STATISTICAL ANALYSIS PLAN

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.

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Contents

ADMINISTRATIVE INFORMATION 4

ABBREVIATIONS 5

1 INTRODUCTION 6

1.1 Background and rationale for the trial 6

1.2 Purpose of statistical analysis plan 6

2 Feasibility trial objectives 6

3 Trial design 7

3.1 General design 7

3.2 Blinding 7

3.3 Participant eligibility criteria 7

3.3.1 Inclusion criteria 7

3.3.2 Exclusion criteria 7

3.4 Randomisation 8

3.5 Feasibility of a definitive RCT 8

3.5.1 Proposed outcome measures for future definitive RCT 8

3.6 Sample size 9

4 Statistical principles 9

4.1 Statistical significance levels 9

4.2 Intervention adherence and protocol compliance 9

4.2.1 Intervention adherence 9

4.2.2 Protocol compliance 10

4.3 Analysis populations 10

4.4 Interim analysis 10

4.5 Time-points of statistical analysis 10

4.6 Data sources and data quality 10

4.6.1 Derived variables 11

4.6.2 Missing data 11

4.6.3 Imputation of missing items within participant reported outcomes 11

5 Statistical Analyses 12

5.1 Study population 12

5.1.1 Baseline characteristics and demographics 13

5.1.2 Participants who discontinue, withdraw or are lost to follow-up 13

5.2 Measures of feasibility 14

5.2.1 Measurement of weight 14

5.2.2 Success of blinding 15

5.3 Participant reported and clinical outcome measures 15

5.4 Safety data 15
5.5 Progression to definitive trial 15
5.6 Sample size for definitive trial 17
5.7 Statistical Software 18
6 References 18
APPENDIX 20
Examples of tables and plots 20
Adult Eating Behaviour Questionnaire and Scoring Information. 42

ADMINISTRATIVE INFORMATION

Title of Trial	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.
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ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CACE	Complier Average Causal Effect
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTU	Clinical Trials Unit
eCRF	Electronic Case Report Form
HEAP	Health economic analysis plan
ICC	Intra-cluster correlation coefficient
ICECAP-A	ICEpop CAPability measure for adults
ISRCTN	International Standard Randomised Controlled Trials Number
PWSO	People with Severe Obesity
PI	Principal Investigator
PIS	Participant Information Sheet
PSG	Programme Steering Group
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SAP	Statistical Analysis Plan
T3	Tier 3

1 INTRODUCTION

1.1 Background and rationale for the trial

Approximately 15 million people in the UK are obese, and at least 5 million of these are severely obese (Body Mass Index (BMI) ≥35kg/m^2)1. Severe obesity is indiscriminate, reaching all sections of society, but particularly the socially disadvantaged. At higher levels of BMI (e.g., 40-45kg/m^2), which is commonly seen in NHS specialist weight management services, average loss of life expectancy is 8-10 years [1], meaning that approximately 1.5 million adults in the UK face early death attributable to this condition – and meanwhile, living with substantially compromised psychosocial health, wellbeing and quality of life [2, 3]. Apart from bariatric surgery (which relatively few people choose), the treatment options for people with severe obesity (PWSO) are variable and of uncertain effectiveness (The British Psychological Society). Although the NHS commissions specialist 'Tier 3' Weight Management Clinics (T3WMC) to support PWSO, the poor evidence base for treatment is recognised [4, 5]. Several studies suggest the potential of group-based intervention in T3. However, PWSO are inadequately represented in research, and previous studies pre-dated new evidence on best practice for developing group-based interventions [6-8]. Therefore, it remains uncertain whether the adoption of group-based intervention in T3 would enhance patient outcomes and be cost-effective. The full background and rationale for the trial is detailed in the PROGROUP feasibility study protocol [Version 2.0, 15/03/2022].

In summary, the PROGROUP programme aims to establish the evidence needed for the successful implementation of a new group-based behavioural intervention ('PROGROUP') for people with severe obesity (PWSO) in T3 services. The aim of this study is to test the feasibility of undertaking a randomised controlled trial (RCT) of PROGROUP versus usual care in people with severe obesity.

1.2 Purpose of statistical analysis plan

The study protocol includes an outline of the statistical methods to be employed in the analysis of the feasibility trial data. The purpose of the Statistical Analysis Plan (SAP) is to provide full details of the planned statistical methods to be used in the primary report of the feasibility trial results. The SAP has been drafted following the SAP Guidelines [9], CONSORT extension for Pilot and Feasibility Studies [10] and also taking cognisance of the CONSORT extensions for reporting patient-reported outcomes [11] and non-pharmacologic treatment interventions [12]. However, it is worth noting that, as this is a feasibility trial, formal/inferential statistical analysis and hypothesis testing of the outcome measures is not appropriate and thus will not be undertaken. There is a separate health economic plan (HEAP), which will include the analysis of ICE-CAP-A and EQ5D-5L data, and a separate process evaluation that will cover analyses of intervention fidelity.

2 Feasibility trial objectives

The research question for the future definitive trial is: In PWSO, does PROGROUP, compared to usual care, lead to greater weight loss at 12 months post-randomisation? To inform the design of a definitive trial to answer this question, a randomised feasibility trial of PROGROUP versus usual care, with parallel process evaluation and health economics evaluation, will provide data to meet the objectives below.

1. Estimate rates of screening and enrolment
2. Ascertain recruitment rate, randomisation rate and retention rate
3. Ascertain adherence to the intervention and to usual care
4. Ascertain completeness of data collection at baseline, 6 and 12 months post-randomisation.

3 Trial design

3.1 General design

This is a multicentre, partially clustered, feasibility, individually randomised controlled trial (RCT) of PROGROUP (group-based intervention) versus usual care (control). The trial will be conducted in the Tier 3 Weight Management services of three NHS secondary care trusts: Coventry and Warwickshire Partnership NHS Trust (site 1), Cardiff and Vale University Health Board (site 2), , and Taunton and Somerset NHS Foundation Trust (site 3). Each of these sites will aim to recruit a pool ('cohort') of ~24 participants, but with flexibility to recruit 16-30, to be individually randomised at a single time point, to intervention or control. Site 1 (Coventry and Warwick) will recruit two separate cohorts of participants. Trial activity at each of the three sites will be overseen by a local site Principal Investigator. Participants will be assessed at baseline, three months, six months, and 12 months after randomisation.

3.2 Blinding

This trial is non-blinded to participants, as it is not possible to conceal the treatment allocation to them. The outcome assessors (i.e., research team members conducting follow-up) will be blinded to treatment allocation. The success of outcome assessor-blinding will be evaluated at follow-up by asking assessors to record the treatment group to which they think a participant has been allocated in the case report form. This information will be used to assess the success of blinding (Section 5.2.2). Outcome assessors will also be asked to report any cases of inadvertent unblinding (e.g. as a result of the participant disclosing their allocated treatment).

