

Does use of the Voy Program improve weight loss percentage and other health outcomes in a population already taking GLP/GIP-1RA medication?

Submission date 15/11/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2025	Condition category 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 trial aims to investigate whether the Voy Program improves weight loss percentage and other health outcomes (blood pressure, cholesterol, blood glucose, quality of life, etc.) in a population that is already taking GLP/GIP-1RA medication. Obesity is a major health problem that affects many people. In 2022, about 64% of adults in England were either overweight or obese. Although obesity is common, the reasons behind it, its symptoms, and how best to treat it are complex and often debated. While the first steps to treat obesity involve improving diet, exercise, and lifestyle habits, studies show that focusing only on eating fewer calories and exercising more doesn't usually lead to long-term weight loss. Digital healthcare technologies could play a key role in changing how we prevent and treat obesity. Remote interventions, like online programs, offer several benefits over traditional methods. Digital solutions allow for personalised, interactive support, which makes it easier for patients to change their behaviour and improve results.

Who can participate?

Adults who have been prescribed a GLP/GIP-1RA medication by Voy as part of their usual care for weight loss.

What does the study involve?

If an eligible participant consents to take part in the trial, they will be randomly allocated into one of the two trial groups. One group will continue with usual care while the other group will utilise the Voy Program. Participants in the intervention group will have full access to the Voy Program which will include personalised sessions with a qualified coach as well as access to resources including managing your nutrition and movement. The frequency of the coaching sessions will be led by the participant but will normally start fortnightly. All participants will be enrolled in the trial for 12 months and will be asked to complete questionnaires on a monthly and quarterly basis.

What are the possible benefits and risks of participating?

It is unknown if the intervention being tested will have additional benefits. The intervention may, or may not, help participants personally, but it is hoped that this trial will help future people to receive the best evidence-based care. There are no known side effects associated with the trial intervention, the Voy Program.

Where is the study run from?

The trial is being run by Lindus Health on behalf of the sponsor Menwell Ltd (trading as Voy). Lindus Health will act as a virtual decentralised site for all participants.

When is the study starting and how long is it expected to run for?

September 2024 to April 2027. Recruitment is due to start in December 2024. Participants will be on the trial for 12 months (with an optional long-term follow-up up to 24 months). The trial is expected to finish in April 2027 (the last patient last follow-up).

Who is funding the study?

Menwell Ltd. (trading as Voy)

Who is the main contact?

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Contact information

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

350648

ClinicalTrials.gov number

NCT06710587

Secondary identifying numbers

LH-MAN-01

Study information**Scientific Title**

A decentralised open-label trial to eValuate the efficacy Of the VoY program in A patient population using GLP/GIP-1RA thERapy

Acronym

VOYAGER

Study objectives

The Voy Program will increase percentage weight loss, and improve other health related outcomes in a population using GLP/GIP-1RA therapy.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/01/2025, North West – Greater Manchester (GM) Central (Meeting held by video-conference via Zoom, -, -, United Kingdom; -, gmcentral.rec@hra.nhs.uk), ref: 24/NW/0378

Study design

Decentralised open-label parallel-group superiority randomized-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Internet/virtual, Medical and other records, Telephone

Study type(s)

Quality of life, Efficacy

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

Current interventions as of 04/12/2024:

This is a decentralised, open-label, parallel-group, superiority, randomised controlled trial assessing the effectiveness of the Voy Program.

Participants will be randomly allocated to receive the standard pathway (GLP/GIP-1RA only - control arm), or the standard pathway (GLP/GIP-1RA) plus the Voy Program (intervention arm).

The intervention in the trial is the 'Voy Program' which includes full access to 5 trial-specific health coaches. Upon randomisation, Voy patients will be randomly assigned to one of the five coaches, who will provide personalised support and use proven coaching techniques grounded in behaviour change psychology around diet, exercise, lifestyle, and behavioural changes. These sessions (a combination of video calls, phone calls, and messaging) will be participant-led but will normally initially occur fortnightly. The intervention will also include full access to the Voy app as a tool to schedule coaching sessions and support behavioural changes. Randomisation is via a secure, fully validated and compliant web-based randomisation system. Randomisation will be completed using permuted blocks and will be stratified by gender and BMI. All participants will be enrolled in the trial for 12 months and will be asked to complete questionnaires on a monthly and quarterly basis.

Previous interventions:

This is a decentralised, open-label, parallel-group, superiority, randomised controlled trial assessing the effectiveness of the Voy Program.

Participants will be randomly allocated into one of the two trial groups. The control group will continue with usual care while the intervention group will use the Voy Program.

The intervention in the trial is the 'Voy Program' which includes full access to 5 trial-specific health coaches. Upon randomisation, Voy patients will be randomly assigned to one of the five coaches, who will provide personalised support and use proven coaching techniques grounded in

behaviour change psychology around diet, exercise, lifestyle, and behavioural changes. These sessions (a combination of video calls, phone calls, and messaging) will be participant-led but will normally initially occur fortnightly. The intervention will also include full access to the Voy app as a tool to schedule coaching sessions and support behavioural changes. Randomisation is via a secure, fully validated and compliant web-based randomisation system. Randomisation will be completed using permuted blocks and will be stratified by gender and BMI. All participants will be enrolled in the trial for 12 months and will be asked to complete questionnaires on a monthly and quarterly basis.

Intervention Type

Behavioural

Primary outcome measure

Percentage weight loss, calculated from weight collected monthly using Bluetooth scales at 12 months

Secondary outcome measures

Current secondary outcome measures as of 04/12/2024:

1. Change in waist: hip ratio measured using a tape measured monthly, at 12 months
2. Metabolic parameters (CRP, HbA1C, lipid profile) measured via blood samples taken quarterly at 12 months
3. Vital signs (blood pressure and heart rate) measured using a device provided monthly, at 12 months
4. The status of obesity-related comorbidities, hypertension, and dyslipidemia collected quarterly during the trial in electronic Case Report Forms at 12 months
5. Quality of life and productivity measured using the EQ-5D-5L, Voy's Weight-related Quality of Life Survey and a productivity questionnaire collected quarterly at 12 months
6. Use and access of healthcare resources/services measured using Patient Activation Measure (PAM-10) and a Health Utility questionnaire collected quarterly at 12 months
7. Body fat percentage, collected from Bluetooth scales provided, at 12 months
8. Anxiety, mental health, and eating disorders measured using the GAD-7 (General Anxiety Disorder-7), Patient Health Questionnaire (PHQ-9), Binge-Eating Scale (BES) and the Three-Factor Eating Questionnaire (TFEQ) at 12 months.
9. The occurrence of adverse events measured using data recorded during the study in an adverse events log at 12 months
10. Diet quality measured using the Rapid Prime Diet Quality Score Screener (rPDQS) over 12 months

Previous secondary outcome measures:

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2. Metabolic parameters (CRP, HbA1C, lipid profile) measured via blood samples taken quarterly at 12 months
3. Vital signs (blood pressure and heart rate) measured using a device provided monthly, at 12 months
4. The status of obesity-related comorbidities, hypertension, and dyslipidemia collected quarterly during the trial in electronic Case Report Forms at 12 months
5. Quality of life and productivity measured using the EQ-5D-5L, Impact of Weight on Quality of Life (IWQOL) and a productivity questionnaire collected quarterly at 12 months
6. Use and access of healthcare resources/services measured using Patient Activation Measure (PAM-10) and a Health Utility questionnaire collected quarterly at 12 months
7. Body fat percentage, collected from Bluetooth scales provided, at 12 months

8. Anxiety, mental health, and eating disorders measured using the GAD-7 (General Anxiety Disorder-7), Patient Health Questionnaire (PHQ-9), Binge-Eating Scale (BES) and the Three-Factor Eating Questionnaire (TFEQ) at 12 months.

