(Cost-)effectiveness of an individualised risk prediction tool (PERSARC) on patient's knowledge and decisional conflict among soft-tissue sarcomas patients: protocol for a parallel cluster randomised trial (the VALUE-PERSARC study)

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(Cost-)effectiveness of an individualised risk prediction tool (PERSARC) on patient's knowledge and decisional conflict among soft-tissue sarcomas patients: protocol for a parallel cluster randomised trial (the VALUE-PERSARC study)

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ABSTRACT

Introduction Current treatment decision-making in high-grade soft-tissue sarcoma (STS) care is not informed by individualised risks for different treatment options and patients' preferences. Risk prediction tools may provide patients and professionals insight in personalised risks and benefits for different treatment options and thereby potentially increase patients' knowledge and reduce decisional conflict. The VALUE-PERSARC study aims to assess the (cost-)effectiveness of a personalised risk assessment tool (PERSARC) to increase patients' knowledge about risks and benefits of treatment options and to reduce decisional conflict in comparison with usual care in high-grade extremity STS patients.

Methods The VALUE-PERSARC study is a parallel cluster randomised control trial that aims to include at least 120 primarily diagnosed high-grade extremity STS patients in 6 Dutch hospitals. Eligible patients (≥18 years) are those without a treatment plan and treated with curative intent. Patients with sarcoma subtypes or treatment options not mentioned in PERSARC are unable to participate. Hospitals will be randomised between usual care (control) or care with the use of PERSARC (intervention). In the intervention condition, PERSARC will be used by STS professionals in multidisciplinary tumour boards to guide treatment advice and in patient consultations, where the oncological/orthopaedic surgeon informs the patient about his/her diagnosis and discusses benefits and harms of all relevant treatment options. The primary outcomes are patients' knowledge about risks and benefits of treatment options and decisional conflict (Decisional Conflict Scale) 1 week after the treatment decision has been made. Secondary outcomes will be evaluated using questionnaires, 1 week and 3, 6 and 12 months after the treatment decision. Data will be analysed following an intention-to-treat approach using a linear mixed model and taking into account clustering of patients within hospitals.

Ethics and dissemination The Medical Ethical Committee Leiden-Den Haag-Delft (METC-LDD) approved this protocol (NL76563.058.21). The results of this study will be reported in a peer-review journal.

Trial registration number NL9160, NCT05741944.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The VALUE-PERSARC trial uses a simple and robust design, that is, a parallel cluster randomised control trial design, which is often used for pragmatic evaluations of healthcare interventions.
⇒ The VALUE-PERSARC trial will be conducted in six soft-tissue sarcoma (STS) expertise centres, together treating approximately 85% of the high-grade extremity STS patients in the Netherlands.
⇒ An extensive analysis of effectiveness, costs and processes will be conducted to gain insight into the usefulness of risk prediction models for clinical practice.
⇒ The results from the Decisional Conflict Scale (one of the primary outcomes) may be hard to interpret.

INTRODUCTION

Soft-tissue sarcomas (STS) are a rare, heterogeneous group of tumours accounting for about 1% of all adult cancers[1] with an estimated incidence of 4 –5 cases per 100 000 population per year.[2] The majority (60%) of STS are localised in the extremities,[3] of which more than half (60%) are aggressive and infiltrating (high-grade) subtypes with poor

prognosis based on the 10% local recurrence, 50% distant metastases and 45% survival at 5 years after diagnosis.[4–6] High-grade extremity STS is mostly treated with surgery and/or (neo)adjuvant radiotherapy, each with their own benefits and risks so that there is not a clear best treatment. For instance, the resection margin may positively influence patients' overall survival,[6–8] but may also negatively affect quality of life especially when limb function must be sacrificed to achieve these tumor-free resection margins. (Neo)adjuvant radiotherapy on the other hand allows for narrower surgical margins, thereby improving functional outcome[9] without compromising the patient's overall survival,[10] but is associated with significant short-term and long-term side effects (ie, wound healing problems, infections, risk of reoperation, increased functional deficit due to radiation induced fibrosis and lymph dysfunction).[11] Given that evidence of the best treatment is lacking,[12 13] treatment choice for individual patients should be guided by weighing the personalised benefits and harms of the treatment options.

