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A group-based programme for weight management (PROGROUP) versus usual care for weight management in adults with severe obesity

Submission date
17/11/2021

Recruitment status
No longer recruiting

Registration date
02/12/2021

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity affects one third of adults (about 15 million people) in the UK. Severe obesity reduces life expectancy due to 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 what the Tier 3 clinics do, and how effective they are is unclear. Our project seeks to better understand these clinics and investigate whether a new, group-based, support programme (called PROGROUP) is more effective and less costly than usual care.

Our principal objective is to conduct a randomised clinical trial of PROGROUP versus usual care in a relatively small number of people with severe obesity, to see whether it's feasible to do so, and acceptable to participants. If we find that this feasibility trial is successful, we will then plan a larger, definitive, trial of the PROGROUP programme.

Who can participate?
Adults aged 18 years and over who are registered with the Tier 3 Weight Management Service and who have a BMI of at least 35, with a pre-existing medical condition or at least 40, without any other medical conditions.

What does the study involve?
Participants in the PROGROUP Intervention group will attend a group-based behavioural intervention, consisting of fifteen sessions over a 5-month period, with a member of the team (facilitator) at the specialist weight management clinic. The facilitator might be a nurse, dietician, or physiotherapist, each trained to provide this coordinated programme of support. Participants meet with the facilitator together, as a group of about twelve people. There are some one-to-one sessions with the facilitator. Over the 5-month period, participants will be shown various techniques to help make lasting changes to their behaviour or habits around eating and physical activity; and they will also be given guidance on nutrition and diet.

What are the possible benefits and risks of participating?
We don't know yet if the PROGROUP intervention is effective; but those participants allocated to the PROGROUP intervention may find the sessions supportive. A special feature of PROGROUP is that participants meet with the facilitator together, as a group of about twelve people. 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.

Trial procedures are non-invasive and pose no significant risk to participants. It's possible that a participant may experience some emotional distress in a qualitative interview, if asked to think about their personal experiences. Qualitative interviews are conducted by experienced researchers trained to manage this, and other related issues, in the course of conducting the interviews.

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?
From May 2021 to May 2023

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

Who is the main contact?
Dr Wendy Ingram
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Study website
https://www.plymouth.ac.uk/research/primarycare/obesity/progroup

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302670

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50790, IRAS 302670, NIHR201038

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 feasibility randomised controlled trial with parallel process evaluation and health economic evaluation

Acronym
PROGROUP Feasibility RCT v1

Study objectives
To test the feasibility of undertaking a randomised controlled trial of a group-based behavioural intervention for weight management (PROGROUP) versus usual care, in adults with severe obesity accessing NHS Tier 3 weight management services

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/11/2021, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)2071048033/53; cornwallandplymouth.rec@hra.nhs.uk), ref: 21/SW/0144

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Severe obesity

Interventions
Patients who have been identified as potentially eligible for the study and who are about to have their first appointment at the NHS weight management service, or have recently had an initial appointment, will be provided with information about the study by the NHS staff. There are a couple of different points that the patient will be offered introductory information about the study. In all cases, patients will receive a short Study Summary Leaflet and a Participant Information Sheet (PIS), and a member of NHS staff will ask the patient if they are willing to be contacted about the study directly by a member of the PROGROUP research team. All patients approached will have the opportunity to discuss the study with a member of staff at the service or a member of the PROGROUP research team.

Consent:
Patients will be given at least 24 h to consider the PIS before being contacted by a member of the PROGROUP research team (only if the patient has given permission for direct contact). The researcher will review eligibility criteria with the participant and explain the study in further detail, addressing any queries raised by the patient, based on their reading of the PIS. If the patient is still willing to participate, informed consent will be taken, ether during the course of the telephone call, or may be rescheduled for a further call if preferred.

