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Real-world exploration of digital innovation for managing excess weight

Submission date
08/12/2025

Recruitment status
Recruiting

Registration date
09/01/2026

Overall study status
Ongoing

Last Edited
09/01/2026

Condition category
Nutritional, Metabolic, Endocrine

[ ] 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
Obesity describes a person who is very overweight, with a lot of body fat. Obesity is a common problem in the UK, affecting one in every four adults. It can cause other health problems, including heart disease, diabetes, some cancers, and can affect mental health. The NHS is struggling to care for all the patients who need support, with parts of the country having no services at all, and others having long waiting lists of over a year. Some programmes are not working well for ethnic minority patients. Digital health solutions are a promising way to make sure everyone can get the care they need to reduce their weight and improve health outcomes, but more evidence is needed to prove these solutions work and are fair for all.

This project will help us understand whether digital weight management programmes can be as helpful as the standard care currently offered to people living with obesity or who are overweight. It will explore whether they can help people lose weight, offer cost savings to the National Health Service, improve experiences of care for patients and staff, and help widen access to the benefits of weight management programmes for as many types of patients as possible.

Who can participate?
Adults who have been accepted into the NHS South East London Tier 3 programme and meet the eligibility criteria for the study.

What does the study involve?
Taking part in the study involves participants using an app-based digital weight loss programme called Roczen for 12 months.

What are the possible benefits and risks of participating?
Possible benefits of participating – study participants will receive free, 12-month access to the Roczen weight management programme app. Study participation will help us to understand whether digital weight management programmes are as effective as the standard of care currently offered to people living with obesity. Information collected during this study may, in the future, result in more/better options available to patients needing weight management services such as the Tier 3 service.

Possible risks of participating – No risks are expected from taking part in the study.

Where is the study run from?
1. Guy's and St Thomas' NHS Foundation Trust, UK.
2. King's College London, UK.

When is the study starting and how long is it expected to run for?
December 2025 to June 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
Dr Andrew Walker, Chief Investigator, Guy's and St Thomas' NHS Foundation Trust, andrew.walker8@nhs.net

Contact information

Type(s)
Scientific, Principal investigator, Public

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Additional identifiers

Central Portfolio Management System (CPMS)
70372

National Institute for Health and Care Research (NIHR)
208095

Integrated Research Application System (IRAS)
351778

Study information

Scientific Title
Real-world Exploration of digital iNnovation managing Excess Weight (RENEW)

Acronym
RENEW

Study objectives
Primary Objectives:
• To investigate clinical- and cost-effectiveness (defined as percentage of weight change and EQ-5D-5L) of Roczen (1-year) versus (vs.) Tier 3 standard care
• To investigate post-Tier 3 clinical and cost-effectiveness (defined as percentage of weight change and EQ-5D-5L) of Roczen for 1 year vs. standard care (discharge to GP)

Secondary Objectives:
• To investigate the feasibility and acceptability (for patients and clinicians) of integrating Roczen as a supportive digital weight-management model of care within existing pathways
• To identify predictors of uptake, retention, and success-in-programme, for both Roczen users and standard-care users (including ethnicity and IMD) to inform development of both personalised weight management and more clinically- and cost-effective weight-management pathways

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/10/2025, East of England-Cambridge East Research Ethics Committee (2 Redmond Place, Stratford, London, EC20 1JQ, United Kingdom; +44 020 7104 8096; CambridgeEast.REC@hra.nhs.uk), ref: 25/EE/0191

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: General Practice, Primary sub-specialty: General Practice; Health Category: Cancer and neoplasms, Cardiovascular, Metabolic and Endocrine, Oral and Gastrointestinal, Stroke; Disease /Condition: Obesity and other hyperalimentation

Interventions
This study is a real-world evaluation of 2.5 years duration. The study will use a quasi-experimental design, which is more practical in answering our research questions. It will allow us to mimic how the Roczen weight management app will be delivered if used as part of a specialist Tier-3 weight management pathway, thereby making the findings generated from the research more generalisable. This design was also used because of the impracticalities of randomly assigning enough patients to ensure the results are valid in the time given.

