SMART-INFORM

Gepubliceerd: 02-03-2017 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON27898

Bron
NTR

Verkorte titel
SMART-INFORM

Aandoening

Personalized medicine
Communication
Cardiovascular Prevention
Shared decision-making

Ondersteuning

Primaire sponsor: Univeristy Medical Center Utrecht
Overige ondersteuning: Univeristy Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient experience with decision-making, measured using the Decisional Conflict Scale (DCS), 1 month post-intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In secondary cardiovascular disease (CVD) prevention, all patients are usually assumed to

have both sufficient risk and potential benefit to prescribe preventative therapy. But this has repeatedly

shown to be overly simplistic and may thus, result in over- and under-treatment for some patients.

Individualized approaches better identify individuals who could benefit from preventative therapy.

In order to participate in sound medical decision-making, both doctors and patients must understand

the reasoning behind preventative treatment. However, the translation from medical jargon to readily

understandable material can be challenging. The REACH-SMART model is an individualized predication

score for secondary CVD prevention and is capable of expressing prognosis both in terms of 10-year risk

of a recurrent event, and in terms of cardiovascular event free life-expectancy.

Study Design: Hypothesis blinded, three-armed, randomized controlled trial nested within the ongoing

SMART-study.

Study population: 1) Patients with clinical manifest vascular disease and using statins. 2) General

practitioners of the randomized patients in this study.

Intervention: Personalized information concerning prognosis and effect of statin-therapy will

be

calculated using the REACH-SMART score. The personalized information described below will be given to

patients on a written leaflet, supplemented by an educational video, and a telephone consultation. The

general practitioners will receive the same written correspondence as the patients. Patients in the

standard (control) group will not receive any additional information. The three randomized groups are:

1. Standard-communication practices (control group)

2. Standard- communication practices and personalized information based on

a. Individualized 10-year absolute risk of a recurrent event

b. Change in individualized absolute risk associated with statin therapy.

3. Standard-communication practices and personalized information based on

a. Individualized recurrent cardiovascular event-free life expectancy

b. Change in recurrent cardiovascular event-free life-expectancy associated with statin

therapy.

Primary Endpoint: Inter-group differences in the Decisional Conflict Scale between groups at 1 month

post-randomization.

Onderzoeksopzet

Baseline, t=0; t=6 months

Onderzoeksproduct en/of interventie

The three-arms of this trial are:

1. Standard-communication practices only (Control Group)

2. Standard- communication practices plus personalized information on

a. Prediction passport: 10-year risk of recurrent event and change in absolute risk associated with statin therapy.

b. Educational video’s

c. Telephone conversation

3. Standard-communication practices plus personalized information on

a. Prediction passport: Recurrent cardiovascular event-free life expectancy and change in recurrent cardiovascular event-free life-expectancy associated with statin therapy

b. Educational video’s

c. Telephone conversation

Contactpersonen

Publiek

UMC Utrecht
Divisie Interne Geneeskunde en Dermatologie, Vasculaire Geneeskunde

Nicole N.M. Jaspers
Universitair Medisch Centrum Utrecht | Kamernummer D.01.229 | Huispostnummer F.02.126

Utrecht
The Netherlands
T: +31 88 75 556 50

Wetenschappelijk

UMC Utrecht
Divisie Interne Geneeskunde en Dermatologie, Vasculaire Geneeskunde

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Inclusion in the SMART study (NL45885.041.13)

2. Clinically manifest cardiovascular disease, such as a confirmed diagnosis or strong clinical suspicion of one of the following: coronary artery disease, cerebrovascular disease, peripheral artery disease.

3. Use of statin medication at baseline

4. Between 18 and 80 years of age

5. Rankin Scale <3

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy

2. Terminal malignancy or short life-expectancy

3. No follow-up possible

4. Inability to effectively communicate in Dutch

5. No informed consent (IC) signed

6. Baseline questionnaire not returned

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-03-2017
Aantal proefpersonen:	264
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-03-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45689
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6080

Register	ID
NTR-old	NTR6227
CCMO	NL58608.041.16
OMON	NL-OMON45689

Resultaten