A Third-Wave Intervention for Internalized Weight Bias Combined With a Weight Loss Program Using Video Conferencing Software

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Study Protocol & Statistical Analysis

Participants

Participants will be recruited for the study using an email Listerv announcement to individuals throughout the university and associated community. Participants must indicate that they are interested in weight loss and are interested in participation for the entire program before being accepted. Other inclusion and exclusion criteria require that participants be 18 or older, at a BMI of 25 kg/m2 or greater, and are not pregnant or planning to become pregnant. Based on average scores for Durso and Latner's (2008) Weight Bias Internalization Scale and in staying consistent with Pearl, Wadden, Bach, Gruber, et al.'s (2020) research, individuals will also be screened for higher-than-average levels of IWB, with a cutoff of 4 or higher. Individuals who have already successfully lost more than 5% of their body weight within the past six months will be excluded. Individuals with current use of medication prescribed for weight loss (such as orlistat, sibutramine, or rimonabant) will also be excluded. In addition, participants must have access to internet, along with a web camera and sound, and be able to use video conferencing software and attend weekly online groups. They will also need access to a reliable scale to weigh themselves weekly.

According to an a priori analyses run using G*Power, a sample size of 40 will be required to detect a medium effect size for a 2 x 2 repeated measures analysis of variance (ANOVA; Faul et al., 2007). A medium effect size was selected for a couple of reasons. First, this is consistent with previous literature, as Pearl, Wadden, Bach, Gruber, et al. (2020) also structured their methodology on detecting a medium effect size. Second, this study aims to examine the efficacy of an intervention. However, an intervention that produces only a small effect may be

less clinically meaningful than an intervention that produces a medium or large effect size. Due to attrition concerns, the sample size for the proposed study will be 70, with 35 individuals per group.

Interventions

Diabetes Prevention Program (DPP). All participants will participate in a behavioral weight loss program (BWLP). The program will be a 12-week adapted version of the DPP. As previously mentioned, the DPP is a widely used, evidence-based program that has been found to be applicable to individuals of varied backgrounds, and has overall become the gold-standard for behavioral weight loss programs (DPP Research Group, 2002a). Several studies have found the DPP to produce statistically significant weight loss when delivered through an online format (Azar et al., 2015; Carels et al., 2021; Vadheim et al., 2010). See Appendix A for a list of session topics.

Third-Wave Based Internalized Weight Bias Intervention. ACT-based programs and self-compassion have shown promise throughout research for lowering IWB (Berman et al., 2016; Levin et al., 2018; Lillis et al., 2009; Palmeira, Cunha, & Pinto-Gouveia, 2017; Palmeira, Pinto-Gouveia, & Cunha, 2017; Forbes et al., 2020). Therefore, using techniques from prior ACT- and self-compassion based programs, a weight bias reduction intervention will be administered. Session topics will include psychoeducation, observing myths and stereotypes, and using internal and external coping for weight bias, and these topics will be viewed through a self-compassionate and ACT-based or DBT-based lens (for example, participants may defuse from internal critical thoughts rather than challenge them). Sessions will also cover acceptance, cognitive defusion, mindfulness, committed action, and self-compassion. Participants will be

asked to keep a self-compassion journal to practice third-wave and self-compassion skills and techniques. See Appendix B for a list of session topics.

Procedure

Participants will complete an initial digital screener to determine eligibility. Once it is determined that eligibility criteria are met, participants will be randomly assigned into one of two groups. Both groups will initially receive a weight loss intervention using the DPP through twelve weekly, hour long virtual sessions as led by clinical health psychology doctoral students with previous weight loss intervention experience. In addition, group leaders will look for opportunities to incorporate weight bias reduction strategies throughout the DPP when possible. However, only one group will be administered a third-wave, ACT and self-compassion-based IWB intervention for 30 minutes after the 60 minute weight loss intervention. Both groups will receive information on how to monitor eating behavior through MyFitnessPal, exercise through MyFitnessPal or smart devices, and will be encouraged to weigh themselves weekly or more. The IWB program will begin after the first four sessions of the DPP so that participants can spend the first month adjusting to weight loss treatment.

Measures

All measures will be completed at baseline and post-intervention online. Demographic information will also be collected at baseline. In addition, participant weight and height will be collected in person, using a digital scale and stadiometer, at baseline and post-intervention. If participants drop out of the study, they will be asked to complete the post-intervention surveys and attend a weigh-in, if possible.

Demographics. All participants will complete demographic questions assessing age, sex, gender, race/ethnicity, sexual orientation, income, education, and self-reported height and weight. Participants will also be asked about their desire for weight loss.

Internalized Weight Bias. IWB will be measured by both the Weight Bias Internalization Scale (WBIS; Durso & Latner, 2008; Appendix C) and Weight Self-Stigma Questionnaire (WSSQ; Lillis et al., 2010; Appendix D). Both measures were chosen for several reasons. First, Pearl, Wadden, Bach, Gruber, et al. (2020) found participant differences on the WSSQ at a 12-week assessment of IWB, but did not see a change on the WBIS. Second, while both are commonly used throughout IWB literature, some IWB interventions only used the WSSQ (Lillis et al., 2009; Palmeira, Cunha, & Pinto-Gouveia, 2017) and some only used the WBIS (Pearl, Hopkins, et al., 2018). Because this study aims to build upon previous approaches to lowering IWB, both scales will be considered to increase generalizability to all relevant past findings. Both scales have been found to be predictive of IWB, have comparable reliability convergent validity, and are strongly correlated (Hübner et al., 2016).

In 2008, Durso and Latner developed the WBIS, which was an 11-item scale used to assess IWB among populations with overweight and obesity using a 7-point Likert scale. According to the authors, the scale was created using existing literature on antifat attitudes and similar questionnaires on internalized homophobia. The WBIS uses questions that assess the extent to which an individual accepts or rejects their weight (e.g., “Because I’m overweight, I don’t feel like my true self.”), the desire to change their weight (e.g., “I wish I could drastically change my weight.”), or how their weight influences their self-perception or mood (“I am less attractive than most other people because of my weight.”). The authors report excellent

internal consistency (α = 0.90) for the scale. In addition, they reported good validity as the WBIS was moderately correlated with measures of antifat attitudes, self-esteem, and body image concerns when controlling for BMI.

Another scale developed by Lillis et al. (2010), entitled the Weight Self-Stigma Questionnaire (WSSQ), uses 12 items to assess IWB among populations with overweight status and obesity on a 5-point Likert scale. The study has two factors; the self-devaluation subscale (with items such as "I feel guilty because of my weight problems" and "I caused my weight problems") and the fear of enacted stigma subscale (with items such as "People discriminate against me because I've had weight problems" and "Others will think I lack self-control because of my weight problems"). The scale was developed based on substance abuse stigma. The WSSQ was found to have good internal consistency (α = 0.88) overall, as well as for the subscales (with α's of 0.869 and 0.812 for the fear of enacted and self-devaluation subscales, respectively) and good construct validity.

Weight Bias. Weight bias will be examined as encountered or experienced by participants using the Stigmatizing Situations Inventory – Brief (SSI-B; Vartanian, 2015; Appendix E) and personally held biases towards higher weight using the Universal Measure of Bias (UMB-FAT; Latner et al., 2008; Appendix F). The SSI-B is a 10-item scale used to measure experiences of weight stigma, including items such as "Overhearing other people making rude remarks about you in public," on a Likert scale ranging from 0 (never) to 9 (daily). The SSI-B has demonstrated good internal consistency (α = 0.91) and demonstrated good validity with related constructs (Vartanian, 2015).

The UMB-FAT is a 20-item scale that assesses attitudes towards fat, using a 7-point scale with “strongly agree” to “strongly disagree” (Latner et al., 2008). It includes four subscales: negative judgment (dislike towards individuals with overweight or obesity), distance (comfort with individuals with overweight or obesity in social situations), equal rights (assessing the belief that individuals with overweight or obesity deserve legal protection against discrimination) and attraction (the extent to which the participant finds individuals with overweight or obesity to be attractive). The scale has demonstrated adequate internal consistency (α=.87), construct validity, and has been demonstrated to directly assess fat bias as opposed to an overall pattern of bias or judgement (Latner et al., 2008).

Healthy Eating. Healthy eating will be assessed through the use of the Dietary History Questionnaire III (DHQ-III; Subar et al., 2001; Appendix G). The DHQ-III was developed using a large, U.S. national nutrient and food group database, and assesses participant caloric intake and macronutrients (including fat, saturated fat, carbohydrates, and protein) and supplies an overall Healthy Eating Index-2015, which is an index assessing compliance with the Dietary Guidelines for Americans (Reedy et al., 2018). The DHQ-III has been found to have reliability for each of the nutrients (Bittoni & Wilkins, 1993).

Physical Activity. Physical activity will be assessed through the revised Morgenstern Physical Activity Questionnaire (PAQ-M; Rubenstein et al., 2011; Appendix H). The PAQ-M measures the frequency of light, moderate, or vigorous physical activity within leisure time. It also assesses physical activity during work, housework, home repairs, yardwork, running errands, caring for others, and includes a question on sedentary activities. The PAQ-M had good

test-retest reliability (intraclass correlation = 0.87) good concurrent validity based on other physical activity questionnaires and BMI.

Eating Behavior. Eating behavior will be assessed using the Three Factor Eating Questionnaire-R18 (TFEQ-18; Anglé et al., 2009; Appendix I) to examine overall disordered eating patterns, and the Eating Disorder Diagnostic Scale (EDDS; Stice et al., 2000; Appendix J) will be used for detecting actual eating disorder-related behavior. The TFEQ-18 is an 18-item measure designed to examine eating behavior through cognitive restraint, uncontrolled eating and emotional eating using a 4-point Likert scale, using "definitely true" to "definitely false". The TFEQ-18 has demonstrated acceptable reliability for each subscale, with alphas of .75 for cognitive restraint, 0.85 for uncontrolled eating, and 0.87 for emotional eating. Further, it has been demonstrated to detect differing eating patterns among a general population (Fleurbaix Laventie Ville Sante (FLVS) Study Group, 2004).

The EDDS – DSM 5 Version is 22-item a questionnaire designed to assess symptoms of anorexia nervosa, bulimia nervosa, and binge-eating disorder per DSM-5 criteria. The questions vary in terms of format, using 6-point Likert ratings from "Not at all" to "Extremely," dichotomous items and asking about frequency of diagnostically relevant behavior over a set period of time (i.e., days per week for over X amount of months). The EDDS has demonstrated reliability for each disorder, including anorexia (kappa = .95), bulimia (kappa = .71), and binge-eating disorder (kappa = .75). Content validity was established through review by 14 eating disorder experts.

Mental Health. Mental health will be assessed using the 21-item Depression Anxiety and Stress Scale (DASS-21; Appendix K), as it can assess clinically relevant depressive symptoms,

anxious symptoms, and stress all within 21-items (Lovibond & Lovibond, 1995). Participants rate to which extent each symptom applied to them within the past week, from 1 (did not apply to me at all) and 4 (applied to me very much, or most of the time). Each scale has demonstrated good reliability, with α's = .91, .80, and .84 for Depression, Anxiety, and Stress, respectively (Sinclair et al., 2011). The scale has also demonstrated constructive validity within a large, non-clinical sample (Henry & Crawford, 2005).

In addition, rumination will specifically be examined using the Ruminative Response Scale-Short Form (RRS-SF; Treynor et al., 2003; Appendix L). Wang et al. (2017) found IWB to be moderately and significantly correlated with brooding rumination (*r* = .56) among a sample of individuals with obesity and binge eating disorder. Thus, rumination may be relevant and of interest to aim three as to how IWB may affect weight loss efforts. The RRS-SF includes nine items with two subscales; brooding and reflection. The form utilizes a 4-point Likert scale ranging from 1 ("almost never") to 4 ("almost always") for various aspects of rumination. The two subscales have shown to have acceptable reliability in a clinical and nonclinical samples, with α's = .79 and .75 for brooding and reflection, respectively. Construct validity was also demonstrated with moderate correlations to the subscales of the DASS-21 (Ruiz et al., 2017).

Self-Esteem. Self-Esteem will be measured utilizing the 10-item Rosenberg Self-Esteem Scale (RSES; Rosenberg, 1965; Appendix M). The RSES uses a 4-point Likert scale from 1 (strongly disagree) to 4 (strongly agree), which higher scores indicating higher self-esteem. The scale has demonstrated good reliability (with an α range of 88 to .90) and convergent validity with other measures of self-esteem (Robins et al., 2001).

Acceptance. Due to the additional third-wave components of treatment, acceptance will also be assessed. The Acceptance and Action Questionnaire – Second Edition (AAQ-II) is a 7-item questionnaire that uses a 7-point Likert scale from 1 (never true) to 7 (always true; Bond et al., 2011; Appendix N). Higher scores indicate less psychological flexibility and higher experiential avoidance. The scale has demonstrated good reliability ($\alpha = .84$) and appropriate convergent validity with measures of psychological distress.