Randomisation:
Because the PROGROUP intervention is group-based, a sufficient number of participants are needed at each site to run the group. Recruitment will continue at the site until a cohort of sufficient size is reached. Only then will participants be randomised to PROGROUP

(intervention) or usual care (control), but participants can expect to randomised within about 4 weeks (we will monitor this).

Baseline assessments:
Upon recruitment of a complete cohort (and randomisation), participants will be emailed a link to complete the online baseline questionnaire. Participants can request support from a researcher if needed. A reminder will be sent by email if participants have not completed the questionnaire (after 48 hours). If questionnaires remain uncompleted, researchers will contact participants to ascertain ongoing willingness to participate and to provide assistance if required.

In the online questionnaire, participants are asked to provide information (using tick boxes) on: demographics, weight management history and co-morbidities (e.g. diabetes status).

Participants are also asked to complete validated questionnaires:
1. Diet and physical activity, Adult Eating Behaviour Questionnaire and International Physical Activity Questionnaire
(IPAQ) short form
2. Health-related quality of life, EQ-5D-5L questionnaire
3. Wellbeing, ICECAP-A, Self-esteem measure, Life satisfaction measure, Social Identification measure, Loneliness
measure, and PHQ-4
4. Resource use questionnaire, use of health, social care, and wider societal resources

Clinical measures are also recorded at baseline, i.e. participant height and weight, HbA1c (glycaemia measure) and lipids, and blood pressure. These will be collected as part of routine care at the initial visit to the weight management clinic.

Receiving usual care:
Participants allocated to the control group will receive usual care provided by the NHS weight management service.

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:
1. 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 preparations for joining the group.
2. 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. Each session will also contain nutrition and dietary advice/education.
3. 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.
4. Weeks 14-20: Four consecutive, fortnightly group sessions: This part of the programme reflects a ‘behavioural maintenance’ phase. Sessions focus on providing the toolkit for managing lapses, consolidating social support networks, making healthy food choices when eating out and during celebrations.
5. Weeks 21-22: 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.

The group sessions will be audio-recorded. Participants receiving the PROGROUP intervention will be asked to complete a session feedback form after each session, and pass this to the facilitator. 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.

At 3 months, participants will complete the Wellbeing, Social Identification and loneliness self-reported measures online, in the same way described above for baseline:

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 min long) with a researcher about their experience of the trial and trial processes, and all participants will be invited to complete a feedback questionnaire on a similar theme. Participants in the PROGROUP intervention, will transition to use care at the service, on completion of the intervention period.

Follow-up at 6 and 12 months:
At 6 months and 12 months, at a face-to-face visit at the weight management service, participant weight will be recorded. The results for blood tests for HbA1c (glycaemia measure) and lipids, and blood pressure, carried out as part of routine care will be recorded. Participants will complete the following self-reported measures online, in the same manner as described for baseline:
1. Co-morbidities
2. Diet and physical activity
3. Health-related quality of life
4. Wellbeing
5. Resource use questionnaire

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is recorded as number of patients screened, consented (as a proportion of patients screened), and randomised (as a proportion of patients screened) at the time of screening and the time of randomisation
2. Retention rates are recorded as the number of recruited patients attending follow up visits at 6 and 12 months
3. Batch randomisation rate is measured as the time required to recruit enough participants within a site to trigger randomisation for a cohort at the time of randomisation
4. Data completeness for outcome measures and acceptability of outcome measures measured by recording number of completed self-report questionnaires and the number of missing items within a questionnaire at baseline, 3, 6, and 12 months
5. Acceptability of planned approach for longer-term follow-up measured using consent rates for additional follow-up data at 5 months
6. Fidelity of PROGROUP training and delivery assessed by fidelity assessment and iteratively refine delivery based on these assessments
7. Acceptability of trial processes and the intervention to the participants measured using intervention attendance rates and intervention engagement at baseline, 1-2, 3, 4, 5, 6, 7, 8, 9, 10, 11-12, 14, 16, 18, 20, and 21-22 weeks
8. Adherence to usual care measured by Tier 3 appointment attendances between baseline and 22 weeks

