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

Submission date
21/02/2012

Recruitment status
No longer recruiting

Registration date
03/05/2012

Overall study status
Completed

Last Edited
01/10/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Health Behaviour Research Centre
Department of Epidemiology and Public Health
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

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 measure

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

Secondary outcome measures
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

Overall study start date
26/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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

England

United Kingdom

Study participating centre
Health Behaviour Research Centre
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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