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Can a structured health dialogue with a primary care nurse reduce risk factors for heart disease, offered to a population 55 years old

Submission date	Recruitment status	[_] Prospectively registered
25/11/2015	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
10/12/2015	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
02/12/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
There are many risk factors associated with cardiovascular heart disease and stroke. These include having high blood pressure, being overweight, not taking enough exercise, high cholesterol and a unhealthy diet. This study is investigating whether a one hour session with a district nurse on how to reduce these risk factors can improve cardiovascular (heart and circulation) health among people over the age of 55.

Who can participate?
Adults aged 55 and registered at one of the participating primary care (GP) centers.

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 (intervention) fill in a health questionnaire, visit a laboratory for blood tests and then meet a district nurse for a structured health dialogue. During this health dialogue the participant is given information from the district nurse about results from their laboratory tests and questionnaire, shown as a health curve. He or she also, with the support of the district nurse, has the opportunity to plan changes to their lifestyle. Those in group 2 (control group) fill in the same questionnaire and also have blood tests but do not participate in the structured health dialogue with a district nurse. Those in group 3 (comparison group) only fill in the same questionnaire and have the same blood tests a year later, along with the participants in the other two groups.

What are the possible benefits and risks of participating?
Participants who have the health dialogue have the opportunity to get information and also motivation for change and improvement to their lifestyle. All participants get their laboratory test results. Participants visit a doctor if laboratory tests indicates a need for that.

Where is the study run from?
Västmanland County Council (Department of Public Health/Centre for Clinical Research), Sweden.

When is study starting and how long is it expected to run for?
May 2010 to December 2012

Who is funding the study?
1. County Council of Västmanland, Sweden
2. Centre for Clinical Research, Västmanland, Sweden.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A health dialogue intervention reduces cardiovascular risk factor levels: a population based randomized controlled trial in primary care setting with one year follow up

Study objectives
Population at the age of 55 who participated in a primary care nurse led health dialogue have at one year follow up significant improved CVD risk factor levels concerning life style, stress and biological markers compared to control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board of Uppsala, Sweden, 15/12/2010, ref: 2010/427

Study design
A single-centre interventional study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

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

Interventions
A computerized randomization was made by the Center of Clinical Research, Västerås Hospital, from a list of 1320 inhabitants born 1956-1957 belonging to five primary care centers. Randomization was conducted within each primary care center. The study population of men and women was assigned to three groups, intervention (n=440), control (n=440) and comparison group (n=440).

Intervention group filled in a health questionnaire, visited a laboratory for blood tests and thereafter met a district nurse for a structured health dialogue.
Control group filled in the same questionnaire and visited the same laboratory examination, but received no health dialogue.
The comparison group was invited only at one year follow up, answering the same questionnaire and doing the same laboratory examination.

Intervention Type
Behavioural

Primary outcome measure
1. Weight, height, waist, hip, systolic and diastolic blood pressure, measured by a district nurse.
1.1.Weight was measured with light clothing and without shoes
1.2. Blood pressure was measured in the right arm in sitting position after five minutes rest.
1.3. BMI (kg/m2) was calculated as weight/ (height x height).
1.4. Waist circumference was measured in the standing position at the level midway between

the 1.5. lower rib margin and the iliac crest.
1.6. Hip circumference was measured at the widest point between hip and buttock
1.7. Waist–hip ratio (WHR) was calculated as waist circumference divided by hip circumference (cm/cm)
1.8. Height was measured without shoes on a fixed wall measure to the nearest centimetre.
2. Cholesterol, HbA1c and fasting plasma glucose measured by laboratory staff.
3. Self reported variables were physical activity, alcohol consumption last week, diet, smoking habits and stress.

All outcomes are measured one year (11-13 months) after baseline measurement and on all participants in the intervention and control group. Baseline measurement was carried out April-December 2011.

Secondary outcome measures
Sub group analysis on high risk groups based on the same measurements as for primary outcomes.

Definition of high risk factor levels: BMI ≥27 for men and BMI ≥29 for women, WHR ≥0.95 for men and ≥0.83 for women, systolic blood pressure ≥140, diastolic blood pressure ≥90, inactive or light physical activity following four degree scale, diet points ≥6 following eleven degree scale, alcohol ≥25 cl 40% liquor equivalents/week for men and ≥17 for women and cholesterol ≥5.0 mmol/l.

Overall study start date
31/05/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Inhabitants at the age of 54 or 55 years old at baseline year 2011, registered at one of the five participating primary care centres.

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
1320 persons.

Total final enrolment
880

Key exclusion criteria
No exclusion criteria were specified.

Date of first enrolment
01/04/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Sweden

Study participating centre
Västmanland County Council (Department of Public Health/Centre for Clinical Research), Sweden
Västerås
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Sponsor information

Organisation
County Council of Västmanland

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/04vz7gz02

Funder(s)

Funder type
Government

Funder Name
Landstinget Västmanland (County Council of Västmanland)

Funder Name
Center of Clinical Research, County Council of Västmanland

Results and Publications

Publication and dissemination plan

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?
Results article	results	22/08/2017	02/12/2020	Yes	No