

Testing a new intervention for weight management called PROGROUP

Submission date 17/08/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/01/2025	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

The aim of the PROGROUP Trial is to test whether a new support programme (called PROGROUP) is successful in helping people who have severe obesity manage their weight, compared to the usual care provided by the NHS.

Obesity affects one third of UK adults (about 15 million people). Severe obesity reduces life expectancy due to the potential development of diabetes, heart disease and cancer. People with severe obesity also report greatly impaired quality of life. The NHS provides specialised weight management services for people with severe obesity, known as Tier 3 services, but it is unclear how effective these are. We designed a new programme to support people with severe obesity to manage their weight, called PROGROUP. When people develop a meaningful sense of social connection to other individuals, this can have a positive effect on behaviour change interventions in health care. In addition, waiting lists for Tier 3 are very long; having groups allows patients to be seen more quickly than they might otherwise as individual patients. In a small feasibility study, we found that PROGROUP was acceptable to people using NHS weight management services.

Our research question: is PROGROUP more effective and less costly than NHS usual care in supporting people with severe obesity to achieve meaningful weight loss.

Who can participate?

Most adults referred to NHS Tier 3 services (or an equivalent service) are eligible to take part in the PROGROUP study. Individuals, who have no other health issues, should have a BMI of at least 40, or 37.5 for some ethnic groups. Individuals who do have other specific health issues may be considered with a lower BMI if they are still eligible for the NHS Tier 3 service. Participants must be willing to be weighed in clinic at baseline, 6-months and 12-months.

Children and adolescents under 18 are not eligible, nor are people who cannot give consent for themselves. Anyone who plans to have bariatric surgery or start weight loss medication during the study period is not eligible.

What does the study involve?

Half the study participants will receive the NHS usual care (Tier 3 or equivalent) programme and half will be in the PROGROUP programme. Participants are allocated to either programme at random (by chance - like tossing a coin) by a computer. Both groups are equally important to this

study.

The usual care programme may vary between the different NHS trusts. Everyone in PROGROUP programme will be shown the same techniques, over a 5-month period, to help them make lasting changes to their behaviour or habits when it comes to eating and physical activity. There are twelve group sessions and 3 one-to-one sessions. A special feature of PROGROUP is that participants meet with the facilitator together, as a group of about twelve people. The facilitator will be a member of the weight management service, typically a nurse, dietitian or physiotherapist, who is trained to provide this coordinated programme of support. At the beginning, at 6 and at 12 months, all participants will have their weight measured at the Tier 3 service, and will complete self-report questionnaires on health, social connection, and NHS use.

What are the possible benefits and risks of participating?

We don't know yet if the PROGROUP support is effective but people allocated to the PROGROUP programme may find the support useful. Those who are not in the PROGROUP group, or do not benefit directly, will help us learn more about the programme and so may help support people who use weight management services in the future.

We are not aware of any risks to people of taking part in this study or receiving PROGROUP support. All participants will have to be willing to give some of their time to be part of the study. Some of the questions in the questionnaire or interviews might cause some distress. We provide participants with contact details for the team, to help in this situation, if needed.

Where is the study run from?

University Hospitals Plymouth NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2023 to April 2026

Who is funding the study?

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

Who is the main contact?

Dr Dawn Swancutt and the PenCTU team, progroup.penctu@plymouth.ac.uk

Study website

<https://www.plymouth.ac.uk/research/primarycare/obesity/progroup>

Contact information

Type(s)

Principal Investigator

Contact name

Prof Jonathan Pinkney

ORCID ID

<http://orcid.org/0000-0002-8927-1266>

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

322662

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 56821, NIHR201038, IRAS 322662

Study information

Scientific Title

A group-based behavioural intervention for weight management (PROGROUP) versus usual care in adults accessing NHS Tier 3 weight management services for treatment of severe obesity: a multi-centre, two-arm, individually randomised controlled, assessor-blinded, adaptive superiority trial with parallel process evaluation and health economic evaluation

Acronym

PROGROUP RCT

Study objectives

Our research question: is PROGROUP more effective and less costly than NHS usual care in supporting people with severe obesity to achieve meaningful weight loss?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/06/2023, West of Scotland REC3 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 3140212; WoSREC3@ggc.scot.nhs.uk), ref: 23/WS/0101

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community, GP practice, Hospital

Study type(s)

Treatment, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Obesity

Interventions

Current interventions as of 16/01/2025:

Randomisation:

The cohort will be randomised in one go – half of the participants to receive the PROGROUP (intervention) and half to receive NHS Tier 3 usual care (control). Participants can expect to be randomised about 6 weeks after they consented to the trial.

