Cardiovascular non-Adherence Tailored Intervention (CATI) care programme

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26090

Source
NTR

Brief title
CATI care programme

Health condition

Cardiovascular medication non-adherence

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Royal Dutch Pharmacists Association (KNMP)

Intervention

Outcome measures

Primary outcome

Self-reported medication adherence is the primary outcome measure. Medication adherence will be assessed at baseline, at follow-up and at endline. Differences between the medication non-adherence at baseline and at endline will be compared. Medication adherence will be assessed with the MARS-5 questionnaire.

Secondary outcome

LDL concentration and BP are clinical secondary outcome measures. The pre-measurement will be included in the selection procedure at baseline and the post-measurement will be assessed after six months. LDL concentration will be measured with a finger prick of blood. Blood pressure will be measured with a sphygmomanometer.

Quality of life will be assessed by using the Short Form 12 Health Survey (SF-12) questionnaire. The SF-12 questionnaire consists of 12 questions covering eight dimension of health i.e. general health perception, physical functioning, limitations due to physical health problems, bodily pain, vitality, social functioning, emotional functioning and general mental health. The eight domains can produce two summary scores for physical health (Physical Component Score, PCS) and mental health (Mental Component Score, MCS).

Study description

Background summary

Cardiovascular disease is a chronic condition, characterized by high mortality and morbidity. Due to inadequately following cardiovascular pharmacological treatment plans, i.e. medication non-adherence, substantial numbers of cardiovascular patients benefit from their medication to a limited extent. Non-adherence is influenced by patient-, social and economic-, condition-, therapy-, healthcare team and system-related factors.

A multi-centre, randomized controlled trial will be performed in 11 community pharmacies, including 176 patients. Patients aged 45–75 years using cardiovascular medication, i.e. antihypertensive and/or lipid-lowering drugs are eligible to participate. Patients must be non-adherent in refilling medication, must be non-adherent measured with a self-report questionnaire and must have at least one abnormal clinical parameters i.e. a high low-density lipoprotein concentration and a high blood pressure. Patients in the intervention group will receive a patient tailored intervention, called the CATI care programme. The CATI care programme is a patient tailored intervention programme to enhance adherence to cardiovascular medication, incorporating the identification of barriers for non-adherence and offering interventions tailored to the specific needs of the patient. The programme will be executed by the pharmacist and consist of different components.

The primary outcome is self-reported medication adherence. Secondary outcome measures are measured clinical parameters and quality of life.

Study objective

In this project the hypothesis is tested that the community pharmacist-led CATI care programme in patients using cardiovascular medication, will have a beneficial effect on patients' adherence to cardiovascular medication and improves clinical parameters, and is cost-effective

Study design

0, 3 and 6 months

Intervention

The CATI care programme is a patient tailored intervention programme to enhance adherence to cardiovascular medication, incorporating the identification of barriers for non-adherence and offering interventions tailored to the specific needs of the patient. The programme will be executed by the pharmacist and consist of different components.

• Invitation

The pharmacist asks the patients to participate in the CATI care programme and invites them for a medication interview in the pharmacy.

• Quick Barrier Scan

The pharmacist interviews the patients according to a semi-structured interview guide, called the Quick Barrier Scan. The aim of the interview is to explore the patient's barriers and problems to adhere to the medication. Based on the answers of the patient, the patient can be classified into a 'barrier profile'. The Quick Barrier Scan incorporates five to six different 'barrier profiles'.

• Tailored Intervention Guide

The results of the Quick Barrier Scan will be evaluated by the pharmacist. A 'barrier profile' will be assigned and appropriate interventions will be selected from the Tailored Intervention Guide. The Tailored Intervention Guide provides an overview with the best suited interventions corresponding to the patients' 'barrier profile'. For example:

Barrier profile A = intervention 1a or 1b

Barrier profile B = intervention 2

Barrier profile C = intervention 3a or 3a

Examples of possible interventions are: addressing side-effects, for instance by performing a medication review; improving knowledge, for instance about the use and effectiveness of the

medication; or providing tools, for instance reminder services and pillboxes.

• Consultation upon initiation

The pharmacist invites the patient to the pharmacy. According to the ‘shared decision making’ approach, the pharmacist and patient decide which intervention to start and how to execute the intervention. The pharmacist will introduce and explain different options for interventions and the patient will be supported in exploring his/her preferences and choosing an intervention. By means of this approach each patient explores what most matters to him/her.

• Telephonic follow-up consultation

Between three and four months after the start of the intervention, the pharmacist will contact the patient for a telephonic follow-up consultation.

Contacts

Public
Van der Boechorststraat 7

Danielle van der Laan
Amsterdam 1081 BT
The Netherlands
+31204441715
Scientific
Van der Boechorststraat 7

Danielle van der Laan
Amsterdam 1081 BT
The Netherlands
+31204441715

Eligibility criteria

Inclusion criteria

1) Age 45-75 years

2) Using cardiovascular medication i.e. antihypertensive and/or lipid-lowering drugs

3) Meeting all three inclusion criteria described below:

a. Being refill non-adherent according to pharmacy dispensing data

b. Being non-adherent according to a self-report questionnaire

c. Having abnormal clinical rates to low-density lipoprotein concentration and/or blood pressure

Exclusion criteria

1) Being unable to speak or read Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	176
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4915
NTR-old	NTR5017
Other	: WC2015-019 VUmc

Study results