UNIVERSITY OF CAMBRIDGE

MRC | Epidemiology Unit

The FENLAND Study Phase 2

Participant Information Leaflet

Version 8.0 18 Oct 2018

What is the purpose of this study?

This research project is designed to investigate the interaction between genetic and lifestyle factors in determining diabetes, obesity, and related metabolic disorders. These conditions are a considerable public health concern, but their causes and predicting factors are not completely understood.

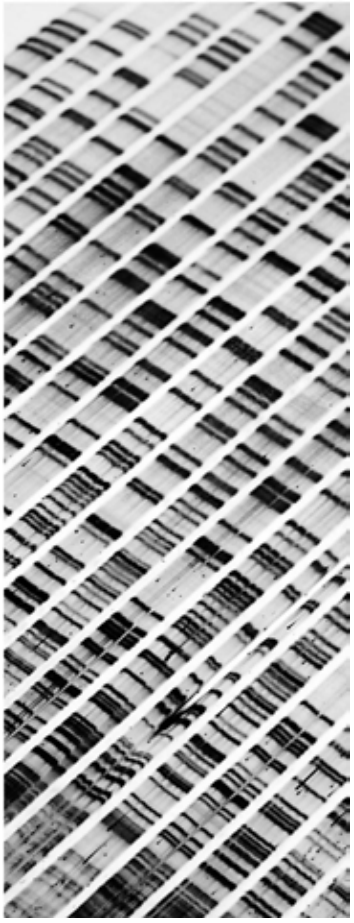
Why have I been chosen?

Approximately 12,500 people from across Cambridgeshire took part in the first phase of the Fenland Study. We would like to invite participants who attended an initial Fenland Study visit between 2005 and 2014 and who agreed to be re-contacted, to participate in phase 2 of the Fenland Study. The information we collect from you will be used to define how changes in and interactions between lifestyle, environmental, genetic and metabolic factors over time determine diabetes, obesity and other relevant health conditions.

Before you decide to take part, we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and feel free to discuss with friends, family or your GP about this study.

Do I have to take part?

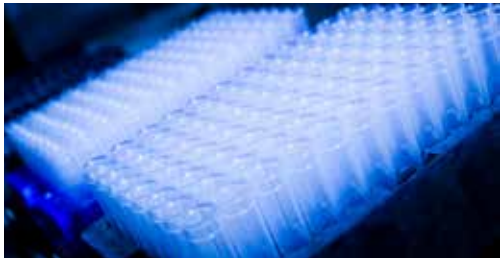
No, it is entirely up to you to decide whether or not to take part. If you decide not to take part, we will completely respect your decision and it will not affect the healthcare you receive in any way. If you decide to take part, we will ask you to sign a consent form when you attend the study visit.



What will happen if I take part in the study?

If you agree to help us with this research, you will visit one of our Research Units at either the Princess of Wales Hospital in Ely, the North Cambs Hospital in Wisbech or the Addenbrooke's Hospital in Cambridge, whichever is most convenient for you.
The study visit will be a **single morning visit** of up to 4 hours, during which we will carry out a number of tests to:

- **Measure your metabolic health** – we will take a blood sample to determine your blood glucose and blood fat (such as cholesterol) levels. To ensure accurate measurement of these we ask that you do not eat or drink anything other than water from 10pm on the evening before your visit. You will then consume a harmless sugary drink and your response to the glucose in the drink will be assessed through a second blood sample taken 2 hours later. This is the standard test to determine whether someone has diabetes or not. If you have been diagnosed with diabetes, you are still eligible to take part. However, we will only take an initial blood sample and you will not consume the sugary drink. Blood samples will be stored for future research aimed at understanding the cause of diabetes and related disorders. These stored samples will not be labelled with any personally identifiable information. We also work with other research groups in order to learn as much as possible about diet and diseases. As part of these research collaborations your anonymous information and samples may be made available to researchers who are working in other countries (including outside the EU) or in commercial companies.



We would also like to take a blood sample for the generation of induced pluripotent stem cells (iPSCs) for research purposes. Pluripotent stem cells are cells early in a chain of development which have the potential to become different cell types, such as those in the liver, pancreas or other organs. We are able to induce these cells from circulating white blood cells. We can then use the experimentally derived different cell types to investigate pathways that link our genetic profiles with metabolic disease. The benefit of this approach is that it allows the study of different cell types without the need for direct sampling, which would otherwise require invasive procedures such as, for example, endoscopy or needle biopsies. The cells we will generate will not be of direct benefit to you or anyone else in the treatment of disease and will only be used for experimental research purposes.

- **Measure your diet and other lifestyle patterns** – we will ask you to complete a range of questionnaires electronically at the visit and both on paper and electronically at home relating to your medical history, normal diet, 24hour dietary recall, physical activity and general lifestyle.

- **Measure your body composition** – Your height and weight, hip and waist circumference, an ECG of your heart and blood pressure measurements will be taken. Using a DEXA scanner and an ultrasound we will assess your body composition. Both measurements take about 5-15 minutes and cause no discomfort. **The DEXA scanner is an x-ray procedure. The x-ray exposure from this equipment is very small indeed, amounting up to approximately 8 hours natural exposure to background radiation. For reference, a single chest x-ray amounts to approximately 3 days background radiation.** The ultrasound requires a small amount of gel to be placed on the midriff to allow a sensor to take a measurement.