Currently, information provision to STS patients by healthcare providers does not include individualised information about the benefits and risks of the available treatment options. Instead, a one-size-fits-all approach is applied. Patients with STS might not be able to adequately weigh the trade-off between the benefits and harms of the treatment options. Consequently, patients could receive treatment that does not match their personal situation. A lack of tailoring of the information to patients' situation could lead to increased feelings of uncertainty and decisional conflict about which treatment is best for their personal situation.[14] Decision supporting interventions may contribute to better informed decision-making and reduce decisional conflict in patients.[15 16] Risk prediction models, for example, may provide patients with personalised prognostic information, thereby generating a more accurate risk perception and better knowledge which may motivate patients to engage in their decision-making process.[17] Providing patients with individualised prognostic information from risk prediction models can thus be a first step towards treatment decisions that are better aligned with patients' values and goals, thereby reducing decisional conflict. To inform multidisciplinary teams and patients alike on the individualised prognosis, our research group developed and validated a personalised risk assessment tool (Personalised Sarcoma Care: PERSARC),[8 18] which provides patients and STS professionals with personalised prognostic information for each treatment option given a patient's age, tumour size, tumour depth and histology. A recent pilot study has already shown that use of PERSARC by STS professionals contributes to a more accurate prediction of local recurrence and overall survival for individual patients.[19] Availability of such accurate estimates during the decision-making process could potentially lead to more patients opting for limb salvage while still achieving survival comparable to more aggressive treatment. However, it is unknown whether use of PERSARC in patient consultations improves patient knowledge and reduces decisional conflict, and thereby in better decisions from the patient perspective.

The VALUE-PERSARC study, therefore, aims to assess whether use of PERSARC increases patients' knowledge about personalised risks and benefits for different treatment options and reduces decisional conflict reported by patients. We hypothesise that the use of PERSARC will stimulate deliberation between STS patients and professionals, thereby resulting in more accurate risk perception and better knowledge about risks and benefits of treatment options, which can be a first step towards treatment decisions aligned with patient's values and goals and reduced decisional conflict.

METHODS AND ANALYSIS

The study protocol follows the Consolidated Standards of Reporting Trials extension for parallel cluster randomised trials[20] and Standard Protocol Items: Recommendations for Interventional Trials checklist to ensure it contains the required information for critical appraisal and trial interpretation.[21] The VALUE-PERSARC study was registered on 8 January 2021 in the Netherlands Trial Register (NL9160) and updated in ClincicalTrials.gov (NCT05741944).

Design and randomisation

The VALUE-PERSARC study will use a parallel cluster randomised controlled trial (parallel CRT) design. A parallel CRT is a commonly used study design for pragmatic evaluations of healthcare intervention.[22] It is a simple and robust design, not at risk of time-varying confounding because the design is balanced on time.[22] In a parallel CRT, half of the hospitals (ie, clusters) are randomly assigned to the control condition and half to the intervention condition (table 1). The six participating hospitals are known as STS expertise centres who are treating approximately 85% of the high-grade extremity STS patients in the Netherlands. Including a follow-up period of 52 weeks, the total duration of the study will be 156 weeks, that is, on average including five patients per month.

Randomisation, with the exception of the Leiden University Medical Center where PERSARC was developed, will be conducted by a statistician not involved in the operation of the study prior to data being collected at each hospital. Due to the nature of the intervention, concealment of allocation is not feasible.

Study population

All patients (>18 years) with primarily diagnosed (histologically confirmed) high-grade (Fédération Nationale des Centres de Lutte Contre le Cancer grade II and III[23]) extremity STS, who do not have a treatment plan yet are eligible for inclusion. Eligible sarcoma subtypes include those included in the PERSARC model that is, high-grade angiosarcoma, malignant peripheral nerve

