SMART-INFORM

No registrations found.

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

Summary

ID

NL-OMON27898

Source
Nationaal Trial Register

Brief title
SMART-INFORM

Health condition

Personalized medicine
Communication
Cardiovascular Prevention
Shared decision-making

Sponsors and support

Primary sponsor: Univeristy Medical Center Utrecht
Source(s) of monetary or material Support: Univeristy Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Prolonged Improved Patient Decision-Making; Measured with Decisional Conflict Scale (DCS) questionnaire at 6 months

2. Self-reported medication adherence;
questionnaire at 1, and 6 months

3. Patients' illness perceptions; Measured with Brief Illness Perception Questionnaire (IPQ) questionnaire; at 1 and 6 months

4. Understanding of therapy-effects; Measured with Understanding of Therapy questionnaire, designed for this study at 1 and 6 months

5. General practitioners' assessment of the intervention; Measured with questionnaire designed for this study at 1 month

6. Patient Activation
questionnaire at and 6 months

7. Patient Reported Shared Decision-Making, measured with the 9 -item Shared Decision Making Questionnaire (SDMQ9), 1 month post intervention.

8. Patient Perception of Statin Efficacy, measured using a visual analog scale at 1 and 6 months.

9. Quality of Life
questionnaire at 6 months.

10. Serum LDL-c (mmol/L) levels, 6 months after intervention, as documented the primary Care Dossier (last observation carried forward)

Study description

Background summary

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.

Study design

Baseline, t=0; t=6 months

Intervention

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

Contacts

Public
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
Scientific
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

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2017
Enrollment:	264
Type:	Anticipated

Ethics review

Positive opinion
Date: 02-03-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45689
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6080
NTR-old	NTR6227
CCMO	NL58608.041.16
OMON	NL-OMON45689

Study results