

Supportive weight Management Interventions referred by dental hEalthcare professionals for adults [SMILE study]

Participant Information Sheet

This information sheet contains details about the study which you may find helpful.

Why have I been approached to take part in this study?

Your dental practice is taking part in a research study called SMILE that is testing whether dental professionals (e.g. dentists/dental nurses) can support people with obesity to improve their health and lose weight.

This approach involves having a short conversation about your health during a routine dental appointment. You have been invited to take part as your weight measurements suggest your health may benefit from losing weight.

Please read this information sheet – it explains why the research is being done and what it means for you. If you have any questions, please contact the study team (details below).

What is the SMILE study about?

The SMILE study will explore if taking weight and height measurements in dental practices is acceptable to patients and dental professionals. It will also see if patients with obesity find it acceptable and helpful to discuss their health at the dentist and be offered support to improve their health.

What will happen if I agree to take part?

At your dental appointment today

- You will be asked to consent to take part in the study and have your height and weight measured.
- You will be asked to complete a short questionnaire about you (age/sex/ethnicity etc.) and your health.
- You will discuss your health and weight with your dental professional(s) and will be offered support to help improve your health.

The study is testing two different ways dental professionals can support people with improving their health and weight loss. You will join one of two groups at random (like tossing a coin). One group will be given information and the other group will be given information and support. The groups are different to help test which approach may help people to lose weight to improve their health more effectively. We cannot select which group you are in - this is done at random by a computer programme. Your conversation at your appointment about your health and weight may be audio-recorded if you give your permission.

- At the end of your appointment, before leaving the practice, we will ask you to complete a short questionnaire (2 questions) to tell us how you found the discussion about your health and weight with your dental professional(s).

In the next 7 days:

The research team will contact you within 7 days to discuss in more detail how you feel about the conversation you had with your dental professional(s). This conversation may be recorded with your permission.

After six weeks:

After six weeks, you will be invited to complete a short questionnaire (5-10 minutes) and asked to send a photograph standing on weighing scales [showing feet and scales only] to the study team at: smile.study@mailbox.lboro.ac.uk The questionnaire will be sent to you via email. A printed version of the questionnaire can be posted to you with free return postage should you prefer. The support you receive to help improve your health may continue after six weeks should you wish.

How long will the study take?

You will be involved in the study for around 6-8 weeks.

What are the possible benefits of taking part?

Participation in the study may help to improve your health. You will be offered a £10 gift voucher when you return your completed questionnaire at 6 weeks. By agreeing to participate you will provide researchers with important information that may help others to improve their health.

What are the possible disadvantages and risks of taking part?

We do not expect any risks or disadvantages from taking part in this study.

What if I do not want to take part?

It is entirely up to you to decide if you want to take part. However, if you do take part, you are free to withdraw at any time, without giving a reason and it will not affect your dental care in any way. You can withdraw from the study at any time by contacting the study team [see contact details below].

Who is organising and funding the research?

This study is part of a PhD study by Miss Jessica Large and is being carried out by a research team at Loughborough University (LU). Loughborough University is the Sponsor for this research. The research is funded by the National Institute for Health and Care Research [Grant Number: NIHR300026].

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given a favourable opinion by East Midlands – Nottingham 1 Research Ethics Committee [Reference: 25/EM/0135].

How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Name
- Age
- Sex (optional)

- Ethnicity (optional)
- If you have a disability or not (optional)
- Height and weight measurements to calculate body mass index (BMI)
- Contact details (home address, email address, telephone number) and your GP contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Loughborough University is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- SMILE Study research team
- Your GP practice
- Your dental practice
- Regulatory authorities
- An external company may be used to type up what you talk about with your dentist/other dental professional when you discuss your health at your dental appointment. Also, the company may be used to type up what we talk about during a telephone call after your dental appointment when we ask you about your experience. Your name and any personal details will be removed from the data and your data will be given a code number instead

We will keep all information about you safe and secure by:

- Ensuring all data will be stored securely at Loughborough University in a password protected file with access only by the research team.
- We will have a confidentiality agreement signed with any external transcription company used.
- We will destroy audio files by deleting the files from the university servers. If we record your interview using an audio recorder, we will save on password protected university computers and delete from the recorder.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we

cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at <https://www.lboro.ac.uk/privacy/research-privacy/>
- by asking one of the research team
- by sending an email to Claire Vallance (Information Governance Manager for Loughborough University): dp@lboro.ac.uk
- by ringing Loughborough University on 01509 226 686

What will happen to the results of the research study?

Once the study has finished, we may write up the findings in a research journal and provide a report for the study sponsor (Loughborough University) and the National Institute of Health and Care Research and the Department of Health and Social Care who funded the study. You will not be identified in any publications and any quotes we may use will have a number instead of names. You will be asked if you would like to receive a summary of our results at your dental appointment.

What if I have any further questions?

If you have any further questions, please contact the study lead Miss Jessica Large, email: smile.study@mailbox.lboro.ac.uk or Tel: 01509 225830 / 07860918640

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

If you are not happy with how the research was conducted or have a complaint, 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.

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/>