# The value of a risk prediction tool (PERSARC) for effectvie treatment decision making: a stepped wedge Randomized Controlled Trial.

Published: 19-05-2021
Last updated: 19-03-2025

To assess whether the use of the personalized risk assessment tool (PERSARC) is (cost)effective in reducing decisional conflict and increasing informed choices in high-grade extremity STS compared to usual care (co-primary outcomes). In addition, we...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Soft tissue therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51872

**Source**
ToetsingOnline

**Brief title**
VALUE-PERSARC

### Condition

- Soft tissue therapeutic procedures

**Synonym**
soft tissue extremity sarcomas

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** KWF kankerbestrijding projectnummer 12642

## Intervention

**Keyword:** informed choice, risk prediction model, sarcomas

## Outcome measures

### Primary outcome

The co-primary outcomes are decisional conflict (Decisional Conflict Scale(DCS) (T1,) and informed choice (T1). Informed choice is a combined outcome incorporating knowledge, attitudes concerning trade-offs between quality and length of life (QQ_Questionnaire) (T1), and treatment decision (T1).

### Secondary outcome

Secondary outcomes, include regret (Decision_Regret_Scale) (T3, T4), worry (Cancer_Worry_scale) (T1, T2, T3, T4), involvement in decision-making according to patients (SDM-Q-9) (T1), patient reported outcome using the Patient Reported Outcome Measures (PROMIS Global health) (T1, 2, 3, 4), and (PROMIS physical function) (T1, 2, 3, 4), utilities for the cost-effectiveness analysis (EQ-5D-5L) (T1, T2, T3, T4), health care cost (iMCQ) (T2, T3, T4) and absenteeism/presenteeism from paid work (T2, T3, T4).

# Study description

### Background summary

Currently, there is no consensus about the optimal treatment for patients with high grade soft tissue sarcomas (STS) which are localized in the extremities. To ensure overall survival, there is a tendency to operate with wide resection margins, but this has a high impact on quality of life especially when limb function must be sacrificed. (Neo)adjuvant radiotherapy allows for narrower

surgical margins but is associated with significant short -and long-term side-effects. As evidence on the best treatment is lacking, treatment choice for individual patients should be driven by their weighing of the benefits and harms of the treatment options in light of their personal situation.

However, current treatment decision-making in STS care is one-size fits all, and not informed by individualized risks of treatment options and patients* preferences. Consequently, there is no guarantee that patients with STS will receive treatment that is appropriate for their situation, and patients experience uncertainty about which treatment is best for their personal situation (decisional conflict).

From literature it is known that decision supporting interventions contribute to a better informed choice and less decisional conflict. Therefore, our research group developed a validated personalized risk assessment tool (Personalised Sarcoma Care: PERSARC) which provides patients and STS professionals insight into the personalized risks and benefits of each treatment option based on patient*s age, tumor size, tumor depth and histology in their decision-making process.

It is hypothesized that use of PERSARC leads to significantly less decisional conflict in patients and more informed decisions compared to usual care (treatment decisions without use of PERSARC) by reducing the uncertainty regarding risks and benefits of treatment options in high-grade extremity STS patients.

**Study objective**

To assess whether the use of the personalized risk assessment tool (PERSARC) is (cost)effective in reducing decisional conflict and increasing informed choices in high-grade extremity STS compared to usual care (co-primary outcomes). In addition, we aim to assess in a process evaluation (a) the extent and way in which PERSARC is used by patients and professionals, (b) how satisfied they were with the use of PERSARC, and (c) whether they experienced barriers and facilitators to the use of PERSARC. These insights in the mechanisms and processes responsible for the success of PERSARC on predefined outcomes will guide future implementation efforts.

**Study design**

To assess the (cost)effectiveness of PERSARC in treatment decisions of high-grade extremity STS-patients, a parallel cluster randomized trial will be conducted in the 8 Dutch hospitals that are STS expertise centers. Hospitals will be randomized between standard care (control condition) or care with the use of PERSARC (intervention). Outcomes will be assessed within one week after treatment decision has been made (T1), and after 3, 6 and 12 months after the

treatment decision has been made (T2, T3, T4) in at least 120 patients. See main study parameters/endpoints for a description of the outcomes that will be measured at these time points. Actual use of PERSARC, satisfaction with/added value of PERSARC and barriers and facilitators using PERSARC by patients and professionals will be measured in a process evaluation using questionnaires, interviews, and audio-recording/observation of consultations and multidisciplinary meetings.

### Intervention

High-grade extremity STS patients will either receive standard care (control group) or care with the use of PERSARC; i.e. PERSARC will be used in multidisciplinary tumour boards to guide treatment advice and in consultation in which the oncological/orthopaedic surgeon informs the patient about his/her diagnoses and discusses the benefits and harms of all relevant treatment options (intervention group).

### Study burden and risks

The risk of this study are comparable with the risk of standard care. However for patients allocated to the intervention group, it can be difficult to hear about ones prognosis and to be actively involved in his/her own treatment decision. Both groups (intervention and control) are asked to fill out questionnaires within one week after the treatment decision has been made, and 3, 6 and 12 months after treatment decision has been made. Each questionnaire can be filled in online and will take approximately 30 minutes. In total study participants spend 130 minutes on this study (including informed consent consultation (+/- 10min).

Furthermore, 5-15 randomly selected patients will be asked for an interview about their experiences of their decision-making process with their orthopaedic surgeon/ oncologist. These interviews will take about 45 minutes.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

• Patients >= 18 years
• Histologically diagnosed with grade 2-3 STS in their extremities.
• Who do not have a treatment plan yet
• Dutch fluency and literacy
• Mentally competent
• Signed informed consent
- Patient owns smartphone with internet access (WiFi)

## Exclusion criteria

• Patient that are treated without curative intent
• Patient that needs to be treated with chemotherapy or isolated limb perfusion
• Patients were surgery is not indicated
• Sarcoma subtypes not mentioned in the PERSARC app

In summary: patients with sarcoma subtypes and/or patients that need to be treated with other treatment modalities than those mentioned in the PERSARC app are excluded.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Health services research

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 24-08-2021 |
| Enrollment: | 120 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | a risk prection tool (PERSARC) in a mobile app |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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| Date: | 19-05-2021 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

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| Date: | 10-06-2021 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 10-06-2022 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

ID: 24454
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL76563.058.21 |
| Other | NL9160 |
| OMON | NL-OMON24454 |