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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

Submission date
13/05/2013

Recruitment status
No longer recruiting

Registration date
30/08/2013

Overall study status
Completed

Last Edited
16/03/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

Contact name
Prof Nick Wareham

Contact details
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Additional identifiers

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

Primary study design
Observational

Study design
Single-centred observational cross-sectional cohort study

Study type(s)
Other

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(s)
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.

Key secondary outcome(s)
N/A

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre

MRC Epidemiology Unit
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University of Cambridge (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No
Other publications		14/03/2023	16/03/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes