UNIVERSITY OF CAMBRIDGE
Department of Public Health and Primary Care

MRC Epidemiology Unit

INFORM Study

An opportunity to learn your individual risk of coronary heart disease and ways to reduce it

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Freephone: 0800 021 7182
Mon to Fri: 09:00–17:00

INFORM study leaflet 13.01.2015 (version 1.2)

INFORM

We would like to invite you to join the Information and Risk Modification (INFORM) trial which 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.

We are recruiting 932 people to the study. The aim is to see whether informing people about their individual risk of coronary heart disease motivates them to change their lifestyle (for example to stop smoking, eat healthier or exercise more). To help people with lifestyle changes, we will provide lifestyle advice.

We will look at this over a three-month period.

Before you decide whether to participate, it is important for you to understand why the study is being conducted and what is involved. Please take the time to read the following information carefully, and discuss it with others if you wish.

If anything is not clear, or if you would like more information, please call the freephone number on **0800 021 7182** to talk to a member of our study team or email **helpdesk@informstudy.org.uk.** More information about the study is also available on our website at **www.informstudy.org.uk**

Thank you for taking the time to consider taking part in the INFORM study.

Why is this study needed?

Cardiovascular disease (CVD) is a term used to describe all the diseases of the heart and blood vessels (circulation). CVD includes coronary heart disease (angina and heart attack), heart failure, heart valve disease, cardiomyopathy (heart muscle disease) and stroke.

Data from the World Health Organisation (WHO) show that CVD is the number one cause of death globally, with an estimated 17 million deaths from CVD in 2011, which represents 3 in every 10 deaths. Of these, 7 million people died of coronary heart disease (which includes a heart attack) and 6.2 million from stroke.

The number of people who die from CVD is expected to increase each year to reach 23.3 million by 2030, and it is projected to remain the single leading cause of death.

The good news is that everyone can do things to lower their risk of coronary heart disease. One of the ways to decrease your risk is to adopt a healthy lifestyle. This means for example, not to smoke, exercise regularly, eat a healthy diet and maintain a healthy weight. Changing your lifestyle may be challenging and researchers all over the world try to understand what helps people to make these changes. Knowing your risk may be an important step in improving your lifestyle and decreasing your risk of CVD. Your 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 CVD’. However, thanks to recent advancements in technology, we can also use blood samples to estimate your genetic risk of developing CVD.

In this study 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.

What does taking part in the study involve?

The INFORM study aims to recruit 932 people from across England who have taken part in the INTERVAL study (www.intervalstudy.org.uk) and completed their two-year questionnaire.

Not everyone who would like to take part will be able to. If you would like to take part, we will ask you to complete an online questionnaire to see if you are eligible. If you are eligible, we will send you two consent forms to read and sign (one copy is for you to keep, and one is for our records). If you are not eligible, we will let you know by email. You will take part in the study for four to five months.

When you start the study, we will ask you to complete an online questionnaire about you and your lifestyle, and we will ask you to wear a physical activity monitor for 7 days to measure your physical activity. If you have worn a physical activity monitor as part of the INTERVAL study, you will not need to do this again at the start.

After this is completed, you will be allocated to one of 4 groups in the study by a process called randomisation (see opposite). There will be 233 people in each group. Unfortunately, you will not be able to request to be in a particular group or change groups.

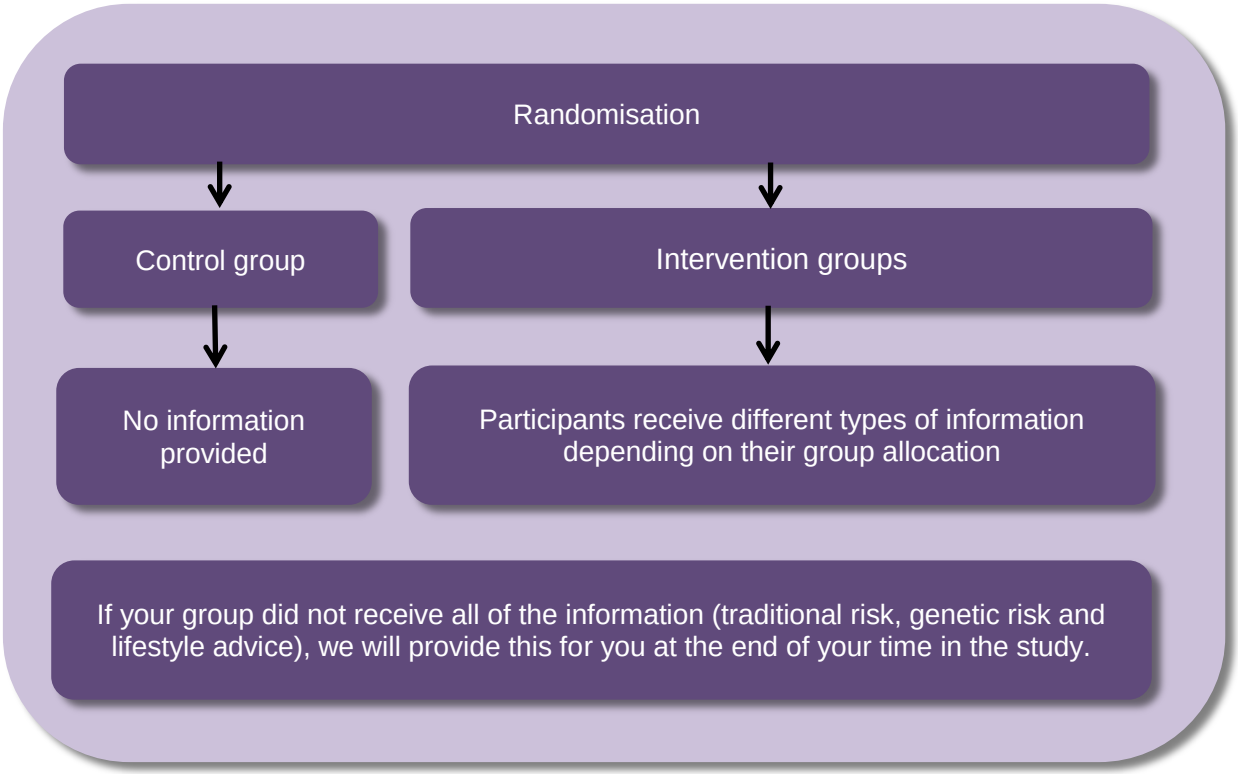
If you are allocated to a group that receives information, you may receive a combination of lifestyle advice, a traditional coronary heart disease risk score and genetic risk information. Exactly what you receive depends on which group you are in. If you are allocated to the control group, you will not receive any information but we will be provide you with all of your information at the end of your time in the study.

The lifestyle advice is delivered via 3 sessions of interactive information online at monthly intervals, tailored to your specific lifestyle from information that you give us in the first questionnaire. You can find out ways to reduce your risk, set goals and print out information for later.

At the end of the three-month period, we will ask you some more questions and monitor your physical activity again for 7 days. We will also ask you to provide a blood sample at your GP's surgery. Some of you will be asked if you would be willing to talk to a researcher about your 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 your views about the risk information or the lifestyle advice that you have received and its impact. Only a small group of participants will be asked to be interviewed or take part in the focus groups and you can still take part in the study even if you do not wish to be interviewed or participate in a focus group.

Randomisation: means you will have an equal chance of being allocated to any one of the INFORM groups.

You will not be able to choose which group you are allocated to.



Taking part in the study will also involve agreeing to have your samples, questionnaire data, health-related and other information stored by the INFORM study team and used, for many years, in an anonymous form by researchers for a broad range of ethically approved scientific health studies.

Am I eligible?

You will be eligible to take part if you:

1. Are aged between 40 and 84 years old
2. Have been participating in and completed the two year questionnaire for the INTERVAL Study (ISRCTN 24760606) and not exited from the study (withdrawn or discontinued), and you have indicated an interest in physical activity and completed any physical activity monitoring undertaken as part of the INTERVAL study
3. Are able to wear a physical activity monitoring device on the wrist
4. Are willing to provide a blood sample
5. Have data available from the INTERVAL study for calculation of traditional and genetic risk estimates for fatal and non-fatal heart attack (we will decide this). These data may not be available for all INTERVAL participants during the INFORM recruitment period as the analysis of the INTERVAL blood samples only commenced towards the end of INTERVAL recruitment (June 2014).
6. Agree to allow trial staff to contact your 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)

You will not be eligible to take part if you:

1. Have a previous history of cardiovascular disease (heart attack, angina, peripheral arterial disease or stroke, surgical or percutaneous coronary revascularisation procedure)
2. Have a medical condition or disability that means you cannot engage in physical activity
3. Are pregnant
4. Are unable to provide informed consent
5. Are currently participating in another interventional clinical trial in cardiovascular risk or lifestyle modification (e.g. diet or physical activity)

We will always check your eligibility and there may be times when you are not able to take part. If you are taking part in another clinical trial other than INTERVAL, please contact the helpdesk and we will check if you can take part.

If you do take part in the study, we will write to your GP to let them know. We will also send them a copy of your coronary heart disease risk information and the results of your blood test.

Do I have to take part?

No, it is completely up to you. If you take part in the study, you are free to withdraw at any time without giving a reason.

What should I do if I want to take part?

If you would like to take part, please complete our online eligibility questionnaire. You can take the questionnaire using the web link in your invitation email.

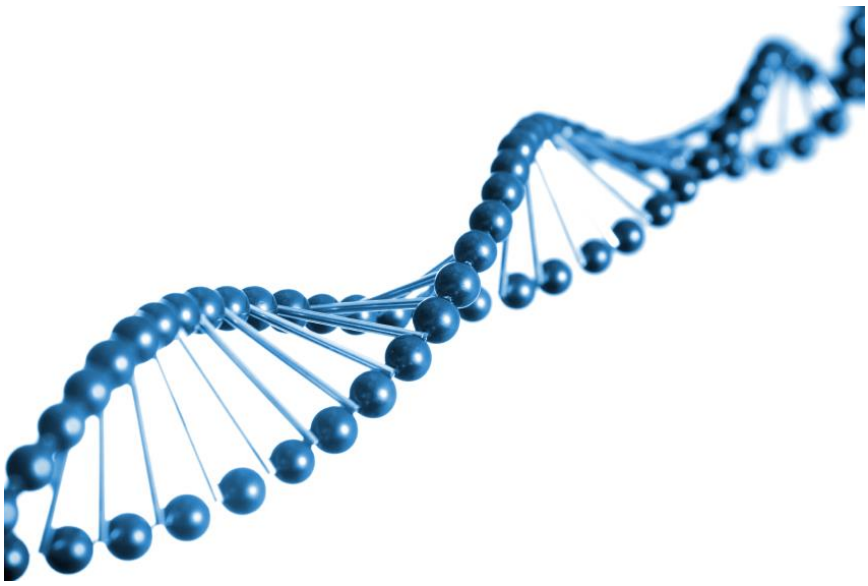
After taking the questionnaire, we will let you know if you are able to take part.

What will happen to my blood samples?

Blood samples collected for the purposes of the research will be:

- Kept securely at central laboratories. They will not be labelled with your name or contact details, but only with a unique study number.
- Stored in freezers as separate components (e.g. plasma and serum) before use
- Used by the study investigators for medical and health-related studies which have the relevant scientific and ethical approval.
- Used to measure biomarkers, which are substances in the body that can easily be measured and give a clue to health (for example, there are biomarkers that show changes in nutrition).

If you take part, we will need your specific consent to use results from the blood sample that you provided for the INTERVAL study for many genes and biomarkers and we need this information so that we can calculate your traditional and genetic risk of developing CVD.



Are there any benefits for me if I join the study?

You will receive your risk information and lifestyle advice to lower your risk. Once you know your risk, you may make changes in your lifestyle to lower your risk of developing CVD. This will be of benefit to your personal health.

In addition, if the study finds that this kind of information sharing improves health, the research could help prevent CVD in others.

Are there any risks for me if I join the study?

There is a chance that you may feel anxious if you find out that your risk of developing CVD is high. This is understandable and our lifestyle advice will help you look at options for reducing your risk. You can also discuss your risk and next steps with your GP. If you feel very anxious after receiving your genetic risk information and wish to discuss it, you can contact the study helpdesk and they will arrange for a medically qualified member of the research team to contact you.

How will information about me be kept confidential?

We will protect your privacy at all times.

The steps taken to ensure confidentiality are detailed below:

- Your samples and data will not include any personal identifying details so researchers working with your samples and data will never know your identity. Your data will be stored using a unique, anonymous study identification number.
- All study data will be stored on a restricted-access study database on secure computers at the University of Cambridge. The study data will be linked to your study identification number, but your personal details (surname, first name, date of birth, address) will never appear in this database. Access to the study database will be password protected and will be used only by named researchers working on this study under the direct supervision of the senior scientific investigators.

What will be stored on the INFORM database?

Your anonymised data will be stored in the INFORM study database and will be used by the study investigators to, for example, understand characteristics (e.g. gender and nutrition)

that influence the risk of developing CVD. Stored anonymised data may also be used for future medical and health-related studies which have relevant scientific and ethical approval.

