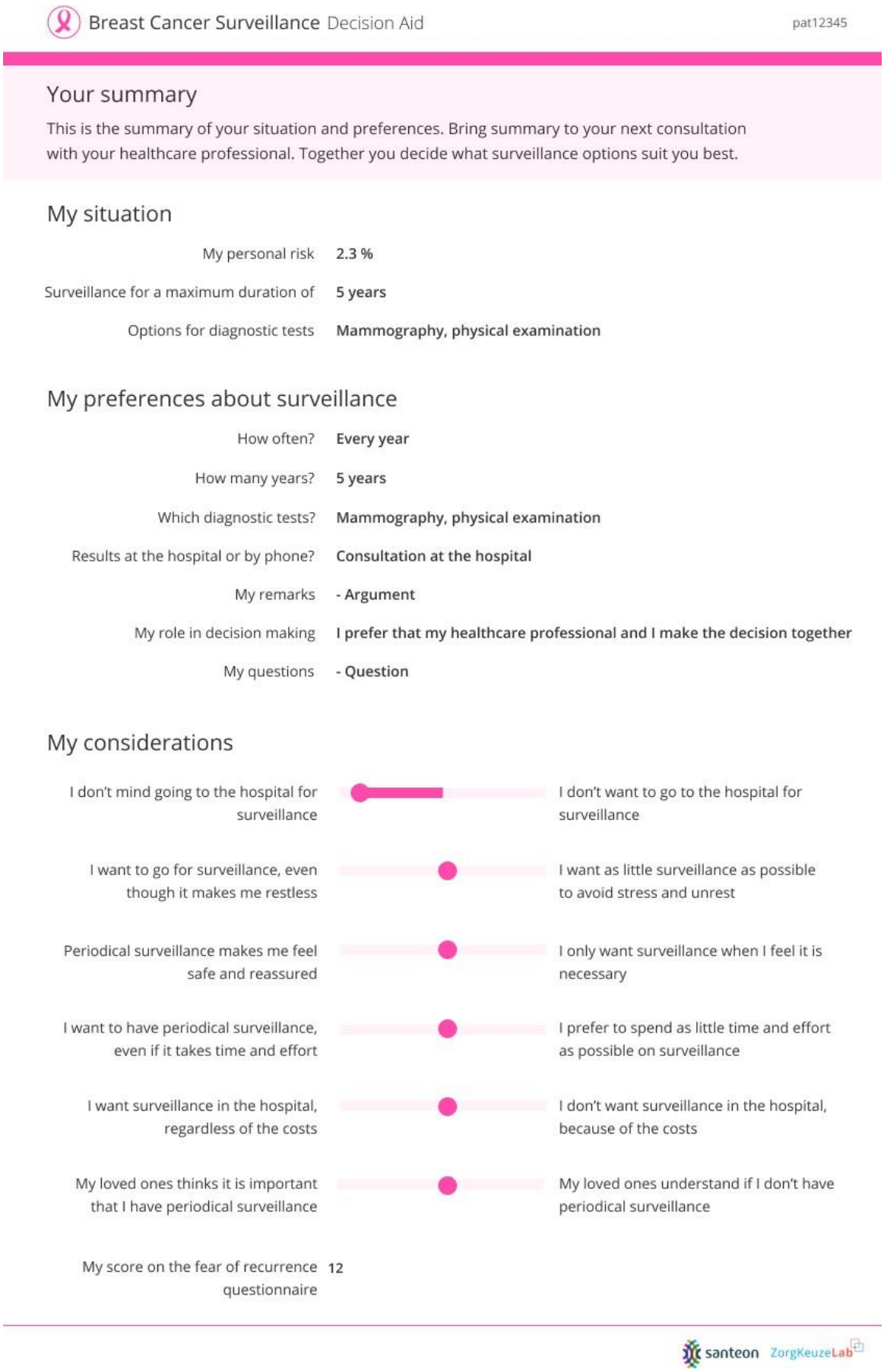
The online interactive PtDA contains information about SDM, post-treatment surveillance, available options and a clarification of the risk estimation. Interactive elements include a knowledge quiz, and value-clarification exercises. As part of using the PtDA, patients are asked to complete a patient-reported

outcome on fear of recurrence.[49] Data is processed in real-time and linked to tailored feedback on individual outcomes including comprehensive self-care advice (tips and tools).



Component 3: summary sheet

A summary sheet (printed or digital), to be used in the clinical consultation, containing women's preferences, personal considerations, and the individual outcomes on fear of recurrence.



Breast Cancer Surveillance Decision Aid

pat12345

Your summary

This is the summary of your situation and preferences. Bring summary to your next consultation with your healthcare professional. Together you decide what surveillance options suit you best.

My situation

My personal risk	**2.3 %**
Surveillance for a maximum duration of	**5 years**
Options for diagnostic tests	**Mammography, physical examination**

My preferences about surveillance

How often?	**Every year**
How many years?	**5 years**
Which diagnostic tests?	**Mammography, physical examination**
Results at the hospital or by phone?	**Consultation at the hospital**
My remarks	**- Argument**
My role in decision making	**I prefer that my healthcare professional and I make the decision together**
My questions	**- Question**

My considerations

I don't mind going to the hospital for surveillance		I don't want to go to the hospital for surveillance
I want to go for surveillance, even though it makes me restless		I want as little surveillance as possible to avoid stress and unrest
Periodical surveillance makes me feel safe and reassured		I only want surveillance when I feel it is necessary
I want to have periodical surveillance, even if it takes time and effort		I prefer to spend as little time and effort as possible on surveillance
I want surveillance in the hospital, regardless of the costs		I don't want surveillance in the hospital, because of the costs
My loved ones thinks it is important that I have periodical surveillance		My loved ones understand if I don't have periodical surveillance

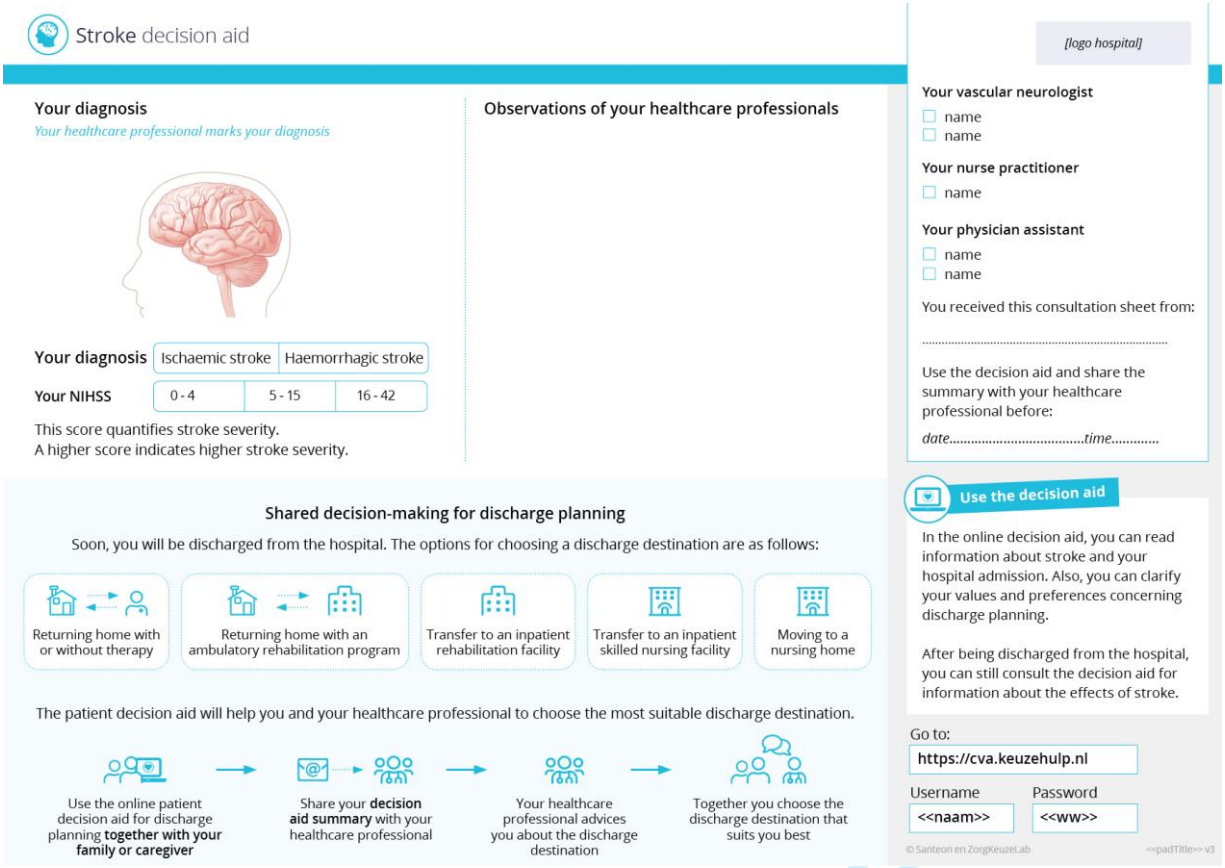
My score on the fear of recurrence questionnaire 12

santeon ZorgKeuzeLab

Stroke patient decision aid

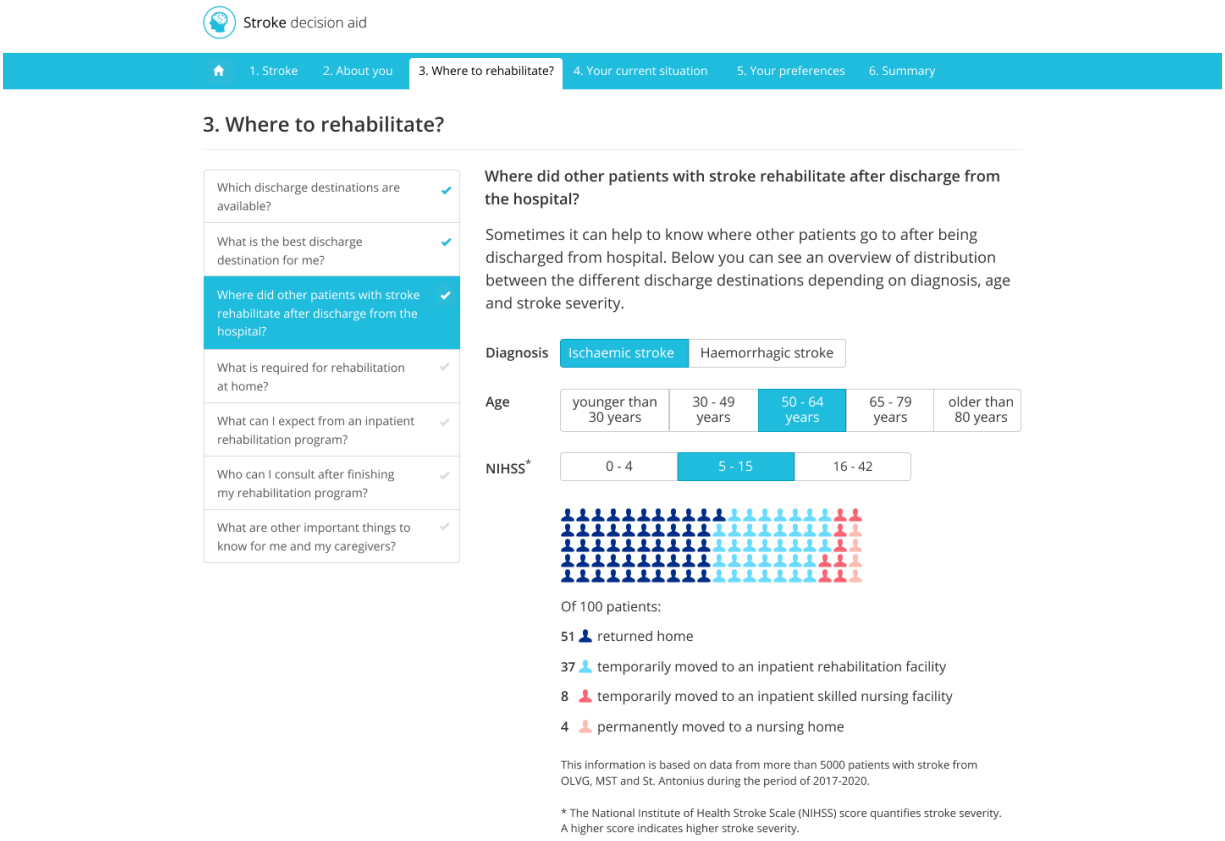
Component 1: consultation sheet

The consultation sheet contains basic information about the diagnosis (i.e. a visual representation of the brain to use as a topic starter on stroke and associated consequences), the type of stroke (i.e. ischemic or hemorrhagic), the individual stroke severity score as measured by the National Institutes of Health Stroke Scale (NIHSS), and options eligible for discharge locations.



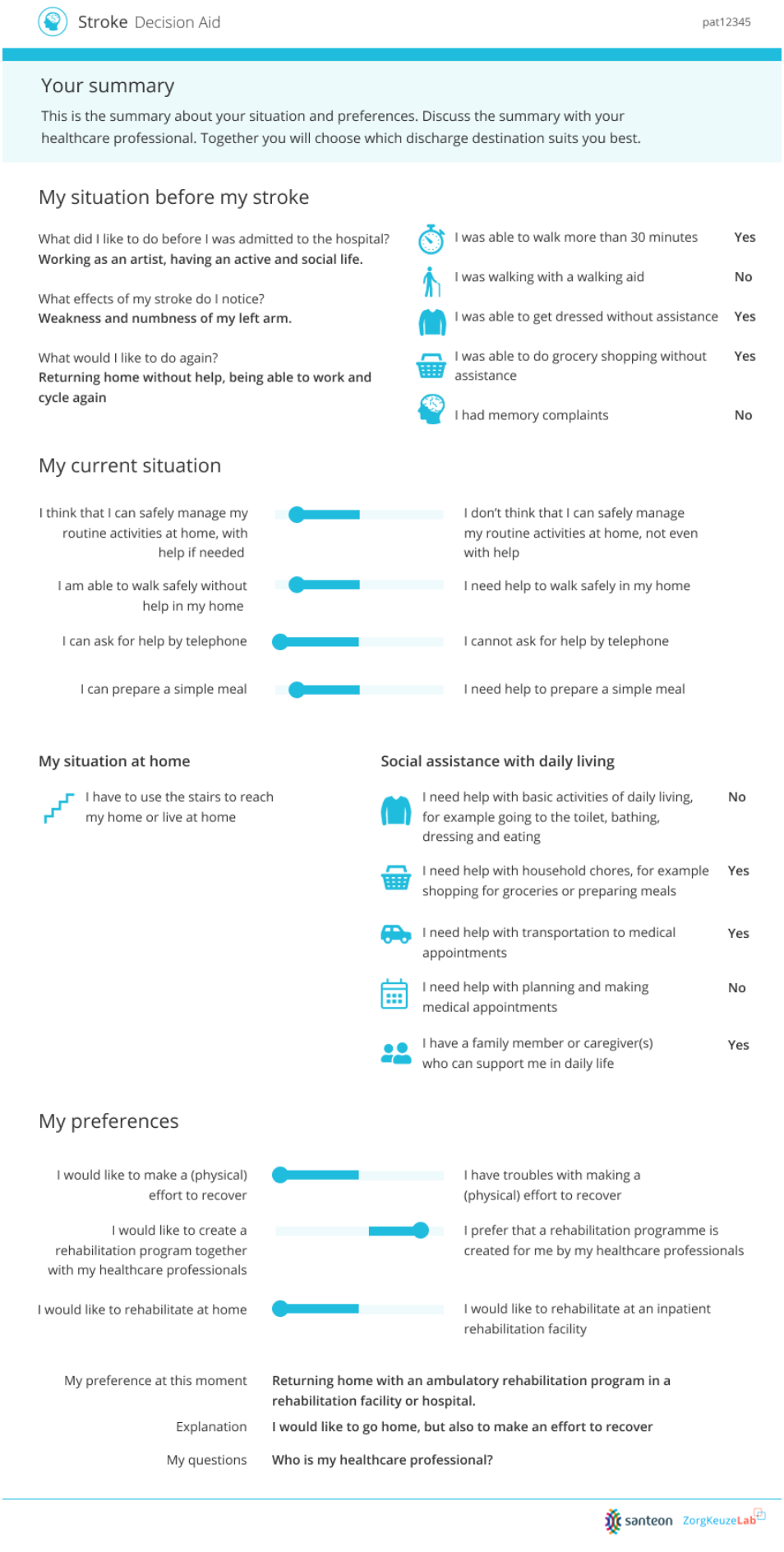
Component 2: online interactive PtDA

The online interactive PtDA contains information about the etiology and impact of stroke, prognosis and discharge planning. As part of the PtDA, patients are asked to complete PROM questionnaires on their physical and mental condition and to elaborate on their situation prior to admission to the hospital, as well as to indicate personal treatment goals. Also, the process of SDM is explained and value clarification exercises are included. The PtDA contains an interactive "patients-like-me" model: patients can enter their type of stroke, stroke severity and age in the model, which then shows the discharge location of comparable patients based on historical Santeon data (N > 4000).



Component 3: summary sheet

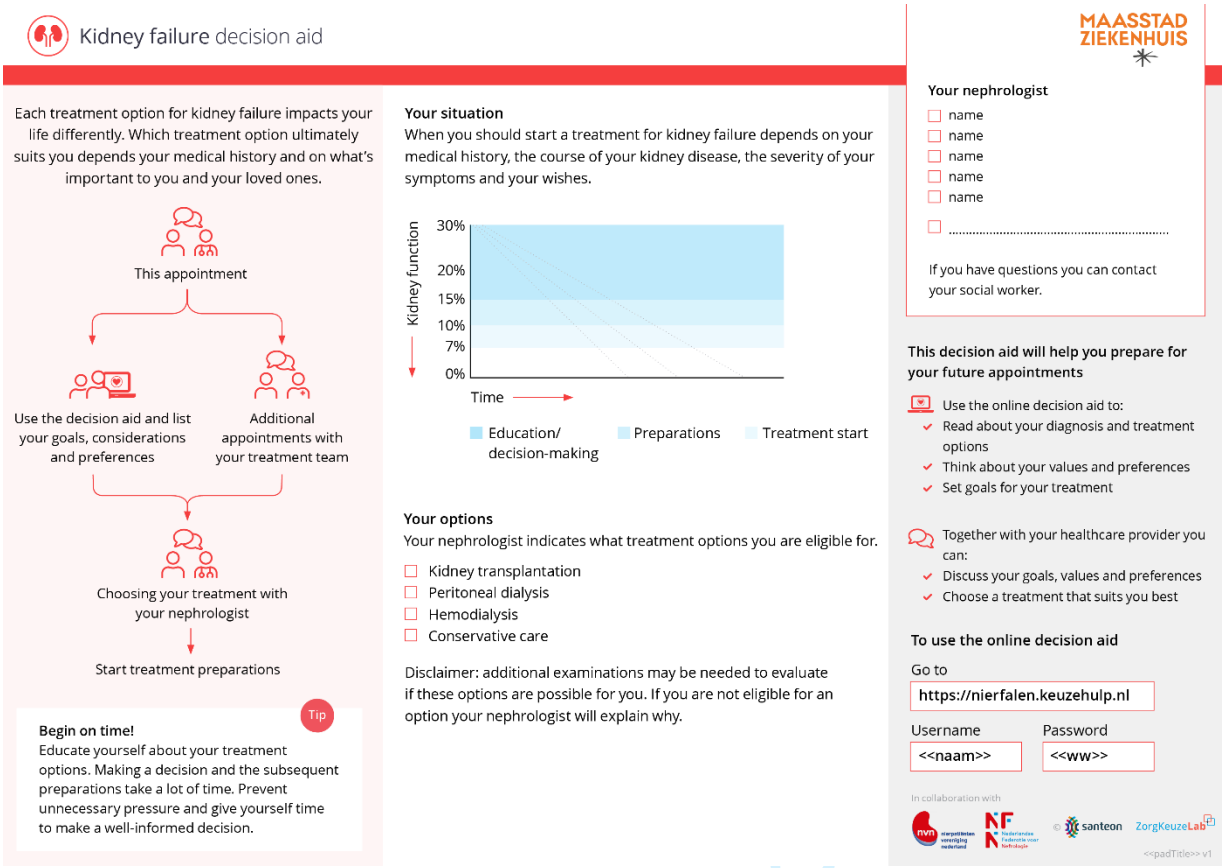
A digital summary sheet containing patients' values, preferences concerning discharge planning, and individual PROM scores to be used in the doctor-patient consultation.


Stroke Decision Aid
pat12345
Your summary
This is the summary about your situation and preferences. Discuss the summary with your healthcare professional. Together you will choose which discharge destination suits you best.
My situation before my stroke
What did I like to do before I was admitted to the hospital?
Working as an artist, having an active and social life.
What effects of my stroke do I notice?
Weakness and numbness of my left arm.
What would I like to do again?
Returning home without help, being able to work and cycle again
I was able to walk more than 30 minutes Yes
I was walking with a walking aid No
I was able to get dressed without assistance Yes
I was able to do grocery shopping without assistance Yes
I had memory complaints No
My current situation
I think that I can safely manage my routine activities at home, with help if needed
I don't think that I can safely manage my routine activities at home, not even with help
I am able to walk safely without help in my home
I need help to walk safely in my home
I can ask for help by telephone
I cannot ask for help by telephone
I can prepare a simple meal
I need help to prepare a simple meal
My situation at home
I have to use the stairs to reach my home or live at home
Social assistance with daily living
I need help with basic activities of daily living, for example going to the toilet, bathing, dressing and eating No
I need help with household chores, for example shopping for groceries or preparing meals Yes
I need help with transportation to medical appointments Yes
I need help with planning and making medical appointments No
I have a family member or caregiver(s) who can support me in daily life Yes
My preferences
I would like to make a (physical) effort to recover
I have troubles with making a (physical) effort to recover
I would like to create a rehabilitation program together with my healthcare professionals
I prefer that a rehabilitation programme is created for me by my healthcare professionals
I would like to rehabilitate at home
I would like to rehabilitate at an inpatient rehabilitation facility
My preference at this moment
Returning home with an ambulatory rehabilitation program in a rehabilitation facility or hospital.
Explanation
I would like to go home, but also to make an effort to recover
My questions
Who is my healthcare professional?
santeon ZorgKeuzeLab

Advanced kidney disease patient decision aid

Component 1: consultation sheet

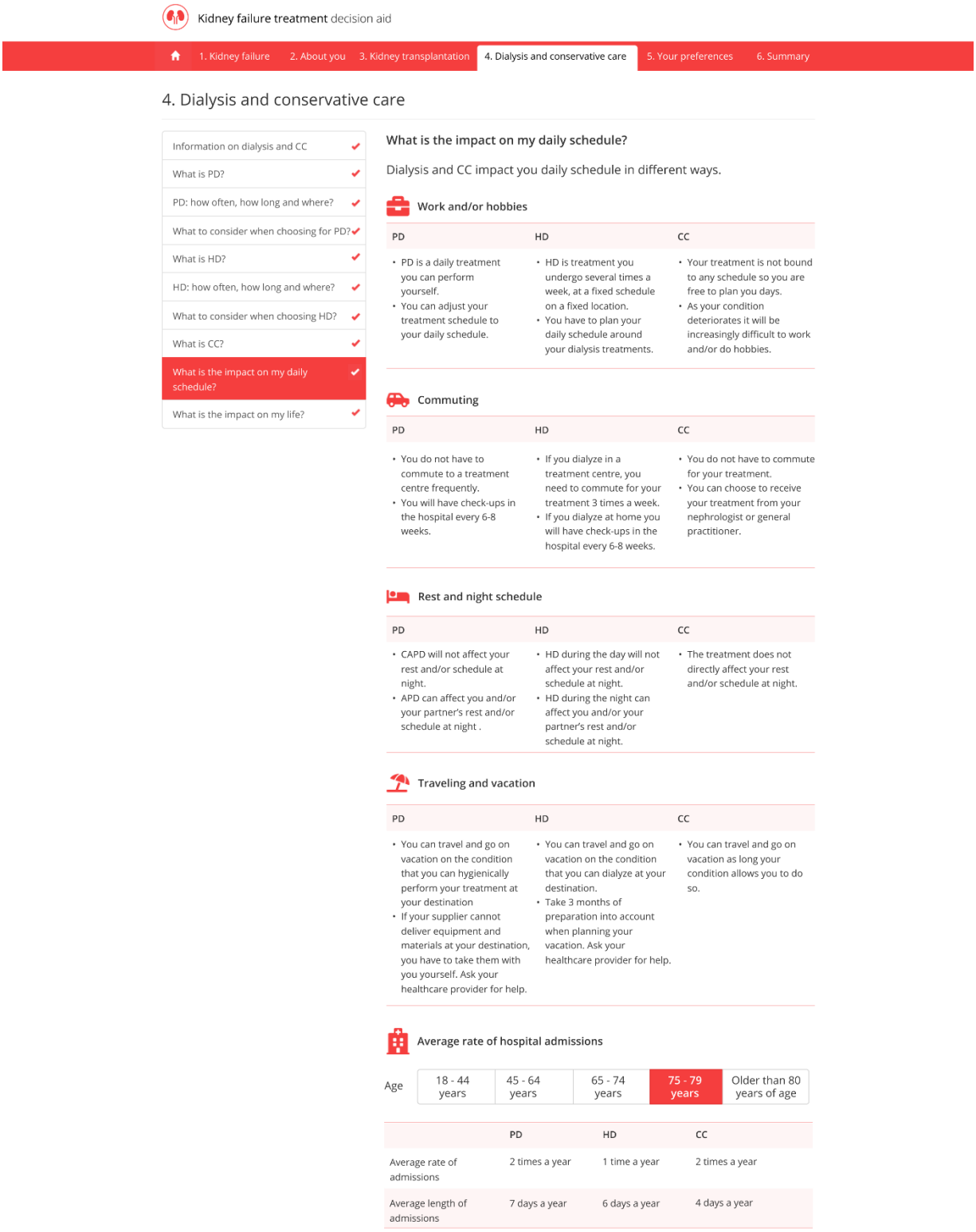
The consultation sheet (printed or digital) contains a flowchart of the kidney failure care path, a graph that healthcare professionals can use to draw the patient's individual eGFR decline, and a table that healthcare professionals can use to mark eligible treatment modalities.



Component 2: online interactive PtDA

The online interactive PtDA contains information on SDM, kidney failure and treatment modalities (hemodialysis, peritoneal dialysis, kidney-transplantation and comprehensive conservative care). Written information is supplemented with videos of patients' experiences. As part of the PtDA, patients are asked to complete PROMs questionnaires on their physical condition and on whether they consider life as completed. Additionally, patients are asked to complete value-clarification exercises regarding kidney transplantation (when applicable), dialysis and conservative care management. The PtDA contains an interactive "patients-like-me" model: patients can enter their age in the model, which then

shows the median survival- and mean hospitalization rates per treatment modality based on both Santeon and national data.



Component 3: summary sheet

A printed or digital summary sheet to be used in a clinical consultation, containing patients' values, preferences concerning discharge planning, and individual PROM scores.

Kidney Failure treatment Decision Aid

pat12345

Your summary

This is the summary of your situation and preferences. You can use this summary at your next appointment to help you and your doctor make a treatment decision that suits you best.

About me

What do I enjoy doing in my daily life?
I enjoy working at my garage with my two sons and nephew. I would give anything to keep working for a couple of more years so one of them can mature and take over my responsibilities.

Who plays an important role in making this decision?
My wife and I are real team players. She's my personal consultant.

Can you continuously walk for 30 minutes or more? **Yes**

Can you dress yourself? **Yes**

Do you do groceries by yourself? **No**

What symptoms are currently bothering you the most?
The nausea and breathlessness.

Tell us what you think

There are things I still want to do with my life — I feel fulfilled with my life

I want a treatment that primarily focuses on extending my life — I want a treatment that primarily focuses on my quality of my life

Kidney transplantation

Do you have moral objections to receiving a kidney from a living donor?
No

Did you talk about living donation kidney transplantation with anyone you know?
I talked about it with my wife, but I don't want to put this burden on my kids.

Has anyone offered to donate you a kidney?
[Not yet]

Do you have any questions or comments about kidney donation?
Am I also eligible for a kidney from a deceased donor?

Dialysis at home or in a hospital?

At home — In a hospital

I don't mind doing dialysis at home — I don't want to feel like a patient at home

I don't want to be in the hospital on a weekly basis — I don't mind being in the hospital on a weekly basis

I want to be flexible and plan my dialysis according to schedule — I don't mind being in the hospital according to a fixed schedule

I feel confident that I can perform dialysis on my own at home — I would rather have a healthcare professionals help me with my dialysis

Comments: **I would prefer doing PD treatment at home**

Dialysis during the day or night?

