

The Fenland Study - investigates the interaction between genetic and lifestyle factors in determining obesity, diabetes and related metabolic disorders which present a considerable public health concern

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| Submission date 13/05/2013 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 30/08/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 16/03/2023 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The aim of the study is to look at genetic, behavioural and environmental factors relating to obesity and diabetes in a group of 10,000 people born between 1950 and 1975.

Who can participate?

Men and women born between 1950 and 1975 registered at participating GP practices in the Fenland and East Cambridgeshire area

What does the study involve?

Interested applicants are invited to attend for a single visit at one of the MRC Epidemiology Unit testing centres. The visit lasts about three hours and includes measures of metabolic health, diet and other lifestyle patterns, body composition, fitness and physical activity. Follow-up visits take place at least 4 years later, in chronological order, so those that took part first of all were invited first.

What are the possible benefits and risks of participating?

The possible benefits of participating are receiving a very thorough health check including a test for diabetes and measurement of blood cholesterol. With the participants' permission their results will be passed to their GP and they will receive detailed individual feedback on the results from the tests. There is no risk involved in the tests.

Where is the study run from?

Addenbrooke's Hospital (UK)

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

December 2004 to March 2021

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Nick Wareham

Study website
<https://www.mrc-epid.cam.ac.uk/research/studies/fenland/>

Contact information

Type(s)
Scientific

Contact name
Prof Nick Wareham

Contact details
MRC Epidemiology Unit
Level 3, Institute of Metabolic Science
Box 285
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The Fenland Study - a population-based cohort study of the interaction between environment and genetic factors in determining obesity, insulin sensitivity and hyperglycemia

Acronym
The Fenland study

Study objectives

The study is designed to investigate how common genetic variations interact with our dietary and physical activity patterns to determine the overall level of body fat and its distribution around the body and key indicators of metabolic health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 01/07/2022:

Phase 1:

Approved 11/05/2004, Cambridge Regional Ethics Committee, ref: 04/Q0108/19

Phase 2:

Approved 05/07/2014, NRES East of England – Cambridge East Research Ethics Committee, ref: 14/EE/0122

COVID 19:

Approved 30/06/2020, South West - Cornwall & Plymouth Research Ethics Committee, ref: 20/SW/0100

Previous ethics approval:

Phase 1: Cambridge Regional Ethics Committee, 11/05/2004, ref: 04/Q0108/19

Phase 2: NRES East of England – Cambridge East Research Ethics Committee, 05/07/2014, ref: 14/EE/0122

Study design

Single-centred observational cross-sectional cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Diabetes, obesity and other metabolic disorders

Interventions

Phase 1:

1. Oral glucose tolerance test
2. Measures of height, weight, waist and hip circumference and blood pressure
3. An ECG is carried out in order to provide information for exclusion from the treadmill test

4. Body fat is assessed by dual X-ray absorptiometry and ultrasonography
5. Habitual diet is assessed by questionnaire and biomarker analysis
6. Physical activity is assessed directly by using a combined sensor able to record heart rate and vertical acceleration. Individual calibration of heart rate and energy expenditure is carried out using a submaximal exercise test on a treadmill. Volunteers wear the sensor for 6 days following the visit to assess their habitual physical activity level

Added 13/05/2019:

Phase 2:

Follow-up visits took place at least 4 years after Phase 1, in chronological order, so those that took part first of all were invited first.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The study is designed to investigate how common genetic variations interact with our dietary and physical activity patterns to determine the overall level of body fat and its distribution around the body and key indicators of metabolic health. All outcomes are measured at the one-off visit. There are no follow-up visits involved in this study.

Secondary outcome measures

N/A

Overall study start date

01/12/2004

Completion date

31/03/2021

Eligibility

Key inclusion criteria

Men and women born between 1950-1975 registered at participating GP practices

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10,000

Total final enrolment

10092

Key exclusion criteria

1. Diagnosed diabetes
2. Psychotic illness
3. Terminal illness
4. Pregnancy
5. Unable to walk unaided

Date of first enrolment

01/12/2004

Date of final enrolment

31/12/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

MRC Epidemiology Unit

Cambridge

United Kingdom

CB2 0QQ

Sponsor information**Organisation**

University of Cambridge (UK)

Sponsor details

c/o Carolyn Read

Research Governance Officer

School of Clinical Medicine

Cambridge

England

United Kingdom

CB2 0QQ

Sponsor type

University/education

Website

<http://www.cam.ac.uk/>

ROR

<https://ror.org/013meh722>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust (Ref: 074548)

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/03/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 28/10/2015 | | Yes | No |
| Other publications | | 14/03/2023 | 16/03/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |