

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

<b>Submission date</b> 16/10/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/10/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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## 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/m<sup>2</sup> 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 Street

London

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NW1 3HP

**Sponsor information****Organisation**

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**Sponsor type**

Industry

**Website**

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# 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