Motivational and behavioral effects of adding genetic test feedback to advice on weight gain prevention

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
21/02/2012				
Registration date	Overall study status	Statistical analysis plan		
03/05/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
01/10/2018	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Background and study aims

Research has shown that genes play a big part in how easily people gain weight. People can find out if they have genes which put them at higher risk for gaining weight by using genetic tests. These tests are available over the internet. However, it is currently not known whether receiving personal results from these tests is useful.

The aim of this study is to find out whether giving people their personal genetic result for risk of weight gain motivates them to try and keep a healthy weight. We will investigate this in young adults at the beginning of university, because weight gain is common in students.

Who can participate?

First year university students, aged between 18 and 25 years, enrolled at University College London, who agree to take part in a larger study will be invited to participate.

What does the study involve?

They will be randomly (i.e. by chance) split into two groups:

One group will receive their personal genetic test result for one gene (FTO) related to risk of weight gain alongside a leaflet with simple weight gain prevention advice.

The other group will receive only the leaflet containing simple weight gain prevention advice. Participants receiving only the leaflet will receive their genetic test result at the end of the study. The study will run over the course of the academic year. We will look at whether people who receive their test result and the leaflet are more motivated to prevent weight gain than people who just receive the leaflet.

What are the possible benefits and risks of participating?

Benefits of taking part include learning about personal genetic risk of weight gain (based on one gene), and receiving advice on how to keep a healthy weight.

There is little risk involved in participation, and we will be available to answer any questions or concerns. We will also conduct interviews to find out more about participants thoughts and feelings after receiving their genetic test result.

Where is the study run from? The study will take place at University College London.

When is study starting and how long is it expected to run for? The study started in September 2010 and will run till September 2013.

Who is funding the study? Cancer Research UK

Who is the main contact? Prof Jane Wardle j.wardle@ucl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Jane Wardle

Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Adding genetic test feedback to advice on weight gain prevention for young adults: a randomized controlled trial

Study objectives

Participants receiving personal genetic test feedback for risk of weight gain in addition to generic weight gain prevention advice will be more motivated to prevent unhealthy weight gain than those receiving generic weight gain prevention advice alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University College London Ethics Committee, Sept 2010, ref: 2471/003

Study design

Open two-arm individually randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of weight gain

Interventions

Feedback group: Providing personal genetic risk status of the fat mass and obesity (FTO) associated gene implicated in weight gain + a leaflet containing generic weight loss prevention advice.

No Feedback group: Only leaflet with generic weight gain prevention advice (feedback returned at end of year).

High risk of contamination between groups prevented us to include a 'Control' group which receives neither genetic feedback nor leaflet.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Self-reported motivation to prevent weight gain immediately after receiving genetic test feedback, assessed with several statements relating to weight gain prevention (Likert scale)

Key secondary outcome(s))

- 1. Self-reported motivation at follow-up
- 2. Self-reported efforts to prevent weight gain at follow-up
- 3. Body fat and weight change from baseline to follow-up, assessed by weighing and bioelectrical impedance
- 4. Interactions between feedback condition and gene test status

Completion date

26/09/2013

Eligibility

Key inclusion criteria

All interested first year students between ages 18 and 25 from University College London, who are able to give consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Inability to consent
- 2. Not aged between 18 and 25

Date of first enrolment

26/09/2010

Date of final enrolment

26/09/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Health Behaviour Research Centre

London United Kingdom WC1E 6BT

Sponsor information

Organisation

University College London (UK)

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (C1418/A10843)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015	Yes	No
Protocol article	protocol	06/12/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes