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Will providing different types of coronary heart disease risk information result in a change in lifestyle?

Submission date
18/12/2014

Recruitment status
No longer recruiting

Registration date
12/01/2015

Overall study status
Completed

Last Edited
08/02/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular disease is a term used to describe all the diseases of the heart and blood vessels (circulation). Cardiovascular disease includes coronary heart disease (angina and heart attack), heart failure, heart valve disease, cardiomyopathy (heart muscle disease) and stroke. Data from the World Health Organization (WHO) show that cardiovascular disease is the number one cause of death globally, with an estimated 17 million deaths from cardiovascular disease in 2011, which represents 3 in every 10 deaths. The commonest form of cardiovascular disease is coronary heart disease. The good news is that everyone can do things to lower their risk of coronary heart disease. One of the ways to decrease the risk of coronary heart disease is to adopt a healthy lifestyle. This means for example, not smoking, being physically active, eating a healthy diet and maintaining a healthy weight. Changing lifestyle may be challenging and researchers all over the world try to understand what helps people to make these changes. Knowing one's risk of coronary heart disease may be an important step in improving lifestyle and decreasing risk. The future risk can be estimated by using various clinical factors (e.g. age, gender, blood pressure, smoking status, blood cholesterol) and we usually refer to this risk as a 'traditional risk of coronary heart disease' or 'phenotypic risk score'. However, thanks to recent advancements in technology, we can also use blood samples to estimate individual's genetic risk of developing coronary heart disease. The NHS has initiated a programme of cardiovascular disease risk reduction (NHS Health Checks) based on assessment of cardiovascular disease risk for all those aged 40-74 years without pre-existing cardiovascular disease and related disorders. However, it is not clear how best to provide this information and whether it has any effect. In this study called INFORM, we will try to understand how people respond to receiving different types of risk information, and the impact that this information has on their lives.

Who can participate?
Participants aged between 40 and 84 years who have taken part in the INTERVAL study (www.intervalstudy.org.uk, ISRCTN24760606) and completed their two-year questionnaire can participate in the INFORM study.

What does the study involve?
At the start of the study we ask participants to complete an online questionnaire about themselves and their lifestyle, and we ask them to wear a small monitor on their wrist for 7 days to measure their physical activity. After this is completed, participants will be allocated by computer to one of 4 groups in the study by a process called randomisation. Randomisation means that everyone has an equal chance of being in the different groups and the number of participants and their characteristics are well balanced between the study groups. If participants are allocated to a group that receives information, they may receive a combination of lifestyle advice, a traditional coronary heart disease risk score and genetic risk information. Exactly what they receive depends on which group they are in. If participants are allocated to the control group, they will not receive any information but we will provide them with all of the information at the end of their time in the study. The lifestyle advice is delivered via 3 sessions of interactive information online at monthly intervals, tailored to the specific lifestyle of participants based on information they provided in the first questionnaire. At the end of the three-month period, we will ask participants some more questions and monitor their physical activity again for 7 days. We will also ask them to provide a blood sample at their GP's surgery. A small group of participants will be asked if they would be willing to talk to a researcher about their participation in the study or take part in a group discussion known as a focus group. The interviews or focus groups will last about an hour. We will discuss in more detail participant's views about the risk information or the lifestyle advice that they have received and its impact. People can still take part in the study even if they do not wish to be interviewed or participate in a focus group.

What are the possible benefits and risks of participating?
Participants will receive information about their risk of coronary heart disease and lifestyle advice to lower the risk. Once they know their risk, they may make changes in their lifestyle to lower the risk of developing coronary heart disease. This will be of benefit to their personal health. In addition, if the study finds that this kind of information sharing improves health, the research could help prevent coronary heart disease in others. There is a chance that a participant may feel anxious if he/she finds out that his/her risk of developing coronary heart disease is high. This is understandable and our lifestyle advice will help participant's look at options for reducing their risk. Participants can also discuss the risk and next steps with their GP.

Where is the study run from?
The INFORM study has been set up by the Department of Public Health and Primary Care and the Medical Research Council Epidemiology Unit at the University of Cambridge.

When is the study starting and how long is it expected to run for?
January 2015 to December 2015

Who is funding the study?
The INFORM study is funded by the European Commission as part of the EPIC-CVD project (http://www.epiccvd.eu/). The overall aim of EPIC-CVD is to provide clinicians and policy makers with evidence-based options for cost-effective individualised CVD risk assessment. It is running in 10 European countries and the INFORM study is part of the work being carried out in the UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
European Commission Framework 7 EPIC-CVD Grant agreement no: 279233

Study information

Scientific Title
Information and Risk Modification Trial (INFORM): A randomised trial to determine if communicating different forms of coronary heart disease risk information and lifestyle advice for risk reduction results in health-related behaviour change.

Acronym
INFORM

Study objectives
The primary objective is to evaluate the effect of provision of phenotypic and genetic coronary heart disease risk scores and lifestyle advice on physical activity at three months measured objectively using an Axivity AX3 3-Axis Logging Accelerometer®, defined as average acceleration (m/s2).

The secondary objectives are to evaluate the effect of provision of phenotypic and genetic coronary heart disease risk scores and lifestyle advice on the following measures:
1. Objectively measured dietary behaviour (key secondary objective): serum carotenoid levels
2. Cardiovascular risk factors: objectively measured total-, high density lipoprotein-, and low-density lipoprotein-cholesterol, triglycerides and fructosamine; self-reported weight, smoking status, alcohol consumption, physical activity and dietary behaviour
3. Current medication and healthcare usage
4. Perceived risk: comparative and absolute perception of risk
5. Cognitive evaluation of provision of coronary heart disease risk scores: participant's acceptability and understanding of the risk scores and accuracy of their risk perception
6. Psychological outcomes: anxiety associated with testing, fatalism, depression, stress and mood

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Central Research Ethics Committee, 03/12/2014, ref: 14/EE/1164

Study design
Single-centre four-arm parallel-group randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Coronary Heart Disease

Interventions
Participants are randomly allocated to one of four groups:

Intervention Group A: Participants receive phenotypic and genetic coronary heart disease risk scores. The genetic risk estimate is based on 49 single nucleotide polymorphisms and the phenotypic risk estimate is based on age, sex, total cholesterol (mmol/l), HDL cholesterol (mmol /l), self-reported use of antihypertensive medication, self-reported diabetes mellitus and smoking status. Both coronary heart disease risk scores are presented in the same format to ensure that the only experimental condition is the addition of information on the risk of a coronary heart disease based on genetic variants (and not the different formats of presenting the coronary heart disease risk information). The phenotypic and genetic coronary heart disease risk scores consist of three pieces of information (Absolute risk, Heart Age and Comparative risk). Participants in this group also receive a lifestyle intervention for coronary heart disease prevention consisting of 3 sessions of interactive tailored information on the web.

Intervention Group B: Participants receive a phenotypic risk estimate for coronary heart disease and the web-based lifestyle intervention for coronary heart disease prevention.

Intervention Group C: Participants receive the web-based lifestyle intervention for coronary heart disease prevention.

Control Group D: Participants do not receive either of the coronary heart disease risk estimates nor a lifestyle intervention for coronary heart disease prevention until after they have completed follow-up.

Intervention Type
Mixed

Primary outcome(s)
Objectively measured physical activity using an Axivity AX3 3-Axis Logging Accelerometer®, defined as average acceleration (m/s2) over a 12 -week observation period.

Key secondary outcome(s))

1. Objectively measured dietary behaviour: serum carotenoid levels
2. Cardiovascular risk factors: objectively measured total-, high density lipoprotein-, and low-density lipoprotein-cholesterol, triglycerides and fructosamine; self-reported weight, smoking status, alcohol consumption, physical activity and dietary behaviour
3. Current self-reported medication and healthcare usage
4. Perceived risk: comparative and absolute perception of risk
5. Cognitive evaluation of provision of cardiovascular risk scores: participant's acceptability and understanding, of the risk scores and accuracy of their risk perception
6. Psychological outcomes: anxiety associated with testing, fatalism, depression, stress and mood
7. Current participation in other interventional clinical trials in cardiovascular disease or lifestyle modification

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Age ≥ 40 and ≤ 84 years
2. Have been participating in and completed the two year follow-up questionnaire for the INTERVAL Study (ISRCTN24760606), and not exiting that study due to withdrawal or lost to follow up
3. Able and willing to wear a physical activity monitoring device on the wrist
4. Willing to provide a blood sample
5. Have sufficient data available to the study team for calculation of phenotypic and genetic risk estimates for fatal and non-fatal heart attack
6. Agree to allow trial staff to contact his or her GP to notify them of trial participation and study test results
7. Have internet access and be willing to provide an email address for study correspondence
8. Have a good understanding of the English language, both written and oral (study materials are not tailored to support non-English language speakers)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
956

Key exclusion criteria
1. Prior history of cardiovascular disease (heart attack, angina, peripheral arterial disease or stroke, surgical or percutaneous coronary revascularisation procedure)

2. Medical condition or disability that means the participant can not engage in physical activity
3. Known pregnancy at time of recruitment
4. Unable to provide informed consent

Date of first enrolment
26/01/2015

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
The INFORM Study
Cardiovascular Epidemiology Unit
Department of Public Health and Primary Care
The INFORM Study
Cardiovascular Epidemiology Unit
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Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
European Commission Directorate-General for Research and Innovation

Alternative Name(s)
EC DG Research

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/12/2016		Yes	No
Results article		13/06/2018		Yes	No
Results article		30/03/2019	08/02/2023	Yes	No
Results article		01/12/2018	08/02/2023	Yes	No
Protocol article		07/09/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes