# Beter Samen Beslissen

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22575

**Source**
NTR

**Brief title**
BSB

**Health condition**

All oncological diseases

### Sponsors and support

**Primary sponsor:** This work was supported with unrestricted grants by oncology network OncoZON/Citrienfonds, health insurers DSW and CZ, Nutricia, and (voluntary) by participating clinicians.
**Source(s) of monetary or material Support:** This study is initiated by the Erasmus MC and was supported with unrestricted grants by oncology network OncoZON/Citrienfonds, health insurers DSW and CZ, Nutricia, and (voluntary) by participating clinicians. Financial project management is done by de Nederlandse Federatie van Kankerpatiëntenorganisaties (NFK).

### Intervention

### Outcome measures

**Primary outcome**

The extent in which clinicians involve their patients in the decision-making process, as scored using the OPTION-5 instrument

### Secondary outcome

As secondary outcome patients will rate their perceived involvement in the decision-making and the duration of the consultations will be registered.

## Study description

### Background summary

Shared decision-making (SDM) is particularly important in oncology since many treatments involve serious side effects, and treatment decisions involve a trade-off of benefits and risks. However, implementation of SDM in oncologic care is challenging and clinicians state that it is difficult to apply SDM in their actual workplace. Training clinicians is known to be an effective means of improving SDM, but is considered time consuming. Therefore, this study addresses the effectivity and feasibility of a pragmatic individual SDM training program, using the concept of deliberate practice.

This multicenter single-blinded randomized clinical trial will be performed in eleven Dutch hospitals. Clinicians involved in decisions with oncology patients are invited to participate in the study and are allocated to the control group or intervention group. All clinicians will record three decision-making processes, with 3 different oncology patients. Clinicians in the intervention group receive the SDM-intervention: completing E-learnings, reflecting on feedback reports, doing a self-assessment and defining 1-3 personal learning questions, and face-to-face coaching. Clinicians in the control group do not receive the SDM-intervention until the end of the study. The primary outcome will be the extent in which clinicians involve their patients in the decision-making process, as scored using the OPTION-5 instrument. As secondary outcome patients will rate their perceived involvement in the decision-making and the duration of the consultations will be registered.

### Study objective

We hypothesize that clinicians exposed to this intervention are more likely to adopt SDM behaviors than clinicians who do not. A secondary aim is to evaluate whether patients perceive more involvement in the decision-making process.

### Study design

Measurements for both the control and intervention group take place during:
- First consultation (baseline measurement)
- Second consultation (4 weeks after first consultation)

- Third consultation (4 weeks after second consultation)

Each of the three consultations are held with different patients.

**Intervention**

The SDM intervention consists of four parts: an E-learning, reflection on feedback report, self-assessment and defining 1-3 personal learning questions, and face-to-face coaching.

# Contacts

**Public**
Amsterdam UMC
Loes Peters

0612948515
**Scientific**
Amsterdam UMC
Loes Peters

0612948515

# Eligibility criteria

## Inclusion criteria

Clinicians should conduct consultations in which a decision is to be made with the patient who is capable and willing to participate. In addition, choices do not have to relate directly to final treatment decision, but may also relate to other aspects of the care process. Consultations with palliatively treated patients with no prospect of cure, for whom decisions are to be made regarding quality of life, are eligible as well. Clinicians-in-training (residents) are also eligible as in the Dutch situation they work under supervision but communicate with patients independently.

## Exclusion criteria

Non-Dutch speaking patients were excluded, unless they were accompanied by a person who spoke Dutch sufficiently. Clinicians who already received individual feedback on consultations and/or participated in a SDM training within the last 3 years are excluded.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-02-2021 |
| Enrollment: | 100 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N/A

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 03-08-2021 |
| Application type: | First submission |

# Study registrations

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

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL9647 |
| Other | METC Delft and Leiden, the Netherlands : N20.170 |

# Study results

**Summary results**
N/A