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Feasibility trial of acceptance and commitment therapy in bariatric patients

Submission date
06/08/2018

Recruitment status
No longer recruiting

Registration date
09/08/2018

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Bariatric (weight loss) surgery is the most effective long-term solution for obesity, but around one in five people who have had this surgery end up putting weight back on. Not being able to enjoy food, losing the comfort from food and finding it hard to resist food can also make depression and addiction problems more likely after surgery. This study compares Acceptance and Commitment Therapy (ACT) with treatment as usual (support group) in patients who have undergone bariatric surgery. ACT teaches awareness of thoughts and feelings which influence behaviour, compassion, and mindful holding of meaningful goals in line with the person's values. These processes have worked in other conditions and this study will therefore test whether people who have had bariatric surgery at least one year ago find 10 weeks of Acceptance and Commitment Therapy (ACT) an acceptable treatment and whether it would be feasible to conduct, in future, a trial to test whether ACT can help sustain and/or improve outcomes in this patient group. Trials big enough to inform us about whether a treatment approach works are costly, so this small study is needed to work out the best methods for the future. This study is the first step in testing whether ACT can help people who have had bariatric surgery.

Who can participate?
Patients aged 18 or over who have undergone bariatric surgery over 1 year ago

What does the study involve?
Participants are randomly allocated to either ACT group therapy or usual care (support group) over 10 weeks of 90-minute workshops led by a psychologist. All participants are followed up after 3, 6, and 12 months. This study assesses whether the methods, such as how people are recruited, allocated to the ACT group, and how data is collected, are likely to work on a bigger scale. Some of the participants are interviewed to understand their views more fully.

What are the possible benefits and risks of participating?
The data obtained from the study will add to the limited current evidence to develop appropriate psychological treatments for bariatric surgery patients. It is hoped that this will reduce the problem of weight regain, the need for further surgeries, and dangerous psychological effects such as depression or alcohol or drug misuse so that more patients will benefit from bariatric surgery long-term in quality of life and improved health. The main risk of

participating is that participants may become distressed during the intervention or data collection processes. This is common during psychological treatment, but clinicians experienced in managing distress will deliver the ACT intervention and support group. An experienced researcher who has worked with distressed patients will be provided with additional training in how to manage sensitive discussions and what to do in the case of disclosures of suicidal ideas /intent. There will be regular supervision of the researcher and clinician delivering the intervention by a psychiatrist and psychologist and it will be made clear to participants that they may leave the study at any time without providing justification.

Where is the study run from?
Imperial Weight Centre (UK)

When is the study starting and how long is it expected to run for?
May 2018 to September 2021

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

Who is the main contact?
Prof. Elizabeth Barley
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38906

Study information

Scientific Title
Addressing a critical need: feasibility of acceptance and commitment therapy for bariatric surgery patients at 15-18 months post-surgery

Acronym
FAB

Study objectives
Bariatric surgery is the most effective long term solution for obesity; however, around one in five people who have had this surgery end up putting weight back on. Not being able to enjoy food, losing the comfort from food and finding it hard to resist food can also make depression and addiction problems more likely after surgery.

This is a randomised controlled feasibility trial comparing acceptance and commitment therapy (ACT) with treatment as usual (support group) in post-operative bariatric surgery patients. ACT teaches awareness of thoughts and feelings which influence behaviour, compassion, and mindful holding of meaningful goals in line with the person's values. These processes have worked in other conditions and the trial will therefore test whether people who have had bariatric surgery at least one year ago find 10 weeks of ACT an acceptable treatment and whether it would be feasible to conduct, in future, a trial to test whether ACT can help sustain and/or improve post-operative outcomes in this patient group.

