

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-055324
Article Type:	Protocol
Date Submitted by the Author:	30-Jul-2021
Complete List of Authors:	<p>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</p>
Keywords:	Stroke < NEUROLOGY, Chronic renal failure < NEPHROLOGY, Breast surgery < SURGERY, MEDICAL EDUCATION & TRAINING

SCHOLARONE™
Manuscripts

1
2
3 **Effectiveness and implementation of SHared decision-making supported by OUTcome**
4
5 **information among patients with breast cancer, stroke and advanced kidney disease:**
6
7 **SHOUT study protocol of multiple Interrupted Time Series**
8
9

10
11
12 Mariska QN Hackert^{#1}, Jet W Ankersmid^{*1,2}, Noel Engels^{*1,3}, Janine CM Prick^{*1,4}, Steven Teerenstra⁵,
13
14 Sabine Siesling^{2,6}, Constance HC Drossaert⁷, Luc JA Strobbe⁸, Yvonne EA van Riet⁹, René MA van
15
16 den Dorpel³, Willem Jan W Bos^{10,11}, Paul B van der Nat^{12,13}, Renske M van den Berg-Vos^{4,14}, Sander M
17
18 van Schaik⁴, Mirjam M Garvelink¹², Philip J van der Wees^{13,15}, Cornelia F van Uden-Kraan¹
19

20 *On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group*
21

22
23
24
25 **Contributed equally*
26

27
28
29 *#Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the*
30
31 *Netherlands. E-mail: m.hackert@santeon.nl*
32

- 33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
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

1
2
3 **Date** 08-07-2021, **Version** 1.0
4
5

6
7 **ABSTRACT**
8

9 **Introduction** Within the value-based healthcare framework, outcome data can be used to inform patients
10 about (treatment) options, and empower them to make shared decisions with their healthcare
11 professional. To facilitate shared decision-making (SDM) supported by outcome data, a multicomponent
12 intervention has been designed, including patient decision aids on the organization of post-treatment
13 surveillance (breast cancer); discharge location (stroke) and treatment modality (advanced kidney
14 disease), and training on SDM for healthcare professionals. The SHared decision-making supported by
15 OUTcome information (SHOUT) study will examine the effectiveness of the intervention and its
16 implementation in clinical practice.
17
18
19
20
21
22
23
24
25

26 **Methods and analysis** Multiple interrupted time series will be used to stepwise implement the
27 intervention. Patients diagnosed with either breast cancer (N = 630), stroke (N = 630) or advanced kidney
28 disease (N = 473) will be included. Measurements will be performed at baseline, 3 (stroke), 6 and 12
29 (breast cancer and advanced kidney disease) months. Trends on outcomes will be measured over a period
30 of 20 months. The primary outcome will be patients' perceived level of involvement in decision-making.
31 Secondary outcomes regarding effectiveness will include patient-reported SDM, decisional conflict, role
32 in decision-making, knowledge, quality of life, preferred and chosen care, satisfaction with the
33 intervention, healthcare utilization and health outcomes. Outcomes regarding implementation will
34 include the implementation rate and a questionnaire on the healthcare professionals' perspective on the
35 implementation process.
36
37
38
39
40
41
42
43
44
45
46

47 **Ethics and dissemination** The Medical research Ethics Committees United in Nieuwegein, the
48 Netherlands, has confirmed that the Medical Research Involving Human Subjects Act does not apply to
49 this study. Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study. The results
50 will contribute to insight in and knowledge on the use of outcome data for SDM, and can stimulate
51 sustainable implementation of SDM.
52
53
54
55
56

57 **Registration** Netherlands Trial Register NL8374, NL8375 and NL8376, registration date: February 12th
58 2020.
59
60

1
2
3 **Keywords** Value-based healthcare, personalized outcome data, clinical outcome data, patient-reported
4
5 outcomes, patient decision aid, shared decision-making, breast cancer, stroke, advanced kidney disease
6
7

8
9 **Strengths and limitations of this study**
10

- 11
12 • Multiple interrupted time series are arguably the strongest quasi-experimental design as
13 randomization is not feasible.
14
15 • All hospitals will implement and therefore benefit from the multicomponent intervention, facilitating
16 shared decision-making supported by personalized outcome data.
17
18 • Multiple components are needed for the intervention to be effective; however, it does not allow for
19 an individual evaluation of each component.
20
21 • By using stepwise implementation and the value-based healthcare organization structure, the
22 hospitals can learn from each other.
23
24 • It allows the multicomponent intervention to be further refined and tested over time.
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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.

1
2
3 This process of value clarification can be fostered by being informed on outcome data of previous
4 patients. In *step 4*, the healthcare professional and the patient together integrate outcome data and
5 preferences to make a shared decision.
6
7

8
9 Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower
10 this threshold, we developed a multicomponent intervention for three patient groups with an oncological
11 (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It
12 consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as
13 training for healthcare professionals and an accompanying implementation strategy. So far, little is
14 known about the impact of using outcome data for SDM.[9, 10]
15
16

17
18 The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess
19 the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to
20 evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight
21 in and knowledge on the use of personalized outcome data for SDM, and can stimulate sustainable
22 implementation of SDM in clinical practice.
23
24
25
26
27
28
29
30
31
32

33 34 **METHODS AND ANALYSIS**

35
36 We used multiple interrupted time series (mITS) [13] to compare the intervention with standard care.
37
38 We followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
39 checklist (see Appendix A).[14,15] mITS will allow for initial testing and refinement of the intervention.
40
41 In participating hospitals, trends on outcomes will be established through a continuous sequence of
42 observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2).
43
44 Trends in the pre-implementation phase will be ‘interrupted’ at planned timepoints by the stepwise
45 implementation of the intervention in each hospital. Direct effects (level change) will be examined, as
46 well as gradual changes over time (slope change).
47
48
49
50
51
52

53 <<INSERT Figure 2>>
54
55
56
57
58
59
60

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
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Reduced consciousness 	<ul style="list-style-type: none"> • 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

1
2
3 to weigh their options. Once patients have completed the PtDA, a summary sheet will automatically be
4 created, containing an overview of the patient's preferences and considerations as a base for final
5 decision-making in a consultation with their healthcare professional (*component 3*).
6
7

8 9 *Breast cancer patient decision aid*

10
11 The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving
12 curative treatment for invasive non-metastasized breast cancer. The PtDA includes the risk for
13 locoregional recurrences estimated using the INFLUENCE nomogram [12] and a patient-reported
14 outcome measures (PROMs) questionnaire on fear of recurrence / cancer worries (translation of the
15 PtDAs in all patient groups was obtained for publication; see Appendix B).
16
17

18 19 *Stroke patient decision aid*

20
21 The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The
22 PtDA includes an interactive “patients-like-me” model on the discharge location of comparable patients
23 based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-
24 being (see Appendix B).
25
26

27 28 *Advanced kidney disease patient decision aid*

29
30 The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive
31 “patients-like-me” model on median survival- and mean hospitalization rates per treatment modality
32 based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see
33 Appendix B).
34
35

36 37 *Training of healthcare professionals*

38
39 Healthcare professionals will be asked to complete an e-learning on applying (personalized) outcome
40 data to support SDM. Consequently, they will be asked to participate in a group training of one daypart.
41 The training includes the theoretical background on SDM, reflection on audio-taped consultations, cases
42 introduced by participants, and practicing SDM consultation skills with an actor. Upon completing the
43 training, follow-up will be offered after one day (by offering a plasticized card or poster containing short
44 written instructions on SDM, and by presenting a publication on using outcome data to support SDM),
45 after one month (by offering tips, tricks, a testimonial by a colleague healthcare professional and an
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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

1
2
3 each hospital will act as its own historical control group and the hospitals will not switch at the same
4
5 time.

6
7 Patients will be asked by their healthcare professional to participate in this study: 1) patients with breast
8
9 cancer will be informed and asked to participate during the follow-up consultation on the occasion of
10
11 their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke
12
13 will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision
14
15 has to be made about renal replacement therapy or conservative care. When interested, patients will
16
17 receive a patient information letter about the study. They will be asked for written informed consent.
18
19 Patients in the post-implementation phase will receive the PtDA.
20
21
22
23

24 **Data collection and methods**

25
26 To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T_0) will
27
28 be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the
29
30 hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T_1) for patients
31
32 with stroke, and after 6 (T_1) and 12 (T_2) months for patients with breast cancer or AKD. Second, the
33
34 consultations, in which the options are being discussed, will be audio-taped to assess patients'
35
36 involvement in the decision-making process from observers' viewpoint. Also, the length of the
37
38 consultations will be determined. Third, to assess the extent to which the intervention leads to changes
39
40 in the utilization and outcomes of healthcare, information will be retrieved from patients' electronic
41
42 health records. To evaluate the implementation, first, the estimated total number of eligible patients and
43
44 the total number of patients who received the PtDA will be determined. Second, participating healthcare
45
46 professionals will receive a questionnaire 6 months after start of the post implementation phase, to assess
47
48 their perspective on the implementation process.
49
50
51
52

53 **Participant timeline**

54
55 The participant timeline is displayed in Figure 3.

56
57 <<INSERT Figure 3>>
58
59
60

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

1
2
3 of life, measured with the 12-item Short Form Health Survey (SF-12) for patients with breast cancer and
4 AKD, and measured with the Patient Reported Outcomes Measurement Information System Global
5 Health (PROMIS-10), five-dimension EuroQol five-levels questionnaire (EQ-5D-5L), and EuroQol
6 Visual Analogue Scale (EQ-VAS) for patients with stroke; preferred and chosen care (and the role of the
7 consultation and outcome data therein), measured with patient group-specific items; satisfaction with the
8 intervention, measured with the Preparation for Decision Making scale (Prep-DM) and study-specific
9 questions; perceived risk and fear of recurrence for patients with breast cancer, measured with the Cancer
10 Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast cancer
11 survivors (IPQ-BCS) and patient group-specific questions; and participation / functioning and
12 caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht
13 Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see
14 Table 3, also for references).

25 26 27 *Observer-reported SDM*

28
29
30 The Observing Patient Involvement in decision-making scale (OPTION-5) [25] will be used to analyze
31 the audio-recordings of encounters from clinical settings. The OPTION-5 includes five core SDM steps,
32 to which a sixth is added to assess the role of personalized outcome data (*'the healthcare professional*
33 *informs the patient on outcomes of different treatment options'*). The item scores will be summed and
34 rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

35 36 37 *Healthcare utilization and outcomes*

38
39
40 Patients' healthcare utilization and clinical outcomes will be extracted from their electronic health
41 records. For patients with breast cancer, the number of hospital visits, the number of mammograms and
42 other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of
43 stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications
44 during admission will be extracted. For patients with AKD, the number of visits to outpatients clinics,
45 hospitals admissions and hospitalization days, and the rate of major treatment-related complications will
46 be extracted.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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
<i>All patient groups:</i>								
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								
<i>Stoke and advanced kidney disease:</i>								
• DRS [33]	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
(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)								
<i>Breast cancer:</i>								
	10 items with 3 response options.		X				X	
<i>Stroke:</i>								
	7 items with 3 – 7 response options.		X				X	
<i>Advanced kidney disease:</i>								
	7 items with 3 – 5 response options.		X				X	
Quality of life								
<i>Breast cancer and advanced kidney disease:</i>								
• SF-12 [35,36]	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
<i>Stroke:</i>								
• 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)									
<i>Breast cancer:</i>		48 items with 3 – 10 response options / open-ended.		X					X
<i>Stroke:</i>		6 items with 3 – 8 response options / open-ended.		X					X
<i>Advanced kidney disease</i>		9 items with 2 – 9 response options / open-ended.		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
<i>Breast cancer:</i>									
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
<i>Stroke:</i>									
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

1
2
3 Healthcare professionals will fill out a questionnaire based on the Measurement Instrument for
4 Determinants of Innovations (MIDI).[27] The MIDI assesses barriers and facilitators of implementation
5 at the level of innovation (PtDA), the user (healthcare professionals) and the organization (hospital).
6
7
8

9 *Physicians' willingness to incorporate shared decision-making*

10
11 Healthcare professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief
12 and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[28]
13
14
15

16
17
18 **Sample size**

19
20 The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary
21 outcome measure with the statistical significance level set at $\alpha = 0.05$ (two-sided). The size of the
22 expected effect of the intervention on the SDM-Q-9 was set to be small to moderate (Cohen's $d = 0.3$ -
23 0.4) as relatively high scores on the SDM-Q-9 are common in the Netherlands.[29] The mITS with seven
24 clusters (i.e. hospitals) had 18 measurement periods (excluding the transition phase, see Figure 2). A
25 non-large Intraclass Correlation Coefficient ($ICC = 0.05$) was assumed. The correlation between monthly
26 measurements was expected to be high ($0.7 - 0.9$) throughout a period of 18 months, although
27 correlations between months farther apart could be lower than for month closer by. A normal
28 autoregressive correlation structure turned out too conservative and a compound symmetry correlation
29 structure too optimistic for this purpose. Therefore, power calculations were primarily based on the linear
30 exponent autoregressive correlation structure [30] that sits in between both and can be characterized by
31 the correlation between subsequent months and the correlation between the first and the last month.
32
33 Correlation between months decreases by distance between months from the highest value (for
34 consecutive months) to the lowest value (for largest distance, i.e. between the first and last month). For
35 patients with breast cancer and stroke, we assumed a high correlation between two consecutive months
36 (at least $r = 0.9$) and a moderate correlation between the first and final month ($r = 0.7$). Five patients per
37 hospital per month was considered feasible, and with a 25% loss to follow-up, this results in a monthly
38 inclusion rate of four patients. This yields more than 80% power and amounts to a study population of
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
N = 504 – 630.

1
2
3 For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals.
4
5 Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting
6
7 a Cohen's $d = 0.4$ assuming a correlation between subsequent months of at least 0.8 and a correlation
8
9 between the first and last month of at least 0.6. This amounts to a study population of $N = 378 - 473$.

13 **Statistical methods**

14
15 An overview of the demographic and clinical characteristics will be provided using descriptive statistics.
16
17 Continuous data will be expressed as a mean with the standard deviation (SD), or as the median
18
19 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless
20
21 stated otherwise.
22

23
24 Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented
25
26 regression will be employed, with the period before and after the introduction of the intervention as
27
28 segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time
29
30 series to exhibit different levels and trends. Correlation between repeated measurements in each time
31
32 series will be accounted for by modelling the error structure. The effect of the intervention will be
33
34 examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using
35
36 the following model:
37

$$38 \quad Y(T) = \beta_0 + \beta_1 \cdot T + \beta_2 \cdot I + \beta_3 \cdot I \cdot t$$

39
40 where β_0 will represent the baseline level at $T = 0$, β_1 will be interpreted as the change in outcomes
41
42 associated with a time unit increase (representing the underlying trend in the pre-implementation phase),
43
44 $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, β_2 will be the level change
45
46 in the post-implementation phase and β_3 will indicate the slope change following the implementation
47
48 phase (using the interaction between time t since the intervention started and the indicator for being in
49
50 the intervention: I). A change in β_2 will constitute an immediate effect, while a change in β_3 will imply
51
52 an effect that was experienced over time (which also allows us to measure the sustainability of the
53
54 impact). Moreover, segmented regression will enable us to control for other variables, that can cause a
55
56 change in level or trend of the outcomes of interest.
57
58
59
60

1
2
3 Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage
4 of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation
5 techniques or sensitivity analyses will be used to assess their impact on the trial results.
6
7

8
9 To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-
10 specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis
11 across all patient groups and hospitals will be performed.
12
13
14
15

16 17 18 **ETHICS AND DISSEMINATION**

19
20 The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the
21 Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number
22 W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference
23 numbers METC 2019-075, -076 and -077).
24
25
26
27

28 The study will be conducted in accordance with local laws and regulations. Eligible patients will fully
29 be informed about the study and asked to participate. They will receive a patient information letter and
30 will be informed by telephone about the implications of participation. Patients will have sufficient
31 opportunity to ask questions and to consider the implications before providing written informed consent.
32
33
34

35 They will be allowed to withdraw from the study without giving a reason, at any time.
36

37
38 The SHOUT study is part of a larger Santeon program on using outcome data for SDM ('Experiment
39 Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and
40 patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals,
41 (inter)national conferences, workshops webinars, and newsletters and social media.
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

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 be 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, YEA_vR, RMA_vdD, WJWB, SM_vS, and CF_vU-K developed the multicomponent intervention. MQNH, ST, PB_vdN, PJ_vdW and CF_vU-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 interpreting the data. The present manuscript was drafted by MQNH and CF_vU-K. JWA, NE, JCMP, ST, SS, CHCD, LJAS, YEA_vR, RMA_vdD, WJWB, PB_vdN, RM_vdB-V, SM_vS, MMG and PJ_vdW 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

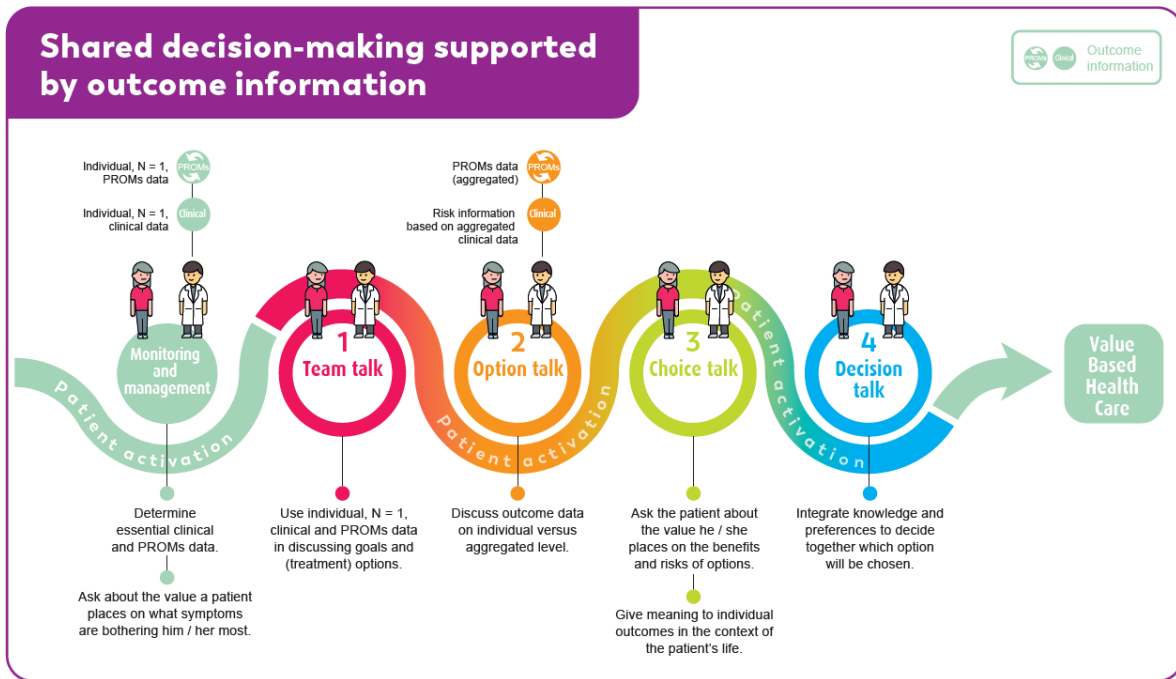
- 1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health outcomes measurement and organizational readiness support quality improvement: a systematic review. *BMC Health Serv Res* 2018;18:1005. <https://doi.org/10.1186/s12913-018-3828-9>.
- 2 Porter ME, Larsson S,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