- **Measure your fitness and physical activity level** – Firstly, we will ask you to rest by lying on a couch for 10 minutes. During this test we will measure your resting energy expenditure by monitoring the air that you breathe. If you are eligible, we will ask you to walk on a treadmill for 16 minutes and if you can, jog for 4 minutes. Alternatively, you may be asked to perform a self-paced walk test. You will also wear a combined heart rate and movement sensor called an Actiheart, which is very light, weighing less than 10 grams. It will be connected to your chest by standard electrodes. After the test you will wear the sensor for six days and nights continuously. The sensor is fully waterproof and has no buttons or displays. We will provide a freepost envelope for you to return the monitor to the study centre at the end of the six days.

In addition to the Actiheart monitor you will be asked if you would like to wear one or two additional monitors; a Global Positioning System Receiver (GPS) which can be worn discreetly on your waist and an accelerometer that is worn on your wrist. One or both can be worn in conjunction with your Actiheart but are both optional. Once we have received the monitors back and processed your data, we will send you a link to a secure website where you can explore your activity data in detail and if you like this website also allows you to provide contextual information on what you were doing at certain times, e.g. when you were at work and when and how you were travelling to/from work.

We will also assess muscular strength by performing a hand grip strength test of both hands.

Expenses & payments	**Travel costs up to £50 will be reimbursed, so please keep a record of your mileage and parking charges, public transport fares etc. If your claim is likely to exceed £50 please contact the office in advance. At the end of the visit we will offer you a voucher for some refreshments at the hospital cafeteria.**

What are the possible disadvantages and risks for taking part?

There are no significant risks involved in the tests but, for the purposes of our study, if there is a possibility that you may be pregnant we will be unable to allow you to take part.

The DEXA scan will expose participants to a low dose of ionising radiation. The typical dose received by a participant (1-2 microSieverts) is equivalent to a few hours of natural background radiation from the atmosphere.

In some instances, individuals may experience minor skin irritation or develop a slight rash from wearing the electrodes used to attach the actiheart. From previous research this was reported for less than 10% of those wearing electrodes. The irritation is localised and goes away on its own.

When taking a blood sample there is a risk of bruising, inflammation and fainting. From phase 1 of the Fenland Study approximately 0.5% of individuals may have felt sick after consuming the glucose drink. We have changed supplier of the glucose drink to make the consumption more palatable, however some individuals may still feel nauseas after consuming the drink.

What are the possible benefits of taking part?

If you decide to take part you will have a **very thorough health check** including a test for diabetes and measurement of your blood cholesterol. With your permission your results will be passed to your GP and you will receive detailed individual feedback from us on the results of your study visit. This will include information on how your body composition and fitness compare to the rest of the population. You will also receive an estimate of the amount of energy you use during six days of your normal life. The information you receive will be straightforward to understand and we will tell you how your measurements impact on your health. This information will be sent to you approximately 6-8 weeks of returning the monitors to the study centre.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. They are contactable on free phone 0800 085 6183. If you remain unhappy and wish to complain formally, you can do this by contacting the Assistant Director of the Research Office, University of Cambridge School of Clinical Medicine on **01223 333543**.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time and without giving any reason. However, if the information you have provided has been included in any analysis prior to your withdrawal then we will be unable to remove these from the results.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of this research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be identified from it. It will not be used or made available for any purpose other than for research. With your permission, information will be stored anonymously by the MRC Epidemiology Unit, University of Cambridge. Codes connecting your individual identity to the stored data records will be kept separately. Cambridge University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this. Cambridge University will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/

Future information on health

In future years we would like to identify any patterns of ill health among participants in this study. We would like to study patterns of hospital admissions or risk of developing particular diseases, including cancer. We will ask you for permission to access information about you held by the NHS for this purpose.

What will happen to the study results?

The study results will allow us to have a better understanding of the causes of diabetes and obesity and how to prevent them. You will not be identified personally in any report or publication.

Who is organising and funding the study?

The study is organised and funded by the Medical Research Council Epidemiology Unit, University of Cambridge.

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Who has reviewed the study?

To protect your interests the Fenland Study has been reviewed by an independent group of people called a Research Ethics Committee. This study has been reviewed and given a favourable opinion by Cambridge East Research Ethics Committee.

What should I do next?

If you decide that you would like to take part, please complete the reply slip sent with your invite letter and send it back to us in the enclosed freepost envelope. Alternatively, call us on free phone **0800 085 6183** or email us at **fenlandstudy@mrc-epid.cam.ac.uk** to arrange an appointment quoting your study participant number found on the reply slip (beginning with a 5, 6 or 7).

Further information

If you would like further information or have any queries about the study, please feel free to contact the study team on our free phone number:

0800 085 6183 Mon to Fri 08:00 – 17:00.

You can also e-mail us at:

fenlandstudy@mrc-epid.cam.ac.uk

In addition feel free to browse our website at:

www.mrc-epid.cam.ac.uk/research/studies/fenland

Thank you for considering contributing to our study

The FENLAND Study