The initial data export provided to the trial statistician undertaking the analyses will not disclose the treatment allocations, so that the analyses of the participant-reported outcomes, as well as the recruitment and retention rates, are blinded. In the event that the Programme Steering Group (PSG) requests unblinded or disaggregated data during the trial, in order to fulfil its data monitoring duties, members of the PenCTU not involved in the conduct of the trial will assist with preparation of the data and transmission to PSG members, in order to maintain blinding of the trial statisticians.

3.3 Participant eligibility criteria

3.3.1 Inclusion criteria

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

- Body Mass Index ≥40 *or* ≥35 kg/m^2 with comorbidity
- Aged ≥18 years
- Willing to be randomised to either PROGROUP or usual care
- Registered with the T3WMC
- Considered suitable for group-based care
- Have capacity to consent

3.3.2 Exclusion criteria

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

- Currently engaged in any other weight management trial
- Are scheduled to undergo bariatric surgery during the course of the trial
- Unwilling or unable to attend group sessions
- Intending to relocate outside the geographical region during the trial period
- 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.

Whist online data capture is the preferred means of collecting self-report outcome measures, alternative methods (postal, telephone) will be made available as needed. As such, lack of access to online services is not grounds for exclusion.

3.4 Randomisation

The group-based nature of PROGROUP necessitates the confirmed recruitment and participation of a sufficient number of participants within a recruiting site prior to randomisation. As such, each site will aim to recruit a pool ('cohort') of ~24 participants (but with flexibility to recruit 16-30) to be randomised at a single time-point. Site 1 (Coventry and Warwick) will recruit two separate cohorts. Recruitment will continue until a cohort of participants is declared complete. The decision to declare a cohort complete will be made by the Co-Chief Investigators, with support from the Trial Management Group, based primarily on recruitment performance and overall project timelines. Declaration of a completely recruited cohort will trigger the issue of baseline self-report assessments to participants in that cohort.

Within each cohort, individual participants will be randomised in a 1:1 ratio to PROGROUP or usual care. For each cohort, randomisation will be achieved using block simultaneous randomisation, provided by PenCTU (using a static list created by a statistician who is not part of the trial team). Randomisation will proceed once a sufficient number of participants have been recruited as described above.

3.5 Feasibility of a definitive RCT

This SAP describes the reporting of the following information which will be used to inform the decision as to whether a definitive RCT is feasible:

- Recruitment rate (overall and by cohort):
    - Number of patients screened and the number and percentage of those screened who were given a PIS
    - Number consented – number and percentage of those screened as well as number and percentage of those given a PIS
    - Number randomised – number and percentage of those screened as well as number and percentage of those given a PIS
- Time required to recruit sufficient number of participants within a site to trigger randomisation for a cohort.
- Retention rate (overall and by cohort) - number and percentage of randomised participants attending each of the follow-up visits.
- Completeness of data collection (see section 3.5.1 below), in particular weight, at baseline, six and 12 months, overall and by site. For self-report questionnaires, this will include number of missing items within a questionnaire at each time point.
- Intervention attendance rates (intervention arm participants only).
- Tier 3 service appointment attendances (all participants).
- Acceptability of planned approach for longer-term follow-up, including consent rates for additional follow-up data after the end of the trial.

3.5.1 Proposed outcome measures for future definitive RCT

Outcome and other measures collected in this feasibility trial that are proposed to be included in the future definitive RCT are listed below. These may be revised for the definitive trial, as informed by this feasibility study and input from the Patient Advisory Group and Programme Steering Committee.

The following measures are scheduled to be assessed at baseline, six and 12 months post-randomisation, unless otherwise stated:

- Weight loss from baseline (proposed primary outcome)

- Percentage of participants achieving ≥5% weight loss from baseline weight (minimum clinically worthwhile weight loss)
- Percentage of participants achieving ≥10% weight loss from baseline weight
- Body Mass Index (BMI)
- Alcohol use – modified Alcohol Consumption Questionnaire (AUDIT-C) *
- Eating behaviour - Adult Eating Behaviour Questionnaire(Hunot C 2016) *
- Physical activity - International Physical Activity Questionnaire (IPAQ) short form (Craig C 2003) *
- Anxiety/Depression - Patient Health Questionnaire-4 (PHQ-4) (Kroenke K 2009)*
- Self-esteem *
- Life satisfaction *
- Social identification – modified Social Identity Questionnaire for Sport (SIQS) (3 and 6 and 12 months post-randomisation) (Bruner 2018)*
- Loneliness (3, 6 and 12 months post-randomisation) (Hughes M 2004)*
- Glycaemia measurement (HbA1c)
- Systolic blood pressure
- Blood lipid profile (Total Cholesterol, HDL Cholesterol, Triglycerides)
- Comorbidities*
- Medication use*

In addition, the following data/outcomes will be collected for which the planned analysis and reporting is covered in the separate health economic analysis plan (HEAP):

- Resource use questionnaire*
- ICEpop CAPability measure for Adults (ICECAP-A) (Flynn TN 2015)*
- EQ-5D-5L questionnaire *

* Self-reported measures.

3.6 Sample size

As an intervention group can comprise 8-15 participants (target is average ~12 participants), the total sample size is anticipated to be between 64 participants (i.e., 4 intervention groups, each with 8 participants, in addition to 32 control participants) and 120 participants (4 intervention groups, each with 15 participants, in addition to 60 control participants). In the worst case (i.e., smallest sample size of 64), it would be possible to estimate recruitment rates with at least +/-13% precision. It is acknowledged that the partially clustered nature of some of the feasibility outcomes, together with the small number of clusters, will result in increased uncertainty in e.g. estimates of retention rates.

4 Statistical principles

4.1 Statistical significance levels

As this is a feasibility trial, no formal inferential hypothesis testing will be undertaken. Feasibility outcomes such as recruitment and retention rates will be presented with two-sided 95% confidence intervals. Between-group differences for proposed full trial outcomes will be presented with 95% confidence intervals allowing for partial clustering as described in section 5.

4.2 Intervention adherence and protocol compliance

4.2.1 Intervention adherence

For participants randomised to the intervention group, the PROGROUP programme consists of 15 contact sessions in total, over five months. PROGROUP is a manualised intervention and will be provided to participants in accordance with the manual by trained facilitators from a multidisciplinary team (including nurses, dieticians, and

physiotherapists) at each site. Whilst no 'minimum dose' is yet established, all participants (both trial arms) will be asked to make every reasonable effort to adhere to their allocated programme schedule (ProGroup or usual care). The importance of engagement with all trial activity will be emphasised in the Participant Information Sheet (PIS), and the importance of engagement in the PROGROUP intervention specifically will be emphasised in a charter, provided to intervention participants after randomisation. Intervention attendance and engagement data obtained in this feasibility study will be used to inform a minimum 'dose' for the main trial, to inform sensitivity/complier average causal effect (CACE) analyses.

4.2.2 Protocol compliance

Non-compliance with protocol will be captured on specific non-compliance report forms according to instructions provided by PenCTU and in accordance with PenCTU standard operating procedures. Protocol non-compliance will be reviewed periodically by the Trial Management Group as part of central monitoring and the number and proportion of participants with any protocol deviations will be summarised by allocated group.

The measurement of face-to-face weight is required to be within four weeks prior to randomisation – further details and the reporting of this is detailed in section 5.2.1.

In addition, the number and proportion of participants with the 12-month post-randomisation follow-up undertaken outside of the pre-specified window (ie. between 11 and 14 months post-randomisation) will be summarised by allocated group (there is no pre-specified window for the three-month and six-month post-randomisation time-points). The length of follow-up will also be described for each of the three-month, six-month and 12-month post-randomisation.

4.3 Analysis populations

Primary descriptive analysis will be undertaken on a modified intention-to-treat basis, where participants are included (as long as their outcome data are not missing, as no imputation is planned – see section 4.6) according to their allocated group regardless of adherence to the protocol or lack of participation if allocated to the intervention. For reporting of safety data, the per-protocol population will consist of all randomised participants, of whom those allocated to the intervention group attended at least one PROGROUP group session.

4.4 Interim analysis

There is no planned formal comparative analysis of outcomes feasibility trial. However, regular monitoring of recruitment, attendance at intervention sessions, and completeness of data will be carried out by the trial management group. An assessment of the feasibility trial progression criteria will be made at approximately six months post-randomisation to allow planning of the full trial.

4.5 Time-points of statistical analysis

Following the scheduled follow-up at six months post-randomisation, data on recruitment, retention and completeness of outcome data collection (particularly weight loss) will be assessed and used to aid discussion regarding progression to full trial. The remaining statistical analysis will be undertaken once the final group of participants has completed the final assessment at 12 months post-randomisation and the trial database is locked.

4.6 Data sources and data quality

Clinical data for this trial will come from information entered onto case report forms completed by a blinded researcher. Participant reported data will be entered by participants directly or by research staff if participants respond over the telephone or by post.

PenCTU data management staff will monitor completeness and quality of data recorded in eCRFs and will correspond regularly with site PIs (or their delegated team member) with the aim of capturing any missing data where possible and ensuring continuous high quality of data. Data quality and completeness checks will be defined by the Data Manager through consultation with the CI, trial statistician, trial manager and other members of the Trial

Management Group as required. Checks will be described in the Data Management Plan. Throughout the trial, the Data Manager will report on the quality and completeness of accumulating data to the Trial Management Group.

4.6.1 Derived variables

The following variables will be derived from the data collected, coding for which will be carried out independently by two statisticians:

Adult Eating Behaviour Questionnaire (AEBQ): the AEBQ is a 35-item questionnaire, each item having five response options on a Likert scale [13]. Values are assigned as follows: Strongly disagree = 1, Disagree = 2, Neither agree nor disagree = 3, Agree = 4, Strongly agree = 5, with reverse scoring for items 'I enjoy tasting new foods', 'I often finish my meals quickly', 'I am interested in tasting new food I haven't tasted before', and 'I enjoy a wide variety of foods'. Eight appetitive traits are assessed [*Food Approach*: Hunger (H), Food Responsiveness (FR), Emotional Over-Eating (EOE), Enjoyment of Food (EF), *Food Avoidance*: Satiety Responsiveness (SR), Emotional Under-eating (EUE), Food Fussiness (FF) and Slowness in Eating (SE)]. The score for each of the eight appetitive traits will be calculated as the mean of their respective items.

International Physical Activity Questionnaire (IPAQ) short form: The IPAQ short form questionnaire is widely used to obtain internationally comparable data on health–related physical activity [14]. It consists of seven questions to capture average daily time spent sitting, walking, and engaging in moderate and vigorous physical activity over the last seven days. Responses to duration will be converted from hours and minutes into minutes and activity scores will then be calculated as the summation of the duration and frequency of each type of activity. In accordance with published guidance [15], responses of less than ten minutes will be re-coded as 'zero' and scores will not be calculated for a participant if any responses are 'don't know' or missing.

Alcohol consumption: This alcohol harm assessment tool consists of the consumption questions from the full alcohol use disorders identification test (AUDIT). Each of the three questions are scored from 0 to 4, with the total score calculated as the sum of all three items [16].

Patient Health Questionnaire (PHQ-4): The PHQ-4 is a four-item questionnaire answered on a four-point Likert-type scale [17]. Its purpose is to allow for ultra-brief and accurate measurement of core symptoms/signs of depression and anxiety. Values assigned as follows: Not at all = 0, Several days = 1, More than half the days = 2, Nearly every day = 3. A total score is calculated, ranging from 0 to 12, and serves as a good measure of 'caseness' (i.e., the higher the score, the more likely there is an underlying depressive or anxiety disorder).

Loneliness: For the three-item loneliness scale, values are assigned as follows: Hardly ever = 1, Some of the time = 2, Often = 3. The total score is the sum of all items [18].

Social Identification: This is a nine-item questionnaire, which asks participants how they feel about their membership of the weight management programme. Each item has an agreement scale from 1 (strongly disagree) to 7 (strongly agree) [19]. The mean of all items will be presented.

4.6.2 Missing data

The completeness of data collection for each of the clinical and participant reported outcomes will be reported. For participant reported questionnaires, the number of missing items, and number of computable scores will be reported.

4.6.3 Imputation of missing items within participant reported outcomes

In the absence of specific published guidance for imputing missing items within the participant reported outcomes, imputation will not be carried out. No clinical data will be imputed.

5 Statistical Analyses

As a feasibility trial, this study is not powered to support any conclusion regarding the efficacy of the intervention. Analyses will therefore be descriptive, informing the design of a fully powered PROGROUP randomised controlled trial. Appropriate plots will be used to illustrate key data and assess potential between-group differences but no formal, inferential statistical comparisons or hypothesis testing between groups will be undertaken.

Continuous measures will be summarised as means, standard deviations and ranges where the distribution appears approximately normally distributed, and as medians, inter-quartile ranges and ranges otherwise. Categorical data will be summarised by frequencies and percentages. Where appropriate, parameter estimates (e.g. between-group differences) will be presented with appropriate confidence intervals (taking into account clustering in the intervention group using mixed effects models).

It is expected that the estimand framework will be applied to the fully powered PROGROUP randomised controlled trial. Therefore, to inform the target estimand for the full trial, we will also report intercurrent events that occur during this feasibility trial. These may include deaths, use of weight loss drugs, attendance of PROGROUP and usual care appointments, and use of other weight loss strategies, the reporting of which is described below.

5.1 Study population

Data from the screening process through to completion of the trial will be recorded and presented in a CONSORT flow diagram. The following data will be reported overall and by site/cohort:

- Number of patients approached
- Number of patients screened for eligibility
- Number and percentage eligible
- Number and percentage of eligible asked to participate
- Number and percentage of eligible who declined to participate
- Number and percentage of eligible who consented to participate but did not proceed to randomisation
- Number and percentage of eligible who consented to participate and proceeded to randomisation
- Number and percentage of participants randomised to each allocated group
- Number and percentage of participants who did not receive their allocated treatment
- Number and percentage of participants who did receive their allocated treatment
- Number and percentage of participants who completed the 3 month post randomisation assessment
- Number and percentage of participants who completed the 6 month post randomisation assessment
- Number and percentage of participants who completed the 12 (11 months to14 months) month post randomisation assessment
- Number and percentage of participants lost to follow up
- Number and percentage of participants analysed.

5.1.1 Baseline characteristics and demographics

The following data collected at baseline will be summarised by allocated group to informally check for balance between groups and provide an overview of the study sample.

Demographics

- IMD-score (from postcode)
- Age
- Gender identity
- Ethnicity
- Religion
- Employment status
- Education status
- Household status
- Learning disability status
- Marital/partner status
- Smoking status

Weight management history

- Any previous referrals to Tier 3 weight management service
- Referral route to the current Tier 3 weight management service
- Treatments received for weight loss

Co-morbidities

- Diabetes status
- Depression
- Longstanding physical or mental impairment, illness or disability
- Alcohol use

Diet and physical activity

- Adult Eating Behaviour Questionnaire
- International Physical Activity Questionnaire (IPAQ) short form

Wellbeing

- Self-esteem measure
- Life satisfaction measure
- Social Identification measure
- Loneliness measure
- PHQ-4

Use of health, social care and wider societal resources (including use of certain medications of interest)

- Resource use questionnaire

5.1.2 Participants who discontinue, withdraw or are lost to follow-up

There is a small potential risk of some participants requesting withdrawal from treatment and/ or from trial follow up. This may be for psychological reasons (e.g., uncomfortable with the group-based format of the PROGROUP arm), or at the discretion of the responsible clinical team.

Reasons for withdrawal or loss to follow up will be summarised where reported, at each stage of the process**Error! Reference source not found.**, including withdrawal prior to randomisation, participants who did not receive their allocated treatment, non-completion of treatment, and loss to follow-up.

5.2 Measures of feasibility

The following will be reported:

Measure	
Recruitment rate	Number of participants recruited per month, overall and by site.
Time required to recruit sufficient numbers of participants within a site to run a PROGROUP group and trigger randomisation.	Number of days elapsed between sites opening and randomisation of cohorts (first cohort in the case of sites opening two).
Screening conversion rates (i.e. screened to consented and to randomised) as proportion of patients screened), overall and by site.	Overall recruitment rates at six and twelve months will be presented with their corresponding 95% confidence intervals.
Retention rate at 6 months and 12 months, overall and by site.	Retention rates at six and twelve months will be presented with their corresponding 95% confidence intervals.
Completeness of proposed outcome measures (in particular weight - see Section 5.2.1), at baseline, 6 and 12 months, overall and by site.	By allocated group and overall: the number (percentage) of participants who completed all items of the outcome measure, and for whom the outcome can be calculated.
Intervention attendance rates (intervention arm participants only).	Descriptive statistics for number of PROGROUP sessions attended:number (percentage) of participants in the intervention group who attended each PROGROUP session (and the cumulative total for each (Table 5)).
Tier 3 service appointment attendances (all participants).	Descriptive statistics for number of appointments scheduled and attended and number (percentage) of participants who attended all scheduled appointments.
Acceptability of planned approach for longer-term follow-up, including consent rates for additional follow-up data after the end of the trial.	Number (percentage) of all consented participants who also consent for additional follow-up.

5.2.1 Measurement of weight

A patient's weight and height, lipid profile, systolic blood pressure and glycaemia status (measured as Hba1c) will be measured and recorded at the initial visit as part of the usual T3 service. During the ongoing COVID-19 pandemic, face-to-face appointments at the T3 service might not be possible (owing to UK Government directives/guidance and/or at a NHS Trust level and/or due to a patient's COVID-related hesitancy to attend this visit). The initial visit to the T3 service might, instead, be conducted remotely (online or telephone). Alternative arrangements to measure weight and height will be offered in this scenario, to derive BMI for assessment against the inclusion criteria for BMI. Such alternatives include: Tier 3 staff obtaining the most recent weight and height measurement from primary care providers; researchers conducting a home visit and measuring weight and height using calibrated scales; accepting a patient-reported weight and height.

It is envisaged that time from eligibility assessment and consent to point of randomisation will be less than four weeks. This time interval will be monitored closely, including the factors that influence it, through central data monitoring and contact with participants. In the event that the interval exceeds four weeks, baseline weight will be rechecked prior to proceeding with randomisation.

As a measure of feasibility we will report, overall and by cohort:

- The number (percentage) of participants who had a face-to-face measurement of BMI within four weeks prior to randomisation
- The number (percentage) of participants who did not have a face-to-face measurement of BMI within four weeks prior to randomisation
- Descriptive statistics for the time elapsed between the face-to-face BMI measurement (used for screening purposes) and randomisation
- The number (percentage) of participants who had a face-to-face measurement of BMI repeated post-randomisation
  - Descriptive statistics for the time elapsed between randomisation and repeat measurement of BMI.

In cases where the face-to-face measurement is measured post-randomisation, the time elapsed between randomisation and the face-to-face measurement will be presented by allocated group. Reasons for baseline BMI being measured post-randomisation will also be reported.

5.2.2 Success of blinding

The success of blinding will be assessed by reporting the frequency and percentage of participants for whom assessors correctly identified the allocation. Reasons for unblinding will also be reported.

