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Personalised advice to aid weight loss

Submission date
16/06/2021

Recruitment status
No longer recruiting

Registration date
16/06/2021

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Being overweight is very common. It is known to increase a person's chance of developing several health conditions. These include heart disease, type 2 diabetes, fatty liver disease, and some cancers. Being overweight results from the interactions of different factors, including a person's genes, their metabolism, their behaviour and their environment. The latter factors include people's eating habits and how much exercise they do. However, both gaining and losing weight are complex because it is now known that the different factors interact (for example a person's genes and what they eat). This is why some people put on weight more easily than others. Therefore, to fully understand weight gain and weight loss, we need to know about more than just what people eat; we also need to know about their genes and physical activity amongst other things. Personalised nutrition (PN) is a new approach which aims to give individuals unique nutrition advice based on their own genetic, environmental and lifestyle factors. Personalisation of interventions may help people to change behaviour in order to improve health outcomes, including weight loss. We plan to compare general advice from a dietitian with more personalised advice to see if the effect on weight loss is different. The personalised advice will be based upon knowing about the participant's genes and different chemicals measured in their blood. The main aim of the study is to compare the effects of standard versus personalised dietary advice on waist circumference. We will also measure a number of other things to do with body weight and health.

Who can participate?
Men and women over the age of 18 years who wish to lose weight. To be enrolled a person will need to have a body mass index of between 25 and 40 and a waist circumference of at least 94 cm for men and at least 80 cm for women.

What does the study involve?
The study involves three clinic visits; the provision of blood, saliva, urine and faecal samples; the completion of questionnaires; dietetic consultations; dietary change; and using an app.

Participants will attend clinic visit1 (V1) in the fasted state (no food or drink apart from water from 9 pm the night before). At V1 informed written consent will be provided. Height, weight, waist and hip circumference as well as body composition will be measured. Participants will provide a saliva sample, a blood sample (20 ml) and a urine sample (20 ml). Participants will be given breakfast after the saliva and blood samples are collected. They will complete two

questionnaires asking about their diet: a food frequency questionnaire and a 3-day food diary. This appointment will last 1.5-2 hours. Participants will be asked to provide a small faecal sample (collected at home) prior to their next visit.

Visit 2 (V2) will be about a month after V1. At this visit participants will complete a set of questionnaires related to diet and lifestyle, quality of life, food shopping habits and physical activity. At this visit participants will be informed which group they have been allocated to and they will have a consultation with the study dietitian. The dietitian will help participants download an app to their phone (or tablet) and show them how to use the app. Participants will be able to contact the dietitian if you need any help in using the app. This appointment will last about 1.5 hours.

Participants will then follow their dietary plan for 4 months. If they are allocated to the group also receiving behaviour change prompts, they will receive information on ways that they can change their food and lifestyle choices via the app. During this 4 month period, all participants will complete a daily food diary using the app. At the end of months 1, 2 and 3 all participants will have a telephone consultation with the dietitian.

Visit 3 (V3) will take place about 4 months after V2. Participants will bring a recent faecal sample to this visit and as for V1 they will attend in the fasted state (no food or drink apart from water from 9 pm the night before). Height, weight, waist and hip circumference as well as body composition will be measured. Participants will provide a blood sample (20 ml) and a urine sample (20 ml). Participants will be given breakfast after the saliva and blood samples are collected. They will complete all questionnaires previously used at V1 and V2. This appointment will last about 2 hours.

What are the possible benefits and risks of participating?
Participants may benefit from losing weight whilst taking part in this study. They may gain helpful insights on how to improve their diet and lifestyle.
As part of the study participants will provide blood samples at the start and end of the study. There is a very small chance of infection and a chance of bleeding and bruising at the site of insertion of the needle for collecting the blood sample, but this will be minimised by using sterile techniques and trained members of staff.

Where is the study run from?
The study is run from The Faculty of Medicine at the University of Southampton (Southampton, UK). Participants will make visits to the NIHR Clinical Research Facility in Southampton General Hospital.

When is the study starting and how long is it expected to run for?
February 2021 to April 2022.

Who is funding the study?
The study is funded by the European Commission.

Who is the main contact?
Professor Philip Calder, pcc@soton.ac.uk

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
283149

Protocol serial number
IRAS 283149

Study information

Scientific Title
Trial of personalised advice to aid weight loss

Study objectives
1. Personalised dietary advice will have a greater effect than standard dietetic advice on waist circumference, body weight, body fat, body mass index, metabolic profile, inflammatory markers and other outcomes in people with overweight or obesity.
2. Personalised dietary advice supported by behaviour change prompts will have a greatest effect on these same outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/02/2021, East Midlands - Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; +44 (0)207 104 8388; leicestercentral.rec@hra.nhs.uk), ref: 20/EM/0297

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Weight management in those with overweight and obesity

Interventions
Participants will be randomly allocated to one of three groups; randomisation will be stratified by age and sex and will be performed using an on-line randomisation programme. The three groups are:
1. Control group who will receive standard dietetic advice based upon assessment of participant's diet.
2. Dietetic advice also informed by knowledge of participant's metabolic, inflammatory and genetic profile.
3. Dietetic advice also informed by knowledge of participant's metabolic, inflammatory and genetic profile and supported by behaviour change prompts.
Duration of intervention will be four months.