Receiving Tier 3 usual care:

Participants allocated to the control group will receive usual care provided by their NHS weight management service. This runs for about 6 months.

Receiving PROGROUP:

Participants allocated to the intervention group will commence PROGROUP. In summary, the PROGROUP programme consists of 15 contact sessions in total, over 5 months, as follows:

(Weeks 1-2) An initial one-to-one meeting: This will consist of a review of weight history, motivations for wanting to lose weight, establishment of an initial dietary and behaviour change programme, and supporting preparations for joining the intervention group.

(Weeks 3-10) Eight consecutive, weekly group sessions: Each session will teach and build upon on behavioural skills of self-monitoring, problem solving, action planning and goal setting. These will be applied to dietary and physical activity behaviours.

(Weeks 11-12) An interim one-to-one meeting. A review of progress, feedback on current behaviour and guided support and advice for progression in the programme, including potential goal revision.

(Weeks 14-18) Three consecutive, fortnightly group sessions: This part of the programme reflects a 'behavioural maintenance' phase with sessions focusing on managing lapses, consolidating social support networks, making healthy food choices when eating out and during celebrations. The process for preparing participants for the end of the intervention features in the latter session.

(Weeks 19-20) A final one-to-one session. A review of progress. Clinical review to develop plans for individualised continuation of programme learning. Discussions about bariatric surgery or onward referrals or case management if necessary.

(Week 22) Final group session: concludes the intervention and focuses on final preparations for continuation of programme learning as a group. Opportunity to celebrate the group achievements.

The group sessions will be audio-recorded so that the content and delivery can be monitored by the research team for the purposes of the study.

PROGROUP participants will also be asked to complete an online questionnaire, at the beginning, middle and end of the intervention period, on 'group processes' such as social identification within the PROGROUP group.

Once the 5 month intervention period at a given site has ended, a sample of amenable participants will be contacted for an in-depth interview (about 45 minutes long) with a researcher about their experience of the PROGROUP intervention and being in the trial. Participants in the PROGROUP intervention, will transition to usual care at the Tier 3 service, on completion of the intervention period.

Follow-up at 3 months:

All participants will be asked to complete the following self-reported measures via an online questionnaire: Wellbeing (Social Identification) and use of certain weight loss medication; travel costs and mode of transport to attend appointments.

Follow-up at 6 months and 12 months:

All participants will attend the Tier 3 clinic for a repeat of the measures taken at baseline: weight measurement, diabetes risk and lipid profile (requires a blood sample) and blood pressure. All participants will be asked to complete an online questionnaire with very similar content to the baseline questionnaire.

Previous interventions:

Randomisation:

The cohort will be randomised in one go – half of the participants to receive the PROGROUP (intervention) and half to receive NHS Tier 3 usual care (control). Participants can expect to be randomised about 6 weeks after they consented to the trial.

Receiving Tier 3 usual care:

Participants allocated to the control group will receive usual care provided by their NHS weight management service. This runs for about 6 months.

Receiving PROGROUP:

Participants allocated to the intervention group will commence PROGROUP. In summary, the PROGROUP programme consists of 15 contact sessions in total, over 5 months, as follows:
(Weeks 1-2) An initial one-to-one meeting: This will consist of a review of weight history, motivations for wanting to lose weight, establishment of an initial dietary and behaviour change programme, and supporting preparations for joining the intervention group.
(Weeks 3-10) Eight consecutive, weekly group sessions: Each session will teach and build upon on behavioural skills of self-monitoring, problem solving, action planning and goal setting. These will be applied to dietary and physical activity behaviours.
(Weeks 11-12) An interim one-to-one meeting. A review of progress, feedback on current behaviour and guided support and advice for progression in the programme, including potential

goal revision.

