ISRCTN01396033 https://doi.org/10.1186/ISRCTN01396033

Health coaching in primary health care for older people at moderate risk for cardiovascular diseases (CVD), diabetes and depression

Submission date
21/10/2011

Recruitment status
No longer recruiting

Registration date
24/11/2011

Overall study status
Completed

Last Edited
09/08/2016

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to improve the health of older people at moderate risk for cardiovascular disease, diabetes or depression, by using health coaching and subsequent activities to promote a better lifestyle and help them live longer and healthier lives.

Who can participate?
Men and women aged 60 to 75 who are at moderate risk for cardiovascular disease, diabetes or depression

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. Both groups receive standard primary health care. Participants in the intervention group also receive motivational talks from a health coach that encourage them to improve their lifestyle. All participants undergo medical tests and complete questionnaires at the start of the study and after 6, 12 and 18 months. The intervention group and the control group are compared to find out whether there are any differences regarding blood pressure, blood sugar, depression, waist circumference, quality of life and lifestyle. The cost effectiveness of the intervention is also assessed.

What are the possible benefits and risks of participating?
All participants are informed about the results of their medical tests and the intervention group may benefit from the motivational talks. There are no risks involved in this study.

Where is the study run from?
21 primary health care centers in Sweden. The study is managed by Umeå University (Sweden).

When is the study starting and how long is it expected to run for?
October 2011 to June 2013

Who is funding the study?
Swedish National Institute of Public Health (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Health coaching in primary health care for older people at moderate risk for CVD, diabetes and depression: a randomized controlled trial in Sweden to promote healthier lifestyle with physical activity, better food and improved social life

Study objectives
One goal in the Swedish public health policy is to give young older people the possibility to live a long and healthy life. The overall aim of this study is to promote a better life style in order to live longer and healthier. The specific objectives are:
1. To give municipalities and county councils better knowledge of how they together with the informal sector can promote healthy aging
2. To increase the opportunities for older persons with moderate risk levels to get better health through health coaching conducted with motivational interviewing and subsequent activities.

The following research questions are in focus:
2.1. Are there some differences between the intervention group and the control group regarding health related quality of life?
2.2. Are there some differences between the intervention group and the control group regarding medical variables and self-reported lifestyle patterns?
2.3. Is the intervention cost effective?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Umeå, 16/08/2011, ref: Dnr 2011-230-31

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Moderate risk for CVD, diabetes and depression in older people

Interventions
The study will compare patients which receive standard primary health care and patients that get standard care plus motivational talks (MI) that encourage the individuals to improve their lifestyle. The method is often referred to as MI (motivational interviewing) and will be conducted at baseline and after 3, 6, 12, and 18 month. 75% of the 2000 participants will be randomized to the intervention group and the rest will a control group receiving standard care. This implies that each county will recruit 500 participants of which 125 are randomized to the control group.

Intervention Type
Behavioural

Primary outcome measure
1. Blood pressure level at baseline and after 6, 12 and 18 months
2. Blood sugar level (Hba1c) at baseline and after 6, 12 and 18 months
3. Depression according to Montgomery-Asberg Depression Scale (MADRS) self rating scale at

baseline and after 6, 12 and 18 months
4. Waist circumference in cm at baseline and after 6, 12 and 18 months

Secondary outcome measures
A questionaire with general and health related questions.
1. Section A- Background questions
2. Section B- Your social life
3. Section C- Life style questions
4. Section D- General health related questions including questions on drug use
5. Section E- EQ5D - including the Visual Analogue Scale (VAS) scale
6. Section F- Montgomery-Åsberg Depression Rating Scale (MADRS) scale on depression

Overall study start date
01/10/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
Men and women between 60 and 75 are recruited to the study at the primary health care centre. Four counties in Sweden are selected and within these counties 21 health care centers have agreed to participate. All of them will enroll participants that fulfill one or more of the four individual inclusion criteria.
1. A minor increase of blood pressure that is not treated with drugs
2. A minor increase of blood sugar that is not treated with drugs
3. A minor depression that is not treated with drugs
4. An increase of waist-circumference

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
2000 (1500 in the intervention group and 500 in the control group)

Key exclusion criteria
Participant uses drugs linked to the inclusion criteria

Date of first enrolment
01/10/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Umeå University
Umeå
Sweden
SE 910 85

Sponsor information

Organisation
Swedish National Institute of Public Health (Sweden)

Sponsor details
Forskarens väg 3
Östersund
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Sponsor type
Government

Website
http://www.fhi.se/en/

ROR
https://ror.org/05x4m5564

Funder(s)

Funder type
Government

Funder Name
Swedish National Institute of Public Health (Sweden)

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	06/03/2013		Yes	No