- 1
2
3 12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of
4 breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of
5 locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36.
6
7 <https://doi.org/10.1007/s10549-015-3490-4>.
8
9
10
11 13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community
12 intervention research. *Prev Sci* 2000;1:31-49. <https://doi.org/10.1023/A:1010024016308>.
13
14
15 14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items
16 for clinical trials. *Ann Intern Med* 2013a;158:200-7. [https://doi.org/10.7326/0003-4819-158-3-](https://doi.org/10.7326/0003-4819-158-3-201302050-00583)
17
18
19
20
21 15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for
22 protocols of clinical trials. *BMJ*. 2013b;346:e7586. <https://doi.org/10.1136/bmj.e7586>.
23
24
25 16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director:
26 Gregory Katz). 2020.
27
28
29 17 Santeon. www.santeon.nl 2021; 22 June.
30
31 18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-
32 effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. <https://doi.org/10.1200/JCO.19.02035>.
33
34
35 19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's)*. 2018.
36
37 [https://www.volksgezondheinzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-](https://www.volksgezondheinzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys)
38
39
40
41
42 20 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient
43 decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710.
44
45 <https://doi.org/10.1177/0272989X13501721>.
46
47
48 21 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch
49 Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een*
50
51
52
53 22 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for
54 localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J*
55
56
57
58
59
60

- 1
2
3 23 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a
4 web-based self-management application “Oncokompas” in routine cancer care: a national pilot
5 study. *Support Care Cancer* 2019;27:2911-20. <https://doi.org/10.1007/s00520-018-4591-5>.
6
7
8
9 24 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and
10 psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared
11 Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care.
12 *PloS ONE* 2015;10(7):e0132158. <https://doi.org/10.1371/journal.pone.0132158>.
13
14
15
16
17 25 Elwyn G, Grande SW, Barr P. *Observer OPTION^s manual. Measuring shared decision making by*
18 *assessing recordings or transcripts of encounters from clinical settings*. The Dartmouth Institute for
19 Health Policy and Clinical Practice, Lebanon, USA, 2018.
20
21
22
23 26 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy
24 in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6.
25 <https://doi.org/10.1007/s11606-008-0520-5>.
26
27
28
29 27 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement
30 instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10.
31 <https://doi.org/10.1093/intqhc/mzu060>.
32
33
34
35 28 Berkowitz J, Martinez-Cambor P, Stevens G, Elwyn G. The development of incorpoRATE: a
36 measure of physicians’ willingness to incorporate shared decision making into practice. *Patient Educ*
37 *Couns* 2021; Feb 25:S0738-3991(21)00140-3. <https://doi.org/10.1016/j.pec.2021.02.040>.
38
39
40
41 29 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt*
42 *samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke*
43 *besluitvorming*. Utrecht: Nivel, 2021.
44
45
46
47 30 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of
48 correlation structures. *Stat Med* 2010;29(17):1825-38. <https://doi.org/10.1002/sim.3928>.
49
50
51
52 31 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a
53 fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient*
54 *Educ Couns* 2013;93(1):102-7. <http://doi.org/10.1016/j.pec.2013.05.009>.
55
56
57 32 O’Connor AM. *User Manual – Decisional Conflict Scale*. OHRI. 1993 (modified 2010);1:1-16.
58
59
60

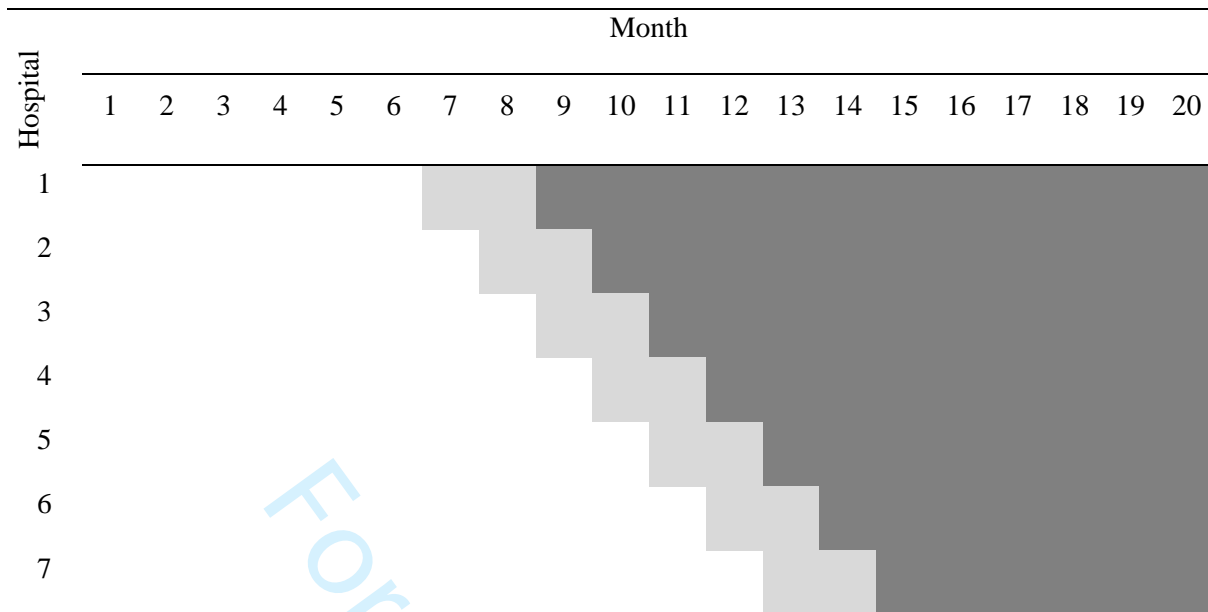
- 1
2
3 33 O'Connor AM. *User Manual – Decision Regret Scale*. Ottawa, Ottawa Hospital Research Institute;
4 1996 (modified 2003).
5
6
7 34 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-
8 43.
9
10
11 35 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and
12 preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33.
13 <https://doi.org/10.1097/00005650-199603000-00003>.
14
15
16
17 36 Ware JE, Kosinski MA, Keller SD. *SF-12: How to score the SF-12 Physical and Mental Health*
18 *Summary Scales*. The Health Institute, New England Medical Center, Boston Massachusetts, 1995.
19
20
21 37 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health
22 summary scores from the patient-reported outcomes measurement information system (PROMIS)
23 global items. *Qual Life Res* 2009;18:873-80. <https://doi.org/10.1007/s11136-009-9496-9>.
24
25
26
27 38 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level
28 version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. [https://doi.org/10.1007/s11136-](https://doi.org/10.1007/s11136-011-9903-x)
29 [011-9903-x](https://doi.org/10.1007/s11136-011-9903-x).
30
31
32
33 39 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for
34 the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52.
35 <https://doi.org/10.1016/j.jval.2016.01.003>.
36
37
38
39 40 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale*. Ottawa, Ottawa
40 Hospital Research Institute, 1995 (modified 2010).
41
42
43 41 Lerman C, Daly M, Masny A, Balshem A. Attitudes about genetic testing for breast-ovarian cancer
44 susceptibility. *J Clin Oncol* 1994;12(4):843-50. <https://doi.org/10.1200/JCO.1994.12.4.843>.
45
46
47 42 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer
48 survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness
49 Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58.
50 <https://doi.org/10.1080/08870446.2016.1275629>.
51
52
53
54
55 43 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and
56 psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol*
57 2006;15(4):306-20. <https://doi.org/10.1002/pon.955>.
58
59
60

- 1
2
3 44 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer
4 recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out*
5 2018;16:30. <https://doi.org/10.1186/s12955-018-0850-x>.
6
7
8
9 45 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric
10 properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11.
11 <https://doi.org/10.1016/j.jpsychores.2005.02.007>.
12
13
14
15 46 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke*
16 2011;42(8):2276-9. <https://doi.org/10.1161/STROKEAHA.111.613273>.
17
18
19 47 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB.
20 Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil*
21 2012;34(6): 478-85. <https://doi.org/10.3109/09638288.2011.608148>.
22
23
24
25 48 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8.
26 <https://doi.org/10.1093/geronj/38.3.344>.
27
28
29 49 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening
30 capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



PROMs, patient-reported outcome measures.

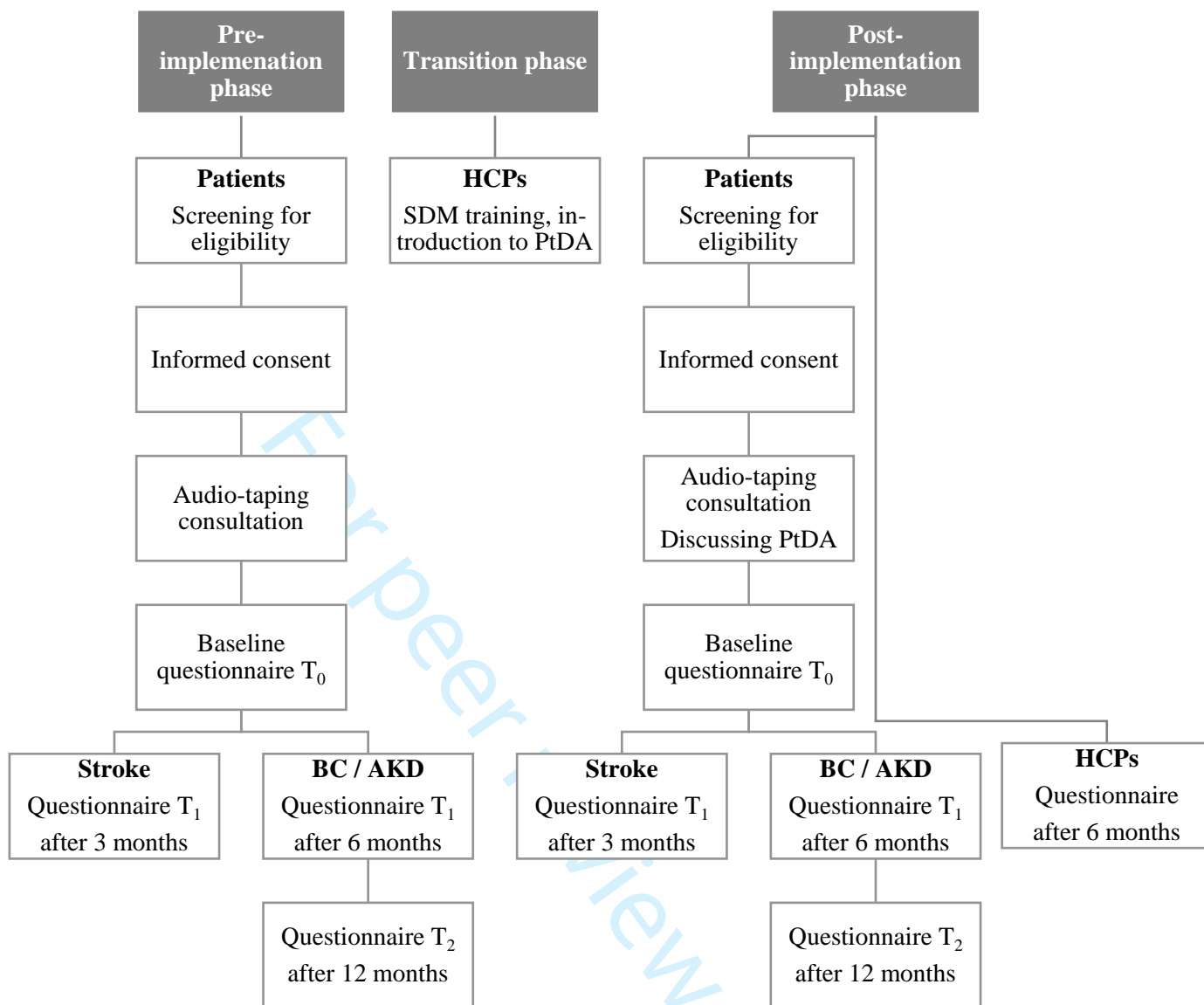
Figure 1. How to use outcome data in the four-step conversational SDM model.



*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.*

For peer review only



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

Figure 3. Participant timeline.



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

1			
2			
3			
4		6b	Explanation for choice of comparators
5			9
6	Objectives	7	Specific objectives or hypotheses
7			4
8	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)
9			4
10			
11	Methods: Participants, interventions, and outcomes		
12			
13	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
14			5
15			
16	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)
17			5 – 6
18			
19	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
20			6 – 8
21			
22		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)
23			NA
24			
25		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
26			NA
27			
28		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
29			NA
30			
31	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
32			10 – 15
33			
34			
35			
36	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)
37			9
38			
39			
40			
41			
42			
43			
44			
45			
46			

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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

1				
2				
3		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
4				
5				
6	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
7				
8				
9				
10	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
11				
12				
13				
14		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
15				
16		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
17				
18				
19	Methods: Monitoring			
20				
21	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
22				
23				
24				
25		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
26				
27				
28	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
29				
30				
31	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
32				
33				
34				
35	Ethics and dissemination			
36				
37	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
38				
39				
40				
41				
42				
43				
44				
45				
46				

1				
2				
3	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
4				
5				
6	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
7				
8				
9				
10		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
11				
12	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
13				
14				
15				
16	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
17				
18				
19	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
20				
21				
22	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
23				
24				
25	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
26				
27				
28				
29		31b	Authorship eligibility guidelines and any intended use of professional writers	19
30				
31		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
32				
33				
34	Appendices			
35				
36	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				

1
2
3 Biological specimens 33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in NA
4 the current trial and for future use in ancillary studies, if applicable
5

6 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments
7 to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs](#)
8 [3.0 Unported](#)" license.
9

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

For peer review only

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]

Breast Cancer Surveillance Decision Aid pat12345 ▾

1. Your situation 2. Surveillance 3. Quiz 4. Considerations 5. Preferences 6. Questionnaire 7. Summary

2. Surveillance

What is post-treatment surveillance?	✓
What is the risk for recurrence of breast cancer?	✓
Which choices do I have about surveillance?	✓
Annual surveillance or less?	✓
Which diagnostic tests for surveillance?	✓
Do I want the results at the hospital or by telephone?	✓
What is cancer survivorship care?	✓
What do I need to pay attention to?	✓
What if I don't have surveillance?	✓

What is the risk for recurrence of breast cancer?

You and your healthcare professional have discussed your personal risk for recurrence of breast cancer. This risk is different for every patient.

The risk for a new breast tumor or recurrence depends on the following characteristics:

- Your age
- The size of the primary breast tumor when it was discovered
- If lymph nodes in the armpit were affected
- The characteristics of the primary breast cancer:
 - if there was one or more tumors in the breast
 - how different the breast cancer cells look from normal breast cells (grade)
 - if the tumor cells were sensitive to hormones (estrogen and/or progesterone)
 - if the tumor cells were sensitive to certain proteins (HER2)
- The treatment you have received for breast cancer

Your personal risk

Your healthcare professional has calculated your personal risk for recurrence of breast cancer. In 2 to 3 out of 100 women with the same characteristics as you, the breast cancer recurs in the breast area within 5 years after treatment.

For the calculation a prediction model was used. The characteristics above are incorporated into this model.

[> Read more about the prediction model](#)

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).

Breast Cancer Surveillance Decision Aid pat12345 ▾

1. Your situation 2. Surveillance 3. Quiz 4. Considerations 5. Preferences 6. Questionnaire 7. Summary

6. Questionnaire

You may feel anxious and insecure after breast cancer. This questionnaire will give you an indication how you currently feel.

	Never	Hardly ever	Sometimes	Almost always
How often have you thought about your chances of getting breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have these thoughts affected your mood?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Have these thoughts interfered with your abilities to do daily activities?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How concerned are you about the possibility of getting breast cancer again one day?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you worry about developing breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much of a problem is this worry?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your score				12

What does your score mean?

A completed questionnaire gives a score between 6 and 24.

A score of 11 or lower indicates that you are *rarely concerned* about recurrence of breast cancer

A score of 12 or higher indicates that you are *regularly concerned* about recurrence of breast cancer

Tip Discuss this with you healthcare professional if you feel limited by fear of recurrence in your daily life. Together you will decide if additional support may be usefull. You can also read more about how to deal with fear or recurrence on the website of the [Breast Cancer Association](#).

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.

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 think 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	

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.

Your diagnosis
Your healthcare professional marks your diagnosis

Your diagnosis Ischaemic stroke Haemorrhagic stroke

Your NIHSS 0 - 4 5 - 15 16 - 42

This score quantifies stroke severity.
A higher score indicates higher stroke severity.

Observations of your healthcare professionals

Use the decision aid

In the online decision aid, you can read information about stroke and your hospital admission. Also, you can clarify your values and preferences concerning discharge planning.

After being discharged from the hospital, you can still consult the decision aid for information about the effects of stroke.

Go to:

Username Password

© Santeon en ZorgKeuzelab <<paidTitle>> v3

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).



1. Stroke 2. About you 3. Where to rehabilitate? 4. Your current situation 5. Your preferences 6. Summary

3. Where to rehabilitate?

Which discharge destinations are available? ✓

What is the best discharge destination for me? ✓

Where did other patients with stroke rehabilitate after discharge from the hospital? ✓

What is required for rehabilitation at home? ✓

What can I expect from an inpatient rehabilitation program? ✓

Who can I consult after finishing my rehabilitation program? ✓

What are other important things to know for me and my caregivers? ✓

Where did other patients with stroke rehabilitate after discharge from the hospital?

Sometimes it can help to know where other patients go to after being discharged from hospital. Below you can see an overview of distribution between the different discharge destinations depending on diagnosis, age and stroke severity.

Diagnosis **Ischaemic stroke** Haemorrhagic stroke

Age younger than 30 years 30 - 49 years 50 - 64 years 65 - 79 years older than 80 years

NIHSS* 0 - 4 5 - 15 16 - 42



Of 100 patients:

- 51 returned home
- 37 temporarily moved to an inpatient rehabilitation facility
- 8 temporarily moved to an inpatient skilled nursing facility
- 4 permanently moved to a nursing home

This information is based on data from more than 5000 patients with stroke from OLVG, MST and St. Antonius during the period of 2017-2020.

* The National Institute of Health Stroke Scale (NIHSS) score quantifies stroke severity. A higher score indicates higher stroke severity.

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.





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.		I was able to walk more than 30 minutes	Yes
What effects of my stroke do I notice? Weakness and numbness of my left arm.		I was walking with a walking aid	No
What would I like to do again? Returning home without help, being able to work and cycle again		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?**

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.

Kidney failure decision aid

Each treatment option for kidney failure impacts your life differently. Which treatment option ultimately suits you depends on your medical history and on what's important to you and your loved ones.

Your situation
When you should start a treatment for kidney failure depends on your medical history, the course of your kidney disease, the severity of your symptoms and your wishes.

Your options
Your nephrologist indicates what treatment options you are eligible for.

Kidney transplantation
 Peritoneal dialysis
 Hemodialysis
 Conservative care

Disclaimer: additional examinations may be needed to evaluate if these options are possible for you. If you are not eligible for an option your nephrologist will explain why.