The study's main aims are to find out how effective Roczen is in treating patients compared to either standard care (Tier-3 treatment) or post-discharge standard care in reducing weight, and to see how the costs compare. It also wants to see if Roczen can be easily used and accepted by patients and NHS staff as a digital tool to help manage weight within current healthcare systems and to find out what makes people start, stick with, and succeed in the Roczen programme compared to standard care. This will help to improve personalized weight management and make weight-management programs more effective and affordable.

There is no random allocation in this study.

Main Study - Intervention Arms

All eligible patients will be invited to participate in the intervention arm of the study from two groups (Group A & Group B) of GSTT Tier-3 patients who will be identified by the GSTT Tier-3 clinical care team. Group A intervention arm will be patients who are being referred to the Tier-3 weight management service and who have been accepted into the GSTT Tier-3 service and are entering the waitlist. Group B intervention arm will be patients who are completing the GSTT Tier-3 programme and will be discharged back to GP care. The intervention arms from both groups will be recruited at the same time.

The study aims to recruit 967 patients to reach 290 participants who complete the 12-month Roczen programme (assuming a 30% retention) in both groups' intervention arm.

Participants in the intervention arms of the study will receive 12 months of weight-management service via the Roczen app. Participants will receive the following activities while using Roczen's services:

Screening

All patients recruited into an intervention arm will be sent a patient information sheet and electronic consent form to review and sign (electronically).

Upon the patient's consent to the study, an SMS invitation from Roczen will be sent to the patient so that they can download the Roczen app to their smartphone.

Onboarding

Once the patient has downloaded the Roczen app, they will have an onboarding appointment with a Roczen clinician via video through the app (timepoint=Month 0).

Virtual consultations (Months 1, 2, 3, 6, 8, and 11 timepoints)

Virtual check-ins will be video calls via the Roczen app with dieticians or nurse specialists.

Clinical messaging support (Months 0-12)

Roczen clinicians will send messages to participants via the app weekly in the first month and then once per month until the end of the study (end of Month 12). Participants can also message clinicians at any time in the app if they have a question.

Moderated group mentoring (Months 0-12)

Mentoring is optional and is available at any time throughout the 12-month programme via the app. This includes monthly video webinars as well as a group messaging channel within the app. The group messaging channel is moderated and facilitated by Roczen staff members who are qualified health coaches.

Universal community support (Months 0-12)

Universal community support is also available at any time throughout the 12-month programme. It is provided via the group messaging channel in the app and includes educational articles, movement videos, and recipes.

Clinical measures

Roczen will ask participants to input their weight into the app once per month for the study

Roczen will ask participants to input their waist circumference measurement into the app once per month during the study. Roczen will ask participants to input their blood pressure numbers 3 times during the study (at Month 0, Month 6, and Month 12)

Questionnaires (Months 0, 6, 12)

Participants will be asked to complete some questionnaires about their health at these time points.

Any serious adverse events (SAEs) will also be recorded for the intervention arms (Months 0-12)

Main Study-Control Arms

Group A contemporaneous control arm will include the data from 290 patients who are coming off the GSTT Tier-3 waitlist and starting the Tier-3 service, and who complete 12 months of Tier-3 service.

Group B contemporaneous control arm will include 290 patients who are approached to participate in the Group B intervention arm of the study but choose not to and are discharged from Tier-3 service back to the care of their GP. To supplement data for the control arm, we will also include fully anonymised data of 4500 previous Tier-3 service users.
Study controls will not be consented to the study. Instead, the NHS National Opt-out will be used.

Participants in both the intervention arm and control arm of both groups (Group A and Group B) will have the following
data collected at the following timepoints:

Month 0 - Demographics, Medical history (obesity-related), Weight, Height, Waist circumference, Blood pressure,
Health questionnaires
Month 6 - Weight, waist circumference, blood pressure, health questionnaires
Month 12 - Weight, waist circumference, blood pressure, health questionnaires

Sub-study: All participants - One qualitative interview will be conducted with 84 patients who were invited to participate in
the main study to explore how feasible and acceptable Roczen is to patients. In addition, there will also be interviews with 20 staff members from both the Roczen and GSTT Tier 3 clinical care teams. Each interview will last around 60 minutes and will mainly be conducted online using Microsoft Teams.

Intervention Type
Mixed

Primary outcome(s)
1. Weight (percentage change in kilograms) measured using standard methods at baseline, 6 months, and 12 months

2. Cost-effectiveness measured using the European Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire at baseline, 6 months, and 12 months

Key secondary outcome(s))
1. Feasibility of implementing the intervention into Tier 3 weight management pathways measured using a qualitative interview with sub-study participants at one time point

2. Acceptability of implementing the intervention into Tier 3 weight management pathways measured using a qualitative interview with sub-study participants at one time point

3. Uptake of the intervention measured using data collected on (yes/no) person enrolled onto the intervention at one time point

4. Retention in the intervention programme measured using data collected on (yes/no) if an enrolled study participant completes 12 months of intervention at one time point

5. Success in the intervention programme measured using clinically significant percentage of weight loss (clinically significant percentage is >=5%) at one time point

6. Economic measurement of Quality Adjusted Life Years (QALYs) associated with weight loss measured using the EQ-5D-5L questionnaire at baseline, 6 months, and 12 months

7. Economic measurement of resource use covering primary and secondary care services from baseline to 12 months measured using data collected from electronic medical records at one time point

8. Economic measurements of unit costs from baseline to 12 months measured using data collected from standard sources, such as NHS reference costs and Personal Social Services Research Unit, at one time point

9. Economic measurements, such as costs between Roczen and standard care groups measured using data collected from standard sources, such as NHS reference costs and Personal Social Services Research Unit, at baseline to 12 months

10. Blood pressure, height in metres, body mass index, and waist circumference in centimetres measured using standard clinical assessments at baseline, 6 months, and 12 months

11. Sub analysis – Use of GLP-1 agonists measured by exposure (never/commenced during study /used throughout) from baseline to 12 months measured using a qualitative interview at one time point

12. Sub analysis – Intervention adherence measured by engagement with the intervention from baseline to 12 months measured using a qualitative interview at one time point

13. Sub-analysis – Comorbidities of obesity measured by the number of obesity-related comorbidities reported from baseline to 12 months measured using a qualitative interview at one time point

14. Sub-analysis – Social demographics collected once at baseline measured using a qualitative interview at one time point

15. Sub-analysis – Social demographics measured using a questionnaire at baseline

Completion date
30/06/2027

Eligibility

Key inclusion criteria
Participants will be included in the Main Study for the following reasons:
1. 18 years of age or older
2. Referred to the South East London Tier 3 weight management pathway by their GP
3. Accepted by the GSTT Tier 3 weight management service

Participants will be included in the Sub-study for the following reasons:
1. 18 years of age or older
2. A patient accepted by the GSTT Tier 3 service, invited to Group A or Group B of the Main Study or a staff member involved in commissioning or delivery of South East London's Tier 3 service or a Roczen service staff member delivering care in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participants will be excluded from the Main Study for the following reasons:
1. Do not have use of a smartphone
2. Do not read, write, or speak English
3. Are unable and/or unwilling to provide informed consent
4. Have a diagnosis of an eating disorder
5. Have had bariatric surgery
6. Currently have deranged thyroid function tests
7. Have type-1 diabetes
8. Are on insulin of sulfonylureas at high risk of hypoglycemia

Participants will be excluded from participating in the Sub-study for the following reasons:
1. Are unable or unwilling to provide informed consent
2. Do not read, write, or speak English

Date of first enrolment
30/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
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Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Organisation
King's College London

ROR
https://ror.org/0220mzb33

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