# Support for weight loss for adults from the dental team when attending routine appointments at dental practices

Submission date	Recruitment status	[X] Prospectively registered
09/07/2025	Not yet recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/07/2025	Ongoing	☐ Results
Last Edited	Condition category	Individual participant data
23/07/2025	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

## Plain English summary of protocol

Background and study aims

Living with obesity can lead to health problems like type 2 diabetes (which affects blood sugar) and heart disease. These health issues can also impact the health of the mouth; for example, people with diabetes are more likely to have gum disease (problems with gums and tissues that support teeth). Good dental care can help improve diabetes control.

The NHS provides support for people living with overweight and obesity to help them improve their health and lose weight. It is important for doctors, dentists, and other healthcare workers to work together to encourage healthier habits. A recent survey of 3,580 adults in the UK found that 60% would be comfortable having their height and weight measured at a dental appointment, and 57% thought it would be acceptable for their dental team to help them with weight management. However, measuring weight at dental visits is not common practice in the UK.

Now, we want to see if measuring height and weight to calculate body mass index (BMI) at dental appointments and discussing weight with dental practitioners could work well. The aim of the study is to examine if weight screening, a discussion regarding weight and offer of supportive weight management interventions to adult patients attending a dental appointment by dental teams is feasible and acceptable.

## Who can participate?

Adults (≥18 years) attending a dental appointment at one of the dental practices participating in the study who meet the eligibility criteria (see inclusion and exclusion criteria).

## What does the study involve?

Participants will have their weight and height taken at their dental appointment. If participants are eligible and wish to take part in the study, they will complete a form to say they agree to take part and a short questionnaire which will ask for their contact details and a few questions about their health. Participants will then have their dental appointment as normal, and their dental team will discuss the participant's health and weight. The study is testing two different ways dental professionals can support people with improving health and weight loss. Participants 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 interventions are different to help test which approach may help people to lose weight to improve their health more effectively. We cannot select which group participants are in – this is done at random by a computer programme. Participants will then have a short questionnaire to complete (2 questions only). Within the next 7 days, the research team will call participants for a short discussion about their experience at their dental appointment. In 6 weeks, the research team will send participants a questionnaire to complete to tell us a bit about any activities they have been doing to help improve their health and it will ask for a weight measurement.

What are the possible benefits and risks of participating?

Participation in the study may help to improve participant health. Participants will be offered a £10 gift voucher on return of their completed questionnaire at 6 weeks. Participants will provide researchers with important information that may help others to improve their health. We do not expect any risks or disadvantages from taking part in this study.

Where is the study run from? Loughborough University (UK)

When is the study starting and how long is it expected to run for? February 2024 to December 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR), Research Professorship Award [Grant /Award Number: NIHR300026].

Who is the main contact?
Miss Jessica Large, J.Large@lboro.ac.uk

## Study website

https://www.lboro.ac.uk/research/climb/

# Contact information

# Type(s)

Public, Scientific, Principal Investigator

#### Contact name

Miss Jessica Large

#### **ORCID ID**

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## Contact details

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# Additional identifiers

## **EudraCT/CTIS** number

Nil known

## **IRAS** number

347182

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

CPMS 65584. NIHR300026

# Study information

#### Scientific Title

Supportive weight Management Interventions referred by dentaL healthcare profEssionals for adults: the SMILE study

## Acronym

**SMILE** 

## **Study objectives**

Hypothesis: Weight screening and offer of supportive weight management interventions for adult patients at dental appointments is acceptable and feasible amongst patients and the dental team.

# Ethics approval required

Ethics approval required

# Ethics approval(s)

Submitted 10/06/2025, East Midlands - Nottingham 1 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8115; nottingham1.rec@hra.nhs.uk), ref: 25/EM/0135

# Study design

Interventional randomized controlled trial

# Primary study design

Interventional

## Secondary study design

Randomised controlled trial

# Study setting(s)

Dental clinic

# Study type(s)

#### Treatment

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Obesity

#### **Interventions**

Adult patients attending routine appointments at their dental practice will be offered height and weight screening. Patients eligible and consenting to participate in the study (see eligibility criteria) will be randomised to one of two groups (intervention or comparator group). Participants (patients) will be provided with an opaque sealed envelope, which will contain a colour-coded randomisation card. Participants will hand this envelope to their dental professional. During the appointment, the dental professional will open the envelope and have a brief conversation about the participant's health and weight. Participants in the intervention group will be offered a free 12-week membership to a weight management programme currently available through NHS 'Better Health'. Participants in the comparator group will be offered a leaflet promoting healthy lifestyles, i.e. encouraging physical activity and a healthy diet. All participants will be contacted within seven days of their appointment by the research team with a further follow-up at six weeks.

## Intervention Type

Behavioural

## Primary outcome measure

- 1. Feasibility and acceptability amongst dental patients (adults) of weight screening and primary care dental team referred weight management interventions measured by:
- 1.1. Number of participants accepting BMI screening at baseline
- 1.2. Number of eligible patients who accept a conversation about their weight with their dental team at baseline
- 1.3. How participants living with obesity feel about discussing their weight through a bespoke questionnaire and qualitative interviews at baseline, 7-day follow-up and 6 week follow up
- 1.4. Number of participants randomised in 6 months
- 2. Feasibility and acceptability amongst dental teams of weight screening and referral to weight management interventions for adult patients in dental practices measured by:
- 2.1. Number of dental practices recruited within the study recruitment period
- 2.2. Pre-study and post-study bespoke questionnaires and focus groups/interviews will examine how dental teams feel about raising the issue of weight opportunistically and signposting to weight management programmes

# Secondary outcome measures

- 1. To examine the feasibility of collecting weight data measured by number of participants providing data at 6 week follow up
- 2. Weight change from baseline to follow-up. Baseline weight: calibrated scales and stadiometer in dental practice. 6-week follow-up: participant to send photo standing on home scales and if not possible, to self-report weight

#### Process outcomes:

1. To examine what actions participants take to manage their weight in response to the

conversation with the dental team measured by:

- 1.1. Number of participants who enrol in a study weight management programme
- 1.2. Number of participants who take action for weight loss following the intervention across both groups as reported in the bespoke follow-up questionnaire at 6 weeks
- 2. To explore if the intervention is likely to deter patients from visiting their dental practice measured by number of participants who report a negative impact on their relationship with their dental team and avoidance of future dental care as a result of the intervention. Measured at 7-day telephone follow up and/or bespoke questionnaire at 6 week follow-up

## Overall study start date

05/02/2024

## Completion date

31/12/2026

# **Eligibility**

## Key inclusion criteria

Step 1: Inclusion criteria for weight and height measurements:

- 1. Aged >=18 years attending a routine dental appointment
- 2. Consent for height and weight measurements to be taken

Step 2: Inclusion criteria for intervention

- 1. Aged >= 18 years attending a dental appointment
- 2. BMI >=30 kg/m² [white ethnicities] or >=27.5 kg/m² [Asian/Asian British/Black/African /Caribbean/Black British/Middle Eastern/Mixed or multiple ethnicities with an Asian/Black /Middle Eastern background]\*
- 3. Able to provide informed written consent
- \* BMI thresholds described are based on the NHS thresholds, adjusted for ethnicity, suggestive of living with obesity and greater risk of comorbidities such as type 2 diabetes and heart disease and to be in accordance with other research.

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

# Target number of participants

Planned Sample Size: 90; UK Sample Size: 90

## Key exclusion criteria

Exclusion criteria for weight and height measurements:

1. Unable to understand English sufficiently to complete the screening

- 2. Pregnant or intending to fall pregnant within the study time period
- 3. Mobility requirements or special needs precluding taking of height and weight measurements with stadiometer and scales

Step 2: Exclusion criteria for intervention:

- 1. Unable to understand English sufficiently to complete the trial assessments
- 2. Pregnant or intending to fall pregnant within the study time period
- 3. Dental team feels it would be unsuitable for a patient to take part in the study (e.g. eating disorder disclosed by patient or patient already enrolled in a clinical weight loss trial or attending a weight management programme)

## Date of first enrolment

02/09/2025

## Date of final enrolment

31/03/2026

# Locations

## Countries of recruitment

United Kingdom

## Study participating centre

3-5 dental practices in England (TBC) providing NHS dental care or a combination of NHS and private dental care.

United Kingdom

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# Sponsor information

## Organisation

Loughborough University

## Sponsor details

Epinal Way Loughborough England United Kingdom LE11 3TU

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rio.nhs.admin@mailbox.lboro.ac.uk

## Sponsor type

University/education

## Website

https://www.lboro.ac.uk

#### **ROR**

https://ror.org/04vg4w365

# Funder(s)

## Funder type

Government

#### Funder Name

National Institute for Health and Care 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**

## Publication and dissemination plan

Planned publication in a peer-reviewed journal

# Intention to publish date

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

https://repository.lboro.ac.uk/CLiMB

All trial data will be shared. Data will be available after publication of the research in a peer-reviewed journal and available for 10 years in line with Loughborough University's policy. No restrictions on criteria. Participant's consent for data sharing is obtained as part of the study. Data will be non-identifiable.

# IPD sharing plan summary

Data sharing statement to be made available at a later date