Your nephrologist

name
 name
 name
 name
 name

If you have questions you can contact your social worker.

This decision aid will help you prepare for your future appointments

Use the online decision aid to:

- Read about your diagnosis and treatment options
- Think about your values and preferences
- Set goals for your treatment

Together with your healthcare provider you can:

- Discuss your goals, values and preferences
- Choose a treatment that suits you best

To use the online decision aid

Go to

Username Password


In collaboration with

rijn ziekenhuis maastricht NF santeon ZorgKeuzeLab

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.

 Kidney failure treatment decision aid

1. Kidney failure 2. About you 3. Kidney transplantation 4. Dialysis and conservative care 5. Your preferences 6. Summary

4. Dialysis and conservative care

Information on dialysis and CC	✓
What is PD?	✓
PD: how often, how long and where?	✓
What to consider when choosing for PD?	✓
What is HD?	✓
HD: how often, how long and where?	✓
What to consider when choosing HD?	✓
What is CC?	✓
What is the impact on my daily schedule?	✓
What is the impact on my life?	✓

What is the impact on my daily schedule?


Dialysis and CC impact you daily schedule in different ways.

 **Work and/or hobbies**


PD	HD	CC
<ul style="list-style-type: none"> • PD is a daily treatment you can perform yourself. • You can adjust your treatment schedule to your daily schedule. 	<ul style="list-style-type: none"> • HD is treatment you undergo several times a week, at a fixed schedule on a fixed location. • You have to plan your daily schedule around your dialysis treatments. 	<ul style="list-style-type: none"> • Your treatment is not bound to any schedule so you are free to plan you days. • As your condition deteriorates it will be increasingly difficult to work and/or do hobbies.

 **Commuting**


PD	HD	CC
<ul style="list-style-type: none"> • You do not have to commute to a treatment centre frequently. • You will have check-ups in the hospital every 6-8 weeks. 	<ul style="list-style-type: none"> • If you dialyze in a treatment centre, you need to commute for your treatment 3 times a week. • If you dialyze at home you will have check-ups in the hospital every 6-8 weeks. 	<ul style="list-style-type: none"> • You do not have to commute for your treatment. • You can choose to receive your treatment from your nephrologist or general practitioner.

 **Rest and night schedule**

PD	HD	CC
<ul style="list-style-type: none"> • CAPD will not affect your rest and/or schedule at night. • APD can affect you and/or your partner's rest and/or schedule at night . 	<ul style="list-style-type: none"> • HD during the day will not affect your rest and/or schedule at night. • HD during the night can affect you and/or your partner's rest and/or schedule at night. 	<ul style="list-style-type: none"> • The treatment does not directly affect your rest and/or schedule at night.

 **Traveling and vacation**

PD	HD	CC
<ul style="list-style-type: none"> • You can travel and go on vacation on the condition that you can hygienically perform your treatment at your destination • If your supplier cannot deliver equipment and materials at your destination, you have to take them with you yourself. Ask your healthcare provider for help. 	<ul style="list-style-type: none"> • You can travel and go on vacation on the condition that you can dialyze at your destination. • Take 3 months of preparation into account when planning your vacation. Ask your healthcare provider for help. 	<ul style="list-style-type: none"> • You can travel and go on vacation as long your condition allows you to do so.

 **Average rate of hospital admissions**

Age	18 - 44 years	45 - 64 years	65 - 74 years	75 - 79 years	Older than 80 years of age
-----	---------------	---------------	---------------	---------------	----------------------------

	PD	HD	CC
Average rate of admissions	2 times a year	1 time a year	2 times a year
Average length of admissions	7 days a year	6 days a year	4 days a year

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 want a treatment that primarily focuses on extending my life 

I feel fulfilled with 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 

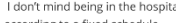
I don't want to be in the hospital on a weekly basis 

I want to be flexible and plan my dialysis according to schedule 

I feel confident that I can perform dialysis on my own at home 

I don't want to feel like a patient at home 

I don't mind being in the hospital on a weekly basis 

I don't mind being in the hospital according to a fixed schedule 


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?

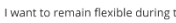
During the day

During the night

I want to sleep without having to deal with my dialysis 

I can free time during the day to make time for my dialysis 

I accept that the quality of my sleep may worsen due to 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**



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:	<i>BMJ Open</i>
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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



1
2
3 **Effectiveness and implementation of SHared decision-making supported by OUTcome**
4 **information among patients with breast cancer, stroke and advanced kidney disease:**
5
6
7 **SHOUT study protocol of multiple Interrupted Time Series**
8
9

10
11
12 Mariska QN Hackert^{#1}, Jet W Ankersmid^{*1,2}, Noel Engels^{*1,3}, Janine CM Prick^{*1,4}, Steven Teerenstra⁵,
13
14 Sabine Siesling^{2,6}, Constance HC Drossaert⁷, Luc JA Strobbe⁸, Yvonne EA van Riet⁹, René MA van
15
16 den Dorpel³, Willem Jan W Bos^{10,11}, Paul B van der Nat^{12,13}, Renske M van den Berg-Vos^{4,14}, Sander M
17
18 van Schaik⁴, Mirjam M Garvelink¹², Philip J van der Wees^{13,15}, Cornelia F van Uden-Kraan¹
19

20
21 *On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group*
22

23
24 **Contributed equally*
25

26
27
28 *#Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the*
29
30 *Netherlands. E-mail: m.hackert@santeon.nl*
31

- 32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
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

57
58 **Word count 4412**

59 **Date 28-03-2022, Version 2.0**
60

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.

1
2
3 **Keywords** Value-based health care; personalized outcome data; clinical outcome data; patient-reported
4 outcomes; patient decision aid; shared decision-making; breast cancer; stroke; advanced kidney disease
5
6
7

8
9 **Strengths and limitations of this study**
10

- 11 • All hospitals will implement and therefore benefit from the multicomponent intervention, facilitating
12 shared decision-making supported by personalized outcome data.
13
- 14 • Multiple components are needed for the intervention to be effective; however, it does not allow for
15 an individual evaluation of each component.
16
- 17 • By using stepwise implementation and the value-based health care organization structure, the
18 hospitals can learn from each other.
19
- 20 • It allows the multicomponent intervention to be further refined and tested over time.
21
- 22 • It is unclear whether the effect size aimed to achieve, constitutes a clinically meaningful difference.
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1 INTRODUCTION

2 Value-based health care (VBHC) is gaining momentum worldwide.[1, 2] The VBHC framework strives
3 to maximize value for patients by achieving the best outcomes while controlling costs.[3] Per patient
4 group, clinical and patient-reported outcomes, costs and process data are measured and compared in a
5 structured, standardized manner. These data are used to identify variation across the care cycle to
6 collectively enhance the value of health care provision on patient group level.[2] Besides the use of
7 outcome data on group level, outcome data can also be used on the individual patient level, by integrating
8 outcomes and value in patient communication. However, in clinical practice, the role of outcome data in
9 patient communication is not common practice. On individual patient level, most importantly, outcome
10 data can provide insight into benefits and harms of treatment options. Integrating outcome data in
11 discussing treatment options between health care professionals and patients, is where VBHC and shared
12 decision-making (SDM) entangle.[4, 5]
13 SDM is the process in which patients and health care professionals make well-informed, collaborative
14 choices by combining the best available evidence and patients' values and preferences.[6, 7] So far, SDM
15 has shown to lead to well-informed, preference-based patient decisions, and to improve patients'
16 relationship with their health care professional.[6, 8, 9] Using outcome data can further strengthen the
17 motivation of health care professionals to apply SDM and empower patients to make shared decisions
18 with their health care professional. In this way, outcome data can accelerate the implementation of SDM
19 and strengthen VBHC.[4, 5, 10, 11]
20 To support SDM, outcome data should be presented to patients in a meaningful way. The four-step
21 conversational SDM model can be used for this purpose ([6]; inspired by [7]). In each step, outcome
22 data, both on patient individual and group level (aggregated), can be incorporated (see Figure 1, based
23 on [6, 9]).

24 <<INSERT Figure 1>>

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

1
2
3 29 characteristics can be entered to display personal estimated risks and to support personalized aftercare
4
5 30 paths.[12] Next (*step 3*), the health care professional and the patient discuss the patient's preferences.
6
7 31 This process of value clarification can be fostered by being informed on outcome data of previous
8
9 32 patients. In *step 4*, the health care professional and the patient together integrate outcome data and
10
11 33 preferences to make a shared decision.

12
13 34 Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower
14
15 35 this threshold, we developed a multicomponent intervention for three patient groups with an oncological
16
17 36 (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It
18
19 37 consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as
20
21 38 training for health care professionals and an accompanying implementation strategy. So far, little is
22
23 39 known about the impact of using outcome data for SDM.[10, 11]

24
25 40 The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess
26
27 41 the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to
28
29 42 evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight
30
31 43 in and knowledge on the use of personalized outcome data for SDM, and can stimulate sustainable
32
33 44 implementation of SDM in clinical practice.

34
35
36
37 45

38 46 **METHODS AND ANALYSIS**

39
40 47 We use multiple interrupted time series (mITS) [13] to compare the intervention with standard care. We
41
42 48 follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see
43
44 49 Appendix A).[14, 15] mITS will allow for initial testing and refinement of the intervention. In
45
46 50 participating hospitals, trends on outcomes will be evaluated through a continuous sequence of
47
48 51 observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2).
49
50 52 Trends in the pre-implementation phase will be 'interrupted' at planned timepoints by the stepwise
51
52 53 implementation of the intervention in each hospital. Direct effects (level change) will be examined, as
53
54 54 well as gradual changes over time (slope change).

55 <<INSERT Figure 2>>
56
57
58
59
60 56

57 **Study setting**

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

69 **Study population**

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

74 *Inclusion criteria*

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

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

85 *Exclusion criteria*

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

88

89 **Table 1.** Exclusion criteria per patient group.

Breast cancer	Stoke	Advanced kidney disease
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Reduced consciousness 	<ul style="list-style-type: none"> • On kidney replacement therapy or conservative care management

90

91 **Intervention**

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

96 *Interactive patient decision aids containing personalized outcome data*

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

1
2
3 105 by telephone (breast cancer, stroke, and advanced kidney disease) among health care professionals.
4
5 106 Detailed results of the developmental process of the PtDAs will be published.
6
7 107 Each PtDA is composed of three components which contain personalized (patient-reported and clinical)
8
9 108 outcome data, both on individual as well as aggregated level. Personalized data is entered into the PtDA
10
11 109 by both health care professionals and patients. From the transition phase onwards (Figure 2), the health
12
13 110 care professional will introduce the PtDA to patients by means of a paper or digital consultation sheet
14
15 111 (*component 1*). Health care professionals provide personalized clinical data (e.g., for patients with stroke:
16
17 112 type of stroke, NIHSS score) when introducing the PtDA. Next, patients will receive a personal login
18
19 113 code to access the online interactive PtDA at home or during hospital admission (*component 2*). Each
20
21 114 PtDA contains evidence-based information about the options and pros and cons. Information is tailored
22
23 115 to relevant options for the patient and presented without favoring any particular outcome. Patients enter
24
25 116 patient-reported data, by means of PROMs, into the PtDA during use (e.g., for patients with advanced
26
27 117 kidney disease: physical condition, treatment goals). The PtDAs actively encourage patients to weigh
28
29 118 their options. Once patients have completed the PtDA, a summary sheet will automatically be created,
30
31 119 containing an overview of patient-reported personalized data and patient's preferences and
32
33 120 considerations, which can be used as a base for final decision-making in a consultation with their health
34
35 121 care professional (*component 3*).

38 39 122 *Breast cancer patient decision aid*

40
41 123 The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving
42
43 124 curative treatment for invasive non-metastasized breast cancer. The PtDA includes patients' personal
44
45 125 risks for locoregional recurrences estimated using the INFLUENCE-nomogram [12], a validated
46
47 126 prediction model with which the five-year risk for locoregional recurrences can be estimated, and a
48
49 127 patient-reported outcome measure (PROM) questionnaire on fear of cancer recurrence (sections of the
50
51 128 PtDAs were translated for publication; see Appendix B).

52 53 129 *Stroke patient decision aid*

54
55 130 The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The
56
57 131 PtDA includes an interactive "patients-like-me" model on the discharge location of comparable patients
58
59
60

1
2
3 132 based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-
4
5 133 being (see Appendix B).

6
7 134 *Advanced kidney disease patient decision aid*

8
9 135 The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive
10
11 136 “patients-like-me” model on median survival- and mean hospitalization rates per treatment modality
12
13 137 based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see
14
15 138 Appendix B).

16
17
18 139 *Training of health care professionals*

19
20 140 Health care professionals will be asked to complete an e-learning on applying (personalized) outcome
21
22 141 data to support SDM. Consequently, they will be asked to participate in a group training of one daypart.
23
24 142 The e-learning is focused on providing theoretical background and practical tips and tricks on applying
25
26 143 outcome information in the four steps of SDM in clinical consultations (including text, videos and self-
27
28 144 assessment tests). Completion of the e-learning takes approximately one hour. The group training
29
30 145 includes theoretical background information on SDM, reflection on audio-taped consultations (provided
31
32 146 by participating health care professionals as part of the data collection for the study), cases introduced
33
34 147 by participants, and practicing SDM conversational skills with an actor. By offering the e-learning before
35
36 148 the group training sessions, we reduce the time spent on theoretical background in the training, leaving
37
38 149 more time to practice on SDM conversational skills. Upon completion of the group training, follow-up
39
40 150 will be offered after one day (by offering a plasticized card or poster containing short written instructions
41
42 151 on SDM, and by presenting a publication on using outcome data to support SDM), after one month (by
43
44 152 offering tips, tricks, a testimonial by a colleague health care professional and an instruction clip on SDM)
45
46 153 and after two months (by offering the possibility to receive individualized feedback by sending an audio-
47
48 154 taped consultation to the trainer).

49
50
51 155 *Implementation strategy for the multicomponent intervention*

52
53 156 The implementation strategy is based on prior successful implementation strategies for PtDAs [23] and
54
55 157 a web-based self-management application using PROMs to monitor quality of life and focuses on
56
57 158 awareness, willingness and behavior of both health care professionals and patients.[24] Core elements
58
59 159 are listed in Table 2.

160

161 **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.
-

162

163 **Study design and procedures**

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

1
2
3 172 Internal validity will be increased, as each hospital will act as its own historical control group and the
4
5 173 hospitals will not switch at the same time.

6
7 174 Patients will be asked by their health care professional to participate in this study: 1) patients with breast
8
9 175 cancer will be informed and asked to participate during the follow-up consultation on the occasion of
10
11 176 their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke
12
13 177 will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision
14
15 178 has to be made about renal replacement therapy or conservative care. When interested, patients will
16
17 179 receive a patient information letter about the study. They will be asked for written informed consent. In
18
19 180 the post-implementation phase, patients that decline participation in the SHOUT-study will still be
20
21 181 offered the SDM supported by outcome information as the standard form of care.
22
23

24 182

25 26 183 **Data collection and methods**

27
28 184 To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T0) will
29
30 185 be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the
31
32 186 hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T1) for patients
33
34 187 with stroke, and after 6 (T1) and 12 (T2) months for patients with breast cancer or AKD. The time it
35
36 188 takes to complete the questionnaires differs per measurement moment. The T0 questionnaire takes about
37
38 189 30 to 45 minutes to complete and the T1 and T2 questionnaires take 15 to 20 minutes. The timing of
39
40 190 follow-up questionnaires differs between the three conditions due to the course and nature of and the
41
42 191 care pathways for the three conditions. Furthermore, some outcome measures are disease-specific and
43
44 192 will therefore only be assessed in the patient groups for which they are suitable.

45
46
47 193 Second, the consultations, in which the options are being discussed, will be audio-taped to assess
48
49 194 patients' involvement in the decision-making process from observers' viewpoint. Also, the length of the
50
51 195 consultations will be determined. Third, to assess the extent to which the intervention leads to changes
52
53 196 in the utilization and outcomes of health care, information will be retrieved from patients' electronic
54
55 197 health records.

56
57
58 198 To evaluate the implementation, first, the estimated total number of eligible patients and the total number
59
60 199 of patients who received the PtDA will be determined. Second, participating health care professionals

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

202

203 **Participant timeline**

204 The participant timeline is displayed in Figure 3.

205 <<INSERT Figure 3>>

206

207 **Outcomes**

208 **Effectiveness**

209 *Primary outcome measure*

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

215

216 *Secondary outcome measures*

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

1
2
3 228 questions; 9) perceived risk and fear of recurrence for patients with breast cancer, measured with the
4
5 229 Cancer Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast
6
7 230 cancer survivors (IPQ-BCS) and patient group-specific questions; and 10) participation / functioning and
8
9 231 caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht
10
11 232 Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see
12
13 233 Table 3, also for references).

14 234 *Observer-reported SDM*

15
16 235 We will combine the SDM-measurement tools, with a more objective score of SDM, as this score may
17
18 236 differ from the patients' subjective interpretation [27]. The Observing Patient Involvement in decision-
19
20 237 making scale (OPTION-5) [28] will be used to analyze the audio-recordings of encounters from clinical
21
22 238 settings. All audio-recordings will be double coded by two raters who have been trained on rating the
23
24 239 OPTION-5. In case of disagreement, a third rater will be consulted. The OPTION-5 includes five core
25
26 240 SDM steps, to which a sixth is added to assess the role of personalized outcome data (*'the health care*
27
28 241 *professional informs the patient on outcomes of different treatment options'*). The item scores will be
29
30 242 summed and rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

31 243 *Health care utilization and outcomes*

32
33 244 Patients' health care utilization and clinical outcomes will be extracted from their electronic health
34
35 245 records. For patients with breast cancer, the number of hospital visits, the number of mammograms and
36
37 246 other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of
38
39 247 stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications
40
41 248 during admission will be extracted. For patients with AKD, the number of visits to outpatient clinics,
42
43 249 hospital admissions and hospitalization days, and the rate of major treatment-related complications will
44
45 250 be extracted.

46
47
48
49
50
51 251
52
53
54
55
56
57
58
59
60

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
<i>All patient groups:</i>								
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								
<i>Stroke and advanced kidney disease:</i>								
• 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)								
<i>Breast cancer:</i>								
	10 items with 3 response options.		X				X	
<i>Stroke:</i>								
	7 items with 3 – 7 response options.		X				X	
<i>Advanced kidney disease:</i>								
	7 items with 3 – 5 response options.		X				X	
Quality of life								
<i>Breast cancer and advanced kidney disease:</i>								
• 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
<i>Stroke:</i>								
• 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)										
<i>Breast cancer:</i>	48 items with 3 – 10 response options / open-ended.		X						X	
<i>Stroke:</i>	6 items with 3 – 8 response options / open-ended.		X						X	
<i>Advanced kidney disease</i>	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
<i>Breast cancer:</i>										
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	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	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	X	X
<i>Stroke:</i>										
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.

1
2
3 **252 *Moderators***

4
5 **253 *Socio-demographic characteristics***

6
7 **254** In the baseline questionnaire, patients' sex, birth year, marital status, occupation, and education level
8
9 **255** will be asked.