Information that will be stored on the database include:

- Gender, month and year of birth
- Data from the online questionnaires
- Your physical activity data
- Results from all laboratory measurements using your blood components.

How do I withdraw if I want to do so?

The study will be most valuable if few people withdraw from it, so it is important to discuss any concerns you may have with a member of the study team before you agree to participate. However, you can withdraw from the study at any time without giving a reason.

You can withdraw by telephoning us on **freephone 0800 021 7182** Mon to Fri: 09.00–17.00 or by emailing helpdesk@informstudy.org.uk or by writing to us at the University of Cambridge (see front of leaflet). This will allow us to discuss your concerns with you and determine the desired level of withdrawal from the following options.

"No further contact": This means that the INFORM team would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously.

"No further use": This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. Please note that we will not be able to remove results of any tests already performed with your samples from the study database but we will prevent your records from being used in any future research. We can also assure you that your blood samples will be removed from the central study repository after we have received your written notification. It will, however, not be possible to remove small volumes of your samples which have already been distributed to research laboratories but results which are generated after you have withdrawn will not be uploaded to the study database. Your signed consent and withdrawal forms will be kept as a record of your wishes.

If, after having discussed the options and your concerns, you decide to withdraw, we will send you a withdrawal form to confirm your wishes in writing. Examples of this form can be viewed on our website www.informstudy.org.uk. This form can be completed by you, or if you are not able to do so for any reason (such as illness), by someone able to act on your behalf. In the unlikely event of a loss of capacity to decide on continued participation in the study, the study team would retain blood samples and personal data collected and continue to use it confidentially in connection for the purposes for which consent has been granted.

Who will be able to use my information and samples?

Your anonymous information and samples will only be available to researchers who have relevant scientific and ethical approval for their planned research.

This could include researchers who are working in other countries and in commercial companies who are looking for new treatments or laboratory tests.

We will not pass on any individual's information, samples or test results to third parties, such as the police, security services, relatives or lawyers, unless forced to by the courts.

Some people are worried that once they've had a genetic test, they may be discriminated against - for example, by insurance companies. At the moment, there is a voluntary agreement (called the Concordat and Moratorium on Genetics and Insurance) between the Department of Health and the Association of British Insurers (ABI). In the agreement, insurers agree that they won't ask customers to tell them about any predictive genetic test results acquired as part of clinical research. Further information can be found at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216821/Concordat-and-Moratorium-on-Genetics-and-Insurance-20111.pdf
If your GP is asked to fill in a medical report for your insurer, they are not allowed to disclose the results of predictive genetic tests even if they have them.

There is a requirement to publish the results of the research arising from the samples and data collected during the study so that people can benefit from it. The results will also be made available to participants and anyone else who may be interested at www.informstudy.org.uk.

Can I know the results obtained from my blood samples?

We will only use your blood samples to calculate your risk of coronary heart disease and all our participants will be informed about their traditional and genetic CVD risk scores.

Who is organising and funding the study?

The INFORM study has been set up by the University of Cambridge and is funded by the European Commission as part of the EPIC-CVD project (www.epiccvd.eu).

EPIC-CVD

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 has approved the study?

All research involving the NHS is reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the Cambridge Central Research Ethics Committee.

What will happen if an invention is made using my sample?

You are giving your samples as an absolute gift, i.e. without receiving a payment and without attaching conditions. The INFORM study is operating on a non-commercial basis, meaning that it does not sell your samples to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions or to private-sector research partners, a fee may be charged to cover the operational costs.

In future, your samples may help researchers in the public and private sector to make an invention, e.g. develop a new product to diagnose, prevent or treat disease. If an invention results from the research undertaken with your samples, you will not receive any compensation or payment. INFORM partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient care; we hope such products are brought into use by the NHS to improve health care in the future.

What happens if something goes wrong?

The risk of participants suffering harm as a result of taking part is minimal, and the INFORM study has insurance in place to provide compensation for any negligent harm caused by participation.

Who do I contact if I have any concerns?

If you have any concerns or complaints about anything to do with the INFORM study then you can telephone the **freephone number** on:

0800 021 7182 Mon to Fri: 09.00–17.00

or you can email us at: **helpdesk@informstudy.org.uk**

Alternatively, if you would like to write to the person in charge, please send your letter to:

The INFORM Study
University of Cambridge
Department of Public Health and Primary Care
Wort's Causeway, Cambridge CB1 8RN

We will reply to your letter promptly in writing, unless you enclose your telephone number and wish to discuss your concerns with us by telephone.