This project will tell us whether the methods, such as how people are recruited, allocated to the ACT group, and how data is collected, are likely to work on a bigger scale. Trials big enough to inform us about whether a treatment approach works are costly, so this small study is needed to work out the best methods for the future. The trialists will also interview some of those who have taken part to understand their views more fully. This project is the first step in testing whether ACT can help people who have had bariatric surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Westminster REC, 21/08/2018, IRAS ref: 233384, REC ref: 18/LO/1256

Study design
Randomised; Both; Design type: Treatment, Process of Care, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Prevention of weight gain in people who have had bariatric surgery

Interventions
Design
This will be a feasibility study for a single-centre, parallel group, single blind, two arm trial with participants randomised to either ACT or control. It will provide information about recruitment and characteristics of the proposed outcome measures to inform an application for a definitive RCT of ACT group therapy for post bariatric surgery patients. The definitive RCT will investigate the effectiveness of ACT in maintaining weight loss, improving wellbeing and healthy lifestyle behaviour and reducing health service costs when delivered at a time point at which there is a high risk of weight regain and reoperation. The feasibility study will compare ACT group therapy at 15-18 months post-surgery with usual care (support group) over 10 weeks.

Setting
Recruitment and research activity will take place within a London-based NHS weight-loss service that carries out bariatric surgery and its associated aftercare. No recruitment problems are expected; however, should the rate of recruitment or follow-up be below that expected, the trialists will invite another local weight loss surgery service to participate. All elements of study participation will take place at the above-mentioned site(s), or, if necessary, the participants' homes via telephone interview (for follow up time points 3 and 6 months).

Sample size
As this is a feasibility study and no hypothesis testing will occur, a power calculation has not been conducted. Literature suggests that at least 30-40 participants are needed for a pilot RCT, however, and we will therefore recruit 58 participants to allow for a 30% drop out rate. While the trialists are not aiming to test for a difference between groups, they will estimate the characteristics of the proposed outcome measures and will calculate the differences between the groups with 95% confidence intervals to inform the power calculation for the definitive trial. They have not estimated the precision of their descriptive outcomes as they will use the quantitative data, together with the practical experience of running the trial to determine the feasibility of the main study.

Anonymised data collection (all eligible participants)
In order to explore selection bias, at the point of invitation the clinician will record anonymised data (gender, age in years, ethnicity, weight, height, postcode) for all eligible participants from clinical notes. To protect anonymity, postcodes will be provided separately to the RA who will calculate the Index of Multiple Deprivation (IMD). No patient data will be seen by anyone outside the clinical team.

Recruitment
Participant identification:
Patients attending their regular follow-up appointment in clinic will be screened by the clinician for eligibility and potential participants will be provided with a brief verbal explanation and a Participant Information Sheet (PIS). Suicidal ideation will be established by looking at Question 9 on the PHQ-9 questionnaire that each patient is required to complete upon admission to the service (questionnaire filed in medical notes that the clinician will be utilising in clinic). Patients will also be asked about their ability to commit to 10 sessions in the foreseeable future, and all patients who are unable to communicate in English (i.e. those requiring an interpreter) will not be presented to the RA. To limit selection bias, eligible patients who do not attend will be posted the PIS with the routine appointment reminder letter by the clinical administrator. Those interested can contact the RA (details on the PIS) who will arrange a screening-appointment. Patients attending clinic whom verbally express an interest in participating in the study to their clinician will be approached by the RA after their appointment and invited to read through the PIS in a separate room attached to the clinic (patient contact details will be personally handed to the RA by the clinician). Patients will then read the PIS and the RA will answer any questions the patient may have, while confirming the patient meets eligibility criteria. If the patient wishes to participate, an appointment will be made to obtain signed consent (the RA will be trained and skilled in establishing capacity to consent), and for randomisation and baseline data collection.

No public advertisement of the study will occur.

Consent:
If a patient demonstrates interest in the study, they will meet face to face with a member of the research team to give written informed consent. In this meeting the researcher will provide another copy of the PIS and check that it has been fully read and understood. The researcher will read through the sheet with the participant or read it out for them if required. At this time, the researcher will answer any questions the participant might have before moving on to explain the consent form. Where participants are unsure of the meaning of any items on the consent form the researcher will ensure they adequately explain them. The researcher will be trained and skilled in establishing capacity to consent. Patients will be made aware that refusal to participate without giving reason, or early drop out from the study will not affect their clinical care. Early dropouts will be provided with details of where to obtain further information about the trial i.e. researchregistry.com, or by telephone or email, if possible. Where a participant is required to re-consent, for example, if new findings develop during the course of the research which may relate to the participant's willingness to continue participation, this will be done so in a timely manner.

The capacity of participants will not be monitored explicitly, but if at any point it becomes clear to the researcher or clinical team that the participant does not have capacity, the participant will not be consented into the study, or if the participant has lost capacity once the study has started, the intervention and follow up procedures will cease and the participant will be withdrawn from the study. Data obtained earlier in the study will be retained as the participant was deemed to have capacity at that time.

Randomisation:
Using a web-based randomisation programme of individual patient randomisation, consenting-participants will be randomised to the intervention (ACT) or support group (usual care/control) at an allocation ratio of 1:1. Randomisation will take place once participants have been recruited and will be managed by a person experienced in randomisation and independent of the project. Randomisation outcome will be fed back to the PI via email and this will then be relayed to participants via letter a timely manner. Both the ACT and usual care support groups will be

configured as clinics on the Trust booking system, and participant will therefore automatically receive a letter and text message once booked into the allocated group by the PI (identified as 'Group A' or 'Group B'). The CI and PI will be unblinded and will know the allocation status of the participants; however, both the RA and statistician will be blind to randomisation status. Participants will be instructed in their letter that randomisation status is confidential and unblinding of the RA will occur after the 12 month follow up data collection point. The statistician will remain blinded throughout the analysis.

One aim of this feasibility study is to examine participants' willingness to be randomised to either ACT or support group.

Trial procedures

Support group (control): The support group comprises attendance of 10 consecutive weeks of 90-minute support groups over 3 months (one session per week for 10 weeks), led by a psychologist trained in bariatric psychological support. The groups will consist of 15 patients and will follow an unstructured outline allowing patients to talk about their difficulties in a minimally facilitated way. If patients request specific advice, self-help guidance, signposting to appropriate sources of help and onward referral to specialist services will be provided by the psychologist.

ACT group (intervention): The ACT arm of the study comprises attendance of 10 consecutive weeks of 90-minute workshops over 3 months (one session per week for 10 weeks), led by a psychologist trained in bariatric psychological support and ACT. The groups will consist of 15 patients and will follow a structured outline exploring the following three components in an interactive way:

1. Achieving values clarity and committing to values-linked behavioural goals (e.g. to be a fit and healthy grandparent vs to lose weight), with the underlying concept that lasting behaviour change is facilitated by internalizing values for change and accepting responsibility for autonomous regulation of behaviours.
2. Achieving metacognitive awareness (e.g. bringing unconscious processes governing behaviour into awareness, to allow better understanding and responses to cues that usually result in over-eating or sedentary behaviour). In certain vulnerable individuals, where there is "hedonic hunger" or craving for palatable foods in the absence of physiological need, eating-related decisions need to be guided by factors other than or in addition to hunger and fullness.
3. Achieving the ability to tolerate experiential distress and reduction in pleasure: The degree to which one accepts versus strives to avoid negative experiences associated with a healthy lifestyle (e.g. sweating, tiredness with exercise, and feelings of deprivation and negative affect when not acting on a craving) is a robust predictor of health and psychological outcomes (e.g., binge eating, alcohol abuse and smoking). Successful self-control requires an ability not just to tolerate distress, but also the ability to accept a state that is predicted/perceived to be less hedonically pleasurable than an alternative state.

The psychologist conducting the ACT intervention will be trained in its delivery and all facilitators (intervention and control) will be supervised by the study team (CI and PI) in weekly debriefing sessions to ensure treatment fidelity. A sample of sessions will be observed by the CI and PI to further assess for fidelity and deviations from the framework will be redirected. A standardised ACT treatment manual will be used to ensure replicability of the intervention.

The ACT group (intervention) and support group (control) will be run from the same venue and will be at the same time of day but on a different day weekly. Each treatment arm will be provided by a different individual: Intervention=psychologist; Control=psychologist or nurse with supervision.

Trial assessments:
Baseline data - This will be collected in clinic from all participants (control and intervention) recruited to the trial by the RA one week before the intervention commences. It will involve the participant answering demographic and medical history questions (age, sex, work status, educational level, ethnicity, literacy level, marital status, number of dependents diagnosis, current or past psychological therapy and medications used), as well as the battery of questionnaires (see 'long term follow-up assessments'). Questionnaires will be self-completed, with the RA available to assist where necessary. Qualitative data will be recorded by responding in writing to the open-ended question, "What are the values by which you live your life?" Weight will also be recorded at baseline. The baseline assessment is expected to take no longer than 1.5 hours.

