

A prospective clinical trial of a multidisciplinary electronic cardiovascular prevention programme

Submission date 21/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/02/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym

PreCardio

Study objectives

A multidisciplinary electronic cardiovascular prevention programme at GP and patient level will lead to changes in medical and cardiovascular risk factors resulting in a lower overall cardiovascular risk

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of University Hasselt, date of approval 18th January 2007

Study design

A prospective clinical trial with an intervention group and a matched control group

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of Cardiovascular diseases

Interventions

1. Medical interventions by GPs: determination of cardiovascular risk using a new computer tool, medical interventions aimed at medical risk factors (e.g. hypertension, high blood glucose level, high cholesterol) and a reduction of overall risk, follow-up dependent on cardiovascular risk
2. Interventions aimed at behaviour change (physical activity, diet, smoking): personalised website with guidelines based on theories on behaviour change + multidisciplinary support based on principles from behaviour therapy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. The effects of medical and behavioural interventions on medical parameters such as systolic blood pressure, diastolic blood pressure, total blood cholesterol level, blood glucose level (HbA1c), overweight and obesity, BMI
2. The effects of medical and behavioural interventions on health related behaviour such as physical activity; fat; fruit and vegetable intake; and smoking behaviour
3. The effects of medical and behavioural interventions on overall cardiovascular risk mediated

by changes in medical and/or behavioural risk factors

4. The proportion of study participants with a 10% reduction in systolic blood pressure with participants with hypertension

5. The proportion of study participants with a 10% reduction in diastolic blood pressure with participants with hypertension

6. The proportion of study participants with a 10% reduction in total cholesterol with patients with hypercholesterol

7. The proportion of study participants with a 10% reduction in HB1Ac with initial HB1Ac >7% (high risk)

8. The proportion study participants with a 10% reduction in weight with initial BMI >25 kg/m²

Key secondary outcome(s)

1. The incidence of cardiovascular events

2. Number and total costs of cardiovascular events leading to loss of productivity

3. The effects of medical and behavioural interventions on psychological constructs as stage of change, attitude towards behaviour, self-identity, perceived behavioural control, autonomous motivation, intention

4. The effects of medical and behavioural interventions on Health Related Quality of Life

5. The effects of social support on health related behaviour (physical activity, fat and fibre intake and smoking behaviour) and psychological constructs (stage of change, attitude towards behaviour, self-identity, perceived behavioural control, autonomous motivation, intention)

6. A cost-effectiveness analysis of the medical and behavioural interventions using incremental cost-effectiveness ratios

Completion date

23/03/2010

Eligibility

Key inclusion criteria

1. Age between 25-65

2. Insured by the Onderlinge Ziekenkas, insuring for guaranteed income in case of illness for self-employed

3. Inhabitants of Limburg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

People with a high cardiovascular risk are not excluded from the PreCardio-study, given the constant supervision GPs and a cardiologist involved in PreCardio. However, high risk

participants are advised not to take part in certain rigorous training schemes available to the participants of the study

Date of first enrolment

23/03/2007

Date of final enrolment

23/03/2010

Locations

Countries of recruitment

Belgium

Study participating centre

University Hasselt

Diepenbeek

Belgium

3590

Sponsor information

Organisation

De Onderlinge Ziekenkas (Belgium)

Funder(s)

Funder type

Industry

Funder Name

De Onderlinge Ziekenkas (Belgium)

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	01/06/2013		Yes	No