(Weeks 14-18) Three consecutive, fortnightly group sessions: This part of the programme reflects a 'behavioural maintenance' phase with sessions focusing on managing lapses, consolidating social support networks, making healthy food choices when eating out and during celebrations. The process for preparing participants for the end of the intervention features in the latter session.

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Follow-up at 3 months:

All participants will be asked to complete the following self-reported measures via an online questionnaire: Wellbeing (Social Identification) and use of certain weight loss medication.

Follow-up at 6 months and 12 months:

All participants will attend the Tier 3 clinic for a repeat of the measures taken at baseline: weight measurement, diabetes risk and lipid profile (requires a blood sample) and blood pressure. All participants will be asked to complete an online questionnaire with very similar content to the baseline questionnaire.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 16/01/2025:

Weight (kg) at baseline and 6 months post-randomisation

Previous primary outcome measure:

Weight (kg) at baseline and 12 months

Secondary outcome measures

Current secondary outcome measures as of 23/01/2025:

Measured at baseline, 6 and 12 months post-randomisation (unless otherwise noted):

1. Change in weight (kg) between baseline and 12 months post-randomisation
2. Weight (kg) to calculate percentage of participants achieving $\geq 5\%$ weight loss from baseline
3. Weight (kg) to calculate percentage of participants achieving $\geq 10\%$ weight loss from baseline
4. BMI (kg/m^2)
5. HbA1c (blood test)
6. Systolic blood pressure (mm Hg) (sphygmomanometer)
7. Total Cholesterol, HDL Cholesterol, Triglycerides (blood test)
8. Alcohol use, measured using self-reported number of alcohol units (AUDIT-C)
9. Eating behaviour, measured using Adult Eating Behaviour Questionnaire (AEBQ)
10. Physical activity measured using International Physical Activity Questionnaire (IPAQ) short form
11. Health-related quality of life measured using EQ-5D-5L questionnaire
12. Well-being measured using ICECAP-A questionnaire
13. Well-being measured using PHQ-4 questionnaire
14. Well-being measured using self-esteem and life satisfaction questionnaire
15. Well-being measured using loneliness measure at 3 months, 6 months, and 12 months post-randomisation compared to baseline
16. Health, social care and wider societal resource use measured using resource use questionnaire i.e. use of primary care and community-based services, use of hospital services, use of pharmacological interventions for weight loss, support from others e.g. family, self-funded weight loss interventions, employment status
17. Co-morbidity measured using patient records
18. Medication use measured using patient records
19. Social identification measured using social identification (non-validated) measure
20. Loneliness measured using Three-Item Loneliness Scale (non-validated)

Previous secondary outcome measures:

Measured at baseline, 6 and 12 months post-randomisation (unless otherwise noted):

1. Weight (kg) to calculate percentage of participants achieving $\geq 5\%$ weight loss from baseline
2. Weight (kg) to calculate percentage of participants achieving $\geq 10\%$ weight loss from baseline
3. BMI (kg/m^2)
4. HbA1c (blood test)
5. Systolic blood pressure (mm Hg) (sphygmomanometer)
6. Total Cholesterol, HDL Cholesterol, Triglycerides (blood test)
7. Alcohol use, measured using self-reported number of alcohol units (AUDIT-C)
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15. Health, social care and wider societal resource use measured using resource use questionnaire i.e. use of primary care and community-based services, use of hospital services, use of pharmacological interventions for weight loss, support from others e.g. family, self-

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16. Co-morbidity measured using patient records

17. Medication use measured using patient records

18. Social identification measured using social identification (non-validated) measure

19. Loneliness measured using Three-Item Loneliness Scale (non-validated)

Overall study start date

04/04/2023

Completion date

30/04/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/01/2025:

Patients must satisfy these criteria to be considered for the study:

1. Referred to the T3WMS within the last 6 months OR if referred to the T3WMS more than 6 months ago there is a clinically confirmed weight and BMI within the last 6 months.

2. In individuals with with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background, Body Mass Index ≥ 37.5 kg/m² or Body Mass Index ≥ 32.5 kg/m² with at least one significant comorbidity.

In all other individuals, Body Mass Index ≥ 40 kg/m² or Body Mass Index ≥ 35 kg/m² with at least one significant comorbidity.