3 and 6 month follow up data - This will be collected from all participants over the telephone by the RA and will involve the participant answering the standard battery of questionnaires and the qualitative component "What are the values by which you live your life?" Participants will be mailed the questionnaires for completion 2 weeks prior to the telephone call, and answers will be relayed over the telephone. Each participant will be contacted, either via email or telephone, preceding the questionnaires being mailed to ensure they are informed of this and to schedule a convenient time to obtain the data. The 3 and 6 month follow up are expected to take no longer than 1 hour to complete.

12 month follow up data - This will be collected from all participants at the routine follow up clinic and, in addition to recording weight, will involve the standard battery of questionnaires and the qualitative component "What are the values by which you live your life?" A semi-structured interview using a topic guide will additionally be used at this time point with 12 research participants to get information about their experience of the study. This is yet to be developed as it will be informed by the study and intervention process, observations made by the PI, CI, RA, study psychologists, participants, and PPI collaborators. It will last approximately 1 hour and interviews will be audio recorded and transcribed for qualitative analysis. Participants will also be asked to rate their satisfaction with the intervention or support group on a visual analogue scale.

The trialists will also record recruitment rates, the number of participants at each stage of the study (i.e. at follow up data collection points and at each session), reasons for attrition, randomisation errors, researcher appraisal of randomisation status for each participant and missing data for outcome measures at each time point. The time taken for assessment at baseline and each follow up point will also be recorded.

Data collection:
Baseline data - Demographic information and self-reported medical history, weight and questionnaire data will be collected at a baseline visit 1 week before the intervention commences. Specifically, this includes:
1. Age, sex, work status, educational level, ethnicity, literacy level, marital status, number of dependents, medical history, diagnosis, current or past psychological therapy and medications used. This will be collected to enable characterisation of our sample and test for homogeneity
2. The time taken to complete baseline assessment will be recorded to help inform the full RCT
3. The King's Obesity Criteria can capture health problems related to obesity and health benefits

after weight loss. It is a reproducible scoring system and may help shift the focus of patients and clinicians from weight loss to health gain
4. The International Physical Activity Questionnaire has acceptable measurement properties for use in many settings and is suitable for national population-based prevalence studies of participation in physical activity. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health–related physical activity
5. The Automated Self-Administered 24-hr Dietary Recall (ASA-24) is a web-based tool that enables multiple, automatically coded, self-administered 24-hour recalls. 24-hour dietary recalls provide high-quality dietary intake data with minimal bias
6. The Brief Mediterranean Diet Questionnaire
7. Client Service Receipt Inventory (CSRI) collects information on service utilisation, income, accommodation and other cost-related variables to allow resource use patterns to be described and support costs to be estimated using an appropriate unit cost
8. EQ-5D is one of the most commonly used generic health status measurement, and its good validity and reliability have been reported in various health conditions
9. ICECAP-A: Unlike most profile measures used in economic evaluations, the ICECAP-A focuses on wellbeing defined in a broader sense, rather than health. The measure covers attributes of wellbeing that were found to be important to adults in the UK
10. The Hospital Anxiety and Depression Scale (HADS) is a tool for the detection of anxiety and depression in people with physical health problems
11. The Distress Tolerance Scale (DTS) is aimed at measuring the perceived capacity to tolerate distress. Specifically, persons with low levels of distress tolerance may be particularly prone to pursuit of negative reinforcement opportunities to escape/avoid or reduce distressing experiential states
12. The Philadelphia Mindfulness Scale is a self-report measure designed to assess mindfulness, and its two key constituents: present-moment awareness and nonjudgmental acceptance
13. The Drexel Defusion Scale (DDS) measures the ability to achieve psychological distance from internal experiences such as thoughts and feelings and has previously been associated with improvements in psychological functioning for patients receiving ACT
14. The Physical Activity Acceptance Questionnaire (PAAQ) measures the degree to which a person avoids exercise-related internal experience
15. The Food Acceptance and Action Questionnaire (FAAQ) measures the degree to which a person avoids food-related internal experiences
16. The Alcohol Use Disorders Identification Test (AUDIT) was developed by the World Health Organization (WHO) and is the gold standard test for identifying hazardous and harmful patterns of alcohol consumption
17. Dutch Eating Behaviour Questionnaire (DEBQ) was developed to assess three distinct eating behaviors in adults: (1) emotional eating, (2) external eating, and (3) restrained eating, with higher scores indicating greater endorsement of the eating behavior