Table 1 Overview of questionnaires at follow-up time points

Treatment consultation	T1: 1 week	T2: 3 months	T3: 6 months	T4: 12 months
Effectiveness				
Main outcome measures				
Decisional conflict				
Decisional Conflict Scale[15]	X			
Knowledge				
STS-specific knowledge questionnaire (self-made)	X			
Secondary outcome measures				
Treatment choice	X			
Decision-making process				
Decision Regret Scale[27]			X	X
Tradeoffs between Quality -Quantity of Life (QQ)[26]	X			
Shared Decision Making (SDM-Q-9)[29]	X			
Cancer worry Scale[28]	X	X	X	X
Patient reported outcomes				
PROMIS Global Health[30]	X	X	X	X
PROMIS Physical Function[31]	X	X	X	X
EuroQol-5D-5L[32]	X	X	X	X
Costs				
Medical Consumption (iMCQ)[33]		X	X	X
Productivity Cost (iPCQ)[34]		X	X	X
Treatment side effects		X	X	X
Process-evaluation				
Satisfaction VALUE-PERSARC app	X			

PROMIS, Patient-Reported Outcome Measures; STS, soft-tissue sarcoma.

sheath tumour, synovial sarcoma, spindle cell sarcoma, myxofibrosarcoma, (myxoid) liposarcoma, leiomyosarcoma, malignant fibrous histiocytoma/undifferentiated pleomorphic sarcoma, (pleomorphic) STS not otherwise specified, malignant rhabdoid tumour, alveolar soft part sarcoma, epithelioid sarcoma, clear cell sarcoma, rhabdomyosarcoma and conventional fibrosarcoma. Patients treated without curative intent or patients requiring other treatment modalities than surgery and/or radiotherapy are excluded. To participate in this study, patients must be willing to download the VALUE-PERSARC app on their personal mobile device. The VALUE-PERSARC app is available in the App store and Google Play store.

Patient recruitment

Recruitment of study participants is similar when the hospital is in the control or intervention condition (figure 1). Patients eligible for study participation will be informed about the study by their treating physician and/or specialist nurse. When the patient is willing to participate in the study and signed the informed consent, the patient is automatically assigned to the condition of the hospital, either intervention or control. Activation of the VALUE-PERSARC app is only possible by entering a code which study participants receive from their treating physician when a signed informed consent is obtained.

Control condition

All patients in control condition receive usual care but also need to download the VALUE-PERSARC app for data collection processes. This allows us to estimate the impact of the PERSARC risk prediction model and its individualised predictions, rather than the combined effect of participating in a trial and receiving access to an app. The version of the VALUE-PERSARC app for patients in the control condition will not include the PERSARC risk prediction tool (see online supplemental additional file 1-figure 1). Patients receive a code from the (control) hospital which only gives access to the app WITHOUT a risk prediction model but with the questionnaires to collect data on outcomes and costs as explained in more detail below. Once a patient has set up an account in the control condition version of the app, he/she will stay in this version of the app for the remainder of the study period and will not have access to the risk prediction model.