10
11 **256 *Clinical characteristics***

12
13 **257** Relevant medical characteristics will be extracted from the baseline questionnaire and the electronic
14
15 **258** health records. For patients with breast cancer, tumor and treatment characteristics will be extracted. For
16
17 **259** patients with stroke, etiology of stroke, and whether or not the patient has been treated with reperfusion
18
19 **260** therapy will be extracted. For patients with AKD, renal function, etiology and duration of kidney failure,
20
21 **261** whether these patients have had other treatment modalities for kidney failure in the past, comorbidity
22
23 **262** and definite treatment modality will be extracted.

24
25
26 **263 *Health literacy***

27
28 **264** Patients' health literacy will be assessed in the baseline questionnaire by the Set of Brief Screening
29
30 **265** Questions (SBSQ).[47] The mean score on the three items will be calculated, with higher scores
31
32 **266** reflecting higher health literacy skills.

33
34
35 **267**

36
37 **268 *Implementation***

38
39 **269 *Implementation rate***

40
41 **270** The implementation rate will be calculated as the proportion of patients who received the PtDA compared
42
43 **271** to the estimated total number of eligible patients during the period of 6 to 12 months in which the PtDA
44
45 **272** will be handed out.

46
47
48 **273**

49 **274 *Health care professionals' view on the implementation process and use of the patient decision aid***

50
51 **275 *Determinants of implementing an innovation***

52
53 **276** Health care professionals will fill out a questionnaire based on the Measurement Instrument for
54
55 **277** Determinants of Innovations (MIDI).[48] The MIDI assesses barriers and facilitators of implementation
56
57 **278** at the level of innovation (PtDA), the user (health care professionals) and the organization (hospital).

58
59
60 **279**

1
2
3 280 *Physicians' willingness to incorporate shared decision-making*

4
5 281 Health care professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief
6
7 282 and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[49]

8
9 283

10
11 284 **Sample size**

12
13 285 The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary
14
15 286 outcome measure with the statistical significance level set at $\alpha = 0.05$ (two-sided). Since there is no
16
17 287 agreement on what constitutes a clinically meaningful difference on the SDM-Q-9, we estimated the size
18
19 288 of the expected effect on previous studies using the SDM-Q-9. The size of the expected effect of the
20
21 289 intervention on the SDM-Q-9 was set to be small to moderate (Cohen's $d = 0.3-0.4$) as relatively high
22
23 290 scores on the SDM-Q-9 are common in the Netherlands.[50] The mITS with seven clusters (i.e. hospitals)
24
25 291 had 18 measurement periods (excluding the transition phase, see Figure 2). For patients with breast
26
27 292 cancer and stroke, a non-large Intraclass Correlation Coefficient ($ICC = 0.05$) was assumed. The
28
29 293 correlation between monthly measurements was expected to be high ($0.7 - 0.9$) throughout a period of
30
31 294 18 months, although correlations between months farther apart could be lower than for months closer
32
33 295 by. A correlation structure where the correlation decreases exponentially with the distance between
34
35 296 months (autoregressive correlation structure) turned out too conservative and a correlation structure
36
37 297 where the correlation between months is the same regardless of the distance between them (compound
38
39 298 symmetry correlation structure) was too optimistic and not realistic for this purpose. Therefore, power
40
41 299 calculations were primarily based on assuming that the correlation between months decreases from 0.9,
42
43 300 for subsequent months, to 0.7, for months that are the farthest apart (i.e. the first and last month). To be
44
45 301 precise, the correlation decreases linearly on the log scale from $\log(0.9)$ to $\log(0.7)$ (linear exponent
46
47 302 autoregressive correlation structure).[51] Five patients per hospital per month was considered feasible,
48
49 303 and with a 25% loss to follow-up, this results in a monthly inclusion rate of four patients. This yields
50
51 304 more than 80% power and amounts to a study population of $N = 504 - 630$.

52
53 305 For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals.

54
55 306 Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting

1
2
3 307 a Cohen's $d = 0.4$ assuming a correlation between subsequent months of at least 0.8 and a correlation
4
5 308 between the first and last month of at least 0.6. This amounts to a study population of $N = 378 - 473$.

6
7 309

8
9 310 **Statistical methods**

10
11 311 An overview of the demographic and clinical characteristics will be provided using descriptive statistics.
12
13 312 Continuous data will be expressed as a mean with the standard deviation (SD), or as the median
14
15 313 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless
16
17 314 stated otherwise.

18
19 315 Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented
20
21 316 regression will be employed, with the period before and after the introduction of the intervention as
22
23 317 segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time
24
25 318 series to exhibit different levels and trends. Correlation between repeated measurements in each time
26
27 319 series will be accounted for by modelling the error structure. The effect of the intervention will be
28
29 320 examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using
30
31 321 the following model:

$$32 322 \quad Y(T) = \beta_0 + \beta_1 \cdot T + \beta_2 \cdot I + \beta_3 \cdot I \cdot t$$

33
34 323 where β_0 will represent the baseline level at $T = 0$, β_1 will be interpreted as the change in outcomes
35
36 324 associated with a time unit increase (representing the underlying trend in the pre-implementation phase),
37
38 325 $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, β_2 will be the level change
39
40 326 in the post-implementation phase and β_3 will indicate the slope change following the implementation
41
42 327 phase (using the interaction between time t since the intervention started and the indicator for being in
43
44 328 the intervention: I). A change in β_2 will constitute an immediate effect, while a change in β_3 will imply
45
46 329 an effect that was experienced over time (which also allows us to measure the sustainability of the
47
48 330 impact). Moreover, segmented regression will enable us to control for other variables, that can cause a
49
50 331 change in level or trend of the outcomes of interest.

51
52 332 Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage
53
54 333 of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation
55
56 334 techniques or sensitivity analyses will be used to assess their impact on the trial results.

1
2
3 335 To correct for multiple testing and the risk of type-1 errors a Bonferroni-Holm procedure will be applied
4
5 336 across the set of primary and secondary endpoints.
6

7 337 To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-
8
9 338 specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis
10
11 339 across all patient groups and hospitals will be performed. Finally, implementation across all patient
12
13 340 groups will be investigated by using several the same outcome measures at a similar points in time.
14

15
16 341
17
18 342 **Patient and public involvement**
19
20 343 Santeon supports that patients with ‘lived experiences’ become members of a research team. Since the
21
22 344 very beginning (composing the grant application), we have engaged a core group of patients and patient
23
24 345 representatives of the patient associations involved. We designed the multicomponent intervention in
25
26 346 collaboration with patients and health care professionals (see the Methods and Analysis). In addition,
27
28 347 patient representatives were involved in the development of the study. Our collaboration with the patient
29
30 348 associations will continue throughout the study. Study findings about the potential benefits of the
31
32 349 multicomponent intervention will be disseminated by means of our project website.
33

34
35 350
36
37 351 **ETHICS AND DISSEMINATION**
38
39 352 The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the
40
41 353 Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number
42
43 354 W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference
44
45 355 numbers METC 2019-075, -076 and -077).
46

47 356 The study will be conducted in accordance with local laws and regulations. Eligible patients will fully
48
49 357 be informed about the study and asked to participate. They will receive a patient information letter and
50
51 358 will be informed by telephone about the implications of participation. Patients will have sufficient
52
53 359 opportunity to ask questions and to consider the implications before providing written informed consent.
54
55 360 They will be allowed to withdraw from the study without giving a reason, at any time.

56
57
58 361 The SHOUT study is part of a larger Santeon program on using outcome data for SDM (‘Experiment
59
60 362 Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and

1
2
3 363 patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals,
4
5 364 (inter)national conferences, workshops webinars, and newsletters and social media.
6

7 365

9 366 **ACKNOWLEDGEMENTS**

11 367 We thank all patients, patient representatives and health care professionals for their contribution to
12
13 368 designing the multi-component intervention and execution the SHOUT study. The SHOUT study is part
14
15 369 of a larger program on using outcome data for SDM ('Experiment Uitkomstindicatoren Santeon'), which
16
17 370 is part of the Outcome-based Health care program initiated by the Dutch Ministry of Health, Welfare and
18
19 371 Sports. We would like to thank ZonMw for funding this project.
20
21

22 372

24 373 **FOOTNOTES**

26 374 **Availability of data and materials**

28 375 Data will be collected and recorded in CASTOR EDC, a cloud-based electronic data capture platform.
29
30 376 This platform is fully compliant with GCP, 21 CFR part 11, GDPR, HIPAA, ISO27001 and ISO 9001.
31
32 377 All data will be coded and password protected. Study participants will be assigned a participant
33
34 378 identification number (PIN). A digital, password protected identifying list relating medical information
35
36 379 of participants to their PIN numbers will be kept on a secured server in the Santeon hospitals. All data
37
38 380 and study documents will deleted and discarded after 15 years. The datasets used and / or analyzed during
39
40 381 the SHOUT study are available from JWA (breast cancer), NE (AKD) and JCMP (stroke) on reasonable
41
42 382 request. The (intellectual) property rights with regard to the generated data will reside at Santeon,
43
44 383 Utrecht, The Netherlands. Interested parties can request a non-exclusive license for research and
45
46 384 educational purposes. The non-exclusive license may be requested only after the completion of the theses
47
48 385 to be written reserving the generated data.
49

50 386

52 387 **Competing interests**

54 388 None declared.
55
56 389
57
58
59
60 390

1
2
3 391 **Funding**
4

5 392 This research project is funded by ZonMw as part of the ‘Experiment Uitkomstindicatoren Santeon’.

6
7 393 This funding had no involvement in collection, management, analysis, and interpretation of the data;

8
9 394 writing this manuscript or the decision to submit the article for publication.
10

11
12 395

13
14 396 **Authors' contributions**

15
16 397 JWA, NE, JCMP, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, SMvS, and CFvU-K developed the

17
18 398 multicomponent intervention. MQNH, ST, PBvdN, PJvdW and CFvU-K contributed to the design of the

19
20 399 study. JWA, NE, JCMP are conducting this study in fulfillment of a PhD and will be responsible for data

21
22 400 collection. JWA, NE, JCMP and ST will be responsible for data analysis. All authors will be responsible

23
24 401 for interpreting the data. The present manuscript was drafted by MQNH and CFvU-K. JWA, NE,

25
26 402 JCMP, ST, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, PBvdN, RMvdB-V, SMvS, MMG and

27
28 403 PJvdW critically revised this manuscript. All authors have read and approved the final manuscript.
29

30 404

31
32 405 **ABBREVIATIONS**

33
34 406 AKD, advanced kidney disease

35
36 407 mITS, multiple interrupted time series

37
38 408 PROM, patient-reported outcome measure

39
40 409 PtDA, patient decision aid

41
42 410 SDM, shared decision-making

43
44 411 VBHC, value-based health care
45

46
47 412
48
49
50
51
52
53
54
55
56
57
58
59
60

413 **REFERENCES**

- 414 1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health
415 outcomes measurement and organizational readiness support quality improvement: a systematic
416 review. *BMC Health Serv Res* 2018;18:1005. <https://doi.org/10.1186/s12913-018-3828-9>.
- 417 2 Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med*
418 2016;374:504-6. <https://doi.org/10.1056/NEJMp1511701>.
- 419 3 Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477-81.
420 <https://doi.org/10.1056/NEJMp1011024>.
- 421 4 Steinmann G, van de Bovenkamp H, de Bont A, Delnoij D. Redefining value: a discourse analysis
422 on value-based health care. *BMC Health Ser Res* 2020;20:862. [https://doi.org/10.1186/s12913-020-](https://doi.org/10.1186/s12913-020-05614-7)
423 05614-7.
- 424 5 Van der Nat PB. The new strategic agenda for value transformation. *Health Serv Manage Res*
425 2021;0(0):1-5. <https://doi.org/10.1177/09514848211011739>.
- 426 6 Stiggelbout AM, Pieterse AH, de Haes JCJM. Shared decision making: concepts, evidence and
427 practice. *Patient Educ Couns* 2015;98(10):1172-9. <https://doi.org/10.1016/j.pec.2015.06.022>.
- 428 7 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen*
429 *Intern Med* 2012;27:1361-7. <https://doi.org/10.1007/s11606-012-2077-6>.
- 430 8 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening
431 decisions. *Cochrane Database Sys Rev* 2017;4:CD001431.
432 <https://doi.org/10.1002/14651858.CD001431.pub5>.
- 433 9 Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the
434 consequences. *Implement Sci* 2016;11:114. <https://doi.org/10.1186/s13012-016-0480-9>.
- 435 10 Damman OC, Jani A, de Jong BA, et al. The use of PROMs and shared decision-making in medical
436 encounters with patients: an opportunity to deliver value-based health care to patients. *J Eval Clin*
437 *Pract* 2020;26:524-40. <https://doi.org/10.1111/jep.13321>.
- 438 11 La Grouw Y, Kee K, Ybema S, Taverne H, Boonen L. *Samen Beslissen in de praktijk:*
439 *praktijkonderzoek i.o.v. het Zorginstituut Nederland*. Equalis / VU,
440 2019. <https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen->
441 [beslissen-in-de-praktijk](https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen-beslissen-in-de-praktijk)

- 1
2
3 442 12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of
4
5 443 breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of
6
7 444 locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36.
8
9 445 <https://doi.org/10.1007/s10549-015-3490-4>.
- 10
11 446 13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community
12
13 447 intervention research. *Prev Sci* 2000;1:31-49. <https://doi.org/10.1023/A:1010024016308>.
- 14
15 448 14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items
16
17 449 for clinical trials. *Ann Intern Med* 2013a;158:200-7. [https://doi.org/10.7326/0003-4819-158-3-](https://doi.org/10.7326/0003-4819-158-3-201302050-00583)
18
19 450 [201302050-00583](https://doi.org/10.7326/0003-4819-158-3-201302050-00583).
- 20
21 451 15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for
22
23 452 protocols of clinical trials. *BMJ*. 2013b;346:e7586. <https://doi.org/10.1136/bmj.e7586>.
- 24
25 453 16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director:
26
27 454 Gregory Katz). 2020.
- 28
29 455 17 Santeon. www.santeon.nl 2021; 22 June.
- 30
31 456 18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-
32
33 457 effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. <https://doi.org/10.1200/JCO.19.02035>.
- 34
35 458 19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's)*. 2018.
36
37 459 [https://www.volksgezondheinzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-](https://www.volksgezondheinzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys)
38
39 460 [dalys](https://www.volksgezondheinzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys).
- 40
41 461 20 Ankersmid JW, Drossaert CHC, van Riet YEA, et al. Needs and preferences of breast cancer
42
43 462 survivors regarding outcome-based shared decision-making about personalised post-treatment
44
45 463 surveillance. *J Cancer Surviv* 2022; <https://doi.org/10.1007/s11764-022-01178-z>.
- 46
47 464 21 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient
48
49 465 decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710.
50
51 466 <https://doi.org/10.1177/0272989X13501721>.
- 52
53 467 22 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch
54
55 468 Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een*
56
57 469 *keuzehulp bij een richtlijn?* Den Haag, The Netherlands, 2018.
- 58
59
60

- 1
2
3 470 23 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for
4
5 471 localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J*
6
7 472 2020;26(2):1194-207. <https://doi.org/10.1177/1460458219873528>.
8
9 473 24 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a
10
11 474 web-based self-management application “Oncokompas” in routine cancer care: a national pilot
12
13 475 study. *Support Care Cancer* 2019;27:2911-20. <https://doi.org/10.1007/s00520-018-4591-5>.
14
15 476 25 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and
16
17 477 psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared
18
19 478 Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care.
20
21 479 *PloS ONE* 2015;10(7):e0132158. <https://doi.org/10.1371/journal.pone.0132158>.
22
23 480 26 Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-Q-9).
24
25 481 Development and psychometric properties in a primary care sample. *Patient Educ Couns*. 2010
26
27 482 Jul;80(1):94-9. doi: 10.1016/j.pec.2009.09.034.
28
29 483 27 Ubbink DT, van Asbeck EV, Aarts JWM, et al. Comparison of the CollaboRATE and SDM-Q-9
30
31 484 questionnaires to appreciate the patient-reported level of shared decision-making. *Patient Educ*
32
33 485 *Couns*, available online 10 March 2022 <https://doi.org/10.1016/j.pec.2022.03.007>
34
35 486 28 Elwyn G, Grande SW, Barr P. *Observer OPTION^s manual. Measuring shared decision making by*
36
37 487 *assessing recordings or transcripts of encounters from clinical settings*. The Dartmouth Institute for
38
39 488 Health Policy and Clinical Practice, Lebanon, USA, 2018.
40
41 489 29 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a
42
43 490 fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient*
44
45 491 *Educ Couns* 2013;93(1):102-7. <http://doi.org/10.1016/j.pec.2013.05.009>.
46
47 492 30 O’Connor AM. *User Manual – Decisional Conflict Scale*. OHRI. 1993 (modified 2010);1:1-16.
48
49 493 31 O’Connor AM. *User Manual – Decision Regret Scale*. Ottawa, Ottawa Hospital Research Institute;
50
51 494 1996 (modified 2003).
52
53 495 32 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-
54
55 496 43.
56
57
58
59
60

- 1
2
3 497 33 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and
4 preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33.
5 498
6
7 499 <https://doi.org/10.1097/00005650-199603000-00003>.
8
9 500 34 Ware JE, Kosinski MA, Keller SD. *SF-12: How to score the SF-12 Physical and Mental Health*
10 *Summary Scales*. The Health Institute, New England Medical Center, Boston Massachusetts, 1995.
11 501
12
13 502 35 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health
14 summary scores from the patient-reported outcomes measurement information system (PROMIS)
15 503 global items. *Qual Life Res* 2009;18:873-80. <https://doi.org/10.1007/s11136-009-9496-9>.
16 504
17
18 505 36 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level
19 506 version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. [https://doi.org/10.1007/s11136-](https://doi.org/10.1007/s11136-011-9903-x)
20 507 [011-9903-x](https://doi.org/10.1007/s11136-011-9903-x).
21
22
23 508 37 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for
24 the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52.
25 509
26
27 510 <https://doi.org/10.1016/j.jval.2016.01.003>.
28
29
30 511 38 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale*. Ottawa, Ottawa
31 512 Hospital Research Institute, 1995 (modified 2010).
32
33
34 513 39 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening
35 514 capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.
36
37
38 515 40 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer
39 516 survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness
40
41
42 517 Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58.
43 518
44
45 518 <https://doi.org/10.1080/08870446.2016.1275629>.
46
47
48 519 41 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and
49 520 psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol*
50 521 2006;15(4):306-20. <https://doi.org/10.1002/pon.955>.
51
52
53 522 42 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer
54 523 recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out*
55 524 2018;16:30. <https://doi.org/10.1186/s12955-018-0850-x>.
56
57
58
59
60