Long term follow up data - All participants will be followed up 3, 6, and 12 months post-baseline. From point of consenting to completion of the final assessment, participants will be active in the study for a total of 12 months.

Under the routine care framework, patients are followed up approximately 2 years post-surgery before being discharged from bariatric services. This timepoint will coincide with the study's 12 month follow up assessment. The 3 and 6 month follow up assessments will be in addition to any routine care usually received.

To retain participants, the 3 and 6 month follow up assessments will be conducted via telephone to eliminate undue burden of returning to clinic, and will take approximately 1 hour to complete.

Participants will only be required to attend for the 12 month follow up visit as this forms part of their routine care. The following battery of questionnaires will be self-reported at 3, 6, and 12 month follow up:
1. The Kings Obesity Criteria
2. The International Physical Activity Questionnaire
3. The Automated Self-Administered 24-hr Dietary Recall
4. The Brief Mediterranean Diet Questionnaire
5. Client Service Receipt Inventory
6. EQ-5D
7. ICECAP-A
8. The Hospital Anxiety and Depression Scale
9. The Distress Tolerance Scale
10. The Philadelphia Mindfulness Scale
11. The Drexel Defusion Scale
12. The Physical Activity Acceptance Questionnaire
13. The Food Acceptance and Action Questionnaire
14. The Alcohol Use Disorders Identification Test
15. Dutch Eating Behaviour Questionnaire

Weight will also be recorded at 12 month follow up. If participants do not attend for the 12 month follow up, they will be contacted and asked to complete the assessment via telephone, and to provide a self-report of their weight. The ACT intervention itself does not require any extra level of participation than the routine care pathway (10 group sessions of manualised ACT versus 10 sessions of unstructured support group (usual care) over 3 months). As this is a feasibility study, and no power calculation has been used to determine the sample size, loss to follow up will only serve to inform the design of the definitive RCT. Should rate of recruitment present problems, the Chelsea and Westminster weight loss surgery service will be invited to participate, and this will form a point for consideration when designing the full trial.

The number of participants at each stage of the study (i.e. at follow up data collection points and at each session), reasons for attrition, randomisation errors, researcher appraisal of randomisation status for each participant, missing data for outcome measures at each time point, and the time taken for assessment at baseline and each follow up point will also be recorded.

Statistics and data analysis

Progression criteria:
Recruitment will be considered satisfactory if 70% of the target is achieved. If <40% is achieved we will then consider what changes to the recruitment strategy should be made for a full trial. If <20% are recruited we would not progress to a full RCT. Outcome measures with >20% missing data will not be used in a full trial. Process measures for the full trial will be selected if exploratory analyses indicate movement in the hypothesised direction. Study and intervention procedures which are identified as problematic through our qualitative work will be altered accordingly for a main trial. The intervention manual will be amended informed by findings of our qualitative work and in collaboration with our PPI collaborators.

Data analysis:
An analysis plan will be devised before data collection. Since this is a feasibility trial, the main analyses will be descriptive and provide estimates of variability. This will include the rate of recruitment, the proportion of approached people who consent to randomisation, the proportion who complete all 10 sessions, and the proportion who complete the FU sessions. An

attrition table and Consort flow diagram will be produced at study close-out and we will also explore factors associated with consenting or non-consenting. The distribution of data on the outcomes and estimated variance of these measures in this population will be described. Further analyses will explore the impact of the intervention on patients' weight and psychological /behavioural outcomes. We will also conduct a cost-consequence analysis looking at the potential impact of the intervention on cost and health outcomes from an NHS perspective.