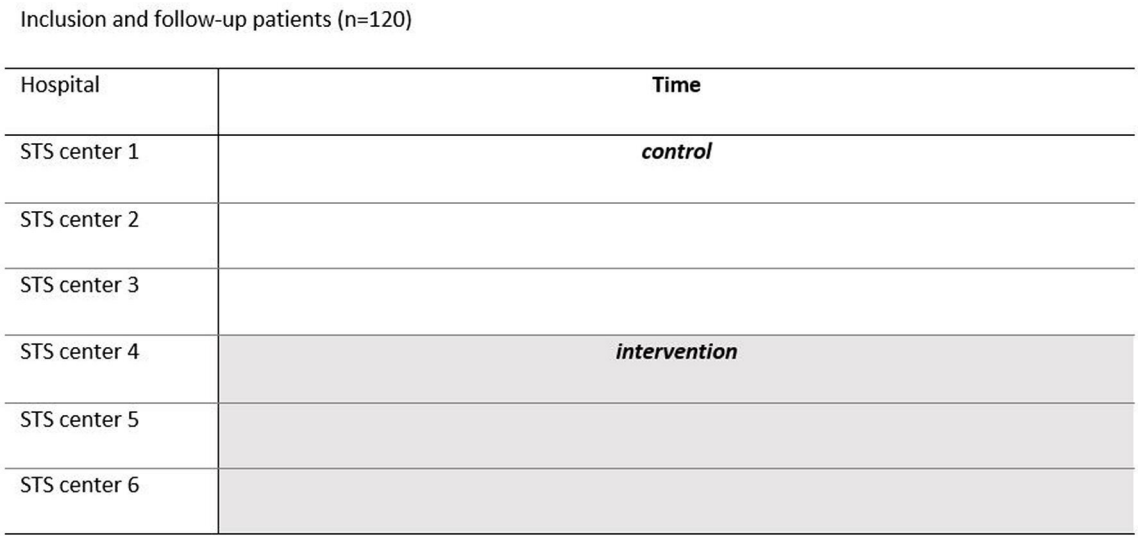

Figure 1 Parallel CRT. Control condition (usual care), intervention condition (usual care+PERSARC). CRT, cluster randomised controlled; STS, soft-tissue sarcoma.

Intervention condition

Patients in the intervention condition receive usual care with PERSARC added at two points in the decision-making process (figure 2). First, PERSARC will be used in multidisciplinary tumour boards (MTB) by STS professionals to guide treatment advice. Second, PERSARC will be used in patient consultations where the oncological/orthopaedic surgeon informs the patient about his/her diagnosis and discusses the benefits and harms of all relevant treatment options. Specifically for this second purpose, the VALUE-PERSARC app was developed to be patient-friendly and includes the PERSARC risk prediction tool which will give personalised risk and benefit estimates for each treatment option (see online supplemental additional file 1-figure 2A,B). Patients receive a code from the (intervention) hospital, which provides access to the app WITH the risk prediction model and the questionnaires to collect data on outcomes and costs.

Blinding

The nature of the intervention in this study makes blinding of the STS professionals impossible, as they know the study protocol and can see that the app in their hospital does not contain the PERSARC risk prediction model. Study information for patients will only provide general information about the aims of the study (ie, that different approaches to communicate risks and benefits of treatment options will be compared) rather than the specifics of the design and the intervention, to prevent that patients' responses on outcomes are influenced by the group they are assigned to. Researchers are not blinded for practical reasons. Data collection is standardised as much as possible to limit potential observer bias.

Outcome measures

The primary outcomes are patients' adequate knowledge of risks and benefits for each treatment option (dichotomous), and decisional conflict (continuous) assessed using questionnaires 1 week (T1) after the treatment decision has been made (table 1).

Patient knowledge is measured using an STS-specific knowledge questionnaire (see online supplemental additional file 2) about risks and benefits of treatment options (T1) and decisional conflict using the Decisional Conflict Scale (DCS) (T1).[15] The STS knowledge questionnaire is a self-developed six-item questionnaire to assess whether a patient understands the information they receive about their disease and treatment options. These items were developed by an expert panel consisting of a radiologist, orthopaedic surgeon and an expert in the field of risk prediction models for clinical decision-making. Items are organised into general items (two items) and items specific for the treatment options and side effects (four items). Items were formulated as statements that can be scored as 'correct' or 'incorrect'. A correct answer will be scored 1 and an incorrect answer 0. For each person, a summary knowledge score will be calculated. Based on other researchers' work, a knowledge score was considered to reflect adequate decision-relevant knowledge if at least 50% of knowledge statements were correctly answered (which means a knowledge score ≥3 for the present study).[24 25]

Secondary outcomes include treatment choice, attitudes concerning trade-offs between quality and length of life (QQ Questionnaire) (T1),[26] regret (Decision Regret Scale) (T3, 4),[27] cancer worry (Cancer Worry scale) (T1, 2, 3, 4),[28] involvement in decision-making according to patients (SDM-Q-9) (T1),[29] Patient-Reported Outcome Measures (PROMIS Global Health (T1, 2, 3, 4)[30] and PROMIS Physical Function (T1, 2, 3, 4)[31]), health-related quality of life (EQ-5D-5L) (T1, 2, 3, 4),[32] healthcare cost (iMCQ) (T2, 3, 4)[33] absenteeism/presenteeism from paid and unpaid work (iPCQ) (T2, 3, 4)[34] and treatment side effects (table 1). See online supplemental additional

