

# THE FENLAND *Study*

## ***What is the purpose of this study?***

This research project is aimed at investigating the interaction between genetic and lifestyle factors in determining obesity, diabetes and related metabolic disorders which present a considerable public health concern. The aim of this study is to investigate strategies for the prevention of these diseases.

## ***Why have I been chosen?***

All people who were born between 1950 and 1975 and are registered at surgeries in the East Cambridgeshire area are being invited to take part.

*The Medical Research Council (MRC) is funded by the UK government and is the major national organisation that supports high quality medical research with the aim of improving human health.*

## ***Do I have to take part?***

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 you will need to sign a consent form when you attend the test. You are still free to withdraw at any time and without giving any reason.

## ***What are the possible benefits and risks for 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 on the results from the tests. 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 within two weeks of returning the sensor to the study centre.



*Travel costs for the visit will be reimbursed, so please keep a record of your mileage and parking charges, public transport fares etc.*

*At the end of the visit we will offer you a voucher for some refreshments at the hospital cafeteria.*

## ***What will happen if I take part in the study?***

If you agree to help us with this research, you will visit our Research Unit at the Princess of Wales Hospital Ely. This will be a ***single visit*** of 3 hours and is to carry out a number of tests to:

***Measure your metabolic health*** – you must not eat anything from 10pm on the evening before your visit to allow an initial blood sample taken on arrival to be assessed for glucose and blood fats such as cholesterol. You then consume a harmless sugary drink and your response to the glucose in the drink is assessed through a second blood sample taken 2 hours later. This is the standard test to define whether someone has diabetes or not. Blood samples will be stored for future research aimed at understanding the cause of diabetes and related disorders. These samples will not be labelled with any personally identifiable information.

***Measure your diet and other lifestyle patterns*** – you will complete four questionnaires relating to your medical history, normal diet, physical activity and general lifestyle. Your height and weight and an ECG of your heart will be taken.

***Measure your body composition*** – using a DXA scanner and ultrasound. Both measurements take about 5 minutes and cause no discomfort. The x-ray exposure from the DXA scanner is very small amounting to less than 10% of a day's natural exposure to background radiation. For reference, a single chest X-ray amounts to about 5 day's 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*** – to indirectly estimate the volume of blood your heart pumps out each beat, we will ask you to breathe a mixture of oxygen and harmless gases which will have completely disappeared from your body 5 minutes after this test. You will then rest lying on a couch for 6 minutes, walk on a treadmill for 16 minutes and if you can, jog for 4 minutes. During this test you will wear a face mask through which you breathe room air to measure your oxygen consumption. You will also wear a combined heart rate and movement sensor, 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.

There is no risk involved in the tests but, for the purposes of our study, if there is a possibility that you may be pregnant, or if you are unable to walk unaided, or if you are already on treatment for diabetes, we will be unable to allow you to take part.

### ***Who will have access to my information?***

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 at the MRC Epidemiology Unit. Codes connecting your individual identity to the stored data records will be kept separately.

If you choose to withdraw from the study, any information that is collected about you will be destroyed. At the end of the study, the confidential records will be kept for 15 years and then destroyed.

### ***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 and is also supported by the Wellcome Trust, an independent charity funding research to improve health.

### ***What should I do next?***

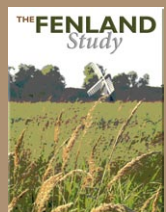
If you decide that you would like to take part, please complete the return slip and send it back to us in the enclosed freepost envelope.

#### ***Further information***

*If you want more information before deciding, or have any queries about anything concerning the study, please feel free to contact the study team on our free phone number :*

**0800 085 6183**

You can also e-mail us at : [fenlandstudy@mrc-epid.cam.ac.uk](mailto:fenlandstudy@mrc-epid.cam.ac.uk)



***Thank you for considering contributing to our study.***