Polyvagal Informed Group Skills Training for Body Awareness and Managing Emotions for People Living with Obesity

Study Protocol and Statistical Analysis Plan

29th of October 2025

Study Protocol and Plan of Investigation

Participants:

The participants will be patients from Ashford and St Peter's NHS Specialist Weight Management Service. The sample size will be 10 participants as this provides enough data points, allowing for 50% drop out, to ensure the study meets the What Works Clearinghouse standards, which set out to assess the quality of single-case experimental designs. What Works Clearinghouse state that for multiple baseline studies to meet their 'standards with reservation' there must be least three data points per phase and a minimum of three phase repetitions (WWC, 2022). The participants will be identified and approached by the clinical team during routine clinical contact and if the patient is interested in taking part, consent to share their details with the research team will be gained. Participants will be informed on the nature of the intervention and provided with a video and information sheet explaining what the group will involve so they are able to decide if they wish to take part. Participants will complete the University of Rhode Island Change Assessment (URICA) to identify their stage of change (Pre-contemplation, Contemplation, Action or Maintenance) before taking part and those in the pre-contemplation stage will not be included. Participants will be informed of this beforehand and a rationale provided.

Inclusion criteria:

- Current service user of Specialist Weight Management Programme (BMI of 40kg/m2 or more, or between 35 kg/m2 and 40kg/m2 or greater in the presence of other significant comorbidities).
- Ages 18-65.
- Good level of English spoken reading and writing.
- Identified by the URICA to be in the Contemplation, Action or Maintenance stage of change.
- Access to device with internet connection to complete online questionnaires and with camera for online group sessions.

Exclusion criteria:

- Identified by the URICA to be in Pre-contemplation stage of change
- Currently in psychological therapy treatment during the 19-week study period
- History of organic brain injury or cognitive impairment
- Clients presenting with suicidal intent

Design:

This study will be a quantitative multiple baseline study using a within-subjects' single case experimental design. The study will take place over three phases; the baseline phase, the intervention phase and the follow-up phase. For the baseline phase, participants will be randomly allocated a baseline period of either or 14, or 21 days using an online random number generator and the intervention phase will start immediately after the individual's baseline period ends. The intervention phase is the polyvagal theory-informed therapy group intervention that will take place over six sessions. Outcomes will be compared at the same stages across participants. The intervention effect will be measured through three daily visual analogue scales and two weekly standardised measures. A four-week follow-up period will take place after the intervention. Participants will complete outcome measures throughout all phases.

Measures:

University of Rhode Island Change Assessment

Participants will complete the University of Rhode Island Change Assessment (URICA) as part of the screening process. The URICA demonstrates strong internal consistency, with coefficient alphas ranging from 0.79 to 0.89 across its four subscales, even in follow-up studies (Andrés et al., 2011). It has proven reliable with strong construct validity and psychometric properties across various behavioural conditions and factor and cluster analyses support its construct validity (McConnaughy et al., 1989). The URICA has been effectively applied to obesity, diet, and weight management (Prochaska et al., 1992).

Difficulties in Emotion Regulation Questionnaire

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) will be completed weekly. It is a 36-item self-report questionnaire assessing six domains: nonacceptance of emotional responses (α = .85), difficulty with goal-directed behaviour (α = .89), impulsive behaviour control (α = .86), emotional awareness (α = .80), access to regulation strategies (α = .88), and emotional clarity (α = .84). It demonstrates good test–retest reliability and adequate construct and predictive validity (Gratz & Tull, 2010) and is sensitive to change in interventions targeting emotion regulation (Gratz et al., 2014; 2015).

Multidimensional Assessment of Interoceptive Awareness

Multidimensional Assessment of Interoceptive Awareness (MAIA-2; Mehling et al., 2018) will be completed weekly and assesses eight aspects of interoceptive awareness through a self-report including noticing (a=.64), not distracting (α =.74), not worrying (α =.67), attention regulation (a=.83), 76 emotional awareness (α =.79), self-regulation (α =.79), body listening

(α =.80) and trust (α =.83). The MAIA has been used in obese populations (Willem et al., 2021).

Visual Analogue Scales

Visual Analogue Scales (VAS) will be the primary outcome measures for the number of skills practised (to measure homework completion), body awareness, emotion regulation and a frequency count of an emotion regulation behaviour (such as emotional eating). These are often used within single-case experimental designs as they can be tailored to fit the investigation and allow for capturing an individual's unique experience (Chalkley, 2015; Morley, 2017). These measures will be completed daily and ask participants to respond to the three questions on a scale of 0 to 20.

Acceptability

To measure if this intervention is acceptable participants will complete a 'Client Feedback Form' once at the end of the intervention phase. This is designed based on Sekhon et al.'s (2018) theoretical framework of acceptability (TFA) for health interventions, where the generic TFA-based questionnaire (Sekhon et al., 2022) will be adapted to ensure suitability for the intervention.

Predictions and planned analyses:

Visual Analogue Scales

The hypothesis is that Visual Analogue Scales scores on emotion regulation will increase and emotional eating will decrease compared to baseline. This hypothesis will be tested using visual analysis, followed by Tau-U and then testing for reliable change (RC) and clinically significant change (CSC).

DERS and MAIA-2

It is hypothesised participants will report increased interoception and decreased emotion dysregulation after completing the group intervention. This will be analysed by assessing reliable change (RC) and clinically significant change (CSC).

Homework completion

The hypothesis that homework completion will predict outcomes whereby greater frequency of homework completion will be associated with greater body awareness and emotion regulation and decreased emotional eating will best be tested using multiple linear regression.

University of Rhode Island Change Assessment (URICA)
A post-hoc analysis will test the hypothesis that the participant's stage of change predicts the intervention outcomes and this is mediated by engagement. This will be analysed using regression mediation analysis.

Acceptability
Descriptive statistics will be calculated for the individual items on the acceptability questionnaire and a general acceptability score will be calculated and any qualitative data collected regarding the experience of the intervention will be included in the final report.

Setting and procedures:
Participants will be asked to commit to a study lasting up to 19 weeks, consisting of three phases: baseline, group intervention and follow-up. The study will take place virtually, where questionnaires will be completed online and the group intervention will take place on an online video platform.

Before starting the study, participants will complete the two one-off brief questionnaires (demographics questionnaire and University of Rhode Island Change Assessment). Participants will be randomly assigned a baseline period of 14 or 21 days. Participants will complete a brief daily questionnaire (four-question Visual Analog Scale) on skills practice, emotional regulation, body awareness and frequency of a chosen behaviour and complete two short online questionnaires weekly that take up to 15 minutes to complete (Difficulties in Emotion Regulation questionnaire, Multidimensional Assessment of Interoceptive Awareness- Version 2).

Participants will take part in a six-session group skills training intervention with a trainee clinical psychologist and qualified clinical psychologist under the supervision of the PVTT manual creator via video call, scheduled fortnightly over a 9-week period. Each session will be two hours long. This will be Polyvagal Theory Informed Therapy (PVTT) and will focus on understanding the autonomic nervous system and learning techniques to enhance body awareness and manage emotions, such as breathing exercises. The content of the sessions will include: introduction to polyvagal theory; application of polyvagal theory to client's difficulties; mapping on the polyvagal ladder; exercises to regulate up the ladder; practicing exercises and mapping on the ladder and summarising and therapy blueprint. Participants will be asked to practice techniques in sessions and applied independently between sessions with the chance to feedback on the application of ideas and techniques each

session. Participants will be contacted via mobile phone or email to remind them of the group appointment and to complete daily and weekly questionnaires.

After participants have completed the group intervention, during the four-week follow-up phase, participants will complete a feedback form that will be used to assess the acceptability of the group. During this phase, participants will continue practicing learned techniques and continue to complete the daily and weekly questionnaires.

Ethical considerations

Informed consent

Participants will be fully informed about the study's purpose, procedures, potential risks, and benefits and a participant information sheet will be provided, outlining the study requirements and procedure. As participation in this research provides a significant time commitment and a high level of engagement, to ensure transparency and integrity, the expectations will be outlined within the information sheet but also explained to the participant verbally and a video will be created to accurately promote the group intervention so all participants know beforehand what they can expect and if the group intervention is suitable for them. Participants will be asked for their informed consent by ticking boxes to confirm that they have read and understood the information with the opportunity to ask questions.

