# 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**
25/11/2015

**Registration date**
10/12/2015

**Last Edited**
02/12/2020

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Circulatory System

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

## 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?
Mr Mats Hellstrand
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# Contact information

## Type(s)
Public

## Contact name
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# Additional identifiers

## Protocol serial number
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

## Study type(s)
Prevention

## 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(s)
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.

## Key secondary outcome(s))
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.

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
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# Sponsor information

### Organisation
County Council of Västmanland

### 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

## 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 |