5.3 Participant reported and clinical outcome measures

Descriptive summary statistics will be presented for the participant reported and clinical outcomes listed in section 3.5.1 at baseline and each follow-up by allocated group, and overall. Continuous measures will be summarised as means, standard deviations and ranges where the distribution appears normal, and as medians, inter-quartile ranges and ranges otherwise. Categorical data will be summarised by frequencies and percentages. Change in each continuous outcome will be calculated for each participant by subtracting their value at baseline from their value at follow-up. The simple, unadjusted, between-group differences in change in each continuous outcome at each follow-up will be presented alongside their corresponding 95% confidence intervals, adjusted for partial clustering. The frequency and percentage (with corresponding exact 95% confidence interval) of participants who lose ≥5% of their weight and ≥10% of their weight at six and twelve months will be tabulated by allocated group and overall. In addition, the standard deviations for weight and weight change and ICC's describing the extent of clustering in the weight outcomes will be presented with a view to informing a review of the sample size calculation for the full trial (see section 5.6).

5.4 Safety data

The likelihood of participants being harmed by either the PROGROUP intervention or any of the trial procedures is very low. As such, the collection and reporting of adverse events (AE's) in the PROGROUP trial is restricted to only those events which are serious. Safety data will be collected from the time of randomisation until the end of trial visit. Safety data will be presented on a per-protocol basis. Serious adverse events (SAE's) will be cross tabulated by group and assessed for clinical relevance. The total number of SAE's and the number of participants with SAE's will be reported.

5.5 Progression to definitive trial

This feasibility study is intended to inform decisions about the proposed definitive RCT. Pre-specified progression criteria are as follows.

It is anticipated that planning for the definitive trial will commence if: (a) progression criteria detailed in Table 1 are met or if the feasibility study has enabled development of strategies to ensure they can be met in a definitive trial according to 'stop-go' green-amber-red criteria; (b) the programme steering group (PSG) supports progression; (c) required numbers of T3WMCs meeting site inclusion criteria have been identified and are committed to participating in the definitive trial; (d) recruitment and retention rates, as predicted by the feasibility study, suggest acceptability of the trial procedures, including the randomisation process, and are sufficient for trial delivery within timescale; (e) the funder approves.

Table 1: Progression criteria and stop/go values for PROGROUP feasibility RCT

Stop-go criteria Green: proceed to trial; amber: revise and review; red: do not proceed without further evaluation.

	Research Questions	Progression criteria	Data source	GREEN	AMBER	RED
1	What are the generalisable principles that underpin an acceptable & feasible group-based intervention for PWSO?	**1)** Each site is able to run PROGROUP **2)** Participant attendance during first 12 weeks of intervention (weekly group meetings) **3)** Sufficient* numbers of T3 services agree to participate in the definitive RCT	**1)** Feedback from feasibility study data **2)** Attendance data **3)** Early feasibility discussions with potential sites	**1)** 2/3 sites are able to run PROGROUP **2)** >70% of participants attend at least 60% of meetings **3)** >6* sites (or enough to achieve 80% of participant recruitment target) agree to trial	**1)** 1/3 sites are able to run PROGROUP **2)** ≥40% of participants attend at least 60% of meetings **3)** 4-6* sites agree to trial (or enough to achieve 50% - 80% of participant recruitment target)	**1)** No sites are able to run PROGROUP **2)** <40% of participants attend at least 60% of meetings **3) <**4* sites agree to trial (or not enough to achieve 50% of participant recruitment target)
2	What are the barriers and facilitators to successful implementation of group-based interventions in T3WMC from the perspectives of ppts, facilitators and organisations?	Participants agree to group-based care	Recruitment rate from feasibility study	>80% of patients invited to participate consent to study	50-80% of patients invited to participate consent to study	<50% of patients invited to participate consent to study
3	Can we collect data needed to answer the question: Is PROGROUP more effective in treating PWSO than usual care?	Each site can provide 6-month weight data for their participants	Site lead	6-month weight data for >80% of randomised participants	6-month weight data for 50-80% of randomised participants	6-month weight data for <50% of randomised participants

** Note the target number of sites for the definitive trial has not yet been confirmed.*

5.6 Sample size for definitive trial

The provisional sample size for the definitive trial will be reviewed and potentially revised, as informed by data collected in the feasibility trial and an updated literature review. As this review will need to take place prior to the 12-month feasibility data collection, the 6-month feasibility data will be need to be used and therefore conservative assumptions made. From the feasibility trial, the standard deviation for weight and weight loss at the six-month and 12-month post-randomisation time-points will be calculated overall and by allocated group and presented with

corresponding two-sided 80% and 95% confidence intervals. ICC's for weight will also be reported with confidence intervals as appropriate (estimated ICC's will be considered when reviewing the definitive sample size calculation but not solely relied upon due to the relatively small number of clusters in the feasibility trial). In addition, an adjustment for the correlation between weight at baseline and weight at follow-up will be considered. As such, estimates of the correlation between weight at baseline and weight at six and 12-months post-randomisation will also be reported alongside corresponding two-sided 80% and 95% confidence intervals.

5.7 Statistical Software

The statistical analyses will be undertaken using STATA version 16 or later, supplemented where required by R.

