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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 01/07/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.S. Koelewijn

Contact details
Maastricht University
Department of General Practice
P.O. Box 61
Maastricht
Netherlands
6200 MD
+ 31 (0)43 3882317
M.Koelewijn@hag.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym
IMPALA

Study objectives
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?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
The multi-faceted intervention for the intervention arm is meant to enhance patient involvement in decision making on cardiovascular risk management and comprises of:- Task delegation, cardiovascular risk management will be delegated to well trained practice nurses- 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.- Use of a graphical risk

communication tool (new).- Use of a decision aid. - Adapted motivational interviewing as a technique to reinforce patients internal motivation for lifestyle changes- Training of the GPs and practice nurses in cardiovascular risk-management conform the current guidelines and motivational interviewing regarding lifestyle and medication use. The 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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 Heart Score, 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 questionnaires. We 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 measures
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 patients 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 training, 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.

Please note that as of 28/08/2007, the short standardised questionnaire to gather process information contained no 5-point likert scales to determine the quality of the performance. We removed these scales to reduce the burden of data collection for the practice nurses.

Overall study start date
01/02/2006

Completion date
01/07/2006

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/08/2007:
Preferably patients:
1. With high blood pressure: greater than or equal to 140 mmHg or already treated for it
2. With high total cholesterol: greater than or equal to 6.5 mmol/l or already treated for it
3. Who are smoking (men greater than or equal to 50 years, women greater than or equal to 55 years)
4. With diabetes

Next to it patients with:
1. Positive family history of CVD
2. Visible obesity

Explanation for change to inclusion and exclusion criteria as of 28/08/2007:
On January 1 2006, the Dutch Institute for Health Care Improvement (CBO) published the Dutch national guideline for Cardiovascular Risk Management, in close collaboration with the Dutch College of General Practitioners (NHG). The indications for a cardiovascular risk assessment were clearly described in the guideline, and we decided to use these indications as inclusion criteria because the GPs and practice nurses had to work with this guideline. We excluded patients with existing cardiovascular diseases. Following the new guideline, these patients are at high risk and the risk table, which is a part of our intervention, is not applicable anymore for these patients. We expected no problems for the inclusion, because we had planned to recruit 20 general practices in our trial but we had such a great response on our recruitment (40 practices were willing) that we decided to let 25 practices participate. The number of patients that each practice had to include was the same as before.

Previous inclusion criteria:
1. Patients aged 40 - 70 years without cardiovascular diseases (CVD) but with an absolute cardiovascular risk of greater than 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

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
720

Key exclusion criteria
Current exclusion criteria as of 28/08/2007:
1. Cardiovascular patients or diabetes patients who are primarily managed in secondary care (eg by cardiologist or internist, in rehabilitation programme)
2. Patients at high-risk based on Familial Hypercholesterolaemia only
3. Patients with existing CVD

Explanation for change to inclusion and exclusion criteria can be found above.

Previous exclusion criteria:
1. Cardiovascular patients or diabetes patients who are primarily managed in secondary care (eg by cardiologist or internist, in rehabilitation programme)
2. Patients at high-risk based on Familial Hypercholesterolaemia only

Date of first enrolment
01/02/2006

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Maastricht University
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
The Research Institute of the University Maastricht (CAPHRI) (Netherlands)

Sponsor details

P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 3882446
e.habets@caphri.unimaas.nl

Sponsor type
Research organisation

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/01/2008		Yes	No
Results article	results	08/12/2009		Yes	No
Results article	results	01/03/2011		Yes	No