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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
Recruiting

Registration date
26/11/2024

Overall study status
Ongoing

Last Edited
01/04/2025

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
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?
Tessa Griffiths, tessa@lindushealth.com

Contact information

Type(s)
Public, Scientific

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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 hypothesis
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

Condition
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:
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, 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

Overall study end date
11/04/2027

Eligibility

Participant 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

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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

Participant 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 ≥ 5kg 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.

Recruitment start date
23/01/2025

Recruitment end date
30/04/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lindus Health
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Sponsor information

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Menwell Ltd

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Sponsor type
Industry

Website
https://www.joinvoy.com/

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