Intervention Type
Behavioural

Primary outcome(s)
Waist circumference (cm) measured using a tape measure at study entry (visit 1) and exit (visit 3)

Key secondary outcome(s))
1. Hip circumference (cm) measured using a tape measure at study entry (visit 1) and exit (visit 3)
2. Waist to hip ratio (unitless) calculated from waist and hip circumferences measured at study entry (visit 1) and exit (visit 3)
3. Weight (kg) measured using weighing scales at study entry (visit 1) and exit (visit 3)
4. Body mass index (kg/m²) calculated from weight and height measurements at study entry (visit 1) and exit (visit 3)
5. Body fat mass (kg and %) and body lean mass (kg and %) by bioelectric impedance at study entry (visit 1) and exit (visit 3)
6. Dietary (amounts of foods) and nutrient (energy in calories and macronutrients in g and as % energy) intake assessed by food frequency questionnaire at study entry (visit 1) and exit (visit 3)
7. Quality of life assessed by questionnaire including a visual analog score at study entry (visit 2) and exit (visit 3)
8. Physical activity assessed by questionnaire at study entry (visit 2) and exit (visit 3)
9. Attitude to food assessed by questionnaire at study entry (visit 2) and exit (visit 3)
10. Serum glucose (mmol/l) and insulin (mU/l) concentrations at study entry (visit 1) and exit (visit 3)
11. HOMA-IR calculated using serum glucose and insulin concentrations at study entry (visit 1) and exit (visit 3)
12. Serum lipid (total, LDL and HDL cholesterol, triglycerides; all mmol/l) concentrations at study entry (visit 1) and exit (visit 3)
13. Serum adipokine (leptin, adiponectin; both ng/ml) concentrations and leptin/adiponectin ratio (unitless) at study entry (visit 1) and exit (visit 3)
14. Serum C-reactive protein (mg/l) concentration at study entry (visit 1) and exit (visit 3)
15. Plasma inflammatory biomarker (IL-6, MCP-1, IL-10, sICAM-1, sCD14, oxidized LDL; all ng/ml) concentrations at study entry (visit 1) and exit (visit 3)
16. Serum liver health markers (ALT, GGT; both U/l) at study entry (visit 1) and exit (visit 3)
17. Serum renal health markers (uric acid (mg/dl), creatinine (umol/l) at study entry (visit 1) and exit (visit 3)
18. Blood pressure (mmHg) at study entry (visit 1) and exit (visit 3)
19. Faecal microbiota (numbers of organisms/g faeces) at study entry (visit 1) and exit (visit 3)

Completion date
30/04/2022

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Body mass index 25 - 40 kg/m²
3. Waist circumference >94 cm (for men) or >80 cm (for women)
4. Possess a mobile phone or other device capable of hosting the app
5. Able to provide written informed consent.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Diagnosed with diabetes or having a serum glucose ≥125 mg/dL (6.9 mmol/l) (at V1 blood sampling), other metabolic and endocrine disorders
2. Presence of chronic disease (cardiovascular disease, kidney disease (or a serum creatinine ≥ 1.7 mg/dl (150 µmol/l) for men and ≥ 1.5 mg/dl (132 µmol/l) for women at V1 blood sampling), cancer, pulmonary diseases, coeliac disease, Crohn's disease, etc.)
3. Body mass index >40 kg/m²
4. Being pregnant or planning to become pregnant within the study period
5. Use of prescribed medicine to control blood glucose, inflammation or dyslipidemia (or LDL-cholesterol ≥4.9 mmol/L (>190 mg/dL) and/or triglycerides ≥4.5 mmol/L (≥400 mg/dL) at V1 blood sampling)
6. Consumption of more than 14 drinks of alcoholic beverages per week
7. Current smoking
8. Use of dietary supplements
9. Blood donation in the previous 3 months
10. No access to the internet
11. Note: Subjects with hypertension and taking antihypertensive drugs (metabolically neutral) will be not excluded and allowed to continue their prescribed dosage

Date of first enrolment
01/07/2021

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Faculty of Medicine
Tremona Road
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Other publications	Cost-effectiveness	01/06/2025	04/06/2025	Yes	No
Participant information sheet	version v5.0 version V5	25/01/2021	08/07/2021	No	Yes

Protocol file	25/01/2021	08/07/2021	No	No