During the day — During the night

I want to sleep without having to deal with my dialysis — I accept that the quality of my sleep may worsen due to my dialysis

I can free time during the day to make time for my dialysis — I want to remain flexible during the day

Comments: **I would prefer doing my PD at night so I can freely manage my garage during the day!**

My preference

My preference at this moment: **Kidney transplantation from a deceased donor or APD**

What goals do I want to achieve with this treatment? **Extending my life while remaining flexible. I want to spend my golden years with my wife after making my sons owners of my garage. They still have a lot to learn though!**

What do I absolutely not want? **CC**

My questions: **no additional questions**

santeon ZorgKeuzeLab

BMJ Open

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-055324.R2
Article Type:	Protocol
Date Submitted by the Author:	01-Jun-2022
Complete List of Authors:	Hackert, Mariska; Santeon Ankersmid, Jet; Santeon; University of Twente, Health Technology and Services Research Engels, Noel; Santeon ; Maasstad Hospital, Internal Medicine Prick, Janine; Santeon; OLVG, Neurology Teerenstra, Steven; Radboudumc, Health Evidence, Biostatistics Siesling, Sabine; Netherlands Comprehensive Cancer Organization , Research & Development; University of Twente, Health Technology and Services Research Drossaert, Stans ; University of Twente, Psychology, Health & Technology Strobbe, Luc; Canisius Wilhelmina Hospital, Surgical Oncology Van Riet, Yvonne; Catharina Hospital, Surgical Oncology van den Dorpel, Marinus; Maasstad Hospital, Internal Medicine Bos, Willem Jan; Sint Antonius Hospital, Internal Medicine; Leiden University Medical Center, Internal Medicine van der Nat , Paul; Sint Antonius Hospital, Value-Based Healthcare; Radboudumc IQ healthcare, Radboud Institute for Health Sciences Van den Berg-Vos, RM; OLVG, Neurology; Amsterdam UMC Locatie AMC, Neurology van Schaik, Sander; OLVG, Neurology Garvelink, Mirjam; Sint Antonius Hospital, Value-Based Healthcare Van der Wees, Philip; Radboudumc IQ healthcare, Radboud Institute for Health Sciences, Rehabilitation Van Uden-Kraan, Cornelia; Santeon
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research
Keywords:	Stroke < NEUROLOGY, Chronic renal failure < NEPHROLOGY, Breast surgery < SURGERY, MEDICAL EDUCATION & TRAINING

Effectiveness and implementation of SHared decision-making supported by OUTcome information among patients with breast cancer, stroke and advanced kidney disease: SHOUT study protocol of multiple Interrupted Time Series

Mariska QN Hackert[#1], Jet W Ankersmid[*1,2], Noel Engels[*1,3], Janine CM Prick[*1,4], Steven Teerenstra[5], Sabine Siesling[2,6], Constance HC Drossaert[7], Luc JA Strobbe[8], Yvonne EA van Riet[9], René MA van den Dorpel[3], Willem Jan W Bos[10,11], Paul B van der Nat[12,13], Renske M van den Berg-Vos[4,14], Sander M van Schaik[4], Mirjam M Garvelink[12], Philip J van der Wees[13,15], Cornelia F van Uden-Kraan[1]

On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group

[*]*Contributed equally*

[#]*Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the Netherlands. E-mail: m.hackert@santeon.nl*

1. Santeon hospital group, Utrecht, The Netherlands
2. Department of Health Technology and Services Research, Technical Medical Center, University of Twente, Enschede, The Netherlands
3. Department of Internal Medicine, Maasstad Hospital, Rotterdam, The Netherlands
4. Department of Neurology, OLVG, Amsterdam, The Netherlands
5. Radboud Institute for Health Sciences, Department for Health Evidence, section Biostatistics, Radboud University Medical Center, Nijmegen, The Netherlands
6. Department of Research and Development, Netherlands Comprehensive Cancer Organization, Utrecht, The Netherlands
7. Department of Psychology, Health and Technology, University of Twente, Enschede, The Netherlands
8. Department of Surgical Oncology, Canisius Wilhelmina Hospital, Nijmegen, The Netherlands
9. Department of Surgical Oncology, Catharina Hospital, Eindhoven, The Netherlands
10. Department of Internal Medicine, St. Antonius Hospital, Nieuwegein, The Netherlands
11. Department of Internal Medicine, Leiden University Medical Center, Leiden, The Netherlands
12. Department of Value-Based Healthcare, St. Antonius Hospital, Nieuwegein, The Netherlands
13. Radboud Institute for Health Sciences, Scientific Centre for Quality of Healthcare (IQ Healthcare), Radboud University Medical Center, Nijmegen, The Netherlands
14. Amsterdam UMC, location AMC, Department of Neurology, Amsterdam, the Netherlands
15. Radboud Institute for Health Sciences, Department of Rehabilitation, Radboud University Medical Center, Nijmegen, The Netherlands

Word count 4341

Date 1-6-2022, **Version** 3.0

ABSTRACT

Introduction Within the value-based healthcare framework, outcome data can be used to inform patients about (treatment) options, and empower them to make shared decisions with their health care professional. To facilitate shared decision-making (SDM) supported by outcome data, a multicomponent intervention has been designed, including patient decision aids on the organization of post-treatment surveillance (breast cancer); discharge location (stroke) and treatment modality (advanced kidney disease), and training on SDM for health care professionals. The SHared decision-making supported by OUTcome information (SHOUT) study will examine the effectiveness of the intervention and its implementation in clinical practice.

Methods and analysis Multiple interrupted time series will be used to stepwise implement the intervention. Patients diagnosed with either breast cancer (N = 630), stroke (N = 630) or advanced kidney disease (N = 473) will be included. Measurements will be performed at baseline, 3 (stroke), 6 and 12 (breast cancer and advanced kidney disease) months. Trends on outcomes will be measured over a period of 20 months. The primary outcome will be patients' perceived level of involvement in decision-making. Secondary outcomes regarding effectiveness will include patient-reported SDM, decisional conflict, role in decision-making, knowledge, quality of life, preferred and chosen care, satisfaction with the intervention, health care utilization and health outcomes. Outcomes regarding implementation will include the implementation rate and a questionnaire on the health care professionals' perspective on the implementation process.

Ethics and dissemination The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act does not apply to this study. Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study. The results will contribute to insight in and knowledge on the use of outcome data for SDM, and can stimulate sustainable implementation of SDM.

Registration Netherlands Trial Register NL8374, NL8375 and NL8376, registration date: February 12th 2020.

Keywords Value-based healthcare; personalized outcome data; clinical outcome data; patient-reported outcomes; patient decision aid; shared decision-making; breast cancer; stroke; advanced kidney disease

Strengths and limitations of this study

- Key stakeholders participated in the development of a multicomponent intervention designed to facilitate shared decision-making supported by personalized outcome information.
- By using stepwise implementation in all participating hospitals, lessons learned can be used to facilitate implementation in subsequent hospitals.
- The proposed multiple interrupted time-series design allows the multicomponent intervention to be refined and evaluated over time.
- The study design does not allow evaluation of each individual component of the multiple component intervention.
- The expected effect size may not be clinically meaningful.

INTRODUCTION

Value-based healthcare (VBHC) is gaining momentum worldwide.[1, 2] The VBHC framework strives to maximize value for patients by achieving the best outcomes while controlling costs.[3] Per patient group, clinical and patient-reported outcomes, costs and process data are measured and compared in a structured, standardized manner. These data are used to identify variation across the care cycle to collectively enhance the value of health care provision on patient group level.[2] Besides the use of outcome data on group level, outcome data can also be used on the individual patient level, by integrating outcomes and value in patient communication. However, in clinical practice, the role of outcome data in patient communication is not common practice. On individual patient level, most importantly, outcome data can provide insight into benefits and harms of treatment options. Integrating outcome data in discussing treatment options between health care professionals and patients, is where VBHC and shared decision-making (SDM) entangle.[4, 5]

SDM is the process in which patients and health care professionals make well-informed, collaborative choices by combining the best available evidence and patients' values and preferences.[6, 7] So far, SDM has shown to lead to well-informed, preference-based patient decisions, and to improve patients' relationship with their health care professional.[6, 8, 9] Using outcome data can further strengthen the motivation of health care professionals to apply SDM and empower patients to make shared decisions with their health care professional. In this way, outcome data can accelerate the implementation of SDM and strengthen VBHC.[4, 5, 10, 11]

To support SDM, outcome data should be presented to patients in a meaningful way. The four-step conversational SDM model can be used for this purpose ([6]; inspired by [7]). In each step, outcome data, both on patient individual and group level (aggregated), can be incorporated (see Figure 1, based on [6, 9]).

<<INSERT Figure 1>>

The individual outcome data can be used to introduce a care decision and to determine available options for the patient *(step 1)*. Related benefits and harms of these options are explained in *step 2*. As these may differ between patients depending on clinical and personal characteristics, it is highly encouraged to display personalized outcomes ("patients-like-me data"),[10] or to use prediction models in which these

characteristics can be entered to display personal estimated risks and to support personalized aftercare paths.[12] Next (*step 3*), the health care professional and the patient discuss the patient's preferences. This process of value clarification can be fostered by being informed on outcome data of previous patients. In *step 4*, the health care professional and the patient together integrate outcome data and preferences to make a shared decision.

Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower this threshold, we developed a multicomponent intervention for three patient groups with an oncological (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as training for health care professionals and an accompanying implementation strategy. So far, little is known about the impact of using outcome data for SDM.[10, 11]

The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight in, and knowledge on, the use of personalized outcome data for SDM, and can stimulate sustainable implementation of SDM in clinical practice.

METHODS AND ANALYSIS

We use multiple interrupted time series (mITS) [13] to compare the intervention with standard care. We follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see Appendix A).[14, 15] mITS will allow for initial testing and refinement of the intervention. In participating hospitals, trends on outcomes will be evaluated through a continuous sequence of observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2). Trends in the pre-implementation phase will be 'interrupted' at planned timepoints by the stepwise implementation of the intervention in each hospital. Direct effects (level change) will be examined, as well as gradual changes over time (slope change).

<<INSERT Figure 2>>

Study setting

Seven independent large Dutch teaching hospitals, which together form the Santeon hospital group, will participate in this study. The hospitals are geographically spread across the Netherlands and account for about 11% of the Dutch hospital care volume. By using VBHC principles, comparing outcome data, collaborating in multidisciplinary improvement teams, and by focusing on SDM supported by personalized outcome data as part of the Experiment Outcome Indicators, Santeon continuously aims to improve quality of care on patient group level.[16, 17] The next step is to use the collected, real-world outcome data to better inform individual patients and health care professionals. Up to now, aggregated outcome data have been gathered in international studies using homogenous samples and population averages. Real-world outcomes in larger, heterogenous groups of patients provide complementary evidence.[18]

Study population

Patients diagnosed with either breast cancer, stroke or AKD, treated in Santeon hospitals, will be asked to participate in this study. These patient groups are sufficiently large and diverse to cover a relatively broad spectrum of hospital healthcare. In addition, both breast cancer and stroke are in the top-20 list of largest medical conditions in terms of national disease burden.[19]

Inclusion criteria

All participants must be aged 18 years or older, and able to understand the Dutch language in speech and writing. Inclusion criteria will be:

1) patients facing the decision for the organization of post-treatment surveillance after curative treatment for invasive non-metastasized breast cancer;
2) hospitalized patients with a (ischemic or hemorrhagic) stroke that have to decide on their discharge location and type of care after discharge from the hospital;
3) patients with AKD (i.e. CDK-KDIGO G4-$G5_{A1-3}$) that have to make a treatment modality decision (hemodialysis, peritoneal dialysis, kidney-transplantation or comprehensive conservative care).

Exclusion criteria

Patients with severe cognitive impairment or physical inability to complete a questionnaire will be excluded. Exclusion criteria per patient group are displayed in Table 1.

Table 1. Exclusion criteria per patient group.

Breast cancer	Stoke	Advanced kidney disease
• Male patients • Predisposing genetic mutations related to breast cancer • Non-invasive breast cancer • History of neoadjuvant systemic therapy or treatment for a recurrence or second primary tumor • Palliative treatment	• Reduced consciousness	• On kidney replacement therapy or conservative care management

Intervention

A multicomponent intervention was developed including PtDAs and a training for health care professionals. Because the implementation of SDM is not only a matter of introducing PtDAs, nor that it is achieved by providing personalized outcome data, we designed an implementation strategy focusing on awareness, willingness and behavior of both health care professionals and patients.

Interactive patient decision aids containing personalized outcome data

A PtDA was developed for each patient group in an iterative process of five co-creation sessions with a multidisciplinary team consisting of patients, patient representatives and health care professionals. A literature review and needs assessment studies among patients and health care professionals served as input.[20] Development was guided by the International Patient Decision Aid Standards (IPDAS) Collaboration framework,[21] and in line with the Dutch guidelines for developing PtDAs.[22] Content was critically revised by the teams in an iterative process and rewritten to B1 language level (Common European Framework of Reference for Languages, CEFR). Usability testing consisted of going through the PtDA, combined with think-aloud sessions with patients, an online survey (stroke) and/or interviews

by telephone (breast cancer, stroke, and advanced kidney disease) among health care professionals. Detailed results of the developmental process of the PtDAs will be published.

Each PtDA is composed of three components which contain personalized (patient-reported and clinical) outcome data, both on individual as well as aggregated level. Personalized data is entered into the PtDA by both health care professionals and patients. From the transition phase onwards (Figure 2), the health care professional will introduce the PtDA to patients by means of a paper or digital consultation sheet *(component 1)*. Health care professionals provide personalized clinical data (e.g., for patients with stroke: type of stroke, NIHSS score) when introducing the PtDA. Next, patients will receive a personal login code to access the online interactive PtDA at home or during hospital admission *(component 2)*. Each PtDA contains evidence-based information about the options and pros and cons. Information is tailored to relevant options for the patient and presented without favoring any particular outcome. Patients enter patient-reported data, by means of PROMs, into the PtDA during use (e.g., for patients with advanced kidney disease: physical condition, treatment goals). The PtDAs actively encourage patients to weigh their options. Once patients have completed the PtDA, a summary sheet will automatically be created, containing an overview of patient-reported personalized data and patient's preferences and considerations, which can be used as a base for final decision-making in a consultation with their health care professional *(component 3)*.

Breast cancer patient decision aid

The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving curative treatment for invasive non-metastasized breast cancer. The PtDA includes patients' personal risks for locoregional recurrences estimated using the INFLUENCE-nomogram [12], a validated prediction model with which the five-year risk for locoregional recurrences can be estimated, and a patient-reported outcome measure (PROM) questionnaire on fear of cancer recurrence (sections of the PtDAs were translated for publication; see Appendix B).

Stroke patient decision aid

The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The PtDA includes an interactive "patients-like-me" model on the discharge location of comparable patients

based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-being (see Appendix B).

Advanced kidney disease patient decision aid

The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive "patients-like-me" model on median survival- and mean hospitalization rates per treatment modality based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see Appendix B).

Training of health care professionals

Health care professionals will be asked to complete an e-learning on applying (personalized) outcome data to support SDM. Consequently, they will be asked to participate in a group training of one daypart. The e-learning is focused on providing theoretical background and practical tips and tricks on applying outcome information in the four steps of SDM in clinical consultations (including text, videos and self-assessment tests). Completion of the e-learning takes approximately one hour. The group training includes theoretical background information on SDM, reflection on audio-taped consultations (provided by participating health care professionals as part of the data collection for the study), cases introduced by participants, and practicing SDM conversational skills with an actor. By offering the e-learning before the group training sessions, we reduce the time spent on theoretical background in the training, leaving more time to practice on SDM conversational skills. Upon completion of the group training, follow-up will be offered after one day (by offering a plasticized card or poster containing short written instructions on SDM, and by presenting a publication on using outcome data to support SDM), after one month (by offering tips, tricks, a testimonial by a colleague health care professional and an instruction clip on SDM) and after two months (by offering the possibility to receive individualized feedback by sending an audio-taped consultation to the trainer).

Implementation strategy for the multicomponent intervention

The implementation strategy is based on prior successful implementation strategies for PtDAs [23] and a web-based self-management application using PROMs to monitor quality of life and focuses on awareness, willingness and behavior of both health care professionals and patients.[24] Core elements are listed in Table 2.

Table 2. Implementation strategy.

1. *Inform and create support for using the PtDA* by deciding on the key moment for introducing a PtDA for these three patient groups, developing the PtDA by means of a participatory design approach, including both health care professionals and patient advocates, and by customizing the PtDA for each individual hospital (i.e. by applying the individual hospital logo).
2. *Document the current care path* in each hospital to find the best way to incorporate the PtDA. Involving both the timing of the PtDA and the health care professionals who will present it.
3. *Remove organizational barriers* that represent obstacles to the process of implementing the PtDA, such as reorganizations, or the simultaneous implementation of different innovations, by asking hospitals when it is most convenient for them to proceed with the implementation.
4. *Informing and involving all (health care) professionals* in the care path by means of an information meeting, and by offering the possibility to make use of an e-learning for these professionals also on applying outcome data in SDM.
5. *Instruction on how to introduce the PtDA* to eligible patients by means of a kick-off meeting organized in the hospitals shortly before the start of the implementation of the PtDA.
6. *Offering support in the workplace*, i.e. by providing plasticized cards containing short written instructions in line with the SDM four-step conversation model, and by stimulating implementation e.g. by distributing promotional posters and informative video's for patients on SDM with personalized outcome data. Support and technical assistance for both health care professionals and patients will be centralized and available through a helpdesk.
7. *Closely monitoring of progress and stimulating implementation* by local ambassador and informed by a dashboard containing usage data of the PtDA.
8. *Offering the training and the PtDA free of charge* during the study period.

Study design and procedures

The intervention will be stepwise implemented in the hospitals over a period of 20 months (see Figure 2). In each hospital, there will be 6 to 12 months in which standard care will be thoroughly assessed (pre-implementation phase), followed by a transition phase of 2 months in which health care professionals will be trained and the PtDA will be introduced. Finally, there will be 6 to 12 months in which the intervention will be assessed (post-implementation phase). Data collection is ongoing. The moment by which hospitals switch from standard care to use of the intervention will not be randomized. To promote that PtDAs will become successfully implemented into routine clinical settings, we will ask involved health care professionals when it will be most convenient for them to proceed with implementation.

Internal validity will be increased, as each hospital will act as its own historical control group and the hospitals will not switch at the same time.

Patients will be asked by their health care professional to participate in this study: 1) patients with breast cancer will be informed and asked to participate during the follow-up consultation on the occasion of their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision has to be made about renal replacement therapy or conservative care. When interested, patients will receive a patient information letter about the study. They will be asked for written informed consent. In the post-implementation phase, patients that decline participation in the SHOUT-study will still be offered the SDM supported by outcome information as the standard form of care.

Data collection and methods

To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T0) will be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T1) for patients with stroke, and after 6 (T1) and 12 (T2) months for patients with breast cancer or AKD. The time it takes to complete the questionnaires differs per measurement moment. The T0 questionnaire takes about 30 to 45 minutes to complete and the T1 and T2 questionnaires take 15 to 20 minutes. The timing of follow-up questionnaires differs between the three conditions due to the course and nature of and the care pathways for the three conditions. Furthermore, some outcome measures are disease-specific and will therefore only be assessed in the patient groups for which they are suitable.

Second, the consultations, in which the options are being discussed, will be audio-taped to assess patients' involvement in the decision-making process from observers' viewpoint. Also, the length of the consultations will be determined. Third, to assess the extent to which the intervention leads to changes in the utilization and outcomes of health care, information will be retrieved from patients' electronic health records.

To evaluate the implementation, first, the estimated total number of eligible patients and the total number of patients who received the PtDA will be determined. Second, participating health care professionals

will receive a questionnaire 6 months after start of the post implementation phase, to assess their perspective on the implementation process.

Participant timeline

The participant timeline is displayed in Figure 3.

<<INSERT Figure 3>>

Outcomes

Effectiveness

Primary outcome measure

The primary outcome to assess effectiveness will be patients' perceived level of involvement in decision-making, measured with the 9-item SDM Questionnaire (SDM-Q-9). [25, 26] Each item describes a different step in the SDM process and will be scored by patients on a 6-point Likert scale. The sum of the item scores will range from 0 – 45, with higher scores indicating a greater level of perceived involvement in SDM.

Secondary outcome measures

Secondary outcomes will be: 1) patient-reported SDM, measured with the CollaboRATE; 2) decisional conflict, measured with the Decisional Conflict Scale (DCS); 3) decision regret for patients with stroke and AKD, measured with the Decision Regret Scale (DRS); 4) preferred and perceived role in decision-making, measured with the Control Preference Scale (CPS); 5) patients' knowledge regarding their disease and treatment options, measured with patient group-specific items; 6) quality of life, measured with the 12-item Short Form Health Survey (SF-12) for patients with breast cancer and AKD, and measured with the Patient Reported Outcomes Measurement Information System Global Health (PROMIS-10), five-dimension EuroQol five-levels questionnaire (EQ-5D-5L), and EuroQol Visual Analogue Scale (EQ-VAS) for patients with stroke; 7) preferred and chosen care (and the role of the consultation and outcome data therein), measured with patient group-specific items; 8) satisfaction with the intervention, measured with the Preparation for Decision Making scale (Prep-DM) and study-specific

questions; 9) perceived risk and fear of recurrence for patients with breast cancer, measured with the Cancer Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast cancer survivors (IPQ-BCS) and patient group-specific questions; and 10) participation / functioning and caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see Table 3, also for references).

Observer-reported SDM

We will combine the SDM-measurement tools, with a more objective score of SDM, as this score may differ from the patients' subjective interpretation [27]. The Observing Patient Involvement in decision-making scale (OPTION-5) [28] will be used to analyze the audio-recordings of encounters from clinical settings. All audio-recordings will be double coded by two raters who have been trained on rating the OPTION-5. In case of disagreement, a third rater will be consulted. The OPTION-5 includes five core SDM steps, to which a sixth is added to assess the role of personalized outcome data *('the health care professional informs the patient on outcomes of different treatment options')*. The item scores will be summed and rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

Health care utilization and outcomes

Patients' health care utilization and clinical outcomes will be extracted from their electronic health records. For patients with breast cancer, the number of hospital visits, the number of mammograms and other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications during admission will be extracted. For patients with AKD, the number of visits to outpatient clinics, hospital admissions and hospitalization days, and the rate of major treatment-related complications will be extracted.

Table 3. Overview of the patient-reported outcomes and instruments used per timepoint.

Measure	Description	Scoring range	Pre-implementation phase			Post-implementation phase		
			Baseline	T1	T2	Baseline	T1	T2
All patient groups:								
Shared decision-making								
• SDM-Q-9 [25, 26] (primary outcome measure)	9-item, 6-point scale measures patients' perceived level of involvement in decision-making.	Range 0 – 45, higher scores indicate a greater level of perceived involvement in decision-making.	X			X		
• CollaboRATE [29]	3-item, 10-point scale measures patient-reported SDM.	Range 0 – 100, higher scores indicate a higher patient-reported SDM.	X			X		
Decisional conflict								
• DCS [30]	16-item, 5-point scale measures personal perceptions of a) uncertainty in choosing options, b) modifiable factors contributing to uncertainty and c) effective decision-making.	Range 0 – 100, higher scores indicate greater decisional conflict.	X			X		
Decision regret								
Stoke and advanced kidney disease: • DRS [31]	5-item, 5-point scale measures distress or remorse after a health care decision.	Range 0 – 100, higher scores indicate greater regret.		X	X		X	X
(Preferred) role in decision-making								
• CPS [32]	1-item with 5 response options to assess the patient's preferred or perceived degree of control when decisions about treatment are being made.		X			X		
Patients' knowledge regarding their disease and treatment options (patient group-specific items)								
Breast cancer:	10 items with 3 response options.		X			X		
Stroke:	7 items with 3 – 7 response options.		X			X		
Advanced kidney disease:	7 items with 3 – 5 response options.		X			X		
Quality of life								
Breast cancer and advanced kidney disease: • SF-12 [33, 34]	12-items with 2 – 6 response options on quality of life.	Mental and physical component score based on the US population scoring system, higher scores indicate greater quality of life.	X	X	X	X	X	X
Stroke:								
• PROMIS Global-10 [35]	10 items with 5 – 11 response options on quality of life.	Physical and mental health summary scores based on the US population scoring system, higher scores indicate greater quality of life.		X			X	
• EQ-5D-5L [36, 37]	5 items, 5-point scale measures patients' health-related quality of life.	Range -0.446 – 1 based on the Dutch population tariff, higher scores indicate greater health-related quality of life.		X			X	
• EQ-VAS [36]				X			X	

	Visual analogue scale measures patients' health-related quality of life.	Range 0 – 100, higher scores indicate greater health-related quality of life.						
Preferred and chosen care (and the role of the consultation and outcome data therein) (patient group-specific items)								
Breast cancer:	48 items with 3 – 10 response options / open-ended.		X			X		
Stroke:	6 items with 3 – 8 response options / open-ended.		X			X		
Advanced kidney disease	9 items with 2 – 9 response options / open-ended.		X			X		
Satisfaction with the intervention								
• Prep-DM [38]	10-item, 5-point scale measures patients' perception of how useful the PtDA is in preparing them to communicate with their health care professional during consultations, and for making a health care decision.	Range 0 – 100, higher scores indicate higher perceived level of preparation for decision-making.				X		
• Study-specific items	24 items with 2 – 8 response options / open-ended to assess a) the way in which the PtDA has been presented to the patient, b) the experience of the patient with using the PtDA, and c) the extent to which the PtDA is of value to the patient.					X		
Breast cancer:								
Perceived risk and fear of recurrence								
• CWS [39]	6-item, 4-point scale measures concerns about cancer recurrence and the impact of these concerns on daily functioning.	Range 6 – 24, higher scores indicate greater worrying.	X	X	X	X	X	X
• IPQ-BCS (cure and personal control subscale) [40]	2x 4-item, 5-point scale measures a) patients' cure beliefs and b) personal control over the risk for recurrences.		X	X	X	X	X	X
• Patient group-specific items based on CRHWS [41], FCR7 [42] and FoP-Q [43]	9 items with 4 – 6 response options to assess patients' feelings about imaging during follow-up and worry about cancer recurrence, and to assess patients' perceived (absolute and comparative) risk of recurrence.		X	X	X	X	X	X
Stroke:								
Participation / functioning								
• Simplified mRS [44]	5-item, 2-point scale measures the degree of dependence of patients with stroke.	Range 0 – 5, higher scores indicate greater dependence.		X			X	
• USER-P restriction subscale [45]	11-item, 5-point scale measures experienced restrictions on 11 domains of participation.			X			X	
Caregivers' strain								
• CSI [46]	13-item, 2-point scale measures strain related to care provision.	Range 0 – 13, ≥ 7 indicates a higher level of strain.		X			X	

9-item Shared Decision Making Questionnaire, SDM-Q-9; Decisional Conflict Scale, DCS; Decision Regret Scale, DRS; Control Preference Scale, CPS; 12-item Short Form Health Survey , SF-12; Patient Reported Outcomes Measurement Information System, PROMIS; five-dimension EuroQol five-levels questionnaire, EQ-5D-5L; Preparation for Decision Making scale, Prep-DM; Cancer Worry Scale, CWS; modified version of the Revised Illness Perception Questionnaire for breast cancer survivors, IPQ-BCS; cancer-related health worries scale, CRHWS; seven-item Fears of Cancer Recurrence, FCR7; Fear of Progression Questionnaire, FoP-Q; modified Ranking Scale, mRS; USER-P, Utrecht Scale for Evaluation of Rehabilitation-Participation; CSI, Caregiver Strain Index.

Moderators

Socio-demographic characteristics

In the baseline questionnaire, patients' sex, birth year, marital status, occupation, and education level will be asked.

Clinical characteristics

Relevant medical characteristics will be extracted from the baseline questionnaire and the electronic health records. For patients with breast cancer, tumor and treatment characteristics will be extracted. For patients with stroke, etiology of stroke, and whether or not the patient has been treated with reperfusion therapy will be extracted. For patients with AKD, renal function, etiology and duration of kidney failure, whether these patients have had other treatment modalities for kidney failure in the past, comorbidity and definite treatment modality will be extracted.

Health literacy

Patients' health literacy will be assessed in the baseline questionnaire by the Set of Brief Screening Questions (SBSQ).[47] The mean score on the three items will be calculated, with higher scores reflecting higher health literacy skills.

Implementation

Implementation rate

The implementation rate will be calculated as the proportion of patients who received the PtDA compared to the estimated total number of eligible patients during the period of 6 to 12 months in which the PtDA will be handed out.

Health care professionals' view on the implementation process and use of the patient decision aid

Determinants of implementing an innovation

Health care professionals will fill out a questionnaire based on the Measurement Instrument for Determinants of Innovations (MIDI).[48] The MIDI assesses barriers and facilitators of implementation at the level of innovation (PtDA), the user (health care professionals) and the organization (hospital).

Physicians' willingness to incorporate shared decision-making

Health care professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[49]

Sample size

The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary outcome measure with the statistical significance level set at alpha = 0.05 (two-sided). Since there is no agreement on what constitutes a clinically meaningful difference on the SDM-Q-9, we estimated the size of the expected effect on previous studies using the SDM-Q-9. The size of the expected effect of the intervention on the SDM-Q-9 was set to be small to moderate (Cohen's d = 0.3-0.4) as relatively high scores on the SDM-Q-9 are common in the Netherlands.[50] The mITS with seven clusters (i.e. hospitals) had 18 measurement periods (excluding the transition phase, see Figure 2). For patients with breast cancer and stroke, a non-large Intraclass Correlation Coefficient (ICC = 0.05) was assumed. The correlation between monthly measurements was expected to be high (0.7 – 0.9) throughout a period of 18 months, although correlations between months farther apart could be lower than for months closer by. A correlation structure where the correlation decreases exponentially with the distance between months (autoregressive correlation structure) turned out too conservative and a correlation structure where the correlation between months is the same regardless of the distance between them (compound symmetry correlation structure) was too optimistic and not realistic for this purpose. Therefore, power calculations were primarily based on assuming that the correlation between months decreases from 0.9, for subsequent months, to 0.7, for months that are the farthest apart (i.e. the first and last month). To be precise, the correlation decreases linearly on the log scale from log(0.9) to log(0.7) (linear exponent autoregressive correlation structure).[51] Five patients per hospital per month was considered feasible, and with a 25% loss to follow-up, this results in a monthly inclusion rate of four patients. This yields more than 80% power and amounts to a study population of N = 504 – 630.

For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals. Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting

a Cohen's d = 0.4 assuming a correlation between subsequent months of at least 0.8 and a correlation between the first and last month of at least 0.6. This amounts to a study population of N = 378 – 473.

Statistical methods

An overview of the demographic and clinical characteristics will be provided using descriptive statistics. Continuous data will be expressed as a mean with the standard deviation (SD), or as the median (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless stated otherwise.

Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented regression will be employed, with the period before and after the introduction of the intervention as segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time series to exhibit different levels and trends. Correlation between repeated measurements in each time series will be accounted for by modelling the error structure. The effect of the intervention will be examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using the following model:

$$Y(T) = \beta 0 + \beta 1 \cdot T + \beta 2 \cdot I + \beta 3 \cdot I \cdot t$$

where $\beta 0$ will represent the baseline level at $T = 0$, $\beta 1$ will be interpreted as the change in outcomes associated with a time unit increase (representing the underlying trend in the pre-implementation phase), $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, $\beta 2$ will be the level change in the post-implementation phase and $\beta 3$ will indicate the slope change following the implementation phase (using the interaction between time t since the intervention started and the indicator for being in the intervention: I). A change in $\beta 2$ will constitute an immediate effect, while a change in $\beta 3$ will imply an effect that was experienced over time (which also allows us to measure the sustainability of the impact). Moreover, segmented regression will enable us to control for other variables, that can cause a change in level or trend of the outcomes of interest.

Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation techniques or sensitivity analyses will be used to assess their impact on the trial results.

To correct for multiple testing and the risk of type-1 errors a Bonferroni-Holm procedure will be applied across the set of primary and secondary endpoints.

To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis across all patient groups and hospitals will be performed. Finally, implementation across all patient groups will be investigated by using several the same outcome measures at a similar points in time.

Patient and public involvement

Santeon supports that patients with 'lived experiences' become members of a research team. Since the very beginning (composing the grant application), we have engaged a core group of patients and patient representatives of the patient associations involved. We designed the multicomponent intervention in collaboration with patients and health care professionals (see the Methods and Analysis). In addition, patient representatives were involved in the development of the study. Our collaboration with the patient associations will continue throughout the study. Study findings about the potential benefits of the multicomponent intervention will be disseminated by means of our project website.

ETHICS AND DISSEMINATION

The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference numbers METC 2019-075, -076 and -077).

The study will be conducted in accordance with local laws and regulations. Eligible patients will fully be informed about the study and asked to participate. They will receive a patient information letter and will be informed by telephone about the implications of participation. Patients will have sufficient opportunity to ask questions and to consider the implications before providing written informed consent. They will be allowed to withdraw from the study without giving a reason, at any time.

The SHOUT study is part of a larger Santeon program on using outcome data for SDM ('Experiment Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and

patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals, (inter)national conferences, workshops webinars, and newsletters and social media.

ACKNOWLEDGEMENTS

We thank all patients, patient representatives and health care professionals for their contribution to designing the multi-component intervention and execution the SHOUT study. The SHOUT study is part of a larger program on using outcome data for SDM ('Experiment Uitkomstindicatoren Santeon'), which is part of the Outcome-based Health care program initiated by the Dutch Ministry of Health, Welfare and Sports. We would like to thank ZonMw for funding this project.

FOOTNOTES

Availability of data and materials

Data will be collected and recorded in CASTOR EDC, a cloud-based electronic data capture platform. This platform is fully compliant with GCP, 21 CFR part 11, GDPR, HIPAA, ISO27001 and ISO 9001. All data will be coded and password protected. Study participants will be assigned a participant identification number (PIN). A digital, password protected identifying list relating medical information of participants to their PIN numbers will be kept on a secured server in the Santeon hospitals. All data and study documents will deleted and discarded after 15 years. The datasets used and / or analyzed during the SHOUT study are available from JWA (breast cancer), NE (AKD) and JCMP (stroke) on reasonable request. The (intellectual) property rights with regard to the generated data will reside at Santeon, Utrecht, The Netherlands. Interested parties can request a non-exclusive license for research and educational purposes. The non-exclusive license may be requested only after the completion of the theses to be written reserving the generated data.

Competing interests

None declared.

Funding

This research project is funded by ZonMw as part of the 'Experiment Uitkomstindicatoren Santeon'. This funding had no involvement in collection, management, analysis, and interpretation of the data; writing this manuscript or the decision to submit the article for publication.

Authors' contributions

JWA, NE, JCMP, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, SMvS, and CFvU-K developed the multicomponent intervention. MQNH, ST, PBvdN, PJvdW and CFvU-K contributed to the design of the study. JWA, NE, JCMP are conducting this study in fulfillment of a PhD and will be responsible for data collection. JWA, NE, JCMP and ST will be responsible for data analysis. All authors will be responsible for interpretating the data. The present manuscript was drafted by MQNH and CFvU-K. JWA, NE, JCMP, ST, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, PBvdN, RMvdB-V, SMvS, MMG and PJvdW critically revised this manuscript. All authors have read and approved the final manuscript.

ABBREVIATIONS

AKD, advanced kidney disease

mITS, multiple interrupted time series

PROM, patient-reported outcome measure

PtDA, patient decision aid

SDM, shared decision-making

VBHC, value-based healthcare

REFERENCES

1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health outcomes measurement and organizational readiness support quality improvement: a systematic review. BMC Health *Serv Res* 2018;18:1005. https://doi.org/10.1186/s12913-018-3828-9.

2 Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med* 2016;374:504-6. https://doi.org/10.1056/NEJMp1511701.

3 Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477-81. https://doi.org/10.1056/NEJMp1011024.

4 Steinmann G, van de Bovenkamp H, de Bont A, Delnoij D. Redefining value: a discourse analysis on value-based health care. *BMC Health Ser Res* 2020;20:862. https://doi.org/10.1186/s12913-020-05614-7.

5 Van der Nat PB. The new strategic agenda for value transformation. *Health Serv Manage Res* 2021;0(0):1-5. https://doi.org/10.1177/09514848211011739.

6 Stiggelbout AM, Pieterse AH, de Haes JCJM. Shared decision making: concepts, evidence and practice. *Patient Educ Couns* 2015;98(10):1172-9. https://doi.org/10.1016/j.pec.2015.06.022.

7 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-7. https://doi.org/10.1007/s11606-012-2077-6.

8 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Sys Rev* 2017;4:CD001431. https://doi.org/10.1002/14651858.CD001431.pub5.

9 Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci* 2016;11:114. https://doi.org/10.1186/s13012-016-0480-9.

10 Damman OC, Jani A, de Jong BA, et al. The use of PROMs and shared decision-making in medical encounters with patients: an opportunity to deliver value-based health care to patients. *J Eval Clin Pract* 2020;26:524-40. https://doi.org/10.1111/jep.13321.

11 La Grouw Y, Kee K, Ybema S, Taverne H, Boonen L. *Samen Beslissen in de praktijk: praktijkonderzoek i.o.v. het Zorginstituut Nederland.* Equalis / VU, 2019. https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen-beslissen-in-de-praktijk

12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36. https://doi.org/10.1007/s10549-015-3490-4.

13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community intervention research. *Prev Sci* 2000;1:31-49. https://doi.org/10.1023/A:1010024016308.

14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013a;158:200-7. https://doi.org/10.7326/0003-4819-158-3-201302050-00583.

15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013b;346:e7586. https://doi.org/10.1136/bmj.e7586.

16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director: Gregory Katz). 2020.

17 Santeon. www.santeon.nl 2021; 22 June.

18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. https://doi.org/10.1200/JCO.19.02035.

19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's).* 2018. https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys.

20 Ankersmid JW, Drossaert CHC, van Riet YEA, et al. Needs and preferences of breast cancer survivors regarding outcome-based shared decision-making about personalised post-treatment surveillance. J Cancer Surviv 2022; https://doi.org/10.1007/s11764-022-01178-z.

21 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710. https://doi.org/10.1177/0272989X13501721.

22 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een keuzehulp bij een richtlijn?* Den Haag, The Netherlands, 2018.

23 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J* 2020;26(2):1194-207. https://doi.org/10.1177/1460458219873528.

24 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a web-based self-management application "Oncokompas" in routine cancer care: a national pilot study. *Support Care Cancer* 2019;27:2911-20. https://doi.org/10.1007/s00520-018-4591-5.

25 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care. *PloS ONE* 2015;10(7):e0132158. https://doi.org/10.1371/journal.pone.0132158.

26 Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. Patient Educ Couns. 2010 Jul;80(1):94-9. doi: 10.1016/j.pec.2009.09.034.

27 Ubbink DT, van Asbeck EV, Aarts JWM, et al. Comparison of the CollaboRATE and SDM-Q-9 questionnaires to appreciate the patient-reported level of shared decision-making. Patient Educ Couns, available online 10 March 2022 https://doi.org/10.1016/j.pec.2022.03.007

28 Elwyn G, Grande SW, Barr P. *Observer OPTION^5 manual. Measuring shared decision making by assessing recordings or transcripts of encounters from clinical settings.* The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, USA, 2018.

29 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns* 2013;93(1):102-7. http://doi.org/10.1016/j.pec.2013.05.009.

30 O'Connor AM. *User Manual – Decisional Conflict Scale.* OHRI. 1993 (modified 2010);1:1-16.

31 O'Connor AM. *User Manual – Decision Regret Scale.* Ottawa, Ottawa Hospital Research Institute; 1996 (modified 2003).

32 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-43.

33 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33. https://doi.org/10.1097/00005650-199603000-00003.

34 Ware JE, Kosinski MA, Keller SD. SF-12: *How to score the SF-12 Physical and Mental Health Summary Scales*. The Health Institute, New England Medical Center, Boston Massachusetts, 1995.

35 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res* 2009;18:873-80. https://doi.org/10.1007/s11136-009-9496-9.

36 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. https://doi.org/10.1007/s11136-011-9903-x.

37 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52. https://doi.org/10.1016/j.jval.2016.01.003.

38 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale.* Ottawa, Ottawa Hospital Research Institute, 1995 (modified 2010).

39 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.

40 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58. https://doi.org/10.1080/08870446.2016.1275629.

41 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol* 2006;15(4):306-20. https://doi.org/10.1002/pon.955.

42 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out* 2018;16:30. https://doi.org/10.1186/s12955-018-0850-x.

43 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11. https://doi.org/10.1016/j.jpsychores.2005.02.007.

44 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke* 2011;42(8):2276-9. https://doi.org/10.1161/STROKEAHA.111.613273.

45 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB. Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil* 2012;34(6): 478-85. https://doi.org/10.3109/09638288.2011.608148.

46 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8. https://doi.org/10.1093/geronj/38.3.344.

47 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6. https://doi.org/10.1007/s11606-008-0520-5.

48 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10. https://doi.org/10.1093/intqhc/mzu060.

49 Berkowitz J, Martinez-Camblor P, Stevens G, Elwyn G. The development of incorpoRATE: a measure of physicians' willingness to incorporate shared decision making into practice. *Patient Educ Couns* 2021; Feb 25:S0738-3991(21)00140-3. https://doi.org/10.1016/j.pec.2021.02.040.

50 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke besluitvorming.* Utrecht: Nivel, 2021.

51 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of correlation structures. *Stat Med* 2010;29(17):1825-38. https://doi.org/10.1002/sim.3928.

Figure legend

- **Figure 1:** How to use outcome data in the four-step conversational SDM model. *PROMs = patient-reported outcome measures.*

- **Figure 2:** Time schedule of the multiple interrupted time series. *White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.*
- **Figure 3:** Participant timeline. *HCPs; health care professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.*

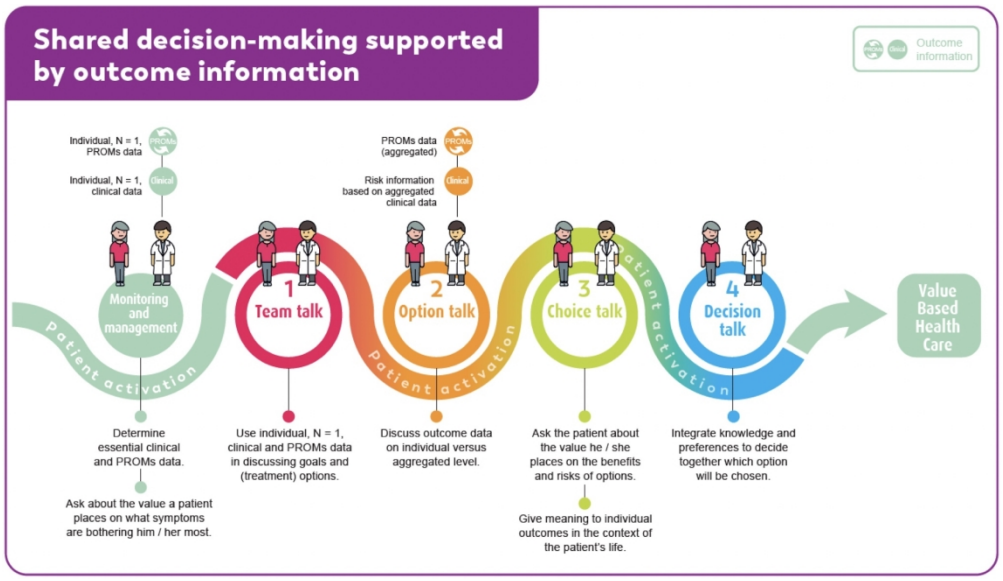


Figure 1: How to use outcome data in the four-step conversational SDM model. / PROMs = patient-reported outcome measures.

361x207mm (300 x 300 DPI)

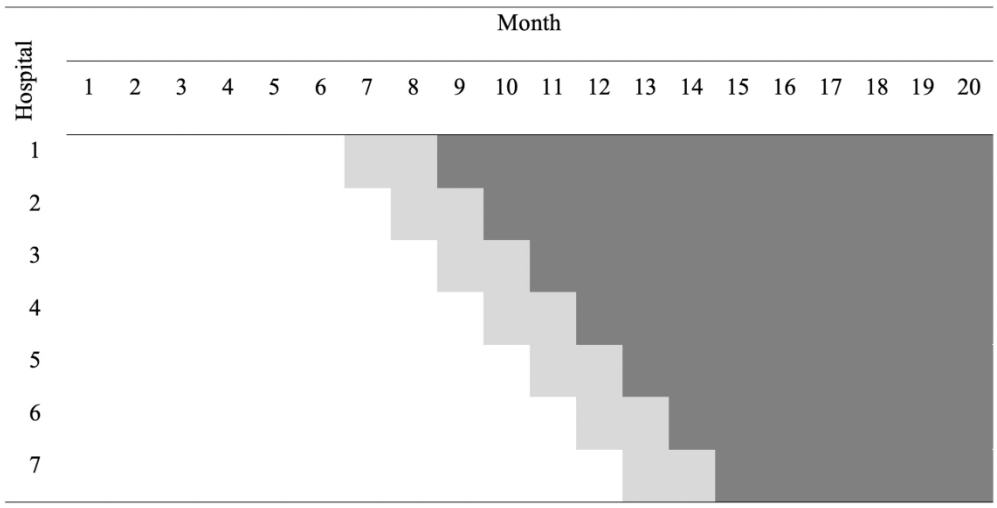


Figure 2: Time schedule of the multiple interrupted time series. / White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.

373x187mm (300 x 300 DPI)

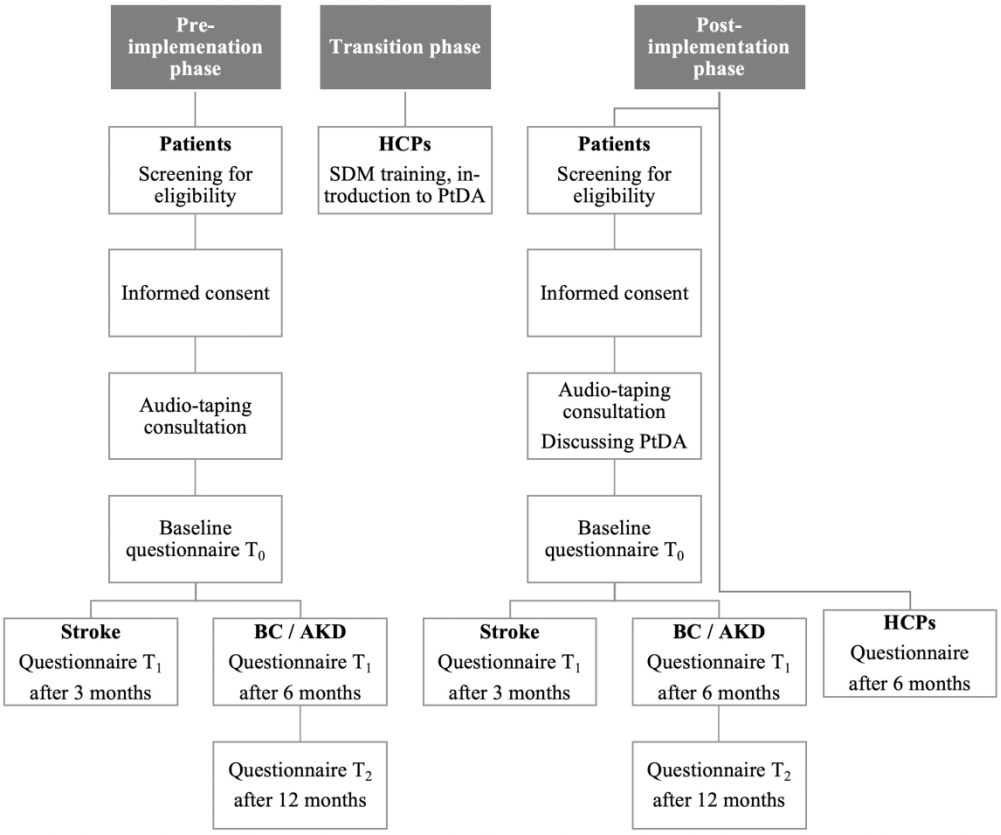


Figure 3: Participant timeline. / HCPs; healthcare professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.

423x352mm (300 x 300 DPI)

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

APPENDIX A

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, 19
	5b	Name and contact information for the trial sponsor	18
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3 – 4

	6b	Explanation for choice of comparators	9
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5 – 6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6 – 8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10 – 15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	15 – 16
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8, 14 – 15
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8 – 9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8 – 9
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16 – 17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	18
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17 – 18
	31b	Authorship eligibility guidelines and any intended use of professional writers	19
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

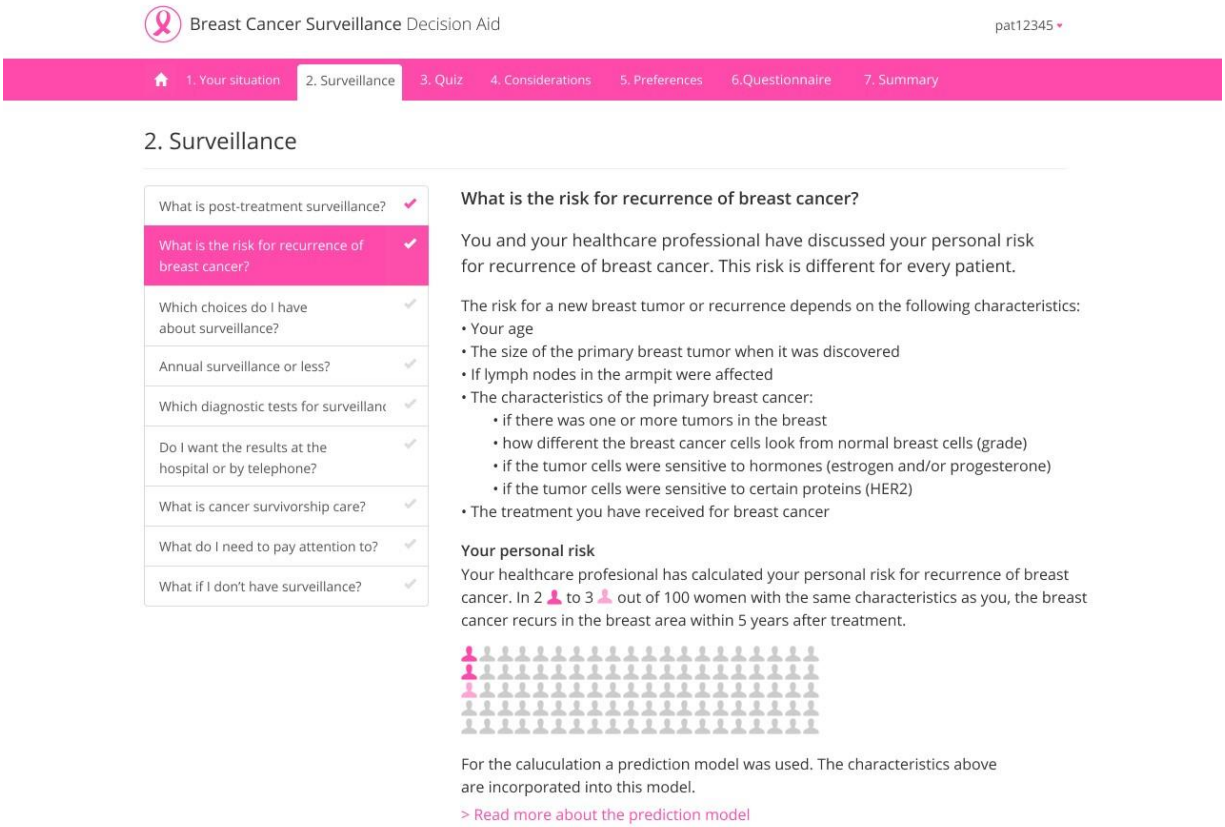
*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

APPENDIX B

Breast cancer patient decision aid

Component 1: consultation sheet

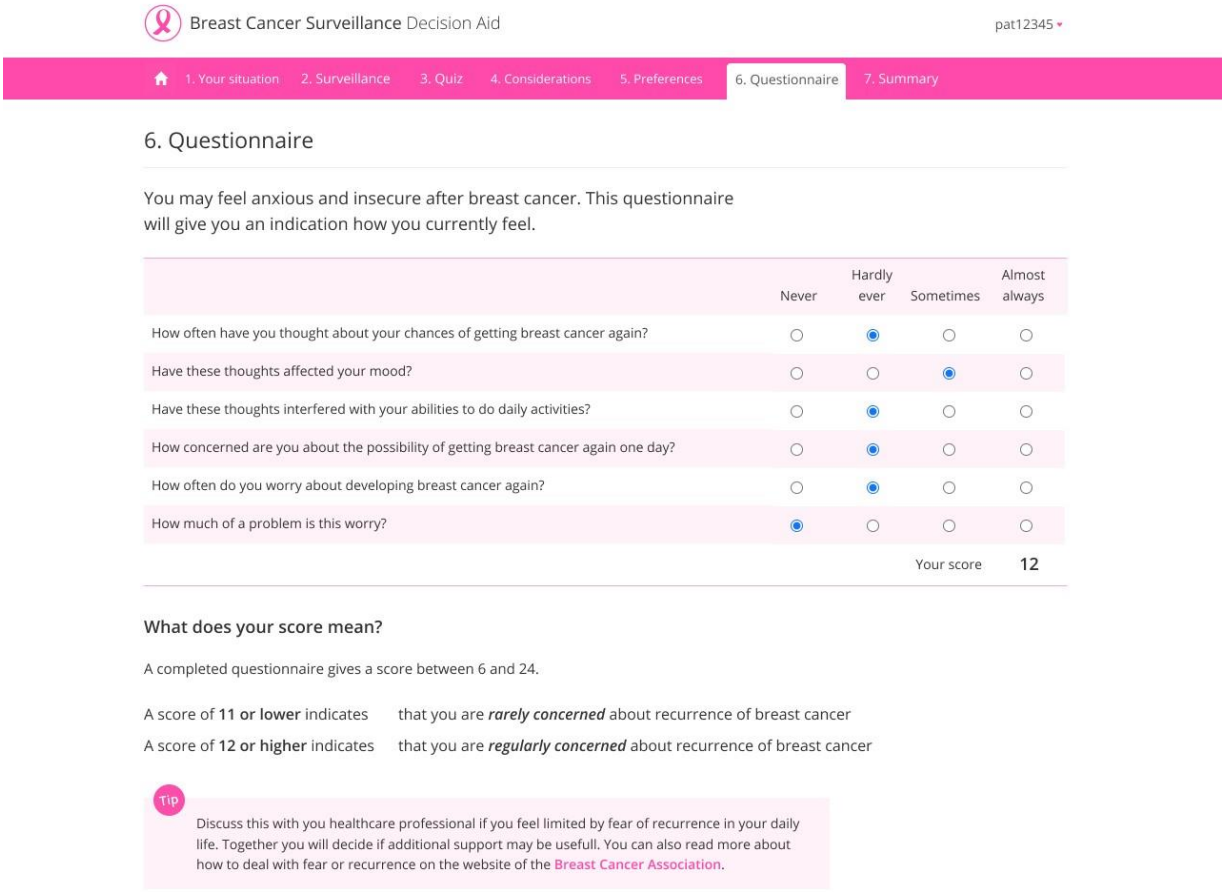
The consultation sheet (printed or digital) contains a visualization of a risk estimation of the personalized risk for breast cancer recurrence (local regional recurrences and secondary primary breast tumors), combined with a display of available options for post-treatment surveillance (e.g. frequency, imaging and duration). The personalized risk is estimated based on individual patient, tumor, and treatment characteristics, using the web-based INFLUENCE-nomogram. The nomogram was validated based on a large set of outcome data from the Netherlands Cancer Registry and shows a good predictive ability in the Dutch population.[12]



Component 2: online interactive PtDA

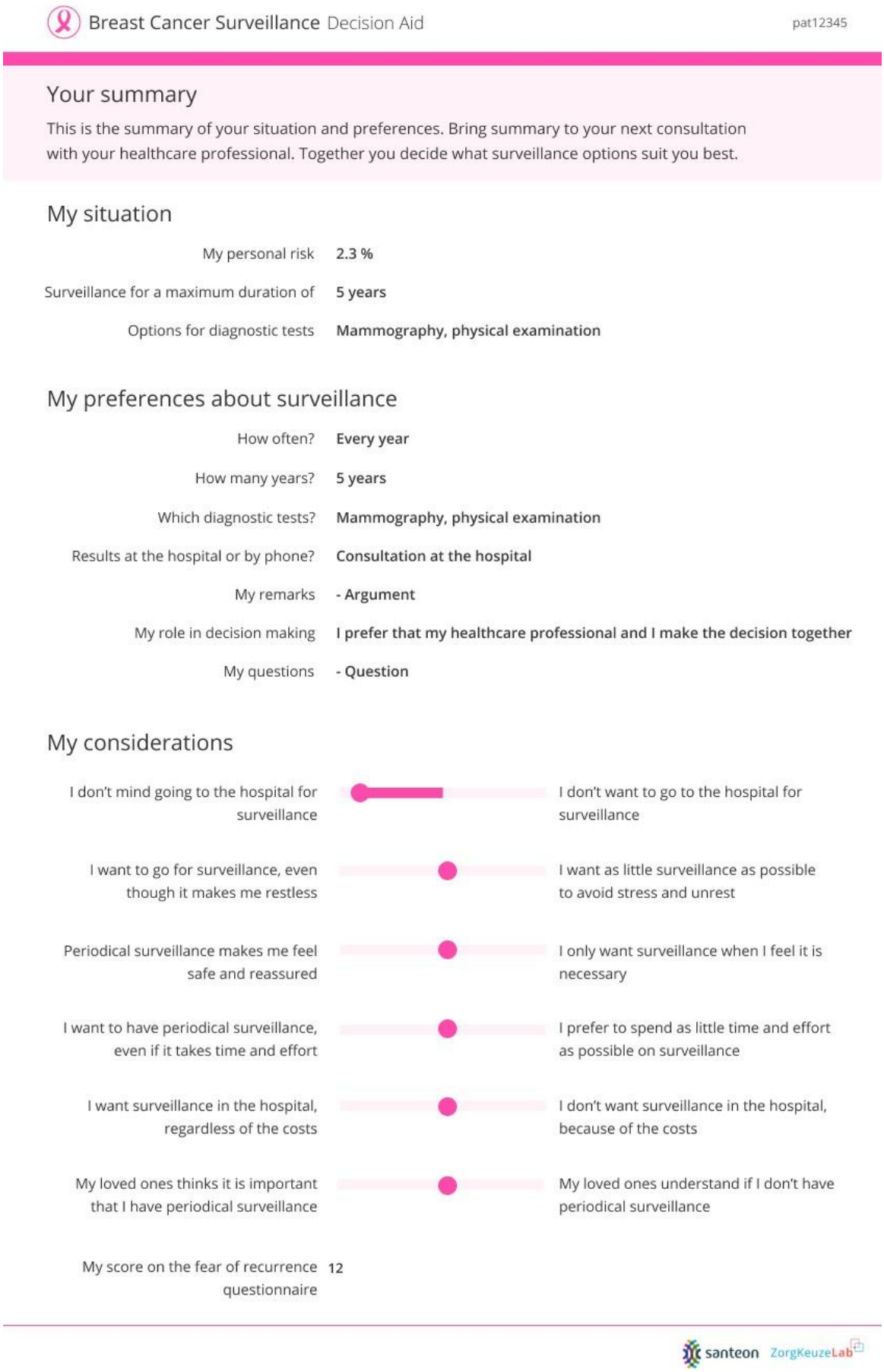
The online interactive PtDA contains information about SDM, post-treatment surveillance, available options and a clarification of the risk estimation. Interactive elements include a knowledge quiz, and value-clarification exercises. As part of using the PtDA, patients are asked to complete a patient-reported

outcome on fear of recurrence.[49] Data is processed in real-time and linked to tailored feedback on individual outcomes including comprehensive self-care advice (tips and tools).



Component 3: summary sheet

A summary sheet (printed or digital), to be used in the clinical consultation, containing women's preferences, personal considerations, and the individual outcomes on fear of recurrence.



Breast Cancer Surveillance Decision Aid

pat12345

Your summary

This is the summary of your situation and preferences. Bring summary to your next consultation with your healthcare professional. Together you decide what surveillance options suit you best.

My situation

My personal risk	**2.3 %**
Surveillance for a maximum duration of	**5 years**
Options for diagnostic tests	**Mammography, physical examination**

My preferences about surveillance

How often?	**Every year**
How many years?	**5 years**
Which diagnostic tests?	**Mammography, physical examination**
Results at the hospital or by phone?	**Consultation at the hospital**
My remarks	**- Argument**
My role in decision making	**I prefer that my healthcare professional and I make the decision together**
My questions	**- Question**

My considerations

I don't mind going to the hospital for surveillance		I don't want to go to the hospital for surveillance
I want to go for surveillance, even though it makes me restless		I want as little surveillance as possible to avoid stress and unrest
Periodical surveillance makes me feel safe and reassured		I only want surveillance when I feel it is necessary
I want to have periodical surveillance, even if it takes time and effort		I prefer to spend as little time and effort as possible on surveillance
I want surveillance in the hospital, regardless of the costs		I don't want surveillance in the hospital, because of the costs
My loved ones thinks it is important that I have periodical surveillance		My loved ones understand if I don't have periodical surveillance

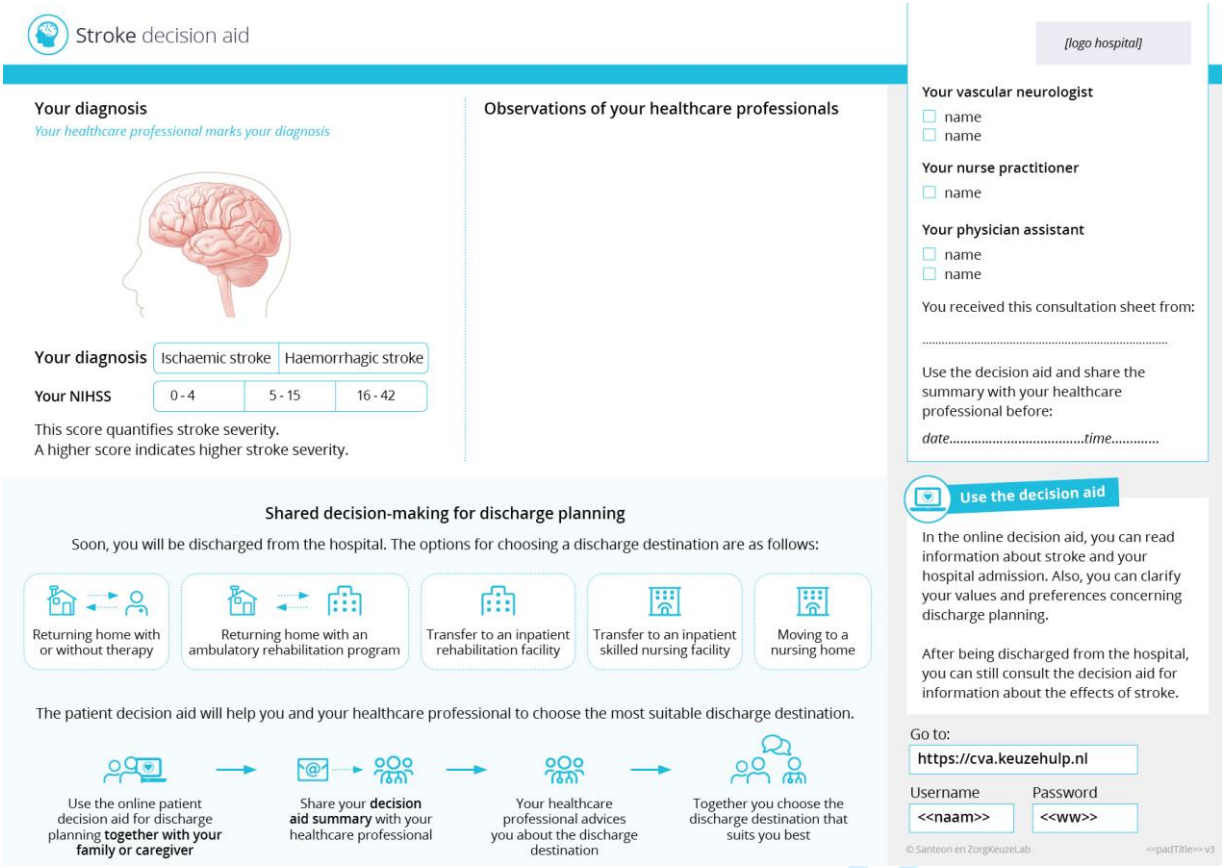
My score on the fear of recurrence questionnaire 12

santeon ZorgKeuzeLab

Stroke patient decision aid

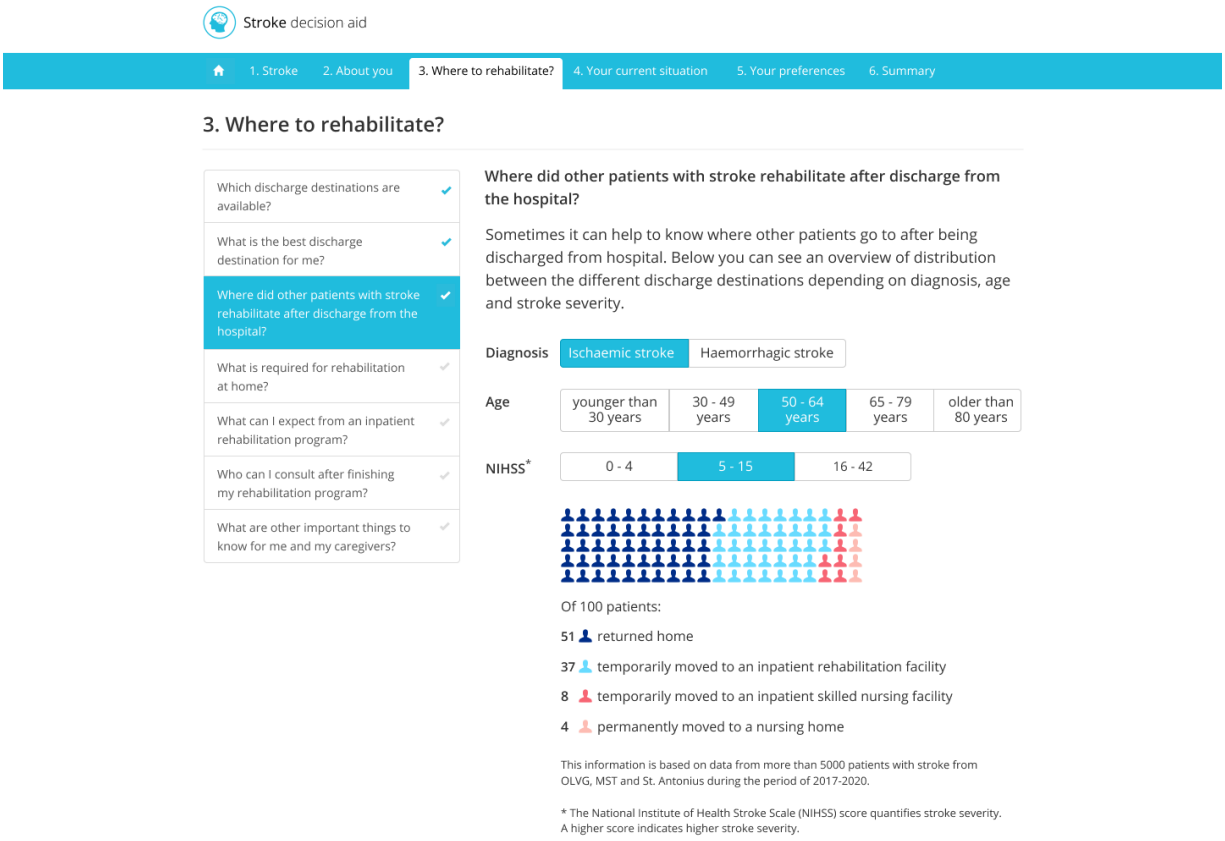
Component 1: consultation sheet

The consultation sheet contains basic information about the diagnosis (i.e. a visual representation of the brain to use as a topic starter on stroke and associated consequences), the type of stroke (i.e. ischemic or hemorrhagic), the individual stroke severity score as measured by the National Institutes of Health Stroke Scale (NIHSS), and options eligible for discharge locations.



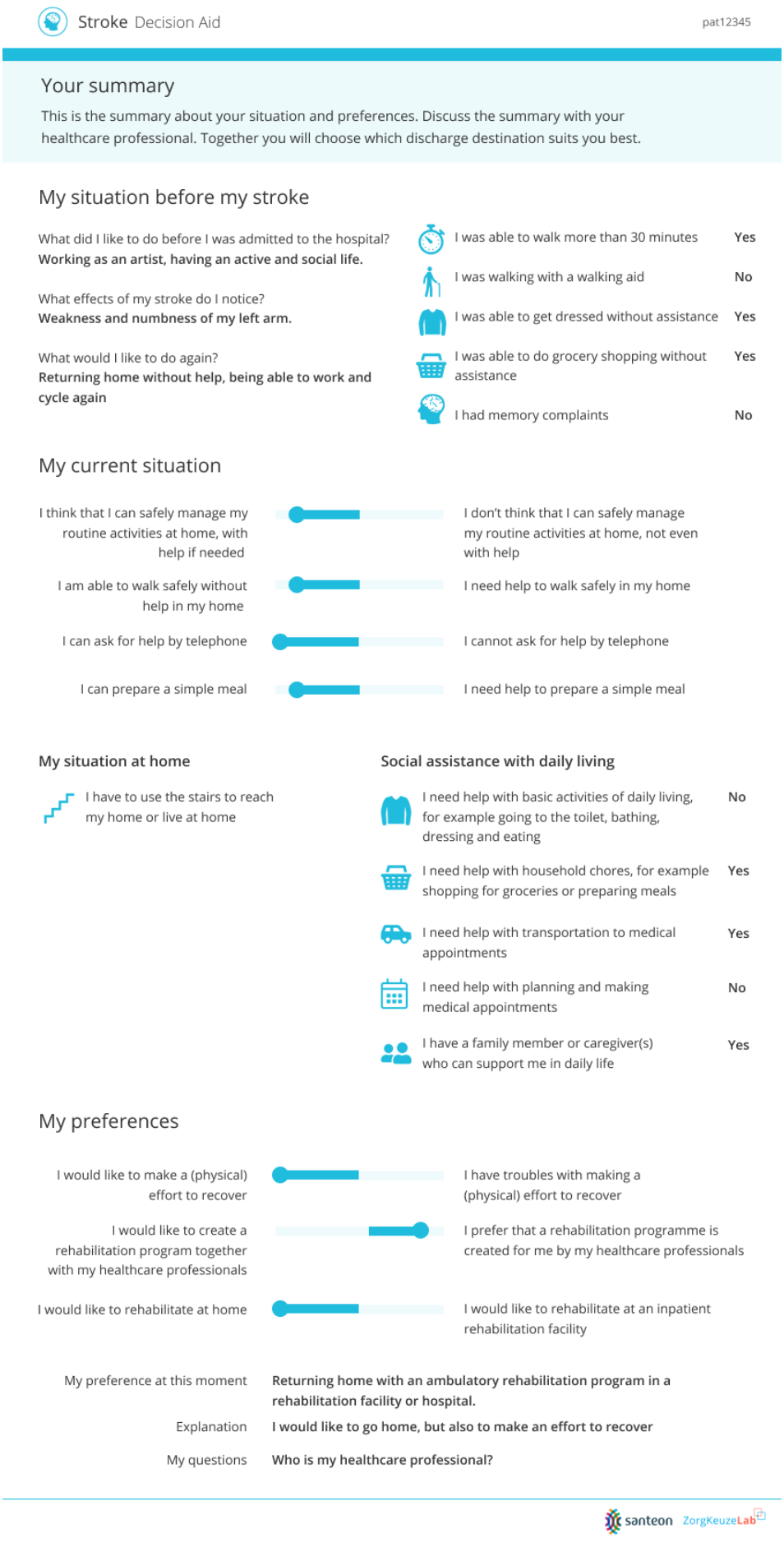
Component 2: online interactive PtDA

The online interactive PtDA contains information about the etiology and impact of stroke, prognosis and discharge planning. As part of the PtDA, patients are asked to complete PROM questionnaires on their physical and mental condition and to elaborate on their situation prior to admission to the hospital, as well as to indicate personal treatment goals. Also, the process of SDM is explained and value clarification exercises are included. The PtDA contains an interactive "patients-like-me" model: patients can enter their type of stroke, stroke severity and age in the model, which then shows the discharge location of comparable patients based on historical Santeon data (N > 4000).