- 1
2
3 525 43 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric
4 526 properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11.
5 527 <https://doi.org/10.1016/j.jpsychores.2005.02.007>.
6
7 528 44 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke*
8 529 2011;42(8):2276-9. <https://doi.org/10.1161/STROKEAHA.111.613273>.
9
10 530 45 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB.
11 531 Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil*
12 532 2012;34(6): 478-85. <https://doi.org/10.3109/09638288.2011.608148>.
13
14 533 46 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8.
15 534 <https://doi.org/10.1093/geronj/38.3.344>.
16
17 535 47 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy
18 536 in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6.
19 537 <https://doi.org/10.1007/s11606-008-0520-5>.
20
21 538 48 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement
22 539 instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10.
23 540 <https://doi.org/10.1093/intqhc/mzu060>.
24
25 541 49 Berkowitz J, Martinez-Cambor P, Stevens G, Elwyn G. The development of incorpoRATE: a
26 542 measure of physicians' willingness to incorporate shared decision making into practice. *Patient Educ*
27 543 *Couns* 2021; Feb 25:S0738-3991(21)00140-3. <https://doi.org/10.1016/j.pec.2021.02.040>.
28
29 544 50 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt*
30 545 *samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke*
31 546 *besluitvorming*. Utrecht: Nivel, 2021.
32
33 547 51 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of
34 548 correlation structures. *Stat Med* 2010;29(17):1825-38. <https://doi.org/10.1002/sim.3928>.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52

530 Figure legend

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

- 1
2
3 553 • **Figure 2:** Time schedule of the multiple interrupted time series. *White blocks: pre-implementation*
4 *phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.*
5 554
6
7 555 • **Figure 3:** Participant timeline. *HCPs; healthcare professionals, SDM = shared decision-making,*
8 *PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.*
9 556
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

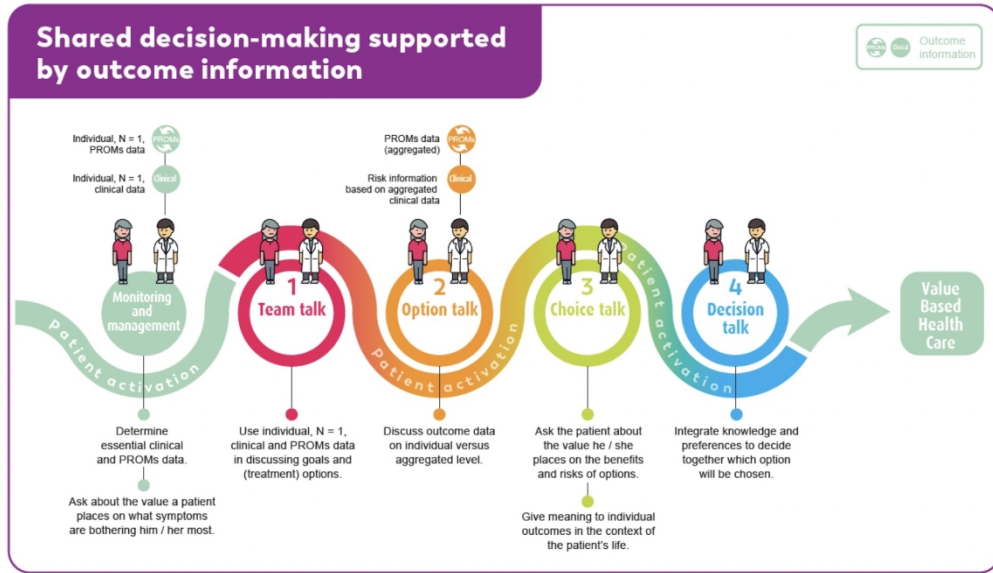


Figure 1: How to use outcome data in the four-step conversational SDM model. / PROMs = patient-reported outcome measures.

361x207mm (300 x 300 DPI)

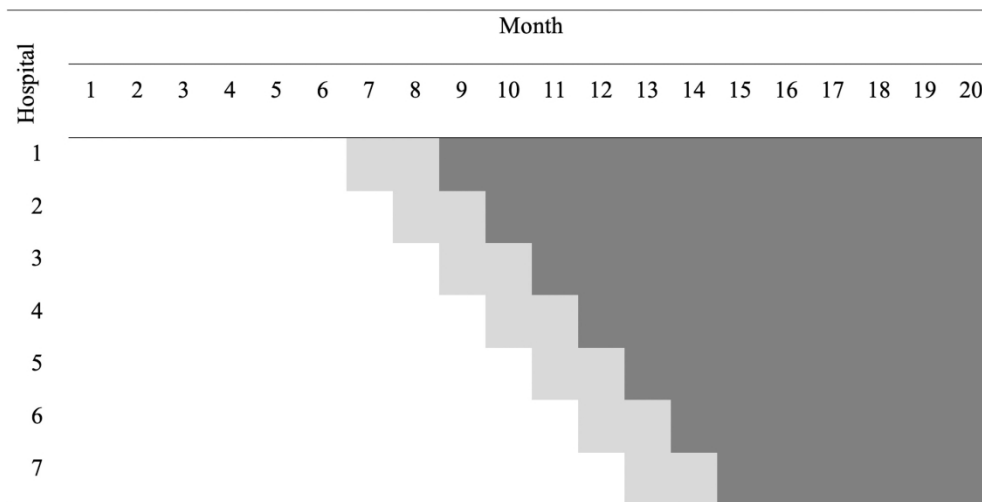


Figure 2: Time schedule of the multiple interrupted time series. / White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.

373x187mm (300 x 300 DPI)

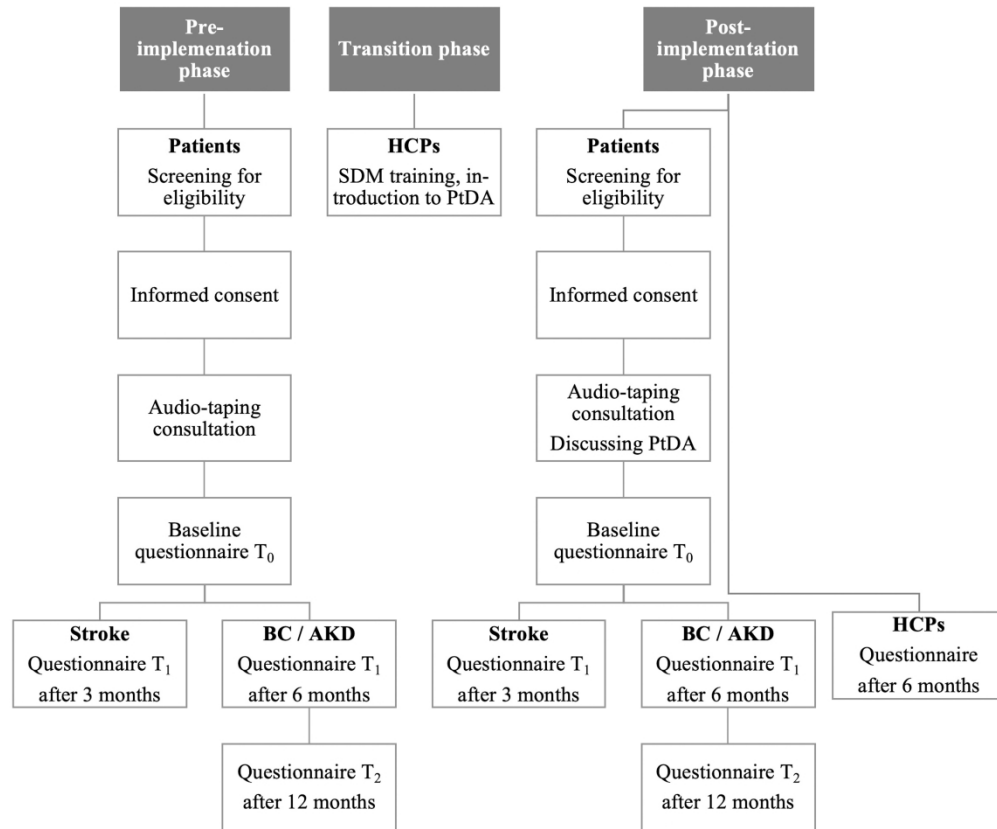


Figure 3: Participant timeline. / HCPs; healthcare professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.

423x352mm (300 x 300 DPI)



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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	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
-------------------------	-----	--	---

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	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

1				
2				
3	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
4				
5				
6	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
7				
8				
9		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
10				
11	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
12				
13				
14				
15	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
16				
17				
18				
19	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
20				
21				
22	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
23				
24				
25	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
26				
27				
28				
29		31b	Authorship eligibility guidelines and any intended use of professional writers	19
30				
31		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
32				
33				
34	Appendices			
35				
36	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

For peer review only

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]

The screenshot shows the 'Breast Cancer Surveillance Decision Aid' web application. The user is logged in as 'pat12345'. The navigation menu includes: 1. Your situation, 2. Surveillance (selected), 3. Quiz, 4. Considerations, 5. Preferences, 6. Questionnaire, and 7. Summary.

The main content area is titled '2. Surveillance' and contains a list of questions on the left and a detailed explanation on the right.

Question	Status
What is post-treatment surveillance?	✓
What is the risk for recurrence of breast cancer?	✓
Which choices do I have about surveillance?	✓
Annual surveillance or less?	✓
Which diagnostic tests for surveillance?	✓
Do I want the results at the hospital or by telephone?	✓
What is cancer survivorship care?	✓
What do I need to pay attention to?	✓
What if I don't have surveillance?	✓

What is the risk for recurrence of breast cancer?

You and your healthcare professional have discussed your personal risk for recurrence of breast cancer. This risk is different for every patient.

The risk for a new breast tumor or recurrence depends on the following characteristics:

- Your age
- The size of the primary breast tumor when it was discovered
- If lymph nodes in the armpit were affected
- The characteristics of the primary breast cancer:
 - if there was one or more tumors in the breast
 - how different the breast cancer cells look from normal breast cells (grade)
 - if the tumor cells were sensitive to hormones (estrogen and/or progesterone)
 - if the tumor cells were sensitive to certain proteins (HER2)
- The treatment you have received for breast cancer

Your personal risk

Your healthcare professional has calculated your personal risk for recurrence of breast cancer. In 2 to 3 out of 100 women with the same characteristics as you, the breast cancer recurs in the breast area within 5 years after treatment.

For the calculation a prediction model was used. The characteristics above are incorporated into this model.

[> Read more about the prediction model](#)

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).



Breast Cancer Surveillance Decision Aid

pat12345 ▾

1. Your situation 2. Surveillance 3. Quiz 4. Considerations 5. Preferences 6. Questionnaire 7. Summary

6. Questionnaire

You may feel anxious and insecure after breast cancer. This questionnaire will give you an indication how you currently feel.

	Never	Hardly ever	Sometimes	Almost always
How often have you thought about your chances of getting breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have these thoughts affected your mood?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Have these thoughts interfered with your abilities to do daily activities?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How concerned are you about the possibility of getting breast cancer again one day?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you worry about developing breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much of a problem is this worry?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
				Your score 12

What does your score mean?

A completed questionnaire gives a score between 6 and 24.

A score of 11 or lower indicates that you are *rarely concerned* about recurrence of breast cancer

A score of 12 or higher indicates that you are *regularly concerned* about recurrence of breast cancer



Discuss this with your healthcare professional if you feel limited by fear of recurrence in your daily life. Together you will decide if additional support may be useful. You can also read more about how to deal with fear or recurrence on the website of the [Breast Cancer Association](#).

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.

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 think 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	

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.

Stroke decision aid

Your diagnosis
Your healthcare professional marks your diagnosis

Your diagnosis

Your NIHSS

This score quantifies stroke severity.
A higher score indicates higher stroke severity.

Observations of your healthcare professionals

Your vascular neurologist
 name
 name

Your nurse practitioner
 name

Your physician assistant
 name
 name

You received this consultation sheet from:
.....

Use the decision aid and share the summary with your healthcare professional before:
date.....time.....

Use the decision aid

In the online decision aid, you can read information about stroke and your hospital admission. Also, you can clarify your values and preferences concerning discharge planning.

After being discharged from the hospital, you can still consult the decision aid for information about the effects of stroke.

Go to:

Username Password

© Santeon en ZorgKeuzelab <<paidTitle>> v3

Shared decision-making for discharge planning

Soon, you will be discharged from the hospital. The options for choosing a discharge destination are as follows:


The patient decision aid will help you and your healthcare professional to choose the most suitable discharge destination.

→ → →

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).

3. Where to rehabilitate?

Which discharge destinations are available? ✓	<p>Where did other patients with stroke rehabilitate after discharge from the hospital?</p> <p>Sometimes it can help to know where other patients go to after being discharged from hospital. Below you can see an overview of distribution between the different discharge destinations depending on diagnosis, age and stroke severity.</p> <p>Diagnosis Ischaemic stroke Haemorrhagic stroke</p> <p>Age younger than 30 years 30 - 49 years 50 - 64 years 65 - 79 years older than 80 years</p> <p>NIHSS* 0 - 4 5 - 15 16 - 42</p>  <p>Of 100 patients:</p> <ul style="list-style-type: none"> 51 returned home 37 temporarily moved to an inpatient rehabilitation facility 8 temporarily moved to an inpatient skilled nursing facility 4 permanently moved to a nursing home <p><small>This information is based on data from more than 5000 patients with stroke from OLVG, MST and St. Antonius during the period of 2017-2020.</small></p> <p><small>* The National Institute of Health Stroke Scale (NIHSS) score quantifies stroke severity. A higher score indicates higher stroke severity.</small></p>
What is the best discharge destination for me? ✓	
Where did other patients with stroke rehabilitate after discharge from the hospital? ✓	
What is required for rehabilitation at home? ✓	
What can I expect from an inpatient rehabilitation program? ✓	
Who can I consult after finishing my rehabilitation program? ✓	
What are other important things to know for me and my caregivers? ✓	

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.





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.		I was able to walk more than 30 minutes	Yes
What effects of my stroke do I notice? Weakness and numbness of my left arm.		I was walking with a walking aid	No
What would I like to do again? Returning home without help, being able to work and cycle again		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


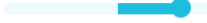

My situation at home

 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?**

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.

Kidney failure decision aid

Each treatment option for kidney failure impacts your life differently. Which treatment option ultimately suits you depends on your medical history and on what's important to you and your loved ones.

Your situation
When you should start a treatment for kidney failure depends on your medical history, the course of your kidney disease, the severity of your symptoms and your wishes.

Your options
Your nephrologist indicates what treatment options you are eligible for.

Disclaimer: additional examinations may be needed to evaluate if these options are possible for you. If you are not eligible for an option your nephrologist will explain why.

Flowchart: This appointment leads to 'Use the decision aid and list your goals, considerations and preferences' and 'Additional appointments with your treatment team'. Both lead to 'Choosing your treatment with your nephrologist', which leads to 'Start treatment preparations'. A tip box says: 'Begin on time! Educate yourself about your treatment options. Making a decision and the subsequent preparations take a lot of time. Prevent unnecessary pressure and give yourself time to make a well-informed decision.'

Graph: Kidney function (0% to 30%) vs Time. Legend: Education/decision-making, Preparations, Treatment start.

Form: Your nephrologist (name, name, name, name, name, name). If you have questions you can contact your social worker.

Checklist: This decision aid will help you prepare for your future appointments. Use the online decision aid to: Read about your diagnosis and treatment options, Think about your values and preferences, Set goals for your treatment. Together with your healthcare provider you can: Discuss your goals, values and preferences, Choose a treatment that suits you best.

To use the online decision aid: Go to <https://nierfalen.keuzehulp.nl>. Username: <<naam>>. Password: <<ww>>.

Logos: nyn, NF, santeon, ZorgKeuzeLab.

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.



Kidney failure treatment decision aid

1. Kidney failure 2. About you 3. Kidney transplantation 4. Dialysis and conservative care 5. Your preferences 6. Summary

4. Dialysis and conservative care

Information on dialysis and CC	✓
What is PD?	✓
PD: how often, how long and where?	✓
What to consider when choosing for PD?	✓
What is HD?	✓
HD: how often, how long and where?	✓
What to consider when choosing HD?	✓
What is CC?	✓
What is the impact on my daily schedule?	✓
What is the impact on my life?	✓

What is the impact on my daily schedule?

Dialysis and CC impact you daily schedule in different ways.



Work and/or hobbies

PD	HD	CC
<ul style="list-style-type: none"> PD is a daily treatment you can perform yourself. You can adjust your treatment schedule to your daily schedule. 	<ul style="list-style-type: none"> HD is treatment you undergo several times a week, at a fixed schedule on a fixed location. You have to plan your daily schedule around your dialysis treatments. 	<ul style="list-style-type: none"> Your treatment is not bound to any schedule so you are free to plan you days. As your condition deteriorates it will be increasingly difficult to work and/or do hobbies.



Commuting

PD	HD	CC
<ul style="list-style-type: none"> You do not have to commute to a treatment centre frequently. You will have check-ups in the hospital every 6-8 weeks. 	<ul style="list-style-type: none"> If you dialyze in a treatment centre, you need to commute for your treatment 3 times a week. If you dialyze at home you will have check-ups in the hospital every 6-8 weeks. 	<ul style="list-style-type: none"> You do not have to commute for your treatment. You can choose to receive your treatment from your nephrologist or general practitioner.



Rest and night schedule

PD	HD	CC
<ul style="list-style-type: none"> CAPD will not affect your rest and/or schedule at night. APD can affect you and/or your partner's rest and/or schedule at night . 	<ul style="list-style-type: none"> HD during the day will not affect your rest and/or schedule at night. HD during the night can affect you and/or your partner's rest and/or schedule at night. 	<ul style="list-style-type: none"> The treatment does not directly affect your rest and/or schedule at night.



Traveling and vacation

PD	HD	CC
<ul style="list-style-type: none"> You can travel and go on vacation on the condition that you can hygienically perform your treatment at your destination If your supplier cannot deliver equipment and materials at your destination, you have to take them with you yourself. Ask your healthcare provider for help. 	<ul style="list-style-type: none"> You can travel and go on vacation on the condition that you can dialyze at your destination. Take 3 months of preparation into account when planning your vacation. Ask your healthcare provider for help. 	<ul style="list-style-type: none"> You can travel and go on vacation as long your condition allows you to do so.




Average rate of hospital admissions

Age	18 - 44 years	45 - 64 years	65 - 74 years	75 - 79 years	Older than 80 years of age
Average rate of admissions					
Average length of admissions					

	PD	HD	CC
Average rate of admissions	2 times a year	1 time a year	2 times a year
Average length of admissions	7 days a year	6 days a year	4 days a year

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 want a treatment that primarily focuses on extending my life 

I feel fulfilled with 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 

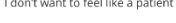
I don't mind doing dialysis at home 


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

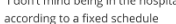
I want to be flexible and plan my dialysis according to schedule 

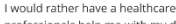
I feel confident that I can perform dialysis on my own at home 

In a hospital 

I don't want to feel like a patient at home 


I don't mind being in the hospital on a weekly basis 


I don't mind being in the hospital according to a fixed schedule 


I would rather have a healthcare professionals help me with my dialysis 


Comments: I would prefer doing PD treatment at home

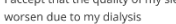
Dialysis during the day or night?

