The effect of a novel high-adherence weight loss programme in achieving weight loss and other health benefits

Submission date 16/10/2024	Recruitment status No longer recruiting	[X] Prospectively registered
		∐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/10/2024	Ongoing	Results
Last Edited	Condition category	Individual participant data
21/10/2024	Nutritional, Metabolic, Endocrine	[] Record updated in last year

Plain English summary of protocol

Background and study aims

This study (the "Study") is designed to assess the effectiveness and acceptability of a novel weight management programme (the "Programme"). The Programme is structured around a mobile application, and aims to provide a high-adherence model of care, support and guidance to participants in order to lose weight. Participants may also be prescribed medication to support their weight loss efforts as part of the Programme where this is deemed clinically appropriate following individual clinical review.

Who can participate?

Adults between the ages of 18 and 65 who meet the eligibility criteria and live in England or Wales. Participants will agree to the normal terms of the Programme, including any monthly fee associated.

What does the study involve?

The Programme involves regular check-ins including weight, side effect monitoring, blood tests and questionnaires. This data will be collected and analyzed as part of this study to draw conclusions concerning the effectiveness and acceptability of the Programme.

What are the possible benefits and risks of participating?

The expected benefit is weight loss and reduction of the complications associated with obesity. In addition, participants will be supported during their journey.

Medications may be prescribed to patients as part of the Programme if this is considered to be appropriate following individual clinical review. Side effects and risks of any medication prescribed will be discussed with patients at the point of prescribing, and informed consent obtained.

Where is the study run from? eMed Healthcare UK Ltd

When is the study starting and how long is it expected to run for? October 2024 to December 2025

Who is funding the study? eMed Healthcare UK Ltd

Who is the main contact?

Dr Matthew Noble, matthew.noble@emed.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

eMed001

Study information

Scientific Title

The effect of and satisfaction with a novel high-adherence weight loss programme in achieving weight loss and other health benefits in adults with obesity: a retrospective observational study

Acronym

HAWLoP

Study objectives

To evaluate the effectiveness and acceptability of a novel high adherence weight management support programme.

Ethics approval required

Ethics approval not required

Ethics approval(s)

This is a retrospective observational study that does not involve any randomisation, treatment or management changes.

Study design

Descriptive case series retrospective observational study in a single centre

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obesity

Interventions

This study is designed to assess the effectiveness and acceptability of a novel weight management programme (the "Programme").

The Programme is structured around a mobile application, and aims to provide a high-adherence model of care, support and guidance to participants in order to lose weight. Participants may also be prescribed medication to support their weight loss efforts as part of the Programme where this is deemed clinically appropriate following individual clinical review. The Programme involves regular check-ins including weight, side effect monitoring, blood tests and questionnaires.

The Programme is already established and collects information on participation, outcomes, satisfaction, side effects, blood test data and other questionnaires as part of usual treatment. This study is designed to retrospectively analyze this routinely-collected data in order to draw conclusions concerning the effectiveness and acceptability of the Programme.

The duration of the study is six months. Patients will be followed up for a further six months.

Intervention Type

Mixed

Primary outcome(s)

BMI kg/m² measured using validated weight and self-reported height at baseline and validated weight and self-reported height at monthly intervals. Weight will be validated by directly observing the participant on a weighing-scale by video call.

Key secondary outcome(s))

1. Patient satisfaction measured using the NHS "Friends and family test" question throughout the duration of the study

- 2. Frequency, severity and nature of adverse events and side effects measured using an internally-developed side-effect reporting questionnaire throughout the duration of the study
- 3. Engagement with programme components such as check-ins measured using internal data to determine the percentage of recommended programme activities that the patient completes throughout the study
- 4. Drop out rate and any reasons provided for leaving the Programme measured using patient self-reporting at the end of the study
- 5. Weight loss of participants compared to that described in evaluations of other programmes measured using validated weight measurements collected at baseline and at the end of the study

Completion date

31/12/2025

Eligibility

Key inclusion criteria

Patients who took part in the Programme provided by the treatment centre

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

64 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/11/2024

Date of final enrolment

01/04/2025

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre eMed Healthcare UK Ltd 184-192 Drummond Steet London United Kingdom NW13HP

Sponsor information

Organisation

eMed Healthcare UK Ltd

Funder(s)

Funder type

Industry

Funder Name

eMed Healthcare UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type **Details** Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 11/11/2025 No Participant information sheet