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APPENDIX

Examples of tables and plots

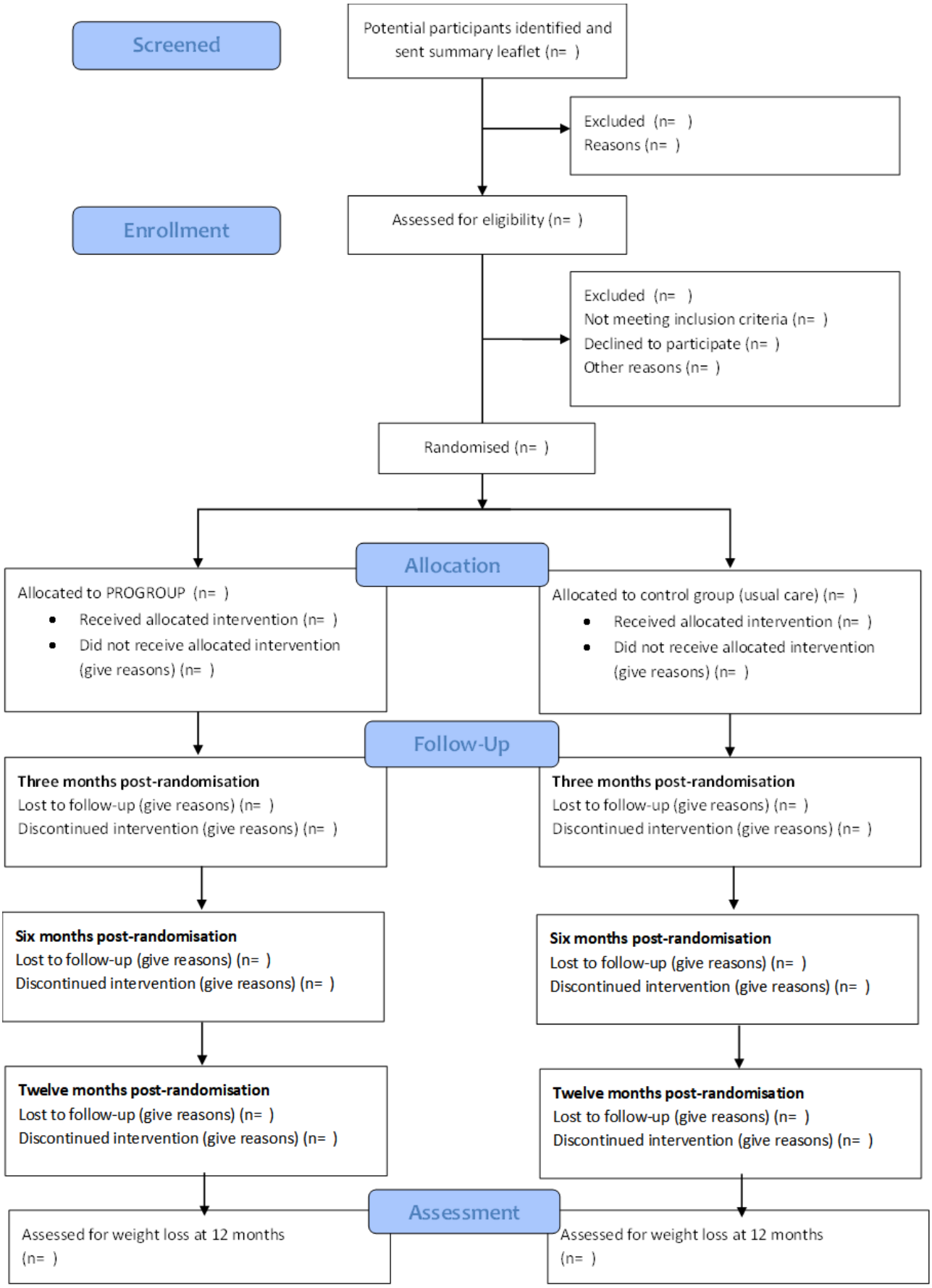

Figure 1. CONSORT diagram of participant flow through the PROGROUP feasibility trial

Table 1. Recruitment by cohort.

	Coventry & Warwick		***Cardiff & Vale***	***Taunton & Somerset***
Number of patients registered at T3 service				
	Cohort 1	*Cohort 2*		
Number (%) of patients approached				
Number (%) of patients eligible				
Number (%) of patients giving consent				
Number (%) agree to provide NHS number for long-term data linkage				
Number (%) agree to be contacted for interview				
Number (%) agree to be contacted after study finish				
Number (%) agree to be contacted for future research				

Table 2. Number (%) of consented and randomised participants with face-to-face weight and height measurements within four weeks prior to randomisation and number (%) of randomised participants who had face-to-face measurements post-randomisation by cohort and overall.

	Coventry & Warwick		***Cardiff & Vale***	***Taunton & Somerset***	***TOTAL***
	Cohort 1	*Cohort 2*			
Consented – face-to-face measurements within four weeks prior to randomisation					
Weight					
Height					
Randomised – face-to-face measurements within four weeks prior to randomisation					
Weight					
Height					
Randomised – face-to-face measurements post-randomisation					
Weight					
Height					

Table 3. Time elapsed between key events by cohort.

Time elapsed (number of days) between	***Coventry & Warwick***		***Cardiff & Vale***	***Taunton & Somerset***
	Cohort 1	*Cohort 2*		
Site opening and first consent				
Issue and completion of baseline questionnaire (mean, SD, range)				
Site opening and randomisation				
Face-to-face weight/height measurement and randomisation (mean, SD, range)				
Randomisation and face-to-face weight/height measurement (mean, SD, range)				
Randomisation and first PROGROUP session (mean, SD, range)				

Table 4 Time elapsed between face-to-face BMI measurements and randomisation by allocated group

Time elapsed (number of days) between	***Usual Care***				***PROGROUP***			
	Coventry 1	***Coventry 2***	***Cardiff***	***Taunton***	***Coventry 1***	***Coventry 2***	***Cardiff***	***Taunton***
Face-to-face weight/height measurement and randomisation (mean, SD, range)								
Randomisation and face-to-face weight/height measurement (mean, SD, range)								
For PROGROUP participants with post-randomisation weight/height measurement:								
Face-to-face weight/height measurement and first PROGROUP session (mean, SD, range)								

Table 5. Number (%) of participants in the intervention group attending PROGROUP sessions.

PROGROUP session		**Number (%) attending in each cohort**				**Cumulative total n (%)**
		Coventry1 n =	Coventry2 n =	Cardiff n =	Taunton n =	
Initial one-to-one meeting	1					
Weekly group sessions	2					
	3					
	4					
	5					
	6					
	7					
	8					
	9					
Interim one-to-one meeting	10					
Fortnightly group sessions	11					
	12					
	13					
	14					
Final one-to-one session	15					

Table 6. Tier 3 service appointment attendances (all participants).

	Usual Care				**PROGROUP – *during* intervention period**				**PROGROUP – *after* intervention period**			
(Mean, SD, range)	Coventry1 n =	Coventry2 n =	Cardiff n =	Taunton n =	Coventry1 n =	Coventry2 n =	Cardiff n =	Taunton n =	Coventry1 n =	Coventry2 n =	Cardiff n =	Taunton n =
Number scheduled												
Percent attendance												

Table 7. Completeness of clinical outcome measures overall and by allocated group.

Outcome	Time-point	Usual Care		PROGROUP		ALL	
		n	%	n	%	n	%
Height	Baseline						
Weight	Baseline 6 months 12 months						
BMI	Baseline 6 months 12 months						
HbA1C	Baseline 6 months 12 months						
Systolic Blood Pressure	Baseline 6 months 12 months						
Total cholesterol	Baseline 6 months 12 months						
HDL cholesterol	Baseline 6 months 12 months						
Triglycerides	Baseline 6 months 12 months						

Table 8. Completeness of participant reported outcome measures – number of missing items and number (%) of randomised participants with all items within individual questionnaires complete.