Component 3: summary sheet

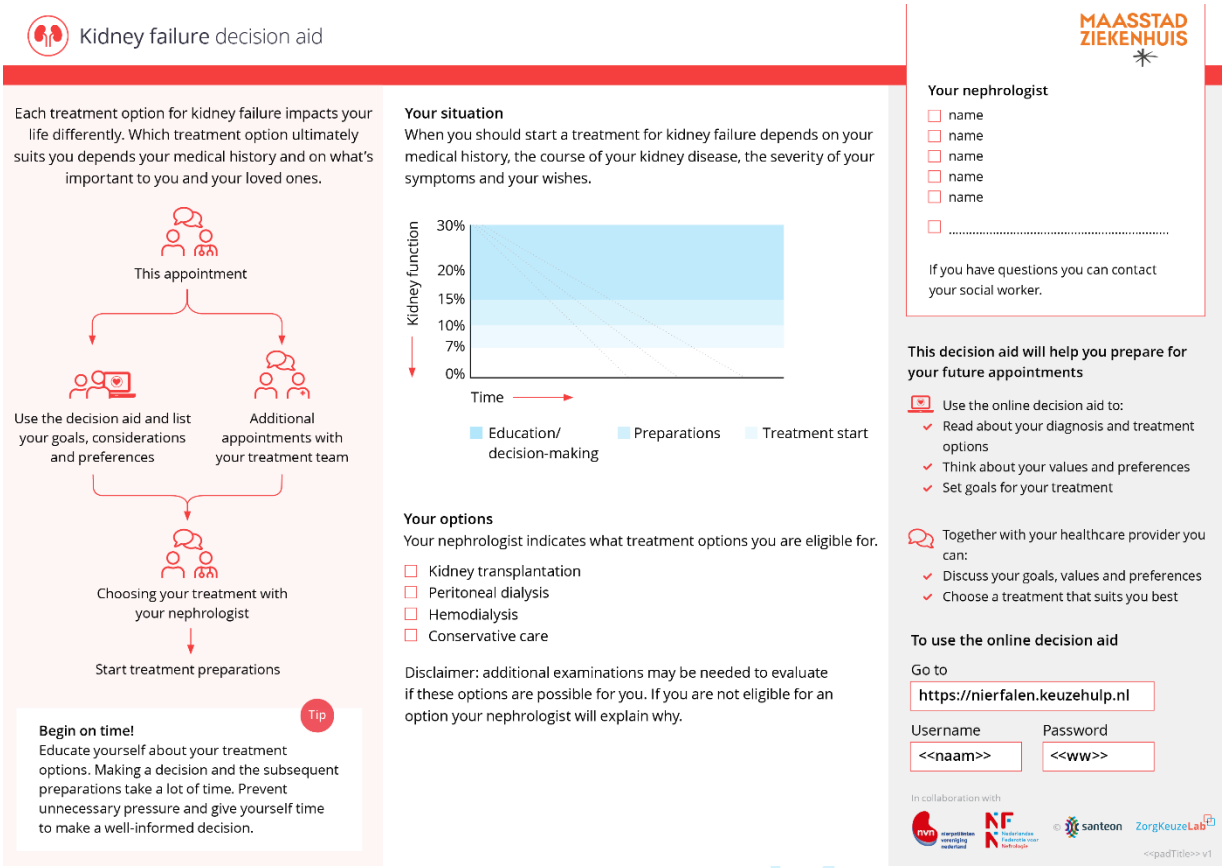
A digital summary sheet containing patients' values, preferences concerning discharge planning, and individual PROM scores to be used in the doctor-patient consultation.


Stroke Decision Aid
pat12345
Your summary
This is the summary about your situation and preferences. Discuss the summary with your healthcare professional. Together you will choose which discharge destination suits you best.
My situation before my stroke
What did I like to do before I was admitted to the hospital?
Working as an artist, having an active and social life.
What effects of my stroke do I notice?
Weakness and numbness of my left arm.
What would I like to do again?
Returning home without help, being able to work and cycle again
I was able to walk more than 30 minutes Yes
I was walking with a walking aid No
I was able to get dressed without assistance Yes
I was able to do grocery shopping without assistance Yes
I had memory complaints No
My current situation
I think that I can safely manage my routine activities at home, with help if needed
I don't think that I can safely manage my routine activities at home, not even with help
I am able to walk safely without help in my home
I need help to walk safely in my home
I can ask for help by telephone
I cannot ask for help by telephone
I can prepare a simple meal
I need help to prepare a simple meal
My situation at home
I have to use the stairs to reach my home or live at home
Social assistance with daily living
I need help with basic activities of daily living, for example going to the toilet, bathing, dressing and eating No
I need help with household chores, for example shopping for groceries or preparing meals Yes
I need help with transportation to medical appointments Yes
I need help with planning and making medical appointments No
I have a family member or caregiver(s) who can support me in daily life Yes
My preferences
I would like to make a (physical) effort to recover
I have troubles with making a (physical) effort to recover
I would like to create a rehabilitation program together with my healthcare professionals
I prefer that a rehabilitation programme is created for me by my healthcare professionals
I would like to rehabilitate at home
I would like to rehabilitate at an inpatient rehabilitation facility
My preference at this moment
Returning home with an ambulatory rehabilitation program in a rehabilitation facility or hospital.
Explanation
I would like to go home, but also to make an effort to recover
My questions
Who is my healthcare professional?
santeon ZorgKeuzeLab

Advanced kidney disease patient decision aid

Component 1: consultation sheet

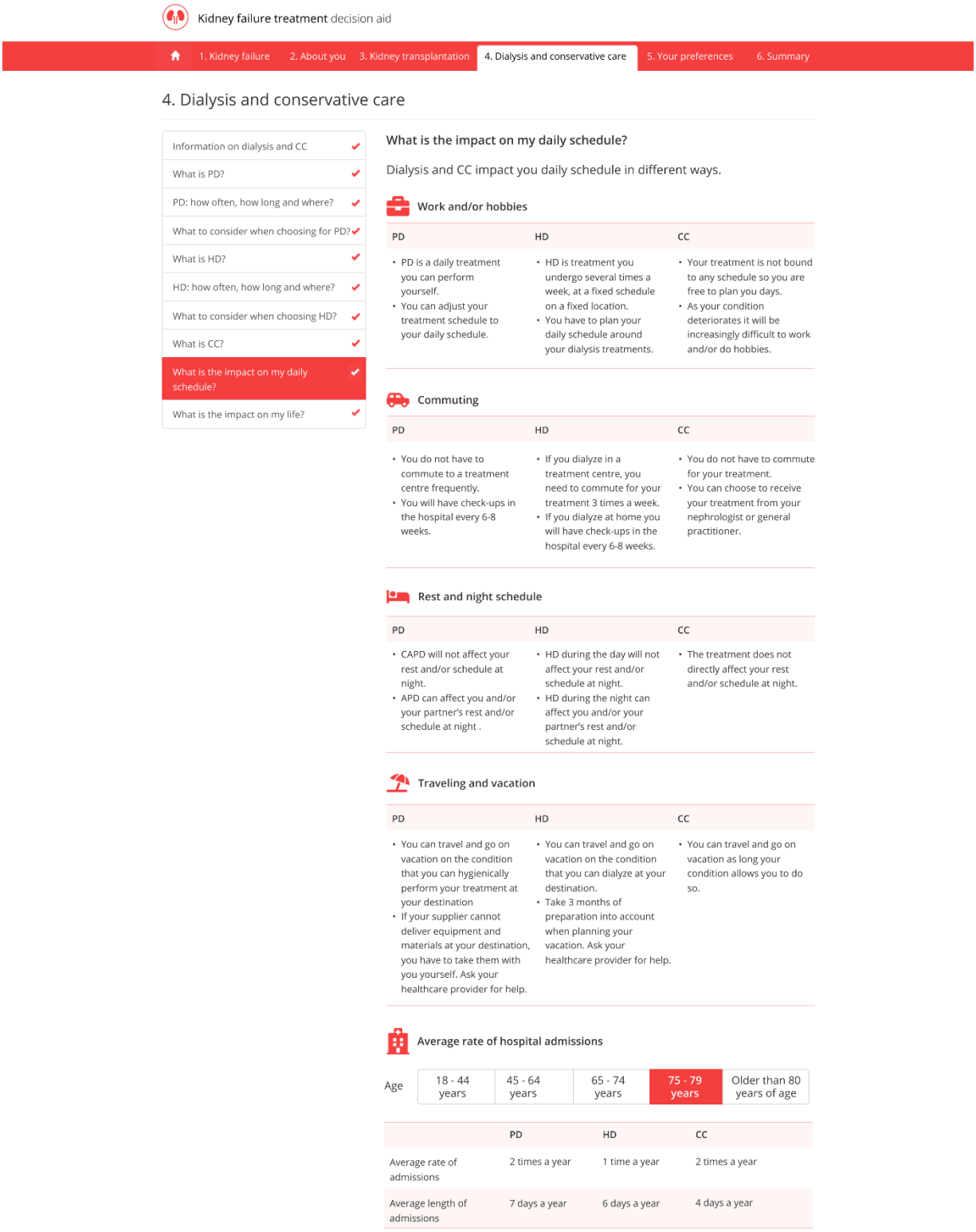
The consultation sheet (printed or digital) contains a flowchart of the kidney failure care path, a graph that healthcare professionals can use to draw the patient's individual eGFR decline, and a table that healthcare professionals can use to mark eligible treatment modalities.



Component 2: online interactive PtDA

The online interactive PtDA contains information on SDM, kidney failure and treatment modalities (hemodialysis, peritoneal dialysis, kidney-transplantation and comprehensive conservative care). Written information is supplemented with videos of patients' experiences. As part of the PtDA, patients are asked to complete PROMs questionnaires on their physical condition and on whether they consider life as completed. Additionally, patients are asked to complete value-clarification exercises regarding kidney transplantation (when applicable), dialysis and conservative care management. The PtDA contains an interactive "patients-like-me" model: patients can enter their age in the model, which then

shows the median survival- and mean hospitalization rates per treatment modality based on both Santeon and national data.



Component 3: summary sheet

A printed or digital summary sheet to be used in a clinical consultation, containing patients' values, preferences concerning discharge planning, and individual PROM scores.

Kidney Failure treatment Decision Aid

pat12345

Your summary

This is the summary of your situation and preferences. You can use this summary at your next appointment to help you and your doctor make a treatment decision that suits you best.

About me

What do I enjoy doing in my daily life?
I enjoy working at my garage with my two sons and nephew. I would give anything to keep working for a couple of more years so one of them can mature and take over my responsibilities.

Who plays an important role in making this decision?
My wife and I are real team players. She's my personal consultant.

Can you continuously walk for 30 minutes or more? **Yes**

Can you dress yourself? **Yes**

Do you do groceries by yourself? **No**

What symptoms are currently bothering you the most?
The nausea and breathlessness.

Tell us what you think

There are things I still want to do with my life — I feel fulfilled with my life

I want a treatment that primarily focuses on extending my life — I want a treatment that primarily focuses on my quality of my life

Kidney transplantation

Do you have moral objections to receiving a kidney from a living donor?
No

Did you talk about living donation kidney transplantation with anyone you know?
I talked about it with my wife, but I don't want to put this burden on my kids.

Has anyone offered to donate you a kidney?
[Not yet]

Do you have any questions or comments about kidney donation?
Am I also eligible for a kidney from a deceased donor?

Dialysis at home or in a hospital?

At home — In a hospital

I don't mind doing dialysis at home — I don't want to feel like a patient at home

I don't want to be in the hospital on a weekly basis — I don't mind being in the hospital on a weekly basis

I want to be flexible and plan my dialysis according to schedule — I don't mind being in the hospital according to a fixed schedule

I feel confident that I can perform dialysis on my own at home — I would rather have a healthcare professionals help me with my dialysis

Comments: **I would prefer doing PD treatment at home**

Dialysis during the day or night?

During the day — During the night

I want to sleep without having to deal with my dialysis — I accept that the quality of my sleep may worsen due to my dialysis

I can free time during the day to make time for my dialysis — I want to remain flexible during the day

Comments: **I would prefer doing my PD at night so I can freely manage my garage during the day!**

My preference

My preference at this moment: **Kidney transplantation from a deceased donor or APD**

What goals do I want to achieve with this treatment? **Extending my life while remaining flexible. I want to spend my golden years with my wife after making my sons owners of my garage. They still have a lot to learn though!**

What do I absolutely not want? **CC**

My questions: **no additional questions**

santeon ZorgKeuzeLab