Improving lifestyle adherence in patients with high risk of cardiovascular diseases in General Practice.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19977

Source
NTR

Brief title
IMPALA

Health condition

Highe risk of (recurrent) cardiovascular disease which is (partly) based on modifiable lifestyle-related risk factors.

Sponsors and support

Primary sponsor: Care and Public Health Research Institute (CAPHRI)
Department of General Practice
Maastricht University
PO Box 616
6200MD Maastricht
The Netherlands
Source(s) of monetary or material Support: ZonMw, The Netherlands Organisation for Health Research and Development.

Intervention

Outcome measures

Primary outcome

Patients' adherence to lifestyle advice and drug treatment. Clinical endpoints will not be measured, but the absolute risk on cardiovascular events in 10 years will be estimated for each patient as a proxy measure for health gain. The 10-years absolute cardiovascular risk will be based on the current Dutch risk table, and on “HeartScore”, a risk table developed by the European Society of Cardiology. Specific behaviours related to smoking, diet, physical exercise, alcohol use and use of medication will be reported by patients, using validated self-reported questionnairesWe will use pedometers at T1 (12 weeks) to measure physical exercise during two weeks. Body mass index will be measured as a proxy-measure for healthy diet and exercise. Pill-count will be applied to validate the self-reported adherence to drugs. Data on the other risk factors will be derived from medical records in general practice (after informed consent by patients), and if absent or unreliable completed with additional data collection in patients. The primary behavioural outcome will be measured at T0 (baseline), T1 (12 weeks) and T2 (52 weeks).

Secondary outcome

Risk perception, anxiety, involvement and confidence in decision, attitudes, perceived social norms, self-efficacy, use of health care resources.

Outcome for process evaluation:

Key features of the intervention:

1st consultation- nurse explains risk by means of the risk communication tool to the patient- nurse explains options for risk reduction by lifestyle change to the patient- nurse hands over decision aid booklet + risk communication tool (for home work)2nd consultation- patient shows up for follow-up consultation- patient has prepared him or herself for the follow-up consultation- nurse checks the patient’s understanding of risk and options for risk reduction by lifestyle change- nurse applies motivational interviewing technique- nurse and patient agree on process of decision making- patient formulates, guided by the nurse, the main personal goal for lifestyle change (if applicable)extra items:- nurses’ attendance to the trianing, time needed per patient contact- time needed for discussing patients with the GP,- preferences for framing formats as expressed by the patients.

The data for the process evaluation will be gathered by the nurse, by means of self-report. He or she will fill in a short standardised questionnaire after each consultation. Each item will be scored as a done/not done binary variable. If the score is ‘done’, the quality of the performance will be scored on a 5-point likert scale.

Study description

Background summary

Objective:

Practice guidelines on cardiovascular disease recommend optimal drug treatment and a healthy lifestyle, but adherence to these recommendations is in about half of the patients less than optimal. Additional interventions are needed to improve adherence. Patient involvement in decision-making on cardiovascular prevention is likely to increase patients' adherence with lifestyle advice.

The aim of this study:

is to determine costs and effects of strategies that enhance patient involvement in decisions on cardiovascular prevention, on adherence to lifestyle recommendations and medical treatment, and on estimated absolute risk on cardiovascular events in 10 years.

Design:

RCT in 20 large general practices.

Population:

A total of 720 patients with high risk for (recurrent) cardiovascular diseases will be prospectively recruited. It concerns patients with established CVD, with diabetes, or with a modifiable high risk according to the available risk charts for absolute 10-year risk in CVD. Measurements will be executed at baseline, 12 and 52 weeks. With expected drop out of 20% 600 patients will be available for final analysis.

Intervention:

The intervention is a mix of strategies with the underlying goal to facilitate patient

involvement in the decisions to be taken on cardiovascular risk management.

The components are:

decision aid, risk communication tool, task delegation to a nurse trained in adapted motivational interviewing, and a follow-up consultation. The decision aid and the follow-up consultation have already been evaluated in a recent trial in Maastricht. The new components of the intervention are the risk communication tool, and delegation of this task to a practice nurse, who is trained in motivational interviewing. Practice nurses are increasingly important in delivering care to patients with high risk of cardiovascular diseases and they may be able to provide the strategy cost-effectively, which would fit well in current developments in primary care. In the first consultation the risk will be clarified by use of the risk communication tool, and the patient's preferences will be explored. In the second consultation, after the patient has read the decision aid at home, the nurse will help the patient to formulate his/her own goals for behaviour change.