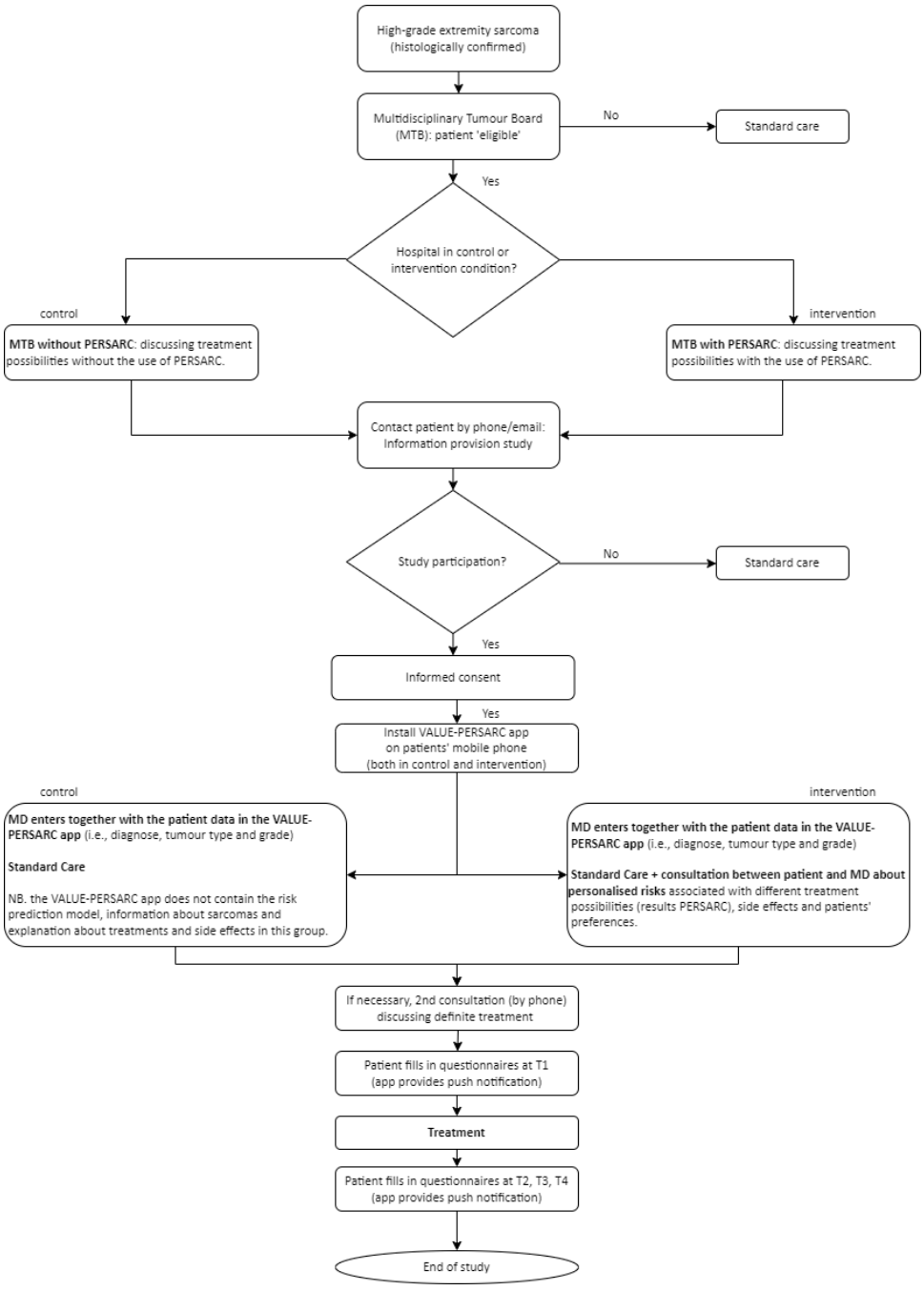

Figure 2 Schematic overview study.

file 3 for an overview of all questionnaires with scoring and interpretation.

Electronic medical records will be reviewed by an independent researcher to extract information on the received treatment including final surgical procedures and whether or not they received preoperative or postoperative radiotherapy, complications, tumour local recurrence and distant metastasis.