All participants randomised, whether they received the study intervention or not, will be subject to data analysis. If capacity is lost, only data collected when capacity was deemed present will be used.

Ethical considerations
Participants may withdraw from the study at any time, without giving any reason and without their care being affected. Any participant thought to be suicidal, either by the researchers (as assessed on depression questionnaires), or by the clinician delivering the intervention will be referred immediately to the psychiatrist overseeing the study. Research staff will have training and regular supervision by clinical staff on how to manage participants demonstrating suicidal tendencies/ideation.

Project Management Group
The project management group, consisting of the Chief Investigator, Principle Investigator (clinical lead), Research Associate, Health Economist, and the Statistician will be responsible for the overall governance and operational management of the trail, specifically aspects such as recruitment and retention, and ensuring timeline targets are met.

Project Advisory Group
The Project Advisory Group will provide an independent review of study progress. It will consist of all members of the Project Management Group and will be co-chaired by a patient representative and advocate who runs the London support group for the patient-led charity BOSPA (The British Obesity Surgery Patient Association) and a post-operative patient, who will provide first-hand insight into the design and development of the trial. The group will meet on at least four occasions throughout the course of the study and members of the group will be invited to:
1. Provide comments and suggestions on the overall study design prior to the start of data collection.
2. Help members of the Project Management Group develop the PIS.
3. Contribute to the development of the topic guide for qualitative interviews.
4. Comment on a draft version of the full study report.
5. Take a lead on writing the project summary that will be sent to all study participants at the end of the trial.

Members of the group will be offered an opportunity to make a contribution to other aspects of the dissemination strategy including the development and design of a subsequent definitive study of this intervention. The team will also provide blogs (e.g. for the charity/support groups) and attend science outreach events suggested by our PPI advisors/service users.

Intervention Type
Behavioural

Primary outcome measure
The primary aim of this study is to establish the feasibility of a definitive RCT of the effectiveness of ACT for preventing weight regain in post-bariatric surgery patients. Outcomes

to be assessed are:
1. The willingness of participants to be randomised. This will be assessed using the number of eligible participants minus the number of patients who agree to randomisation (measured at screening)
2. The number of eligible patients coming through clinic. This will be assessed by calculating the percentage of patients who meet eligibility criteria (measured at baseline)
3. Recruitment and completion rates, follow-up rates, response rates to questionnaires, adherence/compliance rates to the intervention and trial procedures. This will be assessed by the number of participants who consent to participate and who remain in the study until 12 month follow-up, the number of participants who provide complete datasets, and the number of participants who attend all 10 sessions of intervention/support group. Reasons for attrition will also be recorded
4. Time needed to collect data. This will be assessed by how long it takes participants to complete the battery of questionnaires at each time point (measured at baseline, 3, 6 and 12 month follow-up)
5. The acceptability of the intervention to participants. This will be assessed by a visual analogue scale (measured at 12 month follow-up)
6. The standard deviation of potential outcome measures for a future trial (to estimate the required sample size for a future trial) (measured at study close-out)
7. Information to inform the undertaking of an economic evaluation in the definitive RCT and to pilot the data collection methods. This will be assessed by calculating the cost of the intervention and examining data on patients' resource use on the CSRI (measured at study close-out)

Secondary outcome measures

The measures that will be evaluated within this feasibility study are as follows:

MEASURES TO TEST THE PROCESS OF THE ACT INTERVENTION:
1. The ability to tolerate distress measured by the Distress Tolerance Scale at baseline, 3, 6, & 12 month follow-up
2. Present moment awareness and acceptance measured by the Philadelphia Mindfulness Scale at baseline, 3, 6 & 12 month follow-up
3. Experiential distancing measured by the Drexel Defusion Scale at baseline, 3, 6 & 12 month follow-up
4. The extent to which an individual is able to accept or tolerate physical or psychological discomfort, measured by the Physical Activity Acceptance Questionnaire at baseline, 3, 6 & 12 month follow-up
5. Acceptance of food related thoughts and urges measured by the Food Acceptance and Action Questionnaire at baseline, 3, 6 & 12 month follow-up

