



The Fenland Study

Cognitive and Behavioural Measurement Sub-study



What is the purpose of the study?

The Fenland study 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. This sub-study aims to understand whether there are differences in the way people think, behave, and respond to their environment, and whether these differences could influence the likelihood of developing these health conditions.

Why have I been chosen?

The Fenland Study is an important and unique study. Approximately 12,500 people from across Cambridgeshire took part in the first phase of the Fenland Study and over the last 3 years, participants have been returning for phase 2. We are inviting participants who completed a Phase 2 visit and who have consented to be contacted about further follow up to invite them to participate in this sub-study. This additional data will help us to get a more complete understanding of the factors that influence determinants of diabetes, obesity and related health conditions as well as associated health behaviours.

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 or family.

What will happen if I take part in the study?

If you agree to help us with this research, you will be sent an email with a weblink unique to you and instructions for the online software programme. You will need to complete a short online consent form prior to each computer based task. Instructions for each task will be provided on the screen to guide you through. You may need to download a plug-in to use the online platform. This is similar to plug ins that you may download to use media players. Instructions for this are provided.

This sub study will be completed online so you won't need to attend a visit at one of the measurement sites. You can complete these measures in the comfort of your own home. The measures in this sub-study are either questionnaires or a series of short computer-based tasks which measure your response to different words and images. Each of these tasks measures a different aspect of how people think and behave. For example, some of the tasks measure how impulsively you respond and others measure how well you remember information.

Completing these online tasks should take approximately 90 minutes to complete and will be split into three separate sets of tasks (each lasting less than 30 minutes). You can complete as many of these tasks as you like. You don't have to complete all three sets all in one go and you can stop in between sets. You can withdraw from this sub-study at any time and this will not impact your participation in the Fenland Study.

To take part you will need:

MRC Epidemiology Unit
University of Cambridge School of Clinical Medicine
Box 285, Institute of Metabolic Science
Cambridge Biomedical Campus, Cambridge, CB2 0QQ
Tel: +44 (0) 1223 330 315 Fax: +44 (0) 1223 330 316
www.mrc-epid.cam.ac.uk

Your login link contained in your invitation email
Access to a PC/laptop/mobile/pad with chrome/safari/Internet explorer
A quiet place to complete the tasks

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 or the possibility of taking part in future follow ups for the Fenland study. If you decide to take part, we will ask you to confirm online that you consent before you complete the measurements for this study.

Expenses and payments

No payments are available for taking part in this sub-study, These measures will be completed in your own home so there will not be any travelling involved.

What are the possible disadvantages and risks for taking part?

Other than the time it will take to complete the tasks, there are no risks involved.

What are the possible benefits of taking part?

The information you provide in this sub study will help our research into the determinants of diabetes, obesity and related illness and behaviours. Feedback about your results and the findings of the study will be provided once the sub-study has come to an end in 2020 and analysis has been carried out on the results. These will be fed back to you via email.

What if there is a problem?

If you have a concern about any aspect of this sub-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.

Who is organising and funding the study?

The study is organised and funded by the Medical Research Council Epidemiology Unit, University of Cambridge in collaboration with the University of Liverpool, who have helped develop the tasks used in this sub-study.

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. You will be assigned a unique code and this code will be used to label all data collected during the study. It is used in place of personal information. Personal identifiable information, such as the contact details we use to keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge. The results from the online tasks you complete comprise of batches of numbers that are scores in response to your reaction to the tests (which button you pressed, how long it took you to press it). These will be collected and stored anonymously by Millisecond, a US company and software provider. This company will only store these scores, linked to your unique ID number, and will not have access to any other data about you and will not use your results in anyway. The results will be downloaded and stored by the MRC Epidemiology Unit, University of Cambridge, who will link these scores to the rest of the data we have collected from you.

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/>

Your anonymised data will be shared with other members of the research team, including collaborators at the University of Liverpool. With your consent, anonymised data may be used to support other research in the future and may be shared with other researchers, with appropriate credentials, including those overseas or in the commercial sector. This will be solely for the purposes of research.

What will happen to the study results?

The study results will allow us to have a better understanding of the determinants of diabetes, obesity and related health conditions, as well as associated health behaviours. They will be reported at conferences, in academic journals and summary findings will be included in our Volunteer Times newsletter. You will not be identified personally in any report or publication.

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 online consent form to make a start with the measurements. If you have any questions about the sub-study, please call us on free phone 0800 085 6183 or email us at fenlandstudy.cbmss@mrc-epid.cam.ac.uk.

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 – 16:00. You can also e-mail us at fenlandstudy.cbmss@mrc-epid.cam.ac.uk. In addition feel free to browse our website at <http://www.mrc-epid.cam.ac.uk/research/studies/fenland/>

Thank you for considering contributing to our study