ISRCTN13721429 https://doi.org/10.1186/ISRCTN13721429

Testing a new intervention for weight management called PROGROUP

Submission date
17/08/2023

Recruitment status
No longer recruiting

Registration date
25/08/2023

Overall study status
Completed

Last Edited
11/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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? Also, can PROGROUP be used in GP practices to support weight management?

Who can participate?
Most adults who qualify to be 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 the 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.
All participants taking part at GP practices will receive the PROGROUP programme, as this part of the study is to explore whether PROGROUP can be provided in primary care.

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 August 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

Contact information

Type(s)
Principal investigator

Contact name
Prof Jonathan Pinkney

ORCID ID
https://orcid.org/0000-0002-8927-1266

Contact details

Community and Primary Care Research Group
Faculty of Health
University of Plymouth
Plymouth Science Park
Plymouth
United Kingdom
PL6 8BX
+44 1752763498
jonathan.pinkney@plymouth.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
322662

Central Portfolio Management System (CPMS)
56821

National Institute for Health and Care Research (NIHR)
201038

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?

Updated 29/05/2026:
Adjusted to: a cost consequence analysis of PROGROUP versus usual care provided to people with severe obesity for meaningful weight loss and a single-arm implementation study of PROGROUP in primary care.

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

Primary study design
Interventional

Study design
Interventional randomized controlled trial with descriptive statistical analysis, cost-consequence analysis and parallel process evaluation and a single-arm implementation study

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Current interventions for the RCT 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 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 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 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 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.

Updated 29/05/2026:
Current intervention for the implementation study in primary care as of 18/07/2025:
All participants taking part at GP practices will receive the PROGROUP programme as this part of the study is to explore whether PROGROUP can be provided in primary care.

Intervention Type
Behavioural

Primary outcome(s)
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

Key secondary outcome(s)
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 ≥5% weight loss from baseline
3. Weight (kg) to calculate percentage of participants achieving ≥10% weight loss from baseline
4. BMI (kg/m²)
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 ≥5% weight loss from baseline
2. Weight (kg) to calculate percentage of participants achieving ≥10% weight loss from baseline
3. BMI (kg/m²)
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)
8. Eating behaviour, measured using Adult Eating Behaviour Questionnaire (AEBQ)
9. Physical activity measured using International Physical Activity Questionnaire (IPAQ) short form
10. Health-related quality of life measured using EQ-5D-5L questionnaire
11. Well-being measured using ICECAP-A questionnaire
12. Well-being measured using PHQ-4 questionnaire
13. Well-being measured using self-esteem and life satisfaction questionnaire
14. Well-being measured using loneliness measure at 3 months 6 and 12 months post-randomisation compared to baseline.
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-funded weight loss interventions, employment status.

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)

Completion date
27/08/2026

Eligibility

Key inclusion criteria
Current inclusion criteria for the RCT 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

Updated 29/05/2026:
Inclusion criteria for the implementation study in primary care as of 18/07/2025:
Patients must satisfy all of the following criteria to be enrolled in the study:
• Registered with the participating GP practice/consortia.
• Meet the criteria for referral to the local T3WMS.
• In individuals 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.
• Aged ≥18 years.
• Willing to have weight measured on at least two occasions (baseline and 6 months).
• Willing to provide blood samples and blood pressure readings on two occasions (baseline and 6 months) if these are collected as part of usual care. (Where not routinely collected by sites,

participants who decline to provide research bloods may still participate in PROGROUP).
• Considered suitable for group-based care.
• Have capacity to consent.

_____

Previous inclusion criteria:

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
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

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment

Key exclusion criteria
Current exclusion criteria for the RCT 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.

Updated 29/05/2026:
Exclusion criteria for the implementation study in Primary Care as of 18/07/2025:
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 engaged in any other weight management trial.
4. Unwilling or unable to attend the locations for the PROGROUP sessions and study visits.
5. Intending to relocate outside the geographical region during the trial period.
6. 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 the intervention sessions, in the absence of a local provision of translated materials or communication aids.

———

Previous exclusion criteria:

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: 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'.
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
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.

Date of first enrolment
31/05/2024

Date of final enrolment
06/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
James Cook University Hospital Laboratory
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane

Wakefield
England
WF1 3SP

Study participating centre
Danes Camp Medical Centre
Rowtree Road
East Hunsbury
Northampton
England
NN4 0NY

Study participating centre
Towcester Medical Centre
Link Way
Towcester
England
NN12 6HH

Sponsor information

Organisation
University Hospitals Plymouth NHS Trust

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/07/2026	11/11/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes