Addressing Body Image in Weight Management: An Overlooked Risk Factor for Poor Treatment Outcome Among Women

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<u>AIM 1 (ORBIT Phase Ib</u>*)* Modify Body Project (BP) content to more powerfully target Weight and Shape Concern (WSC) among women with overweight or obesity using exploratory sequential mixed methodology.

Procedure Before administering, the BP manual will be revised to address weight-related stigma. Then, in iterative revisions the modified BP (mBP) will be refined through testing with small groups of individuals (n≤10) in 4-6 iterations. The goal of this phase is to understand how women with overweight/obesity and High WSC experience the intervention components using a sequential mixed methodology approach. Participants will complete a quantitative assessment before the first session and after receiving all four weekly (60 minute) mBP sessions. The data collected from these assessments will be used to inform the development of the focus group/qualitative guide which will be administered after the intervention has been delivered. Results of each focus group will be used to guide revision of the manual prior to the next group.

Recruitment and initial screening: Potential participants will contact the research team using the designated phone number and/or email address provided on recruitment materials or by completing the online screening survey via RedCap (HIPAA compliant software for delivering surveys electronically). If potential participants contact the research team, research staff will set a time to call interested individuals to introduce the study briefly and secure permission to send an email with a link to a confidential survey to assess initial eligibility. If participants are unavailable for a phone call, the language from the screening script will be sent via email with the link to the screening survey. Upon completion of the screening procedures, individuals who are deemed eligible based on the screening survey will be contacted to complete the orientation and to sign the consent form.

Orientation and Consent: Eligible individuals based on initial screening will be contacted to schedule a 60-minute orientation with study staff. This meeting will be conducted remotely via video conferencing. A secure, HIPAA-compliant platform will be used for all study activities that are transitioned from in-person to remote format. Examples of a platform for video conferencing that would meet these guidelines include Zoom, Webex. At this time, individuals will be provided with a thorough description of study procedures. Individuals who want to continue will review the consent form with study staff and complete the remote consent procedures.

Study onboarding: After the consent form has been completed and the study staff receive confirmation via RedCap that the consent form transmitted successfully, the staff will finish orienting the participant. Study staff will review important dates with the participant, review expectations for participation in the group meetings via online platform, and guide setup of the LifeData application on the participant's smart phone.

<u>The Modified-Body Project intervention--</u> The original intervention is described below but it will be modified to increase appropriateness, acceptability, and efficacy for adult women who would medically benefit from weight loss. The original structure and content are described below and will provide the core framework and consistent with approaches to adapting evidence-based treatment, the active ingredients will remain the same while modifying content and assignments or exercises to enhance effects among our target population. Key changes include expanding content to address contextual factors that cause negative weight/shape-related thoughts among women with overweight or obesity and to target weight stigma (internalized and experienced), modifying exercises that were reviewed negatively, and incorporating explicit discussion of weight management.

Original Content.

Session 1: The goal of this session is to help women define the thin ideal beauty standard, to differentiate it from a healthy standard, and to explore the costs of pursuing unrealistic beauty standards. Discussion also focuses on who benefits from perpetuating these ideals.

Session 2: The goal of this session is to begin generating arguments against the thin ideal. Role play is used to help participants immerse themselves in this new way of thinking.

Session 3: This session elaborates on session 2 by continuing to practice ways to discourage pro-thin ideal statements and messages within daily life. Individuals are encouraged to think about and share their own

motivations for improving body image and to explore ways that they behaviorally reinforce or subscribe to thin ideal standards (e.g., avoiding mirrors or having photo taken, avoiding swimsuits or certain types of clothing)

Session 4: The last session of the intervention reviews benefits of improving body image, review of experience in the program, and a challenge to identify concrete ways to continue working on body image/undermining thin ideal messages outside of group meetings.

Format. The Body Project consists of four weekly, in-person meetings lasting approximately one-hour. The ideal group size is between 5-10 individuals so that there can be group discussion with a variety of perspectives but few enough individuals so that all participants can contribute and participate in discussion. A group-leader is in charge of delivering all content in accordance with the treatment manual which includes educational components, group discussion, and interactive activities to practice new skills. The protocol is a dissonance-based group intervention developed to decrease internalization of the thin ideal, improve body image, and decrease risk of eating pathology among adolescent females at-risk for eating disorder pathology.

Format modifications for remote delivery: Group meetings will be conducted remotely to reduce face-to-face contact and potential COVID-19 exposure. A secure, HIPAA-compliant platform will be used (examples of a platform for video conferencing that would meet these guidelines include Zoom, Webex). Participants will be required to use a tablet or laptop/desktop computer where all participants in the group are visible (i.e., participants will not be able to use their smartphones because all participant faces cannot be displayed and viewed at the same time), to set aside time and plan ahead to minimize distraction during the group meetings, and to secure a private space for group discussion.

Quantitative measures (collected before and after the group intervention): Participants will be sent a secure link via email to complete study questionnaires via RedCap. RedCap is a HIPAA compliant tool for electronic delivery of surveys and storage of collected data. The survey will be administered 7 days prior to the first session and accompanied by an email reminder for participants to complete the survey and to prepare for the EMA assessment to begin. The survey will be re-administered via RedCap in the 7 days following the last group meeting.

- Demographic and self-reported anthropometric data will be collected including age, race, self-reported height/weight, socioeconomic status (education, employment, food insecurity).
- Weight and shape concern will be assessed with three different measures.
    - The first being the Eating Disorders Examination-Questionnaire. This self-report measure is a 28-item scale that was translated from a clinician-delivered format to assess behavioral features of eating disorders including negative body image as experienced during the past 4-weeks. All items are answered on a 0-6 point scale reflecting either frequency or severity. There are four subscales (Restraint, eating concern, weight concern, shape concern) and the latter two subscales will be used for the current study. Each subscale is comprised of 8-items and 5-items respectively. It will also be assessed with a single item taken from the Eating Disorders Assessment (During the past 6 months, has your weight or the shape of your body mattered to how you feel about yourself? Compare this to how you feel about other parts of your life—like how you get along with family and friends, and how you do at your job.)
- Internalization of the thin ideal will be assessed with the Sociocultural Attitudes Towards Appearance Questionnaire-4. The SATAQ-4 measures the degree to which an individual internalizes the societally prescribed standards of attractiveness or beauty and it includes a subscale focused on the thin ideal.
- Internalized weight bias will be assessed with the Weight Bias Internalization Scale (WBIS). The WBIS is an 11-item questionnaire designed to assess the degree to which an individual believes negative weight-related attributes or weight stigma ideas are accurate and applicable to him/herself.

Ecological Momentary Assessment protocol: participants will complete 7 days of EMA data collection before the first session of the mBP and after the last session to assess negative weight- and shape-related thoughts that occur on a momentary basis. Participants will receive 6 semi-random prompts daily between 9am and 9pm to capture patterns across the full day while also minimizing risk of reactivity which can occur when participants expect a prompt.

Negative weight and shape-related thoughts:

- Participants will be asked “Since the last prompt, how negative have your thoughts been about your body weight or your body shape?” (Participants will answer on a sliding scale ranging from 0-Not negative at all to 10-extremely negative).

Factors or cues for negative weight and shape-related thoughts:

- Next they will be asked to identify what cues in their environment contributed to the thought(s). This answer format will be open-ended to avoid biasing or limiting responses and participants will be encouraged to provide any/all clues that they encountered. This information will be critical for tailoring the intervention material to include triggers for negative weight-related thoughts that are specific to the target sample and for eliciting feedback in the focus groups.

Qualitative measures (Focus groups after treatment) will be conducted within one month of the last session of the intervention. The primary objectives are to 1) identify additional contributors to high WSC that should be incorporated into the manual, 2) assess the degree to which intervention activities achieve the goal of targeting contributors to WSC, and 3) determine the acceptability of intervention activities in regard to content, structure, and timing. A building approach to linking the quantitative and qualitative data will be used such that the quantitative data will be used to develop the focus group guide. A guide will be developed containing a series of open-ended questions designed to elicit as much information as possible from participants.

Data analysis: A sequential mixed methods approach, guided by the ORBIT Model and Framework for Reporting Adaptations and Modifications-Expanded will be used to guide manual adaptations between each group. Quantitative data (including weight and shape concern, internalized thin ideal and internalized weight bias; and ecological momentary assessment of in-the-moment weight and shape concern) will be collected before and after individuals receive the modified Body Project intervention. These data will inform the focus group script administered to participants after receiving the treatment. The qualitative data collected via focus group will be transcribed and dual coded using directed content analysis. This will be conducted using an *a priori* framework of codes developed from two sociocultural models of weight and shape concern (the Dual-pathway model and the Tripartite model). This deductive approach to analysis facilitates a more rapid assessment of qualitative data than traditional inductive approaches but also allows ideas from outside the framework to emerge and be incorporated into manual revisions. The research team will meet regularly to ensure the coding framework is reliable and valid through a discussion and consensus process. These meetings will allow for new items (data not yet coded) to be reviewed and identified as a new category or a subcategory of an existing code. Analysis will identify areas where existing models of weight and shape concern are supported, areas for extension, and to explore the influence of factors such as race and age to ensure appropriateness of the modified BP for the current sample. The qualitative data will then be integrated with quantitative data and facilitator debriefs to identify potential manual changes. Group discussion among content experts will be used to reach consensus on manual changes prior to the next cohort.