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Prevention of cardiovascular disease in current and former employees of the Ford motor company, Germany

Submission date
26/05/2011

Recruitment status
No longer recruiting

Registration date
28/07/2011

Overall study status
Completed

Last Edited
14/03/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiovascular diseases (CVD), including heart disease, heart attack and stroke, are a major cause of suffering and disability in many patients. Therefore, there is an urgent need for treatment strategies to prevent CVD, especially in healthy individuals at high risk for CVD. Decades of research have shown that CVD results from multiple risk factors, including smoking, high blood cholesterol, high blood pressure, obesity, chronic stress and depression. Treatment strategies for single risk factors are available, but, until now, only very few studies have targeted all of the aforementioned risk factors at the same time in a larger sample of healthy individuals at high risk for CVD. This study aims to fill this gap. The aim of this study is to find out whether the PreFord intervention reduces the risk of CVD.

Who can participate?
Adults with no evidence of existing CVD, but at high risk for CVD in the future

What does the study involve?
Participants are randomly allocated to either the PreFord intervention or routine care by their GPs. The PreFord intervention consists of 75 hours (total), divided into 30 sessions (2.5 hours each), two times a week, over a period of 15 weeks. It includes health education (e.g., the heart and vessels, healthy food, heart medication, etc), exercise, a smoking cessation programme if necessary, and LifeSkills, an approach to enhance stress resilience and social relationships at work and leisure time. The intervention is accompanied by a guideline-based drug treatment for high blood cholesterol and high blood pressure, if necessary. Well being, health behaviour and CVD risk factors are assessed before and after the intervention, and annually for 5 years. The intervention and each follow-up assessment are free of charge, and participants are free to join or leave the study whenever they wish.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
German Sports University Cologne

When is the study starting and how long is it expected to run for?
August 2004 to July 2013

Who is funding the study?
Bayer Vital (Germany), Pronova BKK (Germany) and AstraZeneca (Germany)

Who is the main contact?
Prof. Hans-Georg Predel
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multimodal intervention for prímary prevention of cardiovascular disease in current and former employees of the Ford motor company, Germany - the PreFord trial

Acronym
PreFord

Study objectives

A multimodal intervention for primary prevention of cardiovascular disease (CVD) will reduce multiple biological and psychosocial cardiac risk factors and cardiac events.

Re-evaluation of cardiovascular risk and cardiac events annually up to 5 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. North Rhine Medical Association (Aerztekammer North Rhine) Ethics Committee, 20/12/2004, ref: 2004079
2. Faculty of Medicine Ethics Committee, University of Cologne, 02/02/2004, ref: 03-217

Study design
Two-armed randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Prevention of cardiovascular disease

Interventions
Multimodal intervention for outpatients, two sessions a week in the afternoon for three months (75 hours total):
1. Health education
2. Exercise therapy
3. Smoking cessation programme
4. Stress management (LifeSkills)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
European Society of Cardiology risk score

Secondary outcome measures
1. Health behaviour (physical fitness, smoking, BMI)
2. CVD risk factors, e.g. low-density-lipoprotein cholesterol (LDL-C), total cholesterol, trigycerides, blood pressure, diabetes mellitus, depression and anxiety (HADS), Type-D pattern (DS-14)

Overall study start date
01/08/2004

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Adult men and women with no evidence for CVD and elevated risk according to the (European Society of Cardiology) ESC risk score > 5%
2. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
447

Total final enrolment
447

Key exclusion criteria
Severe somatic or psychiatric morbidity, e.g. malignancies, psychosis, drug addiction

Date of first enrolment
01/08/2004

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
Germany

Study participating centre
German Sports University Cologne
Cologne (Koeln)
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Sponsor information

Organisation
German Sports University (Germany)

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Sponsor type
University/education

Website
https://www.dshs-koeln.de/wps/portal

ROR
https://ror.org/0189raq88

Funder(s)

Funder type
Industry

Funder Name
Bayer Vital (Germany)

Funder Name
Pronova BKK (Germany)

Funder Name
AstraZeneca (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/02/2004		Yes	No
Results article	results	01/02/2012		Yes	No
Results article	results	01/09/2017		Yes	No
Other publications	Secondary analysis	23/02/2023	14/03/2023	Yes	No