Patients must satisfy all of the following criteria to be enrolled in the study:

1. Registered with the T3WMC or an equivalent service

2. In individuals with with a South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean family background, Body Mass Index ≥ 37.5 kg/m² or Body Mass Index ≥ 32.5 kg/m² with at least one significant comorbidity at the point of consent.

In all other individuals, Body Mass Index ≥ 40 kg/m² or Body Mass Index ≥ 35 kg/m² with at least one significant comorbidity at the point of consent.

3. Aged ≥ 18 years

4. Willing to be randomised to either PROGROUP or usual care

5. Willing to be weighed on at least three occasions (baseline, 6 months and 12 months)

6. Willing to provide blood samples and blood pressure readings on three occasions (baseline, 6 months and 12 months)

7. Considered suitable for group-based care

8. Have capacity to consent

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Patients must satisfy these criteria to be considered for the study:

1. Referred to the T3WMS within the last 6 months OR if referred to the T3WMS more than 6 months ago there is a clinically confirmed weight and BMI within the last 6 months.

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In all other individuals, Body Mass Index $\geq 40 \text{ kg/m}^2$ or Body Mass Index $\geq 35 \text{ kg/m}^2$ with at least one significant comorbidity at the point of consent.
3. Aged ≥ 18 years
4. Willing to be randomised to either PROGROUP or usual care
5. Willing to be weighed on at least three occasions (baseline, 6 months and 12 months)
6. Willing to provide blood samples and blood pressure readings on three occasions (baseline, 6 months and 12 months)
7. Considered suitable for group-based care
8. Have capacity to consent

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 780; UK Sample Size: 780

Key exclusion criteria

Current exclusion criteria as of 16/01/2025:

Patients who meet any of the following criteria will be excluded from study participation:

1. Already undergone bariatric surgery
2. Are scheduled, or have made their own plans, to undergo bariatric surgery during the course of the trial.
3. Currently taking the following pharmacotherapy for the indication of weight loss: GLP-1 analogues (e.g. Semaglutide, Liraglutide)*, Orlistat, or any off-licence weight-reducing pharmacotherapy such as the stimulant appetite suppressants phentermine and diethylpropion. Commencing these medications from six months post-randomisation is allowable, consistent with NICE guideline 189, 1.8.1: 'consider pharmacological treatment only after dietary, exercise and behavioural approaches have been started and evaluated'
* Taking GLP-1 analogues for diabetes control (rather than weight management) for at least 12 months prior to screening is not an exclusion criterion.
4. Currently engaged in any other weight management trial
5. Unwilling or unable to attend the Tier 3 service for intervention/UC appointments
6. Intending to relocate outside the geographical region during the trial period

7. Participants who have significant difficulties in adequate understanding of English, or a sensory impairment, such that they are unable to sufficiently understand/access the trial documentation or engage in group sessions, in the absence of a local provision of translated materials or communication aids.

Previous exclusion criteria:

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4. Currently engaged in any other weight management trial
5. Unwilling or unable to attend group sessions
6. Intending to relocate outside the geographical region during the trial period
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Date of first enrolment

01/10/2023

Date of final enrolment

30/09/2025

Locations

Countries of recruitment

United Kingdom

Study participating centre

University of Exeter

Heavitree Road

Exeter

United Kingdom

EX1 2LT

Sponsor information

Organisation

University Hospitals Plymouth NHS Trust

Sponsor details

Derriford Hospital
Derriford Road
Derriford
Plymouth
England
United Kingdom
PL6 8DH
+44 1752 432842
plh-tr.rdgovernance@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.plymouthhospitals.nhs.uk/home>

ROR

<https://ror.org/05x3jck08>

Funder(s)**Funder type**

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/04/2026

Individual participant data (IPD) sharing plan

After the Programme has reported, the individual participant data that underlie the results will be available on request from the CI (Jonathan Pinkney, email jonathan.pinkney@plymouth.ac.uk) and Sponsor (University Hospitals Plymouth NHS Trust, email plh-tr.rdgovernance@nhs.net), along with supplementary files as required (e.g. data dictionaries, blank data collection forms, analysis code, etc.). Data will be shared with (or access to the data will be provided to)

requestors whose proposed use of the data has been approved by the CI and Sponsor, under an appropriate data sharing agreement

IPD sharing plan summary

Available on request