Sample size

The sample size is based on one of the primary outcomes, the DCS. The user manual of the DCS reports effect sizes of 0.4–1.2 for studies that assess decision supporting interventions.[15] In previous studies of patients with cancer considering treatment options using a decision supporting intervention, differences in mean pre-DCS and post-DCS scores of 0.3–0.6 were reported.[35 36] To calculate the required sample size for this study, a conservative difference in mean of 0.30 was used with an SD of 0.5,[36] arriving at an effect size of 0.6. To detect this effect size with 80% power and 95% reliability, assuming an intraclass correlation of 0.01, 52 patients per arm (sample size of 104) are needed, that is, 18 patients per hospital. Accounting for a loss to follow of 10%, we aim to include 20 patients per hospital. With 6 hospitals, a total sample

size of 120 patients is needed. With this sample size, we would be able to detect a difference of 80% of patients indicating adequate knowledge in the intervention group vs 50% in the control group (as reported by Hersch *et al*).[37]

Statistical analysis

Effect evaluation

The study will be analysed following an intention-to-treat approach. Patient (ie, age, gender, ASA physical status classification, educational level) and tumour characteristics (ie, tumour size, tumour depth, tumour grade, tumour location and histological subtype) will be compared between study arms, as these may differ due to chance because randomisation occurred at the hospital level. We will test differences between arms using unpaired t-tests for continuous outcomes and χ^2 tests for dichotomous outcomes. Primary outcome measures will be analysed using multilevel regression analysis, including hospital as a random effect to take into account clustering of patients within hospitals. For the secondary outcomes, a linear mixed model will be used to analyse the repeated measurements with a random effect for hospital to adjust for clustering of patients within hospitals (not for participating physicians since all physicians of each individual hospital participate in the same multidisciplinary meeting in which treatment proposals with or without PERSARC are discussed), a fixed effect for time and a fixed effect for the condition (usual care or intervention). An additional analysis will be performed to test for a possible interaction between intervention and time interval and assess if the intervention has influenced the change over time. If participant characteristics vary across participating hospital or time intervals, they will be used as participant-level covariates in the analysis. Missing data patterns will be analysed but mixed models are able to deal with missing data provided that at least baseline data are available and one other follow-up moment. ORs will be reported for dichotomous outcomes and mean differences for continuous outcomes. Two-sided testing will be applied throughout, and findings with an alpha error rate below 0.05 will be considered statistically significant.

Cost-effectiveness evaluation

An economic evaluation will be performed alongside the effectiveness analysis to compare the costs for use of PERSARC with usual care. The evaluation will be performed from a healthcare as well as societal perspective. Differences in costs and effects (in quality-adjusted life-years (QALYs) based on the utilities from the EQ-5D) will be estimated using multilevel modelling, taking into account clustering of patients within hospitals.[38] Cluster bootstrapping will be used to estimate the uncertainty around differences in costs and effects. In a net-benefit analysis, costs will be related to QALYs and presented in a cost-effectiveness acceptability curve.

The costs are divided into healthcare costs, and non-healthcare costs, such as productivity costs (eg, absence of paid and unpaid work). Healthcare costs include the costs of intervention and healthcare use during the follow-up, for example, hospital visits, general practitioner (GP) visits. A microcosting approach will be used to estimate intervention costs, that is, the length of the consultation of patients with and without the use of PERSARC. Patient-reported healthcare use will be measured using questionnaires focusing on healthcare use inside and outside the hospital (iMCQ) and absenteeism/presenteeism from paid work (iPCQ) at T2, T3 and T4.[33 34] For the evaluation of costs, standard prices published in the Dutch costing guidelines will be used.[39] The cost of absenteeism from paid work will be calculated using the friction cost method.

QALYs will be estimated from the EQ-5D-5L. Utilities will be calculated from the EQ-5D-5L questionnaire using the Dutch tariff at different time points (T1, T2, T3, T4).[40] Using the area-under-the-curve method for the utility scores obtained for each patient, the QALY outcome per patient will be obtained.