Primary outcome measures:

Primary behavioural outcome is self-reported adherence to smoking, diet, physical exercise, or alcohol intake. One standardised adherence score will be constructed, which expresses to what extent the behaviour change goal was accomplished. If applicable, adherence to drug treatment will also be measured. Clinical endpoints will not be measured, but the absolute risk on cardiovascular events in 10 years will be estimated for each patient.

Secondary outcome measures:

Risk perception, anxiety, satisfaction with the decision, self-efficacy, and intention to change. Data will be measured by use of validated questionnaires. A more objective instrument, the pedometer, will also be applied to measure physical exercise. The adherence of the nurse to the working protocol will be measured by means of a process evaluation.

Data analysis:

The data will be analysed by hierarchical modelling in regression analysis, to account for clustering of data per practice.
Economic evaluation: Costs will be estimated; costs of the intervention (the patient materials, training of practice nurses, time used by practice nurse for patient contacts) and cost consequences related to the use of health care services for cardiovascular diseases by

patients (hospital admission, visits to GP, use of medication, etc.). An incremental cost-effectiveness ratio will be calculated for the observed costs and effects (cost related to absolute risk on cardiovascular events in 10 years) as well as estimated for patient full lives, estimating cost per life year gained.

Study objective

1. What is the effect of active patient involvement by the practice nurse on decisions regarding cardiovascular risk reduction, adherence to lifestyle advice, cardiovascular risk and other outcomes at 12 weeks and 52 weeks, compared to usual care?

2. What is the incremental cost-effectiveness ratio of patient involvement in decision making by a practice nurse compared to usual care?

Study design

N/A

Intervention

The multi-faceted intervention for the intervention arm is meant to enhance patient involvement in decision making on cardiovascular risk management and comprises of:

1. Task delegation, cardiovascular risk management will be delegated to well trained practice nurses;

2. Two consultations, the first for risk presentation and communication, the second for discussion on objectives for risk reduction by lifestyle change or medical intervention. Each consultation will take about 30 minutes. Thereafter follow-up by telephone if wanted.

3. Use of a graphical risk communication tool (new).

4. Use of a decision aid.

5. Adapted motivational interviewing as a technique to reinforce patients internal motivation for lifestyle changes.

6. Training of the GPs and practice nurses in cardiovascular risk-management conform the current guidelines and motivational interviewing regarding lifestyle and medication useThe GPs and the practice nurses of the control arm receive one hour education on cardiovascular risk-management consistent with current guidelines, including advice regarding lifestyle and medication use (this is optimal 'usual care'). The patients in the control group receive evidence-based patient material. A leaflet and a short version of the decision aid, only the educational part.

Contacts

Public
University Maastricht (UM), Department of General Practice,
P.O. Box 61
M.S. Koelewijn
Maastricht 6200 MD
The Netherlands
+31 (0)43 3882317
Scientific
University Maastricht (UM), Department of General Practice,
P.O. Box 61
M.S. Koelewijn
Maastricht 6200 MD
The Netherlands
+31 (0)43 3882317

Eligibility criteria

Inclusion criteria

1. Patients aged 40-70 years without cardiovascular diseases (CVD) but with an absolute cardiovascular risk of >20% in 10 years;

2. Patients younger then 40 years without CVD, but with an extrapolated high estimation of their risk at an age of 60 due to modifiable lifestyle factors;

3. Diabetes mellitus patients;

4. Patients with established CVD.

Exclusion criteria

1. Cardiovascular patients or diabetes patients who are primarily managed in secondary care (e.g. by cardiologist or internist, in rehabilitation programme);

2. Patients at high-risk based on Familial Hypercholesterolaemia only.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2006
Enrollment:	720
Type:	Actual

Ethics review

Positive opinion

Date:	20-09-2005
Application type:	First submission

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	NL279
NTR-old	NTR317
Other	: N/A
ISRCTN	ISRCTN51556722

Study results

Summary results
BMC Health Serv Res. 2008 Jan 14;8:9.