Right to withdraw

Participants will be made aware that involvement will be voluntary and that they are able to withdraw their consent at any stage without justification and it will not affect the care they receive.

Confidentiality and Data Protection

Participant's data will be anonymised; each participant will be allocated a participant ID and all data will be recorded using this ID and electronic data files will only include this number (no names or other identifying information). All data will be stored on secure University and NHS systems and will be password protected. Only the research team will have access to this data. Data will be stored securely for ten years after the completion of my degree. All the data will be destroyed after this time. The clinical team at Ashford and St Peters Hospital will be informed of the patient's participation and participants will be informed that it is routine practice for information about risk of harm to be shared with their clinical team and potentially other services such as their GP or A&E.

Risk of psychological harm

There is a risk that the content of the group intervention and completing the questionnaires may bring up difficult emotions or feel uncomfortable for participants who will be asked to pay attention to bodily and emotional states, particularly for individuals with trauma histories. The group aims to create a safe space and provides psychoeducation and tools to manage difficult emotional experiences and takes a trauma-informed approach. The intervention focuses on the patients' current experiences rather than their past and any distress that arises during the group will be managed by the group facilitators. Clinical supervision will be provided to discuss and respond to any issues arising in the group or between participants. All patients will be under the care of Ashford and St Peters Specialist Weight Management Service where their established safeguarding and risk protocol will be followed and patients will have access to appropriate support and signposting if needed. As part of the informed consent, we will provide a participant information sheet which includes information on the possible. A full debrief will be provided at the end of the study which will include signposting to further support. Additionally, we will take steps to ensure the intervention is inclusive and consider whether all participants, regardless of socioeconomic background, disability, or cultural differences, can equally benefit.

Lay Summary and Flow Chart

Study title: Group skills training for body awareness and managing emotions for people living with obesity

People living with obesity may find it difficult to notice and cope with emotions. This can lead to unhelpful ways of coping such as emotional eating or other unwanted behaviours. Previous research has shown that psychological skills training, delivered in group settings can help people manage emotions.

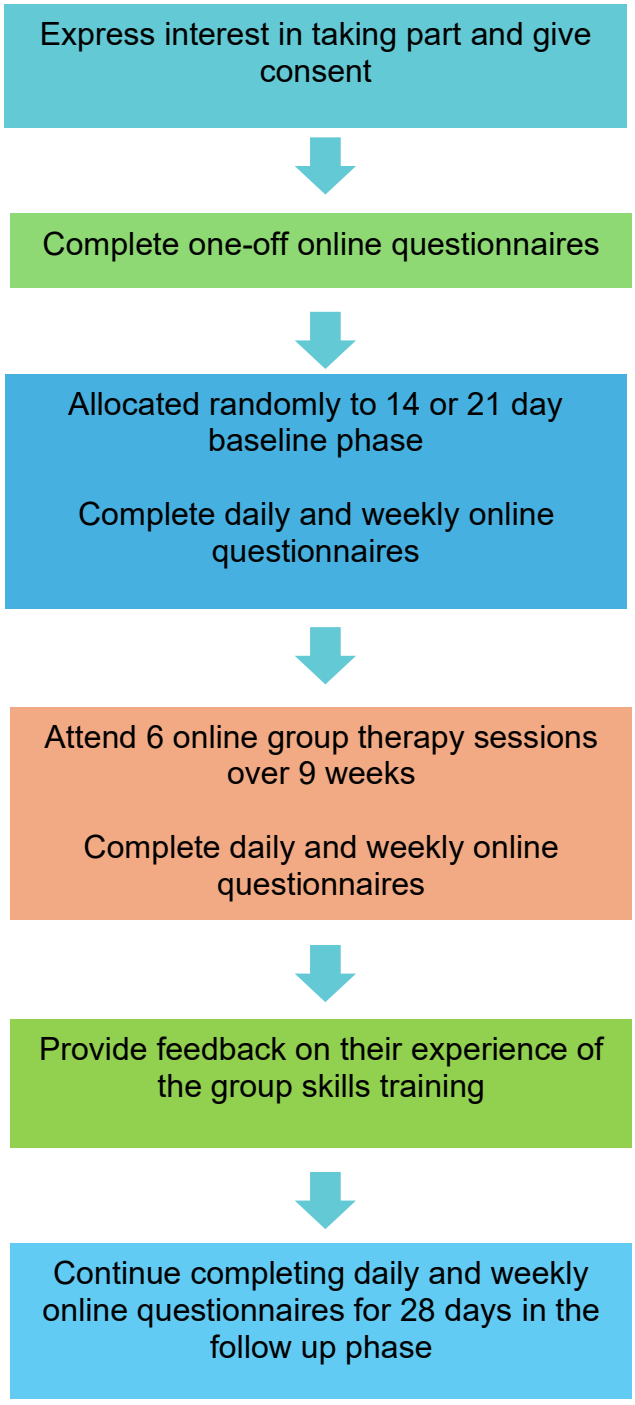
However, these therapies overlook the role the body plays in emotional experience. The autonomic nervous system (ANS) is the system in the body that makes you feel calm, frightened, or numb. It is the ANS that starts your heart beating fast, makes you shake or breath fast when you are annoyed or anxious. It also makes you feel calm, content, and safe. It picks up on things inside your body and the outside world. It can do this so quickly that sometimes you won't even have noticed what has set it off.