Process evaluation

A process evaluation will be performed to assess whether the intervention worked as intended, more specifically (a) the involvement of patients in decision-making, (b) the extent and way in which PERSARC is used by patients and professionals and (c) how satisfied patients and professionals were with the use of PERSARC.

Data collection

Besides collecting the questionnaire data, the VALUE-PERSARC app can also be used to audiorecord patient consultations. Recording the patient consultation to capture the interaction between patient and professional is not mandatory, and is requested separately when patients register in the VALUE-PERSARC app. Thus, outcomes for (a) the involvement of patients in decision-making will be assessed in all eligible patients who agree to tape their consultation. To gain insight into (b) the extent and way in which PERSARC is used by patients, user data from the VALUE-PERSARC app will be evaluated at group level (control vs intervention) (Google Analytics within the app). Use of PERSARC by professionals will be examined through a checklist regarding the use of PERSARC in patient consultations and MTB. The checklist will be sent by email to the orthopaedic/oncological surgeon immediately after every included patient, with reminders sent after 1 week. Additionally, to gain further understanding of the integration of PERSARC in treatment decision-making processes, 5–15 randomly selected patients and 3–4 STS professionals (one per intervention hospital) will be interviewed using a semistructured interview scheme, which was developed in consensus with the research team. Satisfaction with the use of PERSARC (c) for patients and professionals who participated in the intervention arm will be evaluated with a self-developed satisfaction questionnaire. Patients in the intervention arm will fill in the questionnaire within the VALUE-PERSARC app.

Professionals are asked to fill in the questionnaire online, with reminders send after 1 week.

Data analysis

The audiorecordings of the patient consultations will be transcribed verbatim and assessed by two independent reviewers using the OPTION-5,[41] an observer reviewer scale coding the degree of patient involvement by the clinician which includes themes like communication of chances, uncertainty and implicit persuasion.[42] In addition, two observers will independently review recordings to describe how PERSARC is used during the encounter, that is, which treatment options were discussed and (how) were risks discussed. Discrepancies will be discussed until consensus is reached.

The semistructured interviews with patients and professionals will also be transcribed verbatim and transcripts will be analysed to explore the extent and way in which PERSARC is used by patients and professionals. Transcripts of interviews will be imported into ATLAS.ti and will be analysed drawing on the principles of direct content analysis by two researchers independently. In this direct content analysis, we will use the SEIPS model (Systems Engineering Initiative for Patient Safety)[43] as guidance for initial coding. The SEIPS model explores interactions between humans, the technology they use and the environment in which they work and has been successfully applied across healthcare systems.[44] Any discrepancies will be discussed until consensus is reached.

Descriptive statistics will be used to describe the use (Google Analytics data) and satisfaction (questionnaires) of PERSARC by patients and STS professionals.

Ethics and dissemination

This study will be conducted according to the principles of the Declaration of Helsinki version 64, October 2013 and in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and other applicable guidelines or regulations. The Medical Ethical Committee Leiden-Den Haag-Delft (METC-LDD) approved this protocol (NL76563.058.21). Local ethics committees of the participating hospitals were requested for their approval on the feasibility to conduct the study at their site. Written informed consent will be obtained from all participating patients.

The results of this study will be disseminated to various stakeholders, that is (1) patients will be informed through the Sarcomas Patient Platform Foundation, (2) healthcare providers through, among others, the Dutch Sarcoma Group, European Organisation For Research and Treatment of Cancer and the Netherlands Comprehensive Cancer Organisation and (3) scientific bodies. This will be done through presentations, as well as written and online publications.

Patient and public involvement

The project team is advised by patients from the Sarcoma Patients Platform Foundation, the codeveloper of PERSARC (everywhereIM), a nursing specialist and delegates from policy-making bodies in the field of sarcoma care.

Data management

The study data will be collected by the coordinating researcher employed by the initiating centre. Patient data will be stored in password-protected files and computers. Outcome data are collected and stored in a secure online database. The data in the online database are anonymised.

DISCUSSION

The VALUE-PERSARC study aims to assess whether a personalised risk assessment tool (Personalised Sarcoma Care (PERSARC)) is (cost-)effective to increase patients' knowledge about personalised risks and benefits for different treatment options and reduces decisional conflict in high-grade extremity STS patients. We hypothesise that the use of PERSARC will stimulate deliberation between STS patients and professionals resulting in more accurate risk perception and better knowledge, which can be a first step towards treatment decisions better aligned with a patient's values and goals, and reduced decisional conflict.

