ISRCTN12421711 https://doi.org/10.1186/ISRCTN12421711

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

Registration date
21/10/2024

Overall study status
Ongoing

Last Edited
21/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
Dr Matthew Noble

ORCID ID
http://orcid.org/0000-0003-1174-186X

Contact details
184-192 Drummond Street
London
United Kingdom
NW1 3HP
+44 330 303 8000
matthew.noble@emed.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/10/2024

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
1000

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
England

United Kingdom

Wales

Study participating centre
eMed Healthcare UK Ltd
184-192 Drummond Steet
London
United Kingdom
NW1 3HP

Sponsor information

Organisation
eMed Healthcare UK Ltd

Sponsor details
184-192 Drummond Street
London
England
United Kingdom
NW1 3HP
+44 330 303 8000
charlie@emed.com

Sponsor type
Industry

Website
http://www.emed.com/uk

Funder(s)

Funder type
Industry

Funder Name
eMed Healthcare UK Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2025

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