Secondary outcome measures
1. Weight loss measured using weight at baseline, 6, and 12 months post-randomisation.
2. Percentage of participants achieving ≥5% weight loss measured using weight at baseline, 6, and 12 months post-randomisation
3. Percentage of participants achieving ≥10% weight loss measured using weight at baseline, 6, and 12 months post-randomisation
4. BMI derived from height at baseline and weight at baseline, 6, and 12 months post-randomisation
5. Diabetes risk/diagnosis of diabetes/control of diabetes measured using HbA1c at baseline, 6, and 12 months post-randomisation
6. Cardiovascular disease risk calculation measured using:
6.1. Blood Pressure at baseline, 6, and 12 months post-randomisation
6.2. Lipid profile measured using Total Cholesterol, HDL Cholesterol, and Triglyceride at baseline, 6, and 12 months post-randomisation
7. Change in alcohol use (non-validated) at baseline, 6, and 12 months post-randomisation
8. Change in Adult Eating Behaviour Questionnaire at baseline, 6, and 12 months post-randomisation
9. Change in International Physical Activity Questionnaire (IPAQ) short form at baseline, 6, and 12 months post-randomisation
10. Change in EQ-5D-5L questionnaire at baseline, 6, and 12 months post-randomisation
11. Change in ICECAP-A questionnaire at baseline, 6, and 12 months post-randomisation
12. Change in PHQ-4 questionnaire at 6 and 12 months post-randomisation.
13. Change in self-esteem and life satisfaction (non-validated) at baseline, 6, and 12 months post-randomisation
14. Change in health and social care resource use questionnaire at baseline, 6, and 12 months post-randomisation
15. Change in recorded comorbidities at baseline, 6, and 12 months post-randomisation
16. Change in use of relevant medications at baseline, 6, and 12 months post-randomisation
17. Change in social identification (non-validated) measure at baseline, 3, 6, and 12 months post-randomisation
18. Change in loneliness (non-validated) measure at baseline, 3, 6, and 12 months post-randomisation

Overall study start date
01/05/2021

Completion date
12/09/2023

Eligibility

Key inclusion criteria
1. Body Mass Index ≥40 or ≥35 kg/m² with comorbidity
2 Aged ≥18 years
3. Willing to be randomised to either PROGROUP or usual care
4. Registered with the T3WMC
5. Considered suitable for group-based care
6. Have capacity to consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 96; UK Sample Size: 96

Total final enrolment
99

Key exclusion criteria
1. Currently engaged in any other weight management trial
2. Are scheduled to undergo bariatric surgery during the course of the trial
3. Unwilling or unable to attend group sessions
4. Intending to relocate outside the geographical region during the trial period
5. 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
15/04/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University of Exeter
College of Medicine and Health
College House
Heavitree Road
Exeter
United Kingdom
EX1 2LU

Study participating centre
University Hospitals Coventry And Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Somerset NHS Foundation Trust
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Sponsor information

Organisation
University Hospitals Plymouth NHS Trust

Sponsor details
Derriford Hospital
Derriford Road
Plymouth
England
United Kingdom
PL6 8DH
+44 (0)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)

Funder Name
National Institute for Health Research (NIHR) (UK)

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

Publication and dissemination plan
Intend to publish in an open-access peer reviewed journal .

Intention to publish date
31/05/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available after the research programme is published upon request from the Chief Investigator (CI), Prof Jonathan Pinkney, email: progroup.penctu@plymouth.ac.uk. Individual participant-level data

that underlie the results will be available 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) applicants whose proposed use of the data has been approved by the CI and Sponsor, under an appropriate data sharing agreement. Consent to data sharing is obtained from participants. It will not be possible to identify individual participants from the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/09/2022	12/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	09/02/2023	28/07/2025	No	No