OBESITY AND HEALTH OUTCOMES:
1. Class of obesity measured by the Kings Obesity Criteria at baseline and 12 month follow-up
2. Levels of physical activity measured by the International Physical Activity Questionnaire at baseline, 3, 6 & 12 month follow-up
3. Food intake measured by the Automated Self-Administered 24-hr Dietary Recall at baseline, 3, 6 & 12 month follow-up
4. Adherence to a Mediterranean diet measured by the Brief Mediterranean Diet Questionnaire at baseline, 3, 6 & 12 month follow-up
5. Level of risk to alcohol harm measured by the Alcohol Use Disorders Identification Test at baseline, 3, 6 & 12 month follow-up
6. Eating behaviour, in terms of restrained, emotional, and external eating, measured by the Dutch Eating Behaviour Questionnaire at baseline, 3, 6 & 12 month follow-up

WELLBEING OUTCOMES:
1. Levels of anxiety and depression measured by the Hospital Anxiety and Depression Scale at baseline, 3, 6 & 12 month follow-up

HEALTH ECONOMIC OUTCOMES:
1. Service utilisation, income, accommodation and other cost-related variables measured by the Client Service Receipt Inventory at baseline, 3, 6 & 12 month follow-up
2. Health-related quality of life measured by the EQ-5D at baseline, 3, 6 & 12 month follow-up
3. Capability wellbeing measured by the ICECAP-A at baseline, 3, 6 & 12 month follow-up

Overall study start date
01/05/2018

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Adults (aged 18 or over) who have undergone bariatric surgery >1 year ago and have given their consent for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 58; UK Sample Size: 58

Total final enrolment
80

Key exclusion criteria
1. Suicidal ideation (score of > 0 on Question 9, PHQ-9)
2. Inability to communicate in English as the intervention is delivered in English
3. Inability to commit to attendance to 10 sessions

Date of first enrolment
21/09/2018

Date of final enrolment

25/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial Weight Centre
Paterson Centre
St Mary’s Hospital
Praed Street
London
United Kingdom
W2 1NY

Sponsor information

Organisation
West London Mental Health NHS Trust

Sponsor details
Trust Headquarters
St Bernard's Hospital
Uxbridge Road
Southall
England
United Kingdom
UB1 3EU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fgy3p67

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20012

Results and Publications

Publication and dissemination plan

Project outputs will include a full report, articles for peer review journals, and summary reports for various stakeholders, including user organisations such as BOSPA. Data will be owned by the PI of the study and papers will be prepared by the immediate research team for publication in peer reviewed scientific journals in endocrine medicine, obesity, psychology, psychiatry and lay journals and press aimed at obese people in Year 3 (January 2021) onwards. West London Mental Health Trust and the National Institute for Health Research will be acknowledged for their research support and funding contributions, and a summary of findings will be available for research participants and relevant organisations on the research registry database (www.researchregistry.com, UIN No. 3959). Progress reports and results of the study will be made available on the internet through appropriate websites such as web pages at the University of West London, West London Mental Health Trust, and Imperial College Healthcare NHS Trust. The trialists will also present findings from the project at local, national and international meetings. At a local level they will convene a seminar open to the study team, participants and other interested clinicians to discuss study findings. At a national and international level they will present study findings and submit proposals for symposia at psychology, psychiatry and obesity conferences, e.g. the European Health Psychology Society and British Psychological Society Division of Health Psychology Conference, the annual meeting of the Royal College of Psychiatrists, the International Federation for the surgery of obesity and metabolic disorders (IFSO) annual conference, and meetings of the SCOPE school for obesity and the Society for Endocrinology (SFE).

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Elizabeth Barley (e.barley@surrey.ac.uk). Anonymised questionnaire scores will be available for 5 years after the main results of the study have been published. The researchers will aim to make data available to the scientific community with as few restrictions as feasible; data will be shared following review of requests by the principal investigator.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/10/2019	03/06/2020	Yes	No
Results article	results	25/04/2023	27/04/2023	Yes	No
HRA research summary			28/06/2023	No	No

Dataset	Dataset: FAB_fulldata_26SEP2022. (CSV)	18/09 /2024	No	No
Dataset	Questionnaire data. (PDF)	18/09 /2024	No	No