

Beter Samen Beslissen

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22575

Bron

Nationaal Trial Register

Verkorte titel

BSB

Aandoening

All oncological diseases

Ondersteuning

Primaire sponsor: This work was supported with unrestricted grants by oncology network OncoZON/Citrienfonds, health insurers DSW and CZ, Nutricia, and (voluntary) by participating clinicians.

Overige ondersteuning: 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).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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-learning, 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Amsterdam UMC
Loes Peters

0612948515

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	03-08-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A