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The Small Change Study to investigate the acceptability and feasibility of a small change approach to prevent weight gain

Submission date
07/04/2022

Recruitment status
No longer recruiting

Registration date
12/04/2022

Overall study status
Completed

Last Edited
07/11/2023

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
Adults gain between 0.5-1 kg each year because of a very small discrepancy between energy intake and energy expenditure of about 100-200 kcal. To reduce this discrepancy and reduce the prevalence of weight gain within the adult population the aim of this study is to compare two ways to stop people from gaining weight.

Who can participate?
People who are 18 years of age or older who have a body mass index of 20-30 kg/m²

What does the study involve?
The study involves being randomly allocated to one of two groups for 12 weeks. Group 1 will view an educational video that will explain how they can prevent weight gain, receive multiple one-way text messages that support their weight gain prevention efforts, and complete short questionnaires every other week that will assess whether they have been able to use the weight gain prevention strategy described in the educational video. Group 2 will read an informational leaflet about how to lead a healthy lifestyle and be offered access to the main study materials given to Group 1 after the study has ended.

What are the possible benefits and risks of participating?
The study may help prevent people from gaining weight and could therefore improve their overall health.

Where is the study run from?
Loughborough University (UK). This study will take place online and participants will not be asked to attend any sessions.

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

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Henrietta Graham
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1

Study information

Scientific Title
A randomised controlled trial to investigate the acceptability and feasibility of a small change approach to prevent weight gain

Acronym
SMART

Study objectives
The primary aim of this randomised controlled feasibility trial is to investigate the feasibility and acceptability of a brief small change weight gain prevention intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/02/2022, Loughborough University Ethics Online (Loughborough University, Leicestershire, LE11 3TU, UK; +44 (0)1509 222222; Leon@lboro.ac.uk), ref: 2022-6320-7796

Study design
Single-center individually randomized two-arm controlled feasibility trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Weight management

Interventions
Participants are recruited through online and offline social networks, online and paper newsletters and newspapers, through public facilities (including community boards, advertisement boards, notice boards in supermarkets and coffee shops) and through established personal networks. Participants are screened for eligibility and provide their consent remotely through online questionnaires. An independent statistician prepares a computer-generated randomisation list, stratified by body mass index (BMI) using blocks sizes of 6. An independent research assistant not related to the trial conducts the randomisation after baseline measures are taken. Participants are randomised to the trial for 12 weeks on a 2:1 basis with stratification (20-24.9 kg/m² or 25-29.9 kg/m²) to receive either 1) generic information about how to lead a healthy lifestyle (control group) or 2) a video and text message-based Small Change Approach intervention (intervention group). Participants are enrolled into the study groups by the lead researcher. Participants are blinded to study allocation but due to the nature of the trial, the researchers are aware of group allocation after assignment.

Participants in the intervention group will:
1. View an educational video that will explain how to prevent weight gain using a small change approach
2. Select and use one dietary and/or low-intensity physical activity change each day, or seven each week, from a list of 20 dietary and low-intensity physical changes that have been designed to either decrease energy intake or increase energy expenditure by between 100-200 calories
3. Keep track of small changes made to see if the goal is being met
4. Receive multiple one-way text messages to support the use of a small change approach to prevent weight gain
5. Complete short bi-weekly questionnaires that will assess adherence to the small change approach for weight gain prevention

Participants in the control group will:
1. Read an informational leaflet about how to lead a healthy lifestyle
2. Be offered access to the main trial materials given to Group 1 after the study has ended

After 12 weeks, regardless of whether participants were placed into Group 1 or Group 2, the researchers will contact them via email and ask them to complete the online follow-up questionnaire and to provide another picture of their weight as displayed on a set of weighing scales (only feet and weighing scales visible in the picture). Intervention participants may be asked to participate in an interview with a member of the research team.

Intervention Type
Behavioural

Primary outcome(s)
1. The acceptability and feasibility of an intervention that uses a small change approach to decrease calorie intake and/or increase energy expenditure to prevent weight gain, assessed using online questionnaires at weeks 2, 4, 6, 8, 10 and 12:
1.1. The acceptability of the small change intervention will be assessed using questions that will focus on assessing whether they adhered to the small change approach, whether participants liked using this approach and whether participants found it helpful to reduce their calorie intake behaviour. The questions will also assess whether the trial materials (educational video, text messages, small change diary and list of 20 suggested small dietary and physical activity changes) were helpful.
1.2. The feasibility of the small change intervention will be assessed using the number of participants randomised per month and the retention rates at follow-ups

Key secondary outcome(s))
As a feasibility trial, this study will not be powered to detect differences in weight, physical activity or food intake, but the researchers will conduct an exploratory analysis to assess the effect of a small change approach on weight, physical activity and food intake at follow up.

1. Weight: participants will be asked to send a photo of themselves standing on a set of scales (camera facing towards feet) that clearly displays their weight. Weight will be sought through pictures to make the measurement as objective as possible. Participants will be asked to weigh themselves in the morning, after going to the toilet and whilst wearing light or no clothing. Participants will be asked to weigh themselves using pounds or kilograms, but all weights will be converted to kilograms at the end of the study. Measured at baseline and 12-week follow-up
2. Physical activity measured using the Physical Activity Vital Signs questionnaire at baseline and 12-week follow-up
3. Food intake measured by participants reporting the frequency and quantity in which they consume 10 different foods at baseline and 12-week follow-up
4. Cognitive restraint of eating assessed using the revised version of the Three Factor Eating Questionnaire at baseline and 12-week follow-up
5. Self-efficacy for dietary behaviours related to weight management assessed using the Weight Efficacy Lifestyle Questionnaire (WEL-SF) at baseline and 12-week follow-up
6. Self-efficacy for physical activity behaviours related to weight management assessed using the Self-Efficacy for Exercise Scale at baseline and 12-week follow-up
7. Self-regulation of dietary and physical activity behaviours measured using the shortened version of the Self-Regulation Questionnaire (SRQ) at baseline and 12-week follow-up

Completion date
28/06/2022

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Body mass index 20 - 30 kg/m²
3. Access to an internet connection
4. Owns a smartphone
5. Has a UK mobile telephone number
6. Can speak and understand English

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
122

Key exclusion criteria
1. Participating in another weight management trial or programme
2. Inability or unwillingness to provide online consent
3. Pregnant/a planned pregnancy in the next 6 months
4.Taking weight loss medications/other medication that impacts weight
5. Have a history of an eating disorder in the last 5 years/are currently experiencing an eating disorder

Date of first enrolment
14/01/2022

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

National Centre for Sports & Exercise Medicine - East Midlands (ncsem-em)
Loughborough University
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Sponsor information

Organisation
Loughborough University

ROR
https://ror.org/04vg4w365

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All reasonable requests for data will be considered by the author after the main publication. Henrietta Graham (h.graham@lboro.ac.uk) should be contacted for access to the anonymised datasets, consent was obtained from all participants and all data was anonymised using ID codes, there were no ethical restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/11/2023	07/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes