Secondary Manifestations of Arterial Disease - Influence of Cardiovascular Prognosis and Treatment Effect Predictions on Patient and Physician Decision-Making: a Three-armed, Blinded, Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45689

Source
ToetsingOnline

Brief title
SMART-INFORM

Condition

- Other condition

Synonym
Atherosclerosis, Cardiovascular disease

Health condition

Clinically manifest atherosclerotic disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular Prevention, Communication, Personalized medicine, Shared decision-making

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; Measured with the Brief Medication

Questionnaire (BMQ) 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; Measured with Patient Activation Measure (PAM)

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, Measured using the Short Form Survey 36 (SF-36)

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

A patient*s understanding of both prognosis and therapy effects is particularly important in the prevention of cardiovascular disease (CVD). Prevention is associated with (daily) life-long therapy and slowly accruing and unnoticed benefits. Both patients and physicians have developed a preference for the shared decision-making approach, which is believed to have a positive impact on agreed-upon therapy adherence. However, in order to participate in sound medical decision-making, both doctors and patients must understand the reasoning behind preventative treatment. The translation from medical jargon to readily understandable material can be challenging.

Current prevention guidelines often recommend treatment based on 10-year cardiovascular risk, without directly considering an individual patient*s expected benefits. In secondary prevention, all patients are usually assumed to have both sufficient risk and potential benefit to prescribe preventative therapy. Personalized approaches better identify individuals who could benefit from preventative therapy, and therefore potentially represent both a more medically responsible and cost-effective approach. But these approaches are relatively new in secondary prevention. The REACH-SMART model is an individualized model for secondary CVD prevention 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. The score has recently been validated, and is based on readily available clinical predictors.

Statin medications are widely prescribed in secondary prevention. Therefore, for this study we chose to investigate the effect of communicating different individualized predictions on patient decision-making using statin therapy. However, the results could be generalizable to different types of medications used in secondary cardiovascular prevention. To date, the influence of various communication strategies of personalized predictions on patient and physician decision-making has not yet been studied.

Cardiovascular disease prevention is hampered by two issues: the simultaneous over-treatment and under-treatment of different patient groups, and low therapy adherence. The combination of shared decision-making and personalized prevention strategies has the potential to attenuate both two issues.

Study objective

The primary objective is to compare differences between the communication strategies (personalized vs. standard, and personalized using iARR vs. personalized vs. CVD-free prognosis) on decisional certainty in patients with CVD at 1 month post-communication intervention.

Study design

Hypothesis blinded, three-armed randomized controlled trial performed in patients taking preventative therapy within the SMART-study.

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

Study burden and risks

During the 6-month duration of the trial, patients will receive three questionnaires of varying length. These questionnaires take approximately 30 minutes to complete.

Complete participation in the intervention groups requires the patient to read and interpret personalized predictions (to the best of their ability), watch educational video's (approximately 10-20 minutes of length), and participate in a short telephone conversation. Additionally patients give the study team permission to contact the general practitioner to personalized predictions and record request LDL-c concentrations. The burdens are thus low. Risks are negligible. The study is performed in patients taking preventative therapy for cardiovascular disease. The study results are expected to be applicable to the domain of anyone taking preventative therapy.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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. 45-80 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:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-02-2017
Enrollment:	264
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-01-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 27898
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58608.041.16

Study results

Date completed:	07-01-2019
Results posted:	30-01-2020

Actual enrolment: 303

First publication
30-01-2020