ISRCTN23940498 https://doi.org/10.1186/ISRCTN23940498

A prospective clinical trial of a multidisciplinary electronic cardiovascular prevention programme

Submission date 21/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/03/2007	**Overall study status** Completed	
Last Edited 04/02/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neree Claes

Contact details
University Hasselt
Faculty of Medicine-MMC
Agoralaan Building D
BE-3590
Diepenbeek
Belgium
3590
+32 (0)477291588
neree.claes@uhasselt.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

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 prinicples from behaviour therapy

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
23/03/2007

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

Age group
Adult

Sex
Not Specified

Target number of participants
350

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 rigourous 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)

Sponsor details
Louis Mettewielaan 64-76
BE-1080

Brussels
Belgium
1080

Sponsor type
Industry

Website
http://www.ozcm.be/

Funder(s)

Funder type
Industry

Funder Name
De Onderlinge Ziekenkas (Belgium)

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?
Results article	results	01/06/2013		Yes	No