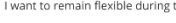
During the day 

I want to sleep without having to deal with my dialysis 

I can free time during the day to make time for my dialysis 

During the night 

I accept that the quality of my sleep may worsen due to 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**



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:	<i>BMJ Open</i>
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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



1
2
3 **Effectiveness and implementation of SHared decision-making supported by OUTcome**
4 **information among patients with breast cancer, stroke and advanced kidney disease:**
5
6
7 **SHOUT study protocol of multiple Interrupted Time Series**
8
9

10
11
12 Mariska QN Hackert^{#1}, Jet W Ankersmid^{*1,2}, Noel Engels^{*1,3}, Janine CM Prick^{*1,4}, Steven Teerenstra⁵,
13
14 Sabine Siesling^{2,6}, Constance HC Drossaert⁷, Luc JA Strobbe⁸, Yvonne EA van Riet⁹, René MA van
15
16 den Dorpel³, Willem Jan W Bos^{10,11}, Paul B van der Nat^{12,13}, Renske M van den Berg-Vos^{4,14}, Sander M
17
18 van Schaik⁴, Mirjam M Garvelink¹², Philip J van der Wees^{13,15}, Cornelia F van Uden-Kraan¹
19

20
21 *On behalf of the Santeon VBHC breast cancer, stroke and chronic kidney disease group*
22

23
24 **Contributed equally*
25

26
27
28 *#Corresponding author. Postal address: Herculesplein 38, 8th floor (Galghenwert), 3584 AA Utrecht, the*
29
30 *Netherlands. E-mail: m.hackert@santeon.nl*
31

- 32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
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

57
58 **Word count 4341**

59 **Date 1-6-2022, Version 3.0**
60

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.

1
2
3 **Keywords** Value-based healthcare; personalized outcome data; clinical outcome data; patient-reported
4 outcomes; patient decision aid; shared decision-making; breast cancer; stroke; advanced kidney disease
5
6
7

8
9 **Strengths and limitations of this study**
10

- 11 • Key stakeholders participated in the development of a multicomponent intervention designed to
12 facilitate shared decision-making supported by personalized outcome information.
13
- 14 • By using stepwise implementation in all participating hospitals, lessons learned can be used to
15 facilitate implementation in subsequent hospitals.
16
- 17 • The proposed multiple interrupted time-series design allows the multicomponent intervention to be
18 refined and evaluated over time.
19
- 20 • The study design does not allow evaluation of each individual component of the multiple component
21 intervention.
22
- 23 • The expected effect size may not be clinically meaningful.
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1 INTRODUCTION

2 Value-based healthcare (VBHC) is gaining momentum worldwide.[1, 2] The VBHC framework strives
3 to maximize value for patients by achieving the best outcomes while controlling costs.[3] Per patient
4 group, clinical and patient-reported outcomes, costs and process data are measured and compared in a
5 structured, standardized manner. These data are used to identify variation across the care cycle to
6 collectively enhance the value of health care provision on patient group level.[2] Besides the use of
7 outcome data on group level, outcome data can also be used on the individual patient level, by integrating
8 outcomes and value in patient communication. However, in clinical practice, the role of outcome data in
9 patient communication is not common practice. On individual patient level, most importantly, outcome
10 data can provide insight into benefits and harms of treatment options. Integrating outcome data in
11 discussing treatment options between health care professionals and patients, is where VBHC and shared
12 decision-making (SDM) entangle.[4, 5]
13 SDM is the process in which patients and health care professionals make well-informed, collaborative
14 choices by combining the best available evidence and patients' values and preferences.[6, 7] So far, SDM
15 has shown to lead to well-informed, preference-based patient decisions, and to improve patients'
16 relationship with their health care professional.[6, 8, 9] Using outcome data can further strengthen the
17 motivation of health care professionals to apply SDM and empower patients to make shared decisions
18 with their health care professional. In this way, outcome data can accelerate the implementation of SDM
19 and strengthen VBHC.[4, 5, 10, 11]
20 To support SDM, outcome data should be presented to patients in a meaningful way. The four-step
21 conversational SDM model can be used for this purpose ([6]; inspired by [7]). In each step, outcome
22 data, both on patient individual and group level (aggregated), can be incorporated (see Figure 1, based
23 on [6, 9]).

24 <<INSERT Figure 1>>

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

1
2
3 29 characteristics can be entered to display personal estimated risks and to support personalized aftercare
4
5 30 paths.[12] Next (*step 3*), the health care professional and the patient discuss the patient's preferences.
6
7 31 This process of value clarification can be fostered by being informed on outcome data of previous
8
9 32 patients. In *step 4*, the health care professional and the patient together integrate outcome data and
10
11 33 preferences to make a shared decision.

12
13 34 Currently, outcome data is often not readily available to be used for SDM in clinical practice. To lower
14
15 35 this threshold, we developed a multicomponent intervention for three patient groups with an oncological
16
17 36 (breast cancer), cardiovascular (stroke) and chronic (advanced kidney disease; AKD) condition. It
18
19 37 consists of condition-specific patient decision aids (PtDAs) with personalized outcome data, as well as
20
21 38 training for health care professionals and an accompanying implementation strategy. So far, little is
22
23 39 known about the impact of using outcome data for SDM.[10, 11]

24
25 40 The aim of the SHared decision-making supported by OUTcome information (SHOUT) study is to assess
26
27 41 the effectiveness of the intervention, facilitating SDM supported by personalized outcome data, and to
28
29 42 evaluate its implementation in clinical practice. The SHOUT study will contribute to obtaining insight
30
31 43 in, and knowledge on, the use of personalized outcome data for SDM, and can stimulate sustainable
32
33 44 implementation of SDM in clinical practice.

34
35
36
37 45

38 39 46 **METHODS AND ANALYSIS**

40
41 47 We use multiple interrupted time series (mITS) [13] to compare the intervention with standard care. We
42
43 48 follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see
44
45 49 Appendix A).[14, 15] mITS will allow for initial testing and refinement of the intervention. In
46
47 50 participating hospitals, trends on outcomes will be evaluated through a continuous sequence of
48
49 51 observations taken repeatedly at equal time intervals from November 2019 onwards (see Figure 2).
50
51 52 Trends in the pre-implementation phase will be 'interrupted' at planned timepoints by the stepwise
52
53 53 implementation of the intervention in each hospital. Direct effects (level change) will be examined, as
54
55 54 well as gradual changes over time (slope change).

56
57
58 55 <<INSERT Figure 2>>
59
60 56

57 **Study setting**

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

69 **Study population**

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

74 *Inclusion criteria*

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

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

85 *Exclusion criteria*

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

88

89 **Table 1.** Exclusion criteria per patient group.

Breast cancer	Stoke	Advanced kidney disease
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Reduced consciousness 	<ul style="list-style-type: none"> • On kidney replacement therapy or conservative care management

90

91 **Intervention**

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

96 *Interactive patient decision aids containing personalized outcome data*

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

1
2
3 105 by telephone (breast cancer, stroke, and advanced kidney disease) among health care professionals.
4
5 106 Detailed results of the developmental process of the PtDAs will be published.
6
7 107 Each PtDA is composed of three components which contain personalized (patient-reported and clinical)
8
9 108 outcome data, both on individual as well as aggregated level. Personalized data is entered into the PtDA
10
11 109 by both health care professionals and patients. From the transition phase onwards (Figure 2), the health
12
13 110 care professional will introduce the PtDA to patients by means of a paper or digital consultation sheet
14
15 111 (*component 1*). Health care professionals provide personalized clinical data (e.g., for patients with stroke:
16
17 112 type of stroke, NIHSS score) when introducing the PtDA. Next, patients will receive a personal login
18
19 113 code to access the online interactive PtDA at home or during hospital admission (*component 2*). Each
20
21 114 PtDA contains evidence-based information about the options and pros and cons. Information is tailored
22
23 115 to relevant options for the patient and presented without favoring any particular outcome. Patients enter
24
25 116 patient-reported data, by means of PROMs, into the PtDA during use (e.g., for patients with advanced
26
27 117 kidney disease: physical condition, treatment goals). The PtDAs actively encourage patients to weigh
28
29 118 their options. Once patients have completed the PtDA, a summary sheet will automatically be created,
30
31 119 containing an overview of patient-reported personalized data and patient's preferences and
32
33 120 considerations, which can be used as a base for final decision-making in a consultation with their health
34
35 121 care professional (*component 3*).

38 39 122 *Breast cancer patient decision aid*

40
41 123 The breast cancer PtDA focusses on the organization of post-treatment surveillance after receiving
42
43 124 curative treatment for invasive non-metastasized breast cancer. The PtDA includes patients' personal
44
45 125 risks for locoregional recurrences estimated using the INFLUENCE-nomogram [12], a validated
46
47 126 prediction model with which the five-year risk for locoregional recurrences can be estimated, and a
48
49 127 patient-reported outcome measure (PROM) questionnaire on fear of cancer recurrence (sections of the
50
51 128 PtDAs were translated for publication; see Appendix B).

52 53 129 *Stroke patient decision aid*

54
55 130 The stroke PtDA focusses on discharge location and type of care after discharge from the hospital. The
56
57 131 PtDA includes an interactive "patients-like-me" model on the discharge location of comparable patients
58
59
60

1
2
3 132 based on historical Santeon data (N > 5000) and a PROMs questionnaire on physical and mental well-
4
5 133 being (see Appendix B).

6
7 134 *Advanced kidney disease patient decision aid*

8
9 135 The AKD PtDA focusses on the treatment modality decision in AKD. The PtDA contains an interactive
10
11 136 “patients-like-me” model on median survival- and mean hospitalization rates per treatment modality
12
13 137 based on Santeon and national data and a PROMs questionnaire on e.g. the physical condition (see
14
15 138 Appendix B).

16
17 139 *Training of health care professionals*

18
19 140 Health care professionals will be asked to complete an e-learning on applying (personalized) outcome
20
21 141 data to support SDM. Consequently, they will be asked to participate in a group training of one daypart.
22
23 142 The e-learning is focused on providing theoretical background and practical tips and tricks on applying
24
25 143 outcome information in the four steps of SDM in clinical consultations (including text, videos and self-
26
27 144 assessment tests). Completion of the e-learning takes approximately one hour. The group training
28
29 145 includes theoretical background information on SDM, reflection on audio-taped consultations (provided
30
31 146 by participating health care professionals as part of the data collection for the study), cases introduced
32
33 147 by participants, and practicing SDM conversational skills with an actor. By offering the e-learning before
34
35 148 the group training sessions, we reduce the time spent on theoretical background in the training, leaving
36
37 149 more time to practice on SDM conversational skills. Upon completion of the group training, follow-up
38
39 150 will be offered after one day (by offering a plasticized card or poster containing short written instructions
40
41 151 on SDM, and by presenting a publication on using outcome data to support SDM), after one month (by
42
43 152 offering tips, tricks, a testimonial by a colleague health care professional and an instruction clip on SDM)
44
45 153 and after two months (by offering the possibility to receive individualized feedback by sending an audio-
46
47 154 taped consultation to the trainer).

48
49 155 *Implementation strategy for the multicomponent intervention*

50
51 156 The implementation strategy is based on prior successful implementation strategies for PtDAs [23] and
52
53 157 a web-based self-management application using PROMs to monitor quality of life and focuses on
54
55 158 awareness, willingness and behavior of both health care professionals and patients.[24] Core elements
56
57 159 are listed in Table 2.

160

161 **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.
-

162

163 **Study design and procedures**

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

1
2
3 172 Internal validity will be increased, as each hospital will act as its own historical control group and the
4
5 173 hospitals will not switch at the same time.
6
7 174 Patients will be asked by their health care professional to participate in this study: 1) patients with breast
8
9 175 cancer will be informed and asked to participate during the follow-up consultation on the occasion of
10
11 176 their first post-treatment surveillance with imaging about one year after surgery, 2) patients with stroke
12
13 177 will be asked during admission to the hospital and 3) patients with AKD will be asked when a decision
14
15 178 has to be made about renal replacement therapy or conservative care. When interested, patients will
16
17 179 receive a patient information letter about the study. They will be asked for written informed consent. In
18
19 180 the post-implementation phase, patients that decline participation in the SHOUT-study will still be
20
21 181 offered the SDM supported by outcome information as the standard form of care.
22
23
24 182

26 183 **Data collection and methods**

28 184 To assess the effectiveness of the multicomponent intervention, first, a baseline questionnaire (T0) will
29
30 185 be sent to patients, via e-mail, post or will be handed out to patients with stroke during admission at the
31
32 186 hospital. Subsequently, patients will receive a follow-up questionnaire after 3 months (T1) for patients
33
34 187 with stroke, and after 6 (T1) and 12 (T2) months for patients with breast cancer or AKD. The time it
35
36 188 takes to complete the questionnaires differs per measurement moment. The T0 questionnaire takes about
37
38 189 30 to 45 minutes to complete and the T1 and T2 questionnaires take 15 to 20 minutes. The timing of
39
40 190 follow-up questionnaires differs between the three conditions due to the course and nature of and the
41
42 191 care pathways for the three conditions. Furthermore, some outcome measures are disease-specific and
43
44 192 will therefore only be assessed in the patient groups for which they are suitable.
45
46 193 Second, the consultations, in which the options are being discussed, will be audio-taped to assess
47
48 194 patients' involvement in the decision-making process from observers' viewpoint. Also, the length of the
49
50 195 consultations will be determined. Third, to assess the extent to which the intervention leads to changes
51
52 196 in the utilization and outcomes of health care, information will be retrieved from patients' electronic
53
54 197 health records.
55
56 198 To evaluate the implementation, first, the estimated total number of eligible patients and the total number
57
58 199 of patients who received the PtDA will be determined. Second, participating health care professionals

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

202

203 **Participant timeline**

204 The participant timeline is displayed in Figure 3.

205 <<INSERT Figure 3>>

206

207 **Outcomes**

208 **Effectiveness**

209 *Primary outcome measure*

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

215

216 *Secondary outcome measures*

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

1
2
3 228 questions; 9) perceived risk and fear of recurrence for patients with breast cancer, measured with the
4
5 229 Cancer Worry Scale (CWS), two subscales of the Revised Illness Perception Questionnaire for breast
6
7 230 cancer survivors (IPQ-BCS) and patient group-specific questions; and 10) participation / functioning and
8
9 231 caregivers' strain for patients with stroke, measured with the modified Ranking Scale (mRS), Utrecht
10
11 232 Scale for Evaluation of Rehabilitation-Participation (USER-P) and the Caregiver Strain Index (CSI) (see
12
13 233 Table 3, also for references).

15 234 *Observer-reported SDM*

17
18 235 We will combine the SDM-measurement tools, with a more objective score of SDM, as this score may
19
20 236 differ from the patients' subjective interpretation [27]. The Observing Patient Involvement in decision-
21
22 237 making scale (OPTION-5) [28] will be used to analyze the audio-recordings of encounters from clinical
23
24 238 settings. All audio-recordings will be double coded by two raters who have been trained on rating the
25
26 239 OPTION-5. In case of disagreement, a third rater will be consulted. The OPTION-5 includes five core
27
28 240 SDM steps, to which a sixth is added to assess the role of personalized outcome data (*'the health care*
29
30 241 *professional informs the patient on outcomes of different treatment options'*). The item scores will be
31
32 242 summed and rescaled to a 0 – 100 scale, with higher scores indicating greater SDM.

34 243 *Health care utilization and outcomes*

36
37 244 Patients' health care utilization and clinical outcomes will be extracted from their electronic health
38
39 245 records. For patients with breast cancer, the number of hospital visits, the number of mammograms and
40
41 246 other imaging during follow-up, and mortality will be extracted. For patients with stroke, the length of
42
43 247 stay, the number of re-admissions to the hospital, and the number of (treatment-related) complications
44
45 248 during admission will be extracted. For patients with AKD, the number of visits to outpatient clinics,
46
47 249 hospital admissions and hospitalization days, and the rate of major treatment-related complications will
48
49 250 be extracted.

51
52 251
53
54
55
56
57
58
59
60

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
<i>All patient groups:</i>								
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								
<i>Stroke and advanced kidney disease:</i>								
• 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)								
<i>Breast cancer:</i>								
	10 items with 3 response options.		X				X	
<i>Stroke:</i>								
	7 items with 3 – 7 response options.		X				X	
<i>Advanced kidney disease:</i>								
	7 items with 3 – 5 response options.		X				X	
Quality of life								
<i>Breast cancer and advanced kidney disease:</i>								
• 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
<i>Stroke:</i>								
• 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)										
<i>Breast cancer:</i>	48 items with 3 – 10 response options / open-ended.		X						X	
<i>Stroke:</i>	6 items with 3 – 8 response options / open-ended.		X						X	
<i>Advanced kidney disease</i>	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	
<i>Breast cancer:</i>										
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	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	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	X	X
<i>Stroke:</i>										
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.

1
2
3 **252 *Moderators***

4
5 **253 *Socio-demographic characteristics***

6
7 **254** In the baseline questionnaire, patients' sex, birth year, marital status, occupation, and education level
8
9 **255** will be asked.

10
11 **256 *Clinical characteristics***

12
13 **257** Relevant medical characteristics will be extracted from the baseline questionnaire and the electronic
14
15 **258** health records. For patients with breast cancer, tumor and treatment characteristics will be extracted. For
16
17 **259** patients with stroke, etiology of stroke, and whether or not the patient has been treated with reperfusion
18
19 **260** therapy will be extracted. For patients with AKD, renal function, etiology and duration of kidney failure,
20
21 **261** whether these patients have had other treatment modalities for kidney failure in the past, comorbidity
22
23 **262** and definite treatment modality will be extracted.

24
25
26 **263 *Health literacy***

27
28 **264** Patients' health literacy will be assessed in the baseline questionnaire by the Set of Brief Screening
29
30 **265** Questions (SBSQ).[47] The mean score on the three items will be calculated, with higher scores
31
32 **266** reflecting higher health literacy skills.

33
34
35 **267**

36
37 **268 *Implementation***

38
39 **269 *Implementation rate***

40
41 **270** The implementation rate will be calculated as the proportion of patients who received the PtDA compared
42
43 **271** to the estimated total number of eligible patients during the period of 6 to 12 months in which the PtDA
44
45 **272** will be handed out.

46
47
48 **273**

49 **274 *Health care professionals' view on the implementation process and use of the patient decision aid***

50
51 **275 *Determinants of implementing an innovation***

52
53 **276** Health care professionals will fill out a questionnaire based on the Measurement Instrument for
54
55 **277** Determinants of Innovations (MIDI).[48] The MIDI assesses barriers and facilitators of implementation
56
57 **278** at the level of innovation (PtDA), the user (health care professionals) and the organization (hospital).

58
59
60 **279**

1
2
3 280 *Physicians' willingness to incorporate shared decision-making*

4
5 281 Health care professionals will also fill out a questionnaire based on items from the incorpoRATE, a brief
6
7 282 and broadly applicable measure of physicians' willingness to incorporate SDM into practice.[49]

8
9 283

10
11 284 **Sample size**

12
13 285 The sample size was estimated using Statistical Analysis System (SAS) with the SDM-Q-9 as primary
14
15 286 outcome measure with the statistical significance level set at $\alpha = 0.05$ (two-sided). Since there is no
16
17 287 agreement on what constitutes a clinically meaningful difference on the SDM-Q-9, we estimated the size
18
19 288 of the expected effect on previous studies using the SDM-Q-9. The size of the expected effect of the
20
21 289 intervention on the SDM-Q-9 was set to be small to moderate (Cohen's $d = 0.3-0.4$) as relatively high
22
23 290 scores on the SDM-Q-9 are common in the Netherlands.[50] The mITS with seven clusters (i.e. hospitals)
24
25 291 had 18 measurement periods (excluding the transition phase, see Figure 2). For patients with breast
26
27 292 cancer and stroke, a non-large Intraclass Correlation Coefficient ($ICC = 0.05$) was assumed. The
28
29 293 correlation between monthly measurements was expected to be high ($0.7 - 0.9$) throughout a period of
30
31 294 18 months, although correlations between months farther apart could be lower than for months closer
32
33 295 by. A correlation structure where the correlation decreases exponentially with the distance between
34
35 296 months (autoregressive correlation structure) turned out too conservative and a correlation structure
36
37 297 where the correlation between months is the same regardless of the distance between them (compound
38
39 298 symmetry correlation structure) was too optimistic and not realistic for this purpose. Therefore, power
40
41 299 calculations were primarily based on assuming that the correlation between months decreases from 0.9,
42
43 300 for subsequent months, to 0.7, for months that are the farthest apart (i.e. the first and last month). To be
44
45 301 precise, the correlation decreases linearly on the log scale from $\log(0.9)$ to $\log(0.7)$ (linear exponent
46
47 302 autoregressive correlation structure).[51] Five patients per hospital per month was considered feasible,
48
49 303 and with a 25% loss to follow-up, this results in a monthly inclusion rate of four patients. This yields
50
51 304 more than 80% power and amounts to a study population of $N = 504 - 630$.