	Time-point	Usual Care		PROGROUP		ALL	
		Number of missing items	All items complete	Number of missing items	All items complete	Number of missing items	All items complete
		Mean (SD) [range]	n (%)	Mean (SD) [range]	n (%)	Mean (SD) [range]	n (%)
Comorbidities (recent diagnoses)	Baseline						
	6 months						
	12 months						
Medication use	Baseline						
	6 months						
	12 months						
Alcohol use	Baseline						
	6 months						
	12 months						
AEBQ: Hunger	Baseline						
	6 months						
	12 months						
AEBQ: Food responsiveness	Baseline						
	6 months						
	12 months						
AEBQ: Emotional over-eating	Baseline						
	6 months						
	12 months						
AEBQ: Enjoyment of food	Baseline						
	6 months						
	12 months						
AEBQ: Satiety responsiveness	Baseline						
	6 months						
	12 months						
AEBQ: Emotional under-eating	Baseline						
	6 months						
	12 months						
AEBQ: Food fussiness	Baseline						
	6 months						
	12 months						
AEBQ: Slowness in eating	Baseline						
	6 months						
	12 months						
PHQ-4	Baseline						
	6 months						
	12 months						
Self-esteem	Baseline						
	6 months						
	12 months						
Life satisfaction	Baseline						
	6 months						
	12 months						
Social identification	Baseline						
	6 months						
	12 months						
Loneliness	Baseline						
	6 months						
	12 months						

Table 9. Summary statistics of participant baseline characteristics and demographics overall and by allocated group.

	Usual Care (n=)	**PROGROUP** (n=)	**ALL** (n=)
Age (years)			
Mean (SD) [range] Median (IQR)			
N missing			
Gender n (%)			
Male Female			
MISSING			
Ethnicity n (%)			
White Mixed/ multiple Asian Black Other			
MISSING			
Religion n (%)			
Christian Hindu Jewish Muslim Sikh Other			
Decline to disclose			
MISSING			
IMD score			
Mean (SD) [range] Median (IQR)			
Education status n (%)			
GCSE's or equivalent A and AS -level Apprenticeships NVQ Degree-level or higher			
MISSING			
Employment status n (%)			
Full-time employment (≥ 30 hours/week) Part-time employment (< 30 hours/week) Self-employed full time (≥ 30 hours/week) Self-employed part time (< 30 hours/week) Voluntary worker Full-time student Unemployed & looking for work Unemployed & not looking for work Unemployed & unable to work for medical reasons Medically retired Retired Other			
MISSING			

	Usual Care (n=)	**PROGROUP** (n=)	**ALL** (n=)
Household status n (%)			
Live alone One other Two to three others More than three others			
Marital status n (%)			
Single Co-habiting Long-term relationship Married Civil partnership Separated Divorced Widowed Not disclosed			
MISSING			
Learning disability n (%)			
Yes No Not disclosed			
MISSING			
Smoking status n (%)			
Yes No			
MISSING			
Medical History n (%)			
Depression Anxiety Obsessive Compulsive Disorder Eating disorder Personality disorder Post-traumatic stress disorder Autism Schizophrenia/psychosis Bipolar Drug addiction			
MISSING			

Table 10. Summary statistics for previous weight management history overall and by allocated group.

	Usual Care (n=)	**PROGROUP** (n=)	**ALL** (n=)
Route of referral to weight management n (%)			
Primary Care (GP) Secondary Care Self-referral Allied Health Tier 3 weight management programme Tier 4 weight management programme			
Previous referral to weight management n (%)			
Yes No			
Previous treatment n (%)			
Diets supervised by dietician Commercial programmes Own diets Medication Gastric band Gastric bypass Sleeve gastrectomy Other			

Table 11 Participant reported weight loss medication overall and by allocated group.

	Time point	**Usual Care** (n=)	**PROGROUP** (n=)	**ALL** (n=)
Name of drug n (%)				
Orlistat (Orlos)	Baseline			
	6 months			
	12 months			
- Prescribed by doctor	Baseline			
	6 months			
	12 months			
- Number of days drug taken (mean, SD, range)	Baseline			
	6 months			
	12 months			
- MISSING n (%)	Baseline			
	6 months			
	12 months			
Liraglutide (Saxenda)	Baseline			
	6 months			
	12 months			
- Prescribed by doctor	Baseline			
	6 months			
	12 months			
- Number of days drug taken (mean, SD, range)	Baseline			
	6 months			
	12 months			
- MISSING n (%)	Baseline			
	6 months			
	12 months			
Semiglutide (Rybelsus (oral), Ozempic (injections), Wegovy)	Baseline			
	6 months			
	12 months			
- Prescribed by doctor	Baseline			

	6 months			
	12 months			
- Number of days drug taken (mean, SD, range)	Baseline			
	6 months			
	12 months			
- MISSING n (%)	Baseline			
	6 months			
	12 months			
Other	Baseline			
	6 months			
	12 months			
- Prescribed by doctor	Baseline			
	6 months			
	12 months			
- Number of days drug taken (mean, SD, range)	Baseline			
	6 months			
	12 months			
- MISSING n (%)	Baseline			
	6 months			
	12 months			

Table 12 Participant reported comorbidities (recent diagnoses) overall and by allocated group.

Recent diagnoses	**Time point**	**Usual Care (n=)**	**PROGROUP (n=)**	**ALL (n=)**
		n (%)	n (%)	n (%)
Diabetes	Baseline			
	6 months			
	12 months			
Angina	Baseline			
	6 months			
	12 months			
Heart attack	Baseline			
	6 months			
	12 months			
Transient ischaemic attack or stroke	Baseline			
	6 months			
	12 months			
Sleep apnoea	Baseline			
	6 months			
	12 months			
Others	Baseline			

	6 months			
	12 months			
Covid-19 in last 6 months	Baseline			
	6 months			
	12 months			
Long covid in last 6 months	Baseline			
	6 months			
	12 months			

Table 13. Summary statistics for clinical outcomes at each time point overall and by allocated group.

Variable	Time point	Usual Care			PROGROUP			ALL		
		N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean (SD)	Range
Weight (kg)	Baseline									
	6 months									
	12 months									
BMI (kg/m^2)	Baseline									
	6 months									
	12 months									
HbA1C (mmol/L)	Baseline									
	6 months									
	12 months									
Triglycerides (mmol/L)	Baseline									
	6 months									
	12 months									
Total cholesterol (mmol/L)	Baseline									
	6 months									
	12 months									
HDL cholesterol (mmol/L)	Baseline									
	6 months									
	12 months									
Systolic blood pressure (mm Hg)	Baseline									
	6 months									
	12 months									

Table 14. Summary statistics for participant reported eating behaviour (adult eating behaviour questionnaire – AEBQ) overall and by allocated group.

Variable	Time point	Usual Care			PROGROUP			ALL		
		N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean (SD)	Range
Food approach										
Hunger	Baseline									
	6 months									
	12 months									
Food responsiveness	Baseline									
	6 months									
	12 months									
Emotional over-eating	Baseline									
	6 months									
	12 months									
Enjoyment of food	Baseline									
	6 months									
	12 months									
Food avoidance										
Satiety responsiveness	Baseline									
	6 months									
	12 months									
Emotional under-eating	Baseline									
	6 months									
	12 months									
Food fussiness	Baseline									
	6 months									
	12 months									
Slowness in eating	Baseline									
	6 months									
	12 months									

Table 15. Summary statistics for participant reported physical activity (International Physical Activity Questionnaire (IPAQ) short form) overall and by allocated group.

		Usual Care			PROGROUP			ALL		
Intensity of physical activity (minutes per week)	**Time point**	**N**	**Mean (SD)**	**Range**	**N**	**Mean (SD)**	**Range**	**N**	**Mean (SD)**	**Range**
Sitting	Baseline									
	6 months									
	12 months									
Walking	Baseline									
	6 months									
	12 months									
Moderate	Baseline									
	6 months									
	12 months									
Vigorous	Baseline									
	6 months									
	12 months									

Table 16. Summary statistics for participant reported alcohol use overall and by allocated group.

	Time point	**Usual Care**		**PROGROUP**		**ALL**	
		N	Mean (SD) [range]	N	Mean (SD) [range]	N	Mean (SD) [range]
AUDIT-C score	Baseline						
	6 months						
	12 months						

Table 17. Summary statistics for participant reported self-esteem, life satisfaction, anxiety & depression, loneliness, and social identification overall and by allocated group.

	Time point	**Usual Care**		**PROGROUP**		**ALL**	
		N	Mean (SD) [range]	N	Mean (SD) [range]	N	Mean (SD) [range]
Self-esteem	Baseline						
	6 months						
	12 months						
Life satisfaction	Baseline						
	6 months						
	12 months						
PHQ-4	Baseline						
	6 months						
	12 months						
Loneliness	Baseline						
	3 months						
	6 months						
	12 months						
Social identification	Baseline						
	3 months						
	6 months						
	12 months						

Table 18. Change in clinical outcomes between baseline to six and 12 months post randomisation by allocated group and between group differences with 95% confidence intervals adjusted for clustering.

Variable	Time point for which change calculated from baseline	Usual Care			PROGROUP			Between-group difference		
		N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean	95% CI
Weight (kg)	6 months									
	12 months									
BMI (kg/m^2)	6 months									
	12 months									
HbA1C (mmol/L)	6 months									
	12 months									
Triglycerides (mmol/L)	6 months									
	12 months									
Total cholesterol (mmol/L)	6 months									
	12 months									
HDL cholesterol (mmol/L)	6 months									
	12 months									
Systolic blood pressure (mm Hg)	6 months									
	12 months									

Table 19. Change in participant reported eating behaviour (adult eating behaviour questionnaire – AEBQ) between baseline to six and 12 months post randomisation by allocated group and between group differences with 95% confidence intervals adjusted for clustering.

Variable	Time point for which change calculated from baseline	Usual Care			PROGROUP			Between-group difference		
		N	Mean (SD)	Range	N	Mean (SD)	Range	N	Mean	95% CI
Food approach										
Hunger	6 months									
	12 months									
Food responsiveness	6 months									
	12 months									
Emotional over-eating	6 months									
	12 months									
Enjoyment of food	6 months									
	12 months									
Food avoidance										
Satiety responsiveness	6 months									
	12 months									
Emotional under-eating	6 months									
	12 months									
Food fussiness	6 months									
	12 months									
Slowness in eating	6 months									
	12 months									

Table 20. *Change in participant reported physical activity (International Physical Activity Questionnaire (IPAQ) short form) between baseline to six and 12 months post randomisation by allocated group and between group differences with 95% confidence intervals adjusted for clustering.*

Intensity of physical activity (minutes per week)	**Time point for which change calculated from baseline**	**Usual Care**			**PROGROUP**			**Between-group difference**		
		N	**Mean (SD)**	**Range**	**N**	**Mean (SD)**	**Range**	**N**	**Mean**	**95% CI**
Sitting	6 months									
	12 months									
Walking	6 months									
	12 months									
Moderate	6 months									
	12 months									
Vigorous	6 months									
	12 months									

Table 21. Change in participant reported alcohol use between baseline to six and 12 months post randomisation by allocated group and between group differences with 95% confidence intervals adjusted for clustering.

Alcohol use	**Time point for which change calculated from baseline**	**Usual Care**			**PROGROUP**			**Between-group difference**		
		N	**Mean (SD)**	**Range**	**N**	**Mean (SD)**	**Range**	**N**	**Mean**	**95% CI**
AUDIT-C score	6 months									
	12 months									

Table 22. Change in participant reported self-esteem, life satisfaction, anxiety & depression, loneliness, and social identification between baseline to six and 12 months post randomisation by allocated group and between group differences with 95% confidence intervals adjusted for clustering.

Intensity of physical activity (minutes per week)	**Time point for which change calculated from baseline**	**Usual Care**			**PROGROUP**			**Between-group difference**		
		N	**Mean (SD)**	**Range**	**N**	**Mean (SD)**	**Range**	**N**	**Mean**	**95% CI**
Self-esteem	6 months									
	12 months									
Life satisfaction	6 months									
	12 months									
PHQ-4	6 months									
	12 months									
Loneliness	3 months									
	6 months									
	12 months									
Social identification	3 months									
	6 months									
	12 months									

Table 23. Number (percentage) of participants achieving weight loss of ≥5% and ≥10% at 6 and 12 months post-randomisation.

Variable	Usual Care		PROGROUP	
	n	%	n	%
Participants achieving ≥ 5% weight loss at 6 months				
Participants achieving ≥ 5% weight loss at 12 months				
Participants achieving ≥ 10% weight loss at 6 months				
Participants achieving ≥ 10% weight loss at 12 months				

Table 24. Estimates of standard deviations of weight and weight change for informing sample size calculations.

Parameter	Point estimate	80% CI	95% CI
Standard deviation of weight at baseline			
Standard deviation of weight at six months			
Standard deviation of weight at 12 months			
Standard deviation of change in weight from baseline to six months			
Standard deviation of change in weight from baseline to 12 months			

Table 25. Estimates of intraclass correlation coefficients (ICC) for weight and weight change.

	ICC	80% CI	95% CI
Weight at 6 months post-randomisation			
Weight at 12 months post-randomisation			
Change in weight from baseline to six months			
Change in weight from baseline to 12 months			

Table 26. Estimates of correlation between baseline weight and weight and weight change at follow-up.

Correlation between baseline weight and:	Point estimate	80% CI	95% CI
Weight at 6 months post-randomisation			
Weight at 12 months post-randomisation			
Change in weight from baseline to six months			
Change in weight from baseline to 12 months			

Table 27. Number and relatedness of serious adverse events.

		Usual Care	PROGROUP	
			During a PROGROUP session	**Not during a PROGROUP session**
Total number of events				
Number of participants with at least one event				
Relatedness	Related			
	Not related			