9. The occurrence of adverse events measured using data recorded during the study in an adverse events log at 12 months

Overall study start date

23/09/2024

Completion date

11/04/2027

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 04/12/2024:

1. Aged 18-65 years old
2. BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with any of the following comorbidities:
 - 2.1. High blood pressure
 - 2.2. High cholesterol
 - 2.3. Obstructive sleep apnoea
 - 2.4. Erectile dysfunction
 - 2.5. Asthma
 - 2.6. Osteoarthritis
 - 2.7. Chronic back pain
 - 2.8. PCOS
 - 2.9. Fatty liver disease
3. Approved for the standard GLP/GIP-1RA pathway by Voy as part of usual care for weight loss
4. People who use either an iOS or Android smartphone using the operating system iOS 16 or Android 8 or later
5. Agree to not use another intervention for weight loss for the duration of the trial
 - 5.1. Other diet-specific interventions such as meal replacement shakes
 - 5.2. Over-the-counter medication/supplements such as appetite suppressants, thermogenics, and herbal supplements
 - 5.3. Any other medicated weight loss program
 - 5.4. Structured weight loss programs such as Weight Watchers, Noom, and Second Nature
 - 5.5. Non-surgical medical weight management such as lipotropic injections and metabolic enhancers
 - 5.6. Surgical interventions such as a gastric bypass, banding, or other bariatric surgery
 - 5.7. Other personalised nutrition programmes, such as ZOE
6. Able and willing to provide Informed Consent and adhere to trial procedures

Previous participant inclusion criteria:

1. Aged 18-65 years old
2. BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with any of the following comorbidities:
 - 2.1. High blood pressure
 - 2.2. High cholesterol
 - 2.3. Obstructive sleep apnoea
 - 2.4. Cardiovascular disease
 - 2.5. Erectile dysfunction
 - 2.6. Asthma

- 2.7. Osteoarthritis
- 2.8. Chronic back pain
- 2.9. PCOS
- 2.10. Fatty liver disease
- 3. Prescribed GLP/GIP-1RA by Voy as part of usual care for weight loss
- 4. People who use either an iOS or Android smartphone using the operating system iOS 16 or Android 8 or later
- 5. Agree to not use another intervention for weight loss for the duration of the trial
 - 5.1. Other diet-specific interventions such as meal replacement shakes
 - 5.2. Over-the-counter medication/supplements such as appetite suppressants, thermogenics, and herbal supplements
 - 5.3. Any other medicated weight loss program
 - 5.4. Structured weight loss programs such as Weight Watchers, Noom, and Second Nature
 - 5.5. Non-surgical medical weight management such as lipotropic injections and metabolic enhancers
 - 5.6. Surgical interventions such as a gastric bypass, banding, or other bariatric surgery
- 6. Able and willing to provide Informed Consent and adhere to trial procedures

Participant type(s)

Service user

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

470

Key exclusion criteria

- 1. Pregnant or breastfeeding women or those planning to get pregnant in the next 12 months
- 2. Known diabetes (Type 1 or 2) or thyroid disease
- 3. Previous surgery or endoscopic intervention for obesity, or planned surgery or endoscopic intervention for obesity in the next 12 months
- 4. Lost ≥ 5 kg in the last 3 months
- 5. Currently using other weight loss medications, or use of other weight loss medications in the past 6 months
- 6. Currently using weight gain medications, including systemic steroids, or used weight gain medications in the past 6 months
- 7. Severe anxiety or depression (either PHQ-9 >15 or GAD7 >10)
- 8. Severe eating disorder (Binge eating scale ≥ 27)
- 9. Participation in another interventional clinical study or use of investigational drugs in the last 6 months
- 10. Any other significant disease or disorder which, in the opinion of the Investigator, may either

put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.

Date of first enrolment

23/01/2025

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Lindus Health**

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Sponsor information

Organisation

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Sponsor type

Industry

Website

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Funder(s)

Funder type

Industry

Funder Name

Menwell Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

15/04/2027

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date