The ANS is always looking for threat, especially if difficult things have happened to you in the past. It is really good at jumping to a conclusion from only a small amount of information, deciding there's threat and triggering a response in your body so that it can help keep you safe. Many people, including people living with obesity may not be aware of what is happening in their bodies. They have become disconnected from the body's signals. The problem isn't that your ANS changes what is going on in your body, rather it is that you are out of the habit of monitoring your bodily sensations and/or that you don't have enough ways of changing how you feel. By knowing what is going on in our bodies we have more choice as we can decide how to manage the emotion we are experiencing.

In this study, we are looking to see whether using this understanding of the ANS can provide a unique benefit. The group skills training aims to help people notice what their ANS and body is doing so they can choose how to manage their emotions

The flow diagram summarises what will happen to participants in the study and is followed by a more detailed description.

NHS
Ashford and St. Peter's Hospitals
NHS Foundation Trust



Participants will be asked to commit to the overall study for up to 16 weeks. There are three phases to the study: baseline, group skills training intervention and follow-up. Before beginning the baseline phase, participants will complete a questionnaire that assesses their readiness to make changes in their lives. They will be encouraged to consider potential changes in their ability to notice and respond to bodily sensations and emotions, as well as behavioural changes. For example, some individuals may wish to reduce emotional eating. This questionnaire will provide information about which 'stage of change' they may be in. This will be discussed with them before and after completing the questionnaire, as it may be determined that now is not the right time to engage in this group intervention due to the high level of commitment and focus on change.

During all three phases, participants will complete a daily questionnaire that contains four questions about body awareness, emotional awareness, a behaviour they would like to change and how frequently they are practicing the skills learned in the group intervention. These daily questionnaires take less than five minutes to complete.

Additionally, during all three phases, participants will complete two short questionnaires once a week. These questionnaires assess their awareness of their body and ability to manage emotions and take approximately 15 minutes each week. All questionnaires will be completed online.

Participants will be randomly allocated to a baseline period of 14 or 21 days, assigned using a computer random number generator, ensuring equal chances of being placed in any of the three baseline lengths. The overall study length and commitment required will depend on the baseline length assigned. No skills training skills training will be provided during the baseline phase. During this period, participants will complete daily and weekly questionnaires to help researchers understand their usual state before any treatment begins.

Following the baseline phase, participants will begin the group skills training phase, during which they will attend six online group skills training sessions over nine weeks. The group skills training sessions will help participants understand how the autonomic nervous system (ANS) functions and teach techniques to increase body awareness and manage emotions. One example is breathing exercises. These techniques will be practised together during the sessions, and participants will continue practising them outside of sessions.

After completing the six group sessions, participants will fill out a feedback form about their experience with the skills training. This feedback will help refine the intervention to make it more relevant and user-friendly for future patients.

Finally, in the follow-up phase, participants will be invited to continue practising the techniques independently while continuing to complete daily and weekly measures for four weeks. This will help researchers determine whether the effects of the skills training are maintained over time.

The Gantt Chart below summarises the measures the participants will complete in each phase.