52
53 305 For patients with AKD, an inclusion rate of four patients was deemed feasible within the hospitals.

54
55 306 Assuming a 25% loss to follow up, three patients per month would give at least 80% power for detecting

1
2
3 307 a Cohen's $d = 0.4$ assuming a correlation between subsequent months of at least 0.8 and a correlation
4
5 308 between the first and last month of at least 0.6. This amounts to a study population of $N = 378 - 473$.

6
7 309

8
9 310 **Statistical methods**

10
11 311 An overview of the demographic and clinical characteristics will be provided using descriptive statistics.
12
13 312 Continuous data will be expressed as a mean with the standard deviation (SD), or as the median
14
15 313 (interquartile range) where appropriate. Categorical data will be expressed as frequencies (%) unless
16
17 314 stated otherwise.

18
19 315 Separate ITS analyses will be performed to analyze the data per patient group per hospital. Segmented
20
21 316 regression will be employed, with the period before and after the introduction of the intervention as
22
23 317 segments. In each segment, linear regression will be fitted to the data, allowing each segment of the time
24
25 318 series to exhibit different levels and trends. Correlation between repeated measurements in each time
26
27 319 series will be accounted for by modelling the error structure. The effect of the intervention will be
28
29 320 examined by comparing the slopes and intercepts in both the pre- and post-implementation phase using
30
31 321 the following model:

$$32 322 \quad Y(T) = \beta_0 + \beta_1 \cdot T + \beta_2 \cdot I + \beta_3 \cdot I \cdot t$$

33
34 323 where β_0 will represent the baseline level at $T = 0$, β_1 will be interpreted as the change in outcomes
35
36 324 associated with a time unit increase (representing the underlying trend in the pre-implementation phase),
37
38 325 $I = 1$ when the hospital is at the time T in the intervention and $I = 0$ otherwise, β_2 will be the level change
39
40 326 in the post-implementation phase and β_3 will indicate the slope change following the implementation
41
42 327 phase (using the interaction between time t since the intervention started and the indicator for being in
43
44 328 the intervention: I). A change in β_2 will constitute an immediate effect, while a change in β_3 will imply
45
46 329 an effect that was experienced over time (which also allows us to measure the sustainability of the
47
48 330 impact). Moreover, segmented regression will enable us to control for other variables, that can cause a
49
50 331 change in level or trend of the outcomes of interest.

51
52 332 Seasonal patterns and outliers will be identified by visualizing the multiple time series. The percentage
53
54 333 of drop-out and missings at each follow-up timepoint will be recorded. If necessary, either imputation
55
56 334 techniques or sensitivity analyses will be used to assess their impact on the trial results.

1
2
3 335 To correct for multiple testing and the risk of type-1 errors a Bonferroni-Holm procedure will be applied
4
5 336 across the set of primary and secondary endpoints.
6

7 337 To explore the average effect per patient group across all hospitals, a meta-analysis of the hospital-
8
9 338 specific effects will be conducted. To examine the overall effect of the SHOUT study, also, meta-analysis
10
11 339 across all patient groups and hospitals will be performed. Finally, implementation across all patient
12
13 340 groups will be investigated by using several the same outcome measures at a similar points in time.
14

15
16 341

17 18 342 **Patient and public involvement**

19
20 343 Santeon supports that patients with ‘lived experiences’ become members of a research team. Since the
21
22 344 very beginning (composing the grant application), we have engaged a core group of patients and patient
23
24 345 representatives of the patient associations involved. We designed the multicomponent intervention in
25
26 346 collaboration with patients and health care professionals (see the Methods and Analysis). In addition,
27
28 347 patient representatives were involved in the development of the study. Our collaboration with the patient
29
30 348 associations will continue throughout the study. Study findings about the potential benefits of the
31
32 349 multicomponent intervention will be disseminated by means of our project website.
33

34
35 350

36 37 351 **ETHICS AND DISSEMINATION**

38
39 352 The Medical research Ethics Committees United in Nieuwegein, the Netherlands, has confirmed that the
40
41 353 Medical Research Involving Human Subjects Act (WMO) does not apply to this study (reference number
42
43 354 W19.154). Bureau Onderzoek & Innovatie of Santeon, the Netherlands, approved this study (reference
44
45 355 numbers METC 2019-075, -076 and -077).
46

47 356 The study will be conducted in accordance with local laws and regulations. Eligible patients will fully
48
49 357 be informed about the study and asked to participate. They will receive a patient information letter and
50
51 358 will be informed by telephone about the implications of participation. Patients will have sufficient
52
53 359 opportunity to ask questions and to consider the implications before providing written informed consent.
54

55
56 360 They will be allowed to withdraw from the study without giving a reason, at any time.

57
58 361 The SHOUT study is part of a larger Santeon program on using outcome data for SDM (‘Experiment
59
60 362 Uitkomstindicatoren). It will contribute to the limited understanding of the impact of using (clinical and

1
2
3 363 patient-reported) outcome data for SDM. We will share our findings through peer-reviewed journals,
4
5 364 (inter)national conferences, workshops webinars, and newsletters and social media.
6

7 365

9 366 **ACKNOWLEDGEMENTS**

11 367 We thank all patients, patient representatives and health care professionals for their contribution to
12
13 368 designing the multi-component intervention and execution the SHOUT study. The SHOUT study is part
14
15 369 of a larger program on using outcome data for SDM ('Experiment Uitkomstindicatoren Santeon'), which
16
17 370 is part of the Outcome-based Health care program initiated by the Dutch Ministry of Health, Welfare and
18
19 371 Sports. We would like to thank ZonMw for funding this project.
20
21

22 372

24 373 **FOOTNOTES**

26 374 **Availability of data and materials**

28 375 Data will be collected and recorded in CASTOR EDC, a cloud-based electronic data capture platform.
29
30 376 This platform is fully compliant with GCP, 21 CFR part 11, GDPR, HIPAA, ISO27001 and ISO 9001.
31
32 377 All data will be coded and password protected. Study participants will be assigned a participant
33
34 378 identification number (PIN). A digital, password protected identifying list relating medical information
35
36 379 of participants to their PIN numbers will be kept on a secured server in the Santeon hospitals. All data
37
38 380 and study documents will deleted and discarded after 15 years. The datasets used and / or analyzed during
39
40 381 the SHOUT study are available from JWA (breast cancer), NE (AKD) and JCMP (stroke) on reasonable
41
42 382 request. The (intellectual) property rights with regard to the generated data will reside at Santeon,
43
44 383 Utrecht, The Netherlands. Interested parties can request a non-exclusive license for research and
45
46 384 educational purposes. The non-exclusive license may be requested only after the completion of the theses
47
48 385 to be written reserving the generated data.
49

50 386

54 387 **Competing interests**

55 388 None declared.
56
57 389
58
59 390

1
2
3 391 **Funding**
4

5 392 This research project is funded by ZonMw as part of the ‘Experiment Uitkomstindicatoren Santeon’.

6
7 393 This funding had no involvement in collection, management, analysis, and interpretation of the data;

8
9 394 writing this manuscript or the decision to submit the article for publication.
10

11 395

12
13 396 **Authors' contributions**

14
15 397 JWA, NE, JCMP, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, SMvS, and CFvU-K developed the

16
17 398 multicomponent intervention. MQNH, ST, PBvdN, PJvdW and CFvU-K contributed to the design of the

18
19 399 study. JWA, NE, JCMP are conducting this study in fulfillment of a PhD and will be responsible for data

20
21 400 collection. JWA, NE, JCMP and ST will be responsible for data analysis. All authors will be responsible

22
23 401 for interpreting the data. The present manuscript was drafted by MQNH and CFvU-K. JWA, NE,

24
25 402 JCMP, ST, SS, CHCD, LJAS, YEAvR, RMAvdD, WJWB, PBvdN, RMvdB-V, SMvS, MMG and

26
27 403 PJvdW critically revised this manuscript. All authors have read and approved the final manuscript.
28
29 404

30
31 405 **ABBREVIATIONS**

32
33 406 AKD, advanced kidney disease

34
35 407 mITS, multiple interrupted time series

36
37 408 PROM, patient-reported outcome measure

38
39 409 PtDA, patient decision aid

40
41 410 SDM, shared decision-making

42
43 411 VBHC, value-based healthcare

44
45 412
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

413 **REFERENCES**

- 414 1 Kampstra NA, Zipfel N, van der Nat PB, Westert GP, van der Wees PJ, Groenewoud AS. Health
415 outcomes measurement and organizational readiness support quality improvement: a systematic
416 review. *BMC Health Serv Res* 2018;18:1005. <https://doi.org/10.1186/s12913-018-3828-9>.
- 417 2 Porter ME, Larsson S, Lee TH. Standardizing patient outcomes measurement. *N Engl J Med*
418 2016;374:504-6. <https://doi.org/10.1056/NEJMp1511701>.
- 419 3 Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477-81.
420 <https://doi.org/10.1056/NEJMp1011024>.
- 421 4 Steinmann G, van de Bovenkamp H, de Bont A, Delnoij D. Redefining value: a discourse analysis
422 on value-based health care. *BMC Health Ser Res* 2020;20:862. [https://doi.org/10.1186/s12913-020-](https://doi.org/10.1186/s12913-020-05614-7)
423 05614-7.
- 424 5 Van der Nat PB. The new strategic agenda for value transformation. *Health Serv Manage Res*
425 2021;0(0):1-5. <https://doi.org/10.1177/09514848211011739>.
- 426 6 Stiggelbout AM, Pieterse AH, de Haes JCJM. Shared decision making: concepts, evidence and
427 practice. *Patient Educ Couns* 2015;98(10):1172-9. <https://doi.org/10.1016/j.pec.2015.06.022>.
- 428 7 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen*
429 *Intern Med* 2012;27:1361-7. <https://doi.org/10.1007/s11606-012-2077-6>.
- 430 8 Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening
431 decisions. *Cochrane Database Sys Rev* 2017;4:CD001431.
432 <https://doi.org/10.1002/14651858.CD001431.pub5>.
- 433 9 Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the
434 consequences. *Implement Sci* 2016;11:114. <https://doi.org/10.1186/s13012-016-0480-9>.
- 435 10 Damman OC, Jani A, de Jong BA, et al. The use of PROMs and shared decision-making in medical
436 encounters with patients: an opportunity to deliver value-based health care to patients. *J Eval Clin*
437 *Pract* 2020;26:524-40. <https://doi.org/10.1111/jep.13321>.
- 438 11 La Grouw Y, Kee K, Ybema S, Taverne H, Boonen L. *Samen Beslissen in de praktijk:*
439 *praktijkonderzoek i.o.v. het Zorginstituut Nederland*. Equalis / VU,
440 2019. <https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen->
441 [beslissen-in-de-praktijk](https://www.zorginstituutnederland.nl/publicaties/rapport/2019/06/14/rapportage-samen-beslissen-in-de-praktijk)

- 1
2
3 442 12 Witteveen A, Vliegen IMH, Sonke GS, Klaase JM, IJzerman MJ, Siesling S. Personalisation of
4
5 443 breast cancer follow-up: a time-dependent prognostic nomogram for the estimation of annual risk of
6
7 444 locoregional recurrence in early breast cancer patients. *Breast Cancer Res Treat* 2015;152:627-36.
8
9 445 <https://doi.org/10.1007/s10549-015-3490-4>.
- 10
11 446 13 Biglan A, Ary D, Wagenaar AC. The value of interrupted time-series experiments for community
12
13 447 intervention research. *Prev Sci* 2000;1:31-49. <https://doi.org/10.1023/A:1010024016308>.
- 14
15 448 14 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items
16
17 449 for clinical trials. *Ann Intern Med* 2013a;158:200-7. [https://doi.org/10.7326/0003-4819-158-3-](https://doi.org/10.7326/0003-4819-158-3-201302050-00583)
18
19 450 [201302050-00583](https://doi.org/10.7326/0003-4819-158-3-201302050-00583).
- 20
21 451 15 Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for
22
23 452 protocols of clinical trials. *BMJ*. 2013b;346:e7586. <https://doi.org/10.1136/bmj.e7586>.
- 24
25 453 16 EIT Health. *Implementing Value-Based Health Care in Europe: Handbook for Pioneers* (Director:
26
27 454 Gregory Katz). 2020.
- 28
29 455 17 Santeon. www.santeon.nl 2021; 22 June.
- 30
31 456 18 Templeton AJ, Booth CM, Tannock IF. Informing patients about expected outcomes: the efficacy-
32
33 457 effectiveness gap. *J Clin Oncol* 2020;38(15):1651-5. <https://doi.org/10.1200/JCO.19.02035>.
- 34
35 458 19 RIVM. *Ranglijst aandoeningen op basis van ziektelast (in DALY's)*. 2018.
36
37 459 [https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-](https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys)
38
39 460 [dalys](https://www.volksgezondheidenzorg.info/ranglijst/ranglijst-aandoeningen-op-basis-van-ziektelast-dalys).
- 40
41 461 20 Ankersmid JW, Drossaert CHC, van Riet YEA, et al. Needs and preferences of breast cancer
42
43 462 survivors regarding outcome-based shared decision-making about personalised post-treatment
44
45 463 surveillance. *J Cancer Surviv* 2022; <https://doi.org/10.1007/s11764-022-01178-z>.
- 46
47 464 21 Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient
48
49 465 decision aids: a modified Delphi consensus process. *Med Decis Making* 2014;34(6):699-710.
50
51 466 <https://doi.org/10.1177/0272989X13501721>.
- 52
53 467 22 Patiëntenfederatie Nederland, Nederlands Huisartsen Genootschap (NHG), Federatie Medisch
54
55 468 Specialisten (FMS), Verpleegkundigen & Verzorgenden Nederland (V&VN). *Hoe maak ik een*
56
57 469 *keuzehulp bij een richtlijn?* Den Haag, The Netherlands, 2018.
- 58
59
60

- 1
2
3 470 23 Van Tol-Geerdink JJ, van Oort IM, Somford DM, et al. Implementation of a decision aid for
4
5 471 localized prostate cancer in routine care: a successful implementation strategy. *Health Inform J*
6
7 472 2020;26(2):1194-207. <https://doi.org/10.1177/1460458219873528>.
8
9 473 24 De Wit LM, van Uden-Kraan CF, Lissenberg-Witte BI, et al. Adoption and implementation of a
10
11 474 web-based self-management application “Oncokompas” in routine cancer care: a national pilot
12
13 475 study. *Support Care Cancer* 2019;27:2911-20. <https://doi.org/10.1007/s00520-018-4591-5>.
14
15 476 25 Rodenburg-Vandenbussche S, Pieterse AH, Kroonenberg PM, et al. Dutch translation and
16
17 477 psychometric testing of the 9-item Shared Decision Making Questionnaire (SDM-Q-9) and Shared
18
19 478 Decision Making Questionnaire-physician version (SDM-Q-Doc) in primary and secondary care.
20
21 479 *PloS ONE* 2015;10(7):e0132158. <https://doi.org/10.1371/journal.pone.0132158>.
22
23 480 26 Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-Q-9).
24
25 481 Development and psychometric properties in a primary care sample. *Patient Educ Couns*. 2010
26
27 482 Jul;80(1):94-9. doi: 10.1016/j.pec.2009.09.034.
28
29 483 27 Ubbink DT, van Asbeck EV, Aarts JWM, et al. Comparison of the CollaboRATE and SDM-Q-9
30
31 484 questionnaires to appreciate the patient-reported level of shared decision-making. *Patient Educ*
32
33 485 *Couns*, available online 10 March 2022 <https://doi.org/10.1016/j.pec.2022.03.007>
34
35 486 28 Elwyn G, Grande SW, Barr P. *Observer OPTION^s manual. Measuring shared decision making by*
36
37 487 *assessing recordings or transcripts of encounters from clinical settings*. The Dartmouth Institute for
38
39 488 Health Policy and Clinical Practice, Lebanon, USA, 2018.
40
41 489 29 Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a
42
43 490 fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient*
44
45 491 *Educ Couns* 2013;93(1):102-7. <http://doi.org/10.1016/j.pec.2013.05.009>.
46
47 492 30 O’Connor AM. *User Manual – Decisional Conflict Scale*. OHRI. 1993 (modified 2010);1:1-16.
48
49 493 31 O’Connor AM. *User Manual – Decision Regret Scale*. Ottawa, Ottawa Hospital Research Institute;
50
51 494 1996 (modified 2003).
52
53 495 32 Degner LF, Sloan JA, Venkatesh P. The Control Preference Scale. *Can J Nurs Res* 1997;29(3):21-
54
55 496 43.
56
57
58
59
60

- 1
2
3 497 33 Ware J, Kosinski M, Keller S. A 12-item Short-Form Health Survey: Construction of scales and
4 preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-33.
5 498
6
7 499 <https://doi.org/10.1097/00005650-199603000-00003>.
8
9 500 34 Ware JE, Kosinski MA, Keller SD. *SF-12: How to score the SF-12 Physical and Mental Health*
10 *Summary Scales*. The Health Institute, New England Medical Center, Boston Massachusetts, 1995.
11 501
12
13 502 35 Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health
14 summary scores from the patient-reported outcomes measurement information system (PROMIS)
15 503 global items. *Qual Life Res* 2009;18:873-80. <https://doi.org/10.1007/s11136-009-9496-9>.
16 504
17
18 505 36 Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level
19 506 version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727-36. [https://doi.org/10.1007/s11136-](https://doi.org/10.1007/s11136-011-9903-x)
20 507 [011-9903-x](https://doi.org/10.1007/s11136-011-9903-x).
21
22
23 508 37 Versteegh MM, Vermeulen KM, Evers SMAA, de Wit GA, Prenger R, Stolk EA. Dutch tariff for
24 the five-level version of EQ-5D. *Value Health* 2016;19(4):343-52.
25 509
26 510 <https://doi.org/10.1016/j.jval.2016.01.003>.
27
28
29 511 38 Graham ID, O'Connor AM. *User Manual – Preparation for Decision Making Scale*. Ottawa, Ottawa
30 512 Hospital Research Institute, 1995 (modified 2010).
31
32
33 513 39 Custers JAE, Kwakkenbos L, van de Wal M, Prins JB, Thewes B. Re-validation and screening
34 capacity of the 6-item version of the Cancer Worry Scale. *Psycho-Oncol* 2018;27(11):2609-15.
35 514
36
37 515 40 Moon Z, Moss-Morris R, Hunter MS, Hughes LD. Measuring illness representations in breast cancer
38 survivors (BCS) prescribed tamoxifen: modification and validation of the Revised Illness
39 516 Perceptions Questionnaire (IPQ-BCS). *Psychol Health* 2017;32(4):439-58.
40 517
41 518 <https://doi.org/10.1080/08870446.2016.1275629>.
42
43
44 519 41 Deimling GT, Bowman KF, Sterns S, Wagner LJ, Kahana B. Cancer-related health worries and
45 520 psychological distress among older adult, long-term cancer survivors. *Psycho-Oncol*
46 521 2006;15(4):306-20. <https://doi.org/10.1002/pon.955>.
47 522
48
49 523 42 Humphris GM, Watson E, Sharpe M, Ozakinci G. Unidimensional scales for fear of cancer
50 524 recurrence and their psychometric properties: the FCR4 and FCR7. *Health Qual Life Out*
51 2018;16:30. <https://doi.org/10.1186/s12955-018-0850-x>.
52
53
54
55
56
57
58
59
60