Some challenges should be noted that may occur during the study. First, decisional conflict is commonly used as an outcome measure in studies investigating the effectiveness of decision aids in clinical decision-making.[45] The purpose of the DCS is to measure a person's perceived difficulty in making a decision and perceived uncertainty.[15] Many studies have reported lower decisional conflict after implementation of a decision aid for health decisions,[46] but others reported no effect.[47] In a recently published editorial by Vickers, the value of conflict as endpoint is debated as it rests on the assumption that 'decisional conflict and uncertainty represent an undesirable state that is detrimental to decision-making'.[48] Vickers points out that deliberation about alternative outcomes and personal goals, as well as ongoing engagement in the decision-making process may increase conflict rather than reduce it. For example, imagine a patient who is actively involved in the decision-making process and considers all the risks and benefits of treatment options, compared with a patient who simply asks the doctor what's best. The first patient may be better informed but at the

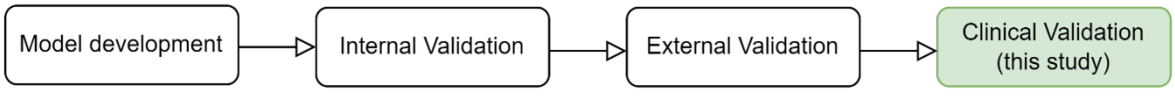

Figure 3 Steps in the process of development, validation and clinical use of risk-prediction models.

same time experience more decisional conflict. Subscales of the DCS must be reported to gain insight in different aspects of the decision-making process. The results from the DCS may thus be hard to interpret. However, using the outcomes from the subscales together with patients' knowledge to indicate an informed choice as well as with the secondary outcomes (ie, decision regret, cancer worry) and outcomes of the process evaluation will likely give valuable insights into the mechanisms and processes behind the use of PERSARC for treatment decisions of STS patients.

Risk prediction models may provide various opportunities to be used in clinical decision-making. In the last decade, there has been enormous growth in the number of clinical risk prediction models, which is encouraging as healthcare professionals seek to better understand the outcomes of their patients and how to optimise these outcomes. However, there are also important challenges including the design, development and testing of these risk prediction models. Until now, studies have mostly focused on developing risk prediction models.[49] For example, there are many risk prediction models for several cancer types, but these models have not been validated and are, therefore, frequently not appropriate for use in clinical practice.[50] The use of risk prediction models in clinical practice for patients with cancer is another important challenge. Risk prediction models are currently only widely used in breast cancer (eg, PREDICT, Oncotype DX and Mammaprint), to make treatment decisions before consultations with patients, and to inform and/or help patients decide about their treatment in clinical practice.[51] The use of prediction models and their demonstrated effects regarding decisional conflict and knowledge from a patient's perspective is unknown and a key step towards personalised treatment and greater patient satisfaction with treatment. At last, little is known about the integration of risk prediction tools in patient–clinician encounters. Most studies investigating a risk prediction tool focusses on barriers related to the risk prediction tool but not necessarily on the integration of the tool in clinical practice. Furthermore, it is unknown how professionals interact with new technology and how this changes their work process. Results of this study provide further understanding of what is needed for prediction models to be effective in the workflow of patient–clinician consultations (figure 3).

The data obtained in the VALUE-PERSARC study will allow us to draw conclusions about effects and costs of the use of PERSARC in high-grade extremity STS in comparison with usual care. Even more, the results of this study will give valuable insight in the integration of other risk-prediction models in clinical practice and will guide future implementation strategies. In conclusion, if the intervention is (cost-)effective, there is a high potential for transferring the use of PERSARC into routine practice.

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Contributors All authors made substantial contributions to the conception and design of the VALUE-PERSARC study. AAK, MAJvdS and LvB-V drafted the manuscript. RLH, EMvdA-vM, PM-vdM and EGE coauthored the writing of the manuscript. All authors edited the manuscript and approved the final version of the manuscript.

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