

**The SMART Weight Gain Prevention Trial**

**Participant Information Sheet**

**Investigators Details:**

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**Section A:**

We would like to invite you to take part in a study that aims to stop people gaining weight. Before you decide whether you would like to take part or not, we would like you to understand why the research is being done and what it would involve for you. Please feel free to ask one of our team members any questions you may have. Talk to others about the study before making a decision if you wish.

**What is the purpose of the study?**

This study will compare two ways to stop people gaining weight.

**Who is doing this research and why?**

This study is part of a research project supported by Loughborough University. Henrietta Graham ([h.graham@lboro.ac.uk](about:blank)), a PhD student at Loughborough University, will be carrying out this study, under the supervision of Dr Claire Madigan ([c.madigan@lboro.ac.uk](about:blank)), and Professor Amanda Daley ([a.daley@lboro.ac.uk](about:blank)).

**Who can take part?**

You can take part in this study if you:

* Are 18 years of age or older
* Have a body mass index (BMI) of 20-30 kg/m² (you can calculate it here: [https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/](about:blank))
* Have access to an internet connection
* Own a set of weighing scales
* Own a smart phone with a UK mobile phone number
* Can speak and understand English

You cannot take part in this study if you:

* Are participating in another weight management trial or programme
* Are not able/are unwilling to provide consent to participate
* Are pregnant or have a planned pregnancy in the next 6 months
* Are taking weight loss medications/other medications that impact weight
* Have a history of an eating disorder in the last 5 years/are currently experiencing an eating disorder

**What will I be asked to do?**

If, after reading this participant information leaflet, you would like to take part in the study, you should complete the “Expression of Interest Questionnaire” that follows the information provided here. Once you have completed this questionnaire, a member of the research team will contact you, via email, and ask you to click on a personalised link to complete an online consent form. If you agree with the statements written in the consent form, you should type your initials next to each statement and verify your signature at the end of the form by typing your email address in the response box provided. Shortly after you have completed the online consent form, we will send a link via email and ask you to complete an eligibility screening form.

If you are eligible to take part, we will ask you to complete a short online questionnaire and to email the lead researcher a photograph of your current weight as displayed on a set of weighing scales (only your feet and weighing scales will be visible). Once you have completed this questionnaire and emailed a picture of your current weight, we will randomly place you into one of two groups (Group 1 or Group 2).

Group 1 will:

* View an educational video that will explain how you can prevent weight gain
* Receive multiple one-way text messages that support your weight gain prevention efforts
* Complete short questionnaires every other week that will assess whether you have been able to use the weight gain prevention strategy described in the educational video

Participants in Group 2 will:

* Read an informational leaflet about how to lead a healthy lifestyle
* Be offered access to the main study materials given to Group 1 after the study has ended

After 12-weeks, regardless of whether you were in Group 1 or Group 2, you will be asked to complete another short online questionnaire and to provide a final picture of your weight as displayed on a set of weighing scales. You may be asked to participate in an interview with a member of the research team that we will arrange either over the phone or through an online platform.

**Once I take part, can I change my mind?**

After you have read this information and asked any questions you may have, if you are happy to participate, we will ask you to complete a consent form online. However, if at any time you wish to withdraw from the study please contact the main investigator (Henrietta Graham). You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing.

However, once the results of the study are published or Henrietta Graham’s dissertation has been submitted, it may not be possible to withdraw your individual data from the research.

**Will I be asked to attend any sessions and where will these be?**

This study will take place online and you will not be asked to attend any sessions.

**How long will the study take?**

The study will run for 12 weeks, and the amount of time dedicated towards the study will depend on what group you are placed into.

**If you are placed into Group 1**, you will spend **approximately 70 minutes** (1 hour 10 mins**)** on this study**.** See below for further details.

* Completing the online questionnaire at the start and end of study: 15-20 minutes on each occasion
* Providing weight measurements at the start and end of study: approximately 3 minutes on each occasion.
* Watching the educational video: approximately 10 minutes
* Reading content of text messages: 10-15 seconds on each occasion (33 text messages in total).
* Completing the questionnaires every other week: 15-30 seconds on each occasion (5 questionnaires in total).

**If you are allocated to Group 2**, you will spend **approximately 60 minutes** (1 hour) on this study. See below for further details.

* Completing the online questionnaire at the start and end of study: 15-20 minutes on each occasion
* Providing weight measurements at the start and end of study: approximately 3 minutes on each occasion
* Reading the informational leaflet: approximately 10 minutes

**Are there any disadvantages or risks in participating?**

We do not anticipate any risks or disadvantages to taking part.

**Section B:**

**What are the possible benefits of participating?**

The study may help prevent you from gaining weight and could therefore improve your overall health.

**Data Protection Privacy Notice**

Loughborough University will be using information/data from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

**What personal information will be collected from me and how will it be used?**

You full name, email address, postcode, mobile phone number, weight, height, age, gender and ethnicity will be collected.

Your name, email address and mobile phone number will be collected so that we can contact you throughout the study period. Your weight and height (height needed to calculate body mass index) will be collected so that we can see if the study had any effect on your weight or body mass index from 0 to 12 weeks. Your age, gender, postcode and ethnicity will be collected so we can see who takes part in our study.

**What is the legal basis for processing my personal information?**

Personal data will be processed on the public task basis. For further details on the data protection legislation see: [https://ico.org.uk/your-data-matters/](about:blank). Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as “sensitive data”. The processing of this data is necessary for scientific research in accordance with safeguards. This means that the study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

**How long will my personal information be retained?**

We will keep identifiable personal information until 30.09.2024. After this, it will be destroyed.

**Will my personal information be shared with others?**

Your personal information will only be shared with the two other investigators involved with this study (Professor Amanda Daley & Dr Claire Madigan).

**Will my taking part in this study be kept confidential?**

Yes. Data collected in this research study will be stored confidentially and anonymously coded where possible, in line with General Data Protection Regulations. Each participant will be given an ID number and data collected will only be identified by that number. The data will be stored on the University’s IT cloud-based storage and only accessed by the researchers and the study supervisors.

**How will the anonymised data/results collected from me be used?**

The anonymised data/results collected will be used in Henrietta Graham’s doctoral dissertation. The anonymised data/results collected may also be used in journal publications, conference papers and the media promoting the results of the study.

**How long will be anonymised data/results be retained?**

All anonymised data collected in this research, including anonymised personal information, will be deposited in the Loughborough University data repository and available indefinitely so that it can be made publicly available for future research at the end of the project.

**I have some more questions; who should I contact?**

If you have any questions, please contact Henrietta Graham at [h.graham@lboro.ac.uk](about:blank).

**What if I am not happy with how the research was conducted?**

If you are not happy with how the research was conducted, please contact the Secretary of the Ethics Review Sub-Committee, Research & Enterprise Office, Hazlerigg Building, Loughborough University, Epinal Way, Loughborough, LE11 3TU. Tel: 01509 222423. Email: [researchpolicy@lboro.ac.uk](mailto:researchpolicy@lboro.ac.uk). Or you can contact the study primary supervisor, Professor Amanda Daley, by email: [a.daley@lboro.ac.uk](about:blank).

The University also has policies relating to Research Misconduct and Whistle Blowing which are available online at <https://www.lboro.ac.uk/internal/research-ethics-integrity/research-integrity/>. If you require any further information regarding the General Data Protection Regulations, please see: <https://www.lboro.ac.uk/privacy/research-privacy/>.