

Using digital technology to support people living with obesity

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| Submission date | Recruitment status | <input checked="" type="checkbox"/> Prospectively registered |
| 06/08/2025 | Recruiting | <input checked="" type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 04/09/2025 | Ongoing | <input type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 04/02/2026 | Nutritional, Metabolic, Endocrine | <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Obesity affects over a quarter of the UK population and can lead to serious health issues. NHS Specialist Weight Management Services (WMS) offer treatments including lifestyle advice, psychological support, and medications, but access and availability vary by region. Although around 4 million people could be eligible for NHS Specialist WMS annually, capacity is limited to 35,000, severely limiting overall access for those who need it. While digital technology has started to be used in WMS, more evidence is needed to confirm its long-term effectiveness, acceptability, and cost-effectiveness. This study explores the use of Gro Health W8Buddy, a digital platform and app providing remote Specialist WMS. It aims to determine the long-term health benefits of the remote WMS pathway Gro Health W8Buddy compared to standard NHS WMS delivered in hospitals, and to improve patients' access to services.

Who can participate?

Adult patients with obesity class 2 and at least 1 medical complication (e.g., prediabetes, type 2 diabetes) or patients with obesity class 3 ($BMI \geq 40 \text{ kg/m}^2$), without complication.

What does the study involve?

The study is a real-world evaluation with observational data collection. Study participants will be recruited from four NHS specialist WMS who will choose either the standard NHS WMS or the digital pathway Gro Health W8Buddy. The study will measure and analyse health outcomes, including weight loss, time taken to be treated and cost-effectiveness, at 18 and 24 months. It will gather experiential data from patients and healthcare professionals through surveys, observation, and interviews.

The study is structured around four distinct work packages, each employing a unique research methodology. The digital intervention has been co-created with NHS staff and patients and is backed by research. This research methodology has been shaped by PPI input from all four NHS sites. The study methods enable Real World Evidence to be generated by allowing participants to choose their pathway and will therefore provide credible evidence for further roll-out of digital technology in weight management services across the UK. Allocation is, by design, not randomly allocated, which may lead to more participants in digital care or vice versa.

What are the possible benefits and risks of participating?

No benefits and risks given at registration

Where is the study run from?

University of Warwick, UK

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

November 2024 to October 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
355370

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PH648124, NIHR208100, CPMS 69222

Study information

Scientific Title

Long-term health and economic impact of using digital tool Gro Health W8Buddy to support people accessing specialist weight management services

Acronym

W8Buddy Study

Study objectives

To determine changes in body weight after 18 months of using either (i) a fully digital weight management program (remote digital pathway Gro Health W8Buddy) or (ii) site-specific delivered weight management programs incorporating face-to-face and/or virtual group sessions (standard care). Both programmes will deliver weight loss medication in line with usual medication provision as determined in local services.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/07/2025, Leicester South REC (3 Piccadilly Place, London Road, Manchester, M1 3BN, United Kingdom; +44 (0)2071048193; leicestersouth.rec@hra.nhs.uk), ref: 25/EM/0147

Study design

Multi-centre prospective observational cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Class 2 obesity (BMI $\geq 35 \text{ kg/m}^2$) with at least one medical complication (e.g., prediabetes, type 2 diabetes [T2DM]); or patients with obesity class 3 (BMI $\geq 40 \text{ kg/m}^2$), without any complications.

Interventions

W8Buddy is a virtual specialist WMS pathway. It is accessed through a digital behavioural change platform called the Gro Health app. Participants will either use (i) a fully digital weight management program (remote digital pathway Gro Health W8Buddy) or (ii) site-specific delivered weight management programs incorporating face-to-face and/or virtual group sessions (standard care). Both are 18-month programmes that will deliver weight loss medication in line with usual medication provision as determined in local services.

This is a multi-site prospective comparative observational cohort study with embedded cost-effectiveness analysis and process evaluation, comprising four work packages (WP) to assess the following:

1. Set up, Patient and Public Involvement and Engagement (PPIE) & Stakeholder engagement
2. Clinical impact
3. Health economic impact
4. Process evaluation

The W8Buddy app provides personalised WMS to support patients in achieving their self-selected health goals and support weight loss with real-time remote monitoring. The digitally

enabled WMS service at UHCW uses W8Buddy and augments traditionally delivered NHS care. The key features of W8Buddy include provision of one-to-one services by a medically qualified obesity specialist (specialist dietitian, psychologist and a GP with a special interest in weight management), clinical support via a multi-disciplinary team (MDT), group work (e.g. education modules, virtual sessions) and behaviour change activities, plus signposting to local and national services. The digital pathway is delivered through app contents, in-app chat, video teleconferencing and telephone. Prescribing is led by a Clinical Pharmacist who has an appointment with the patient during Week 1. There are then monthly medication reviews for the first 6 months and then every 12 weeks. Medication tracking is supported in the W8Buddy application. Side effects can be logged through the W8Buddy application and are discussed at the medication reviews that take place. Individualised support will be offered to those people who do not have access to a digital device, as appropriate to their needs.

Intervention Type

Behavioural

Primary outcome(s)

Body weight measured using specialist scales provided as part of the digital pathway or specialist scales used in NHS sites as part of standard of care at baseline and months 6, 12, 18 and 24, with reporting at month 18

Key secondary outcome(s)

1. Cost-effectiveness of W8Buddy measured using validated tools recommended by a health economist at baseline and months 6, 12, 18 and 24, with reporting at month 18
2. The Impact of W8Buddy on multiple long-term conditions associated with obesity, measured using mixed methods approaches including surveys and interviews at baseline and months 6, 12, 18 and 24, with reporting at month 18
3. Implementation and use of W8Buddy within Weight Management Services (WMS), measured using mixed methods approaches including surveys and interviews at baseline and months 6, 12, 18 and 24, with reporting at month 18
4. Manual for safe incorporation of a digital pathway delivering weight loss medication into existing WMS across the UK, created using mixed methods approaches, including surveys and interviews throughout the duration of the study
5. Recommendations for how we can optimise the existing infrastructure of WMS to improve ongoing RWE generation, created using mixed methods approaches, including surveys and interviews throughout the duration of the study

Completion date

31/10/2027

Eligibility

Key inclusion criteria

1. Adults aged 18 years and above
2. Class 2 obesity ($BMI \geq 35 \text{ kg/m}^2$) with at least one medical complication (e.g., prediabetes, type 2 diabetes [T2DM]); or patients with obesity class 3 ($BMI \geq 40 \text{ kg/m}^2$), without any complications.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Pregnant or breastfeeding
2. Type 1 diabetes mellitus
3. End-stage renal disease (eGFR <15, receiving renal replacement therapy)
4. Active or untreated alcohol or drug dependency
5. Decompensated liver disease
6. History of anorexia, undergoing treatment or awaiting treatment for DSM-V classified eating disorder
7. Severe mental health disease, including acute mental health crisis or self-harm in the last 12 months
8. Unstable mental health disease, including unstable personality disorder, schizophrenia and bipolar disorder
9. Unwilling or unable to commit to participation across the length of the research study
10. Patients targeting bariatric surgery within the length of the research study
11. Participating in another weight management research intervention
12. Participating in the diabetes remission program

Date of first enrolment

09/12/2025

Date of final enrolment

24/08/2026

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

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Study participating centre

University Hospitals Birmingham NHS Foundation Trust - Oxford Covid19 Trials

Queen Elizabeth Hospital
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Study participating centre

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Sponsor information

Organisation

University of Warwick

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 21/01/2026 | 22/01/2026 | Yes | No |