- 1
2
3 525 43 Herschbach P, Berg P, Dankert A, et al. Fear of progression in chronic diseases: psychometric
4 526 properties of the Fear of Progression Questionnaire. *J Psychosom Res* 2005;58(6):505-11.
5 527 <https://doi.org/10.1016/j.jpsychores.2005.02.007>.
6
7 528 44 Bruno A, Akinwuntan AE, Lin C, et al. Simplified modified Ranking Scale questionnaire. *Stroke*
8 529 2011;42(8):2276-9. <https://doi.org/10.1161/STROKEAHA.111.613273>.
9
10 530 45 Post MWM, van der Zee CH, Hennink J, Schafrat CG, Visser-Meily JMA, van Berlekom SB.
11 531 Validity of the Utrecht scale for evaluation of rehabilitation-participation. *Disabil Rehabil*
12 532 2012;34(6): 478-85. <https://doi.org/10.3109/09638288.2011.608148>.
13
14 533 46 Robinson BC. Validation of a Caregiver Strain Index. *J Gerontol* 1983;38(3):344-8.
15 534 <https://doi.org/10.1093/geronj/38.3.344>.
16
17 535 47 Chew LD, Griffin JM, Partin MR, et al. Validation of screening questions for limited health literacy
18 536 in a large VA outpatient population. *J Gen Intern Med* 2008;23:561-6.
19 537 <https://doi.org/10.1007/s11606-008-0520-5>.
20
21 538 48 Fleuren MAH, Paulussen TGWM, van Dommelen P, van Buuren S. Towards a measurement
22 539 instrument for determinants of innovations. *Int J Qual Health C* 2014;26(5):501-10.
23 540 <https://doi.org/10.1093/intqhc/mzu060>.
24
25 541 49 Berkowitz J, Martinez-Cambor P, Stevens G, Elwyn G. The development of incorpoRATE: a
26 542 measure of physicians' willingness to incorporate shared decision making into practice. *Patient Educ*
27 543 *Couns* 2021; Feb 25:S0738-3991(21)00140-3. <https://doi.org/10.1016/j.pec.2021.02.040>.
28
29 544 50 Van der Hulst F, Meijer M, Holst L, Brabers A, de Jong J. *Infographic. Mate waarin arts en patiënt*
30 545 *samen beslissen over een behandeling nauwelijks veranderd tussen 2016-2020. Gezamenlijke*
31 546 *besluitvorming*. Utrecht: Nivel, 2021.
32
33 547 51 Simpson SL, Edwards LJ, Muller KE, Sen PK, Styner MA. A linear exponent AR(1) family of
34 548 correlation structures. *Stat Med* 2010;29(17):1825-38. <https://doi.org/10.1002/sim.3928>.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52

530 Figure legend

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

- 1
2
3 553 • **Figure 2:** Time schedule of the multiple interrupted time series. *White blocks: pre-implementation*
4 *phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.*
5 554
6
7 555 • **Figure 3:** Participant timeline. *HCPs; health care professionals, SDM = shared decision-making,*
8 *PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.*
9 556
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

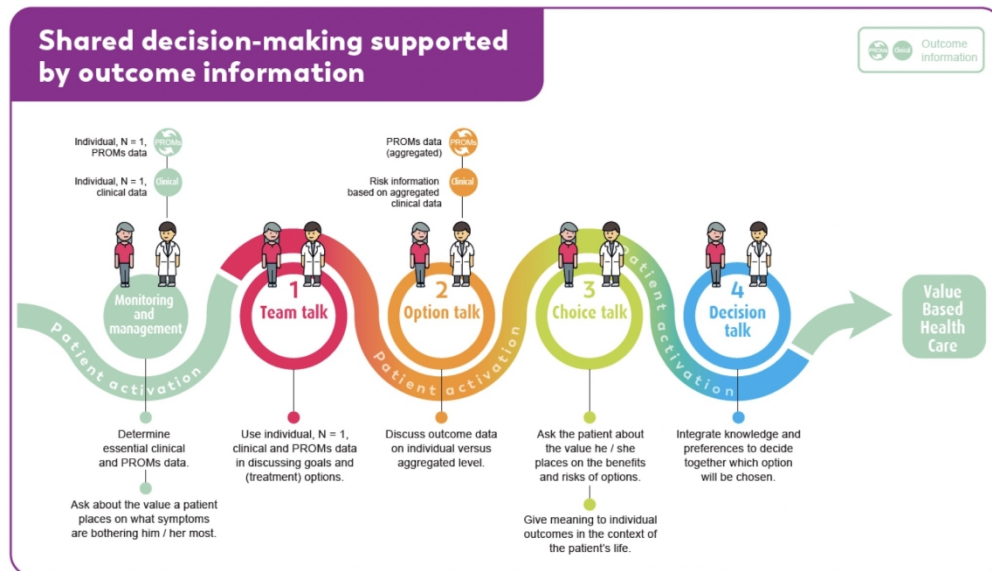


Figure 1: How to use outcome data in the four-step conversational SDM model. / PROMs = patient-reported outcome measures.

361x207mm (300 x 300 DPI)

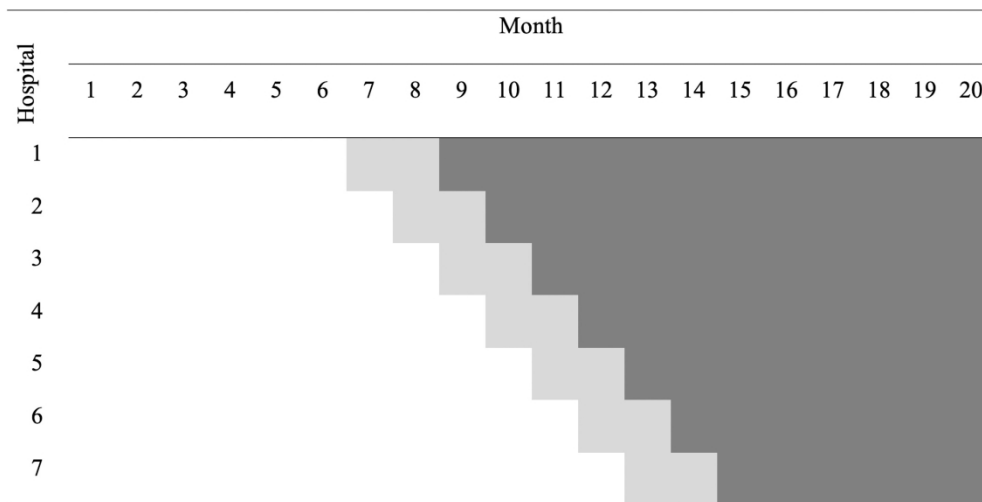


Figure 2: Time schedule of the multiple interrupted time series. / White blocks: pre-implementation phase; light grey blocks: transition phase; dark grey blocks: post-implementation phase.

373x187mm (300 x 300 DPI)

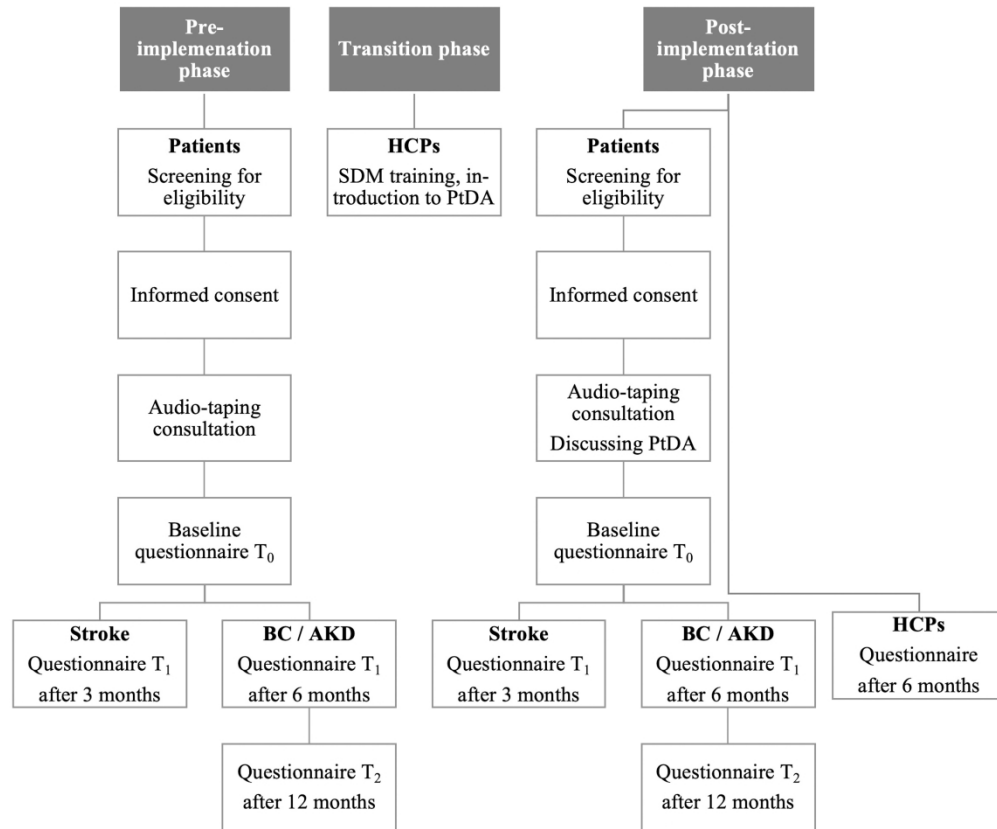


Figure 3: Participant timeline. / HCPs; healthcare professionals, SDM = shared decision-making, PtDA = patient decision aid, BC = breast cancer, AKD = advanced kidney disease.

423x352mm (300 x 300 DPI)



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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	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

1				
2				
3	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
4				
5				
6	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	8, 14 – 15
7				

8 **Methods: Assignment of interventions (for controlled trials)**

9 Allocation:

10				
11				
12				
13	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
14				
15				
16				
17	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
18				
19				
20				
21	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8 – 9
22				
23				
24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	NA
25				
26				
27				
28		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
29				
30				

31 **Methods: Data collection, management, and analysis**

32				
33	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
34				
35				
36				
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

	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

1				
2				
3	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
4				
5				
6	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
7				
8				
9				
10		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
11				
12	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
13				
14				
15	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
16				
17				
18				
19	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
20				
21				
22	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
23				
24				
25	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
26				
27				
28				
29		31b	Authorship eligibility guidelines and any intended use of professional writers	19
30				
31		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	18
32				
33				
34	Appendices			
35				
36	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Patient Consent Forms
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

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. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](#)" license.

For peer review only

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]

Breast Cancer Surveillance Decision Aid pat12345 ▾

1. Your situation 2. Surveillance 3. Quiz 4. Considerations 5. Preferences 6. Questionnaire 7. Summary


2. Surveillance

What is post-treatment surveillance? ✓	<p>What is the risk for recurrence of breast cancer?</p> <p>You and your healthcare professional have discussed your personal risk for recurrence of breast cancer. This risk is different for every patient.</p> <p>The risk for a new breast tumor or recurrence depends on the following characteristics:</p> <ul style="list-style-type: none"> Your age The size of the primary breast tumor when it was discovered If lymph nodes in the armpit were affected The characteristics of the primary breast cancer: <ul style="list-style-type: none"> if there was one or more tumors in the breast how different the breast cancer cells look from normal breast cells (grade) if the tumor cells were sensitive to hormones (estrogen and/or progesterone) if the tumor cells were sensitive to certain proteins (HER2) The treatment you have received for breast cancer <p>Your personal risk</p> <p>Your healthcare professional has calculated your personal risk for recurrence of breast cancer. In 2 to 3 out of 100 women with the same characteristics as you, the breast cancer recurs in the breast area within 5 years after treatment.</p> <p>For the calculation a prediction model was used. The characteristics above are incorporated into this model.</p> <p>> Read more about the prediction model</p>
What is the risk for recurrence of breast cancer? ✓	
Which choices do I have about surveillance? ✓	
Annual surveillance or less? ✓	
Which diagnostic tests for surveillance? ✓	
Do I want the results at the hospital or by telephone? ✓	
What is cancer survivorship care? ✓	
What do I need to pay attention to? ✓	
What if I don't have surveillance? ✓	

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).

 Breast Cancer Surveillance Decision Aid pat12345 ▾

1. Your situation 2. Surveillance 3. Quiz 4. Considerations 5. Preferences 6. Questionnaire 7. Summary

6. Questionnaire

You may feel anxious and insecure after breast cancer. This questionnaire will give you an indication how you currently feel.

	Never	Hardly ever	Sometimes	Almost always
How often have you thought about your chances of getting breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Have these thoughts affected your mood?	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Have these thoughts interfered with your abilities to do daily activities?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How concerned are you about the possibility of getting breast cancer again one day?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often do you worry about developing breast cancer again?	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much of a problem is this worry?	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your score				12

What does your score mean?

A completed questionnaire gives a score between 6 and 24.

A score of 11 or lower indicates that you are *rarely concerned* about recurrence of breast cancer

A score of 12 or higher indicates that you are *regularly concerned* about recurrence of breast cancer

Tip Discuss this with your healthcare professional if you feel limited by fear of recurrence in your daily life. Together you will decide if additional support may be useful. You can also read more about how to deal with fear or recurrence on the website of the [Breast Cancer Association](#).

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.

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 think 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	

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.

Stroke decision aid

Your diagnosis
Your healthcare professional marks your diagnosis

Your diagnosis Ischaemic stroke Haemorrhagic stroke

Your NIHSS 0 - 4 5 - 15 16 - 42

This score quantifies stroke severity.
A higher score indicates higher stroke severity.

Observations of your healthcare professionals

Shared decision-making for discharge planning
Soon, you will be discharged from the hospital. The options for choosing a discharge destination are as follows:

- Returning home with or without therapy
- Returning home with an ambulatory rehabilitation program
- Transfer to an inpatient rehabilitation facility
- Transfer to an inpatient skilled nursing facility
- Moving to a nursing home

The patient decision aid will help you and your healthcare professional to choose the most suitable discharge destination.

Use the decision aid

In the online decision aid, you can read information about stroke and your hospital admission. Also, you can clarify your values and preferences concerning discharge planning.

After being discharged from the hospital, you can still consult the decision aid for information about the effects of stroke.

Go to:

Username Password

© Santeon en ZorgKeuzelab <<paidTitle>> v3

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).

3. Where to rehabilitate?

Which discharge destinations are available? ✓	<p>Where did other patients with stroke rehabilitate after discharge from the hospital?</p> <p>Sometimes it can help to know where other patients go to after being discharged from hospital. Below you can see an overview of distribution between the different discharge destinations depending on diagnosis, age and stroke severity.</p> <p>Diagnosis Ischaemic stroke Haemorrhagic stroke</p> <p>Age younger than 30 years 30 - 49 years 50 - 64 years 65 - 79 years older than 80 years</p> <p>NIHSS* 0 - 4 5 - 15 16 - 42</p>  <p>Of 100 patients:</p> <ul style="list-style-type: none"> 51 returned home 37 temporarily moved to an inpatient rehabilitation facility 8 temporarily moved to an inpatient skilled nursing facility 4 permanently moved to a nursing home <p><small>This information is based on data from more than 5000 patients with stroke from OLVG, MST and St. Antonius during the period of 2017-2020.</small></p> <p><small>* The National Institute of Health Stroke Scale (NIHSS) score quantifies stroke severity. A higher score indicates higher stroke severity.</small></p>
What is the best discharge destination for me? ✓	
Where did other patients with stroke rehabilitate after discharge from the hospital? ✓	
What is required for rehabilitation at home? ✓	
What can I expect from an inpatient rehabilitation program? ✓	
Who can I consult after finishing my rehabilitation program? ✓	
What are other important things to know for me and my caregivers? ✓	

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.





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.	 I was able to walk more than 30 minutes	Yes
What effects of my stroke do I notice? Weakness and numbness of my left arm.	 I was walking with a walking aid	No
What would I like to do again? Returning home without help, being able to work and cycle again	 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?	

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.

Kidney failure decision aid

Each treatment option for kidney failure impacts your life differently. Which treatment option ultimately suits you depends on your medical history and on what's important to you and your loved ones.

Your situation
When you should start a treatment for kidney failure depends on your medical history, the course of your kidney disease, the severity of your symptoms and your wishes.

Your options
Your nephrologist indicates what treatment options you are eligible for.

Disclaimer: additional examinations may be needed to evaluate if these options are possible for you. If you are not eligible for an option your nephrologist will explain why.

Flowchart: This appointment leads to 'Use the decision aid and list your goals, considerations and preferences' and 'Additional appointments with your treatment team'. Both lead to 'Choosing your treatment with your nephrologist', which leads to 'Start treatment preparations'. A tip box says: 'Begin on time! Educate yourself about your treatment options. Making a decision and the subsequent preparations take a lot of time. Prevent unnecessary pressure and give yourself time to make a well-informed decision.'

Graph: Kidney function (0% to 30%) vs Time. Legend: Education/decision-making, Preparations, Treatment start.

Options:

- Kidney transplantation
- Peritoneal dialysis
- Hemodialysis
- Conservative care

Form:

Your nephrologist

name

name

name

name

name

.....

If you have questions you can contact your social worker.

This decision aid will help you prepare for your future appointments

Use the online decision aid to:

- Read about your diagnosis and treatment options
- Think about your values and preferences
- Set goals for your treatment

Together with your healthcare provider you can:

- Discuss your goals, values and preferences
- Choose a treatment that suits you best

To use the online decision aid

Go to

Username Password

In collaboration with: nyn, NF, santeon, ZorgKeuzeLab

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

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 want a treatment that primarily focuses on extending my life

I feel fulfilled with 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 be in the hospital on a weekly basis

I want to be flexible and plan my dialysis according to schedule

I feel confident that I can perform dialysis on my own at home

I don't want to feel like a patient at home

I don't mind being in the hospital on a weekly basis

I don't mind being in the hospital according to a fixed schedule

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 can free time during the day to make time for my dialysis

I accept that the quality of my sleep may worsen due to 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

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>