Self-Compassion. In further consideration of the additional third-wave components of treatment, self-compassion will be assessed as well. The Self-Compassion Scale – Short Form (SCS-SF) is a 12-item scale that uses a 5-point Likert scale ranging from 1 (almost never) to 5 (almost always; Raes et al., 2003; Appendix O). The scale has six subscales; the first three represent crucial/core components of self-compassion: self-kindness, common humanity, and mindfulness, and the remaining three serve as counters to these core components, with self-judgement, isolation, and overidentification (becoming wrapped up in negative emotions). The three core components are added together, along with reverse-scored counter components, to create an overall score in which higher scores indicate higher self-compassion. The SCS has good internal consistency ($\alpha = .86$) and good construct validity.

Treatment Acceptability. Upon treatment conclusion, participants will be asked to rate the extent to which they found the treatment to be effective and feasible and the extent to which they felt connected to their behavioral coach using an adapted Satisfaction With Therapy and Therapist Scale—Revised (STTS–R; Po Oei & Green, 2008; Appendix P). The STTS-R assesses satisfaction with therapy and therapist using a 5-point Likert scale, from 1 (Strongly Disagree) to 5 (Strongly Agree). Questions regarding treatment will be adapted for the telehealth, BWLP

situation (i.e., “I am satisfied with the quality of the therapy I received” will be adapted to “I am satisfied with the quality of the telehealth weight loss treatment I received”). Similarly, questions about the therapist will be changed to “weight loss coach.” The STTS-R has been shown to have reliability for both the scale as a whole (α = .90) and the subscales Satisfaction with Therapy (α = .91) and Client Evaluation of Therapist (α = .80).

Statistical Analysis Plan

All analyses will be conducted in SPSS 28 (IBM Corp., 2021). Data will be cleaned and screened before proceeding with analysis. Descriptive statistics will first be examined for the overall sample. Then, demographics among each group will be examined. Preliminary analyses will be run to ensure that there were no significant group differences in terms of basic demographics. Continuous variables will be examined using t-tests or ANOVA (for example, BMI) while dichotomous and categorical variables will be examined using chi-square (i.e., race/ethnicity). While it is hoped that randomization will provide even group characteristics, any potential group differences will be included as a covariate in analyses. Also, upon study conclusion, group differences will also be examined in terms of attrition and number of sessions attended to check whether treatment impacted these factors.

Hypothesis One and Hypothesis Two. A series of 2 x 2 (time x group) repeated measures ANOVA will be utilized to examine whether the BWLP only and Third-Wave + BWLP groups were successful with lowering weight, IWB, and weight bias and increasing healthy eating and physical activity and whether there are differences between the BWLP only group with the Third-Wave + BWLP group for each outcome.

Exploratory Analyses. Additional 2 x 2 RM-ANOVA's for each outcome variable, including depressive and anxious symptoms, rumination, maladaptive eating, self-esteem, cognitive flexibility and self-judgement will be examined.

Finally, significant changes in weight bias and IWB will be examined as predictors of weight loss and psychological outcomes.

East Carolina University

Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

A Third-Wave Intervention for Internalized Weight Bias Combined with a Weight Loss Program Using Video Conferencing Software

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Researchers at East Carolina University (ECU) study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

Why am I being invited to take part in this research?

The purpose of this research is to examine the effectiveness of a novel weight loss approach which compares a standard weight loss intervention with an approach that includes an intervention on internalized weight bias for some participants. You are being invited to take part in this research because you referred yourself and/or are interested in losing weight. The decision to take part in this research is yours to make. By doing this research, we hope to learn about the effectiveness of providing weight loss treatment to individuals wanting to lose weight using a virtual approach.

If you volunteer to take part in this research, you will be one of about 200 people to do so.

Are there reasons I should not take part in this research?

I understand I should not volunteer for this study if I am less than 18 years of age, have a BMI less than 27, or have a serious chronic condition (e.g. Congestive Heart Failure or any condition that makes it unsafe to exercise or restrict your dietary intake). This intervention may not be safe or appropriate for these individuals.

What other choices do I have if I do not take part in this research?

You can choose not to participate. You may be referred to campus resources, including the ECU PASS clinic or the Brody School of Medicine as a treatment resource.

Where is the research going to take place and how long will it last?

The research will be conducted in the Rawl Building and online. You will need to come to the Rawl 301 or Rawl 303 or Rawl 123 at the initial and follow-up points of the study. The study involves a weight loss intervention in which everyone will have access to a treatment manual and will attend weight loss

intervention groups with other participants online. This phase will last 3 months with three assessment points in which you will be asked to come back to Rawl 301 or Rawl 303 or Rawl 123. Group counseling will consist of twelve weekly sessions that last approximately 60-minutes or 90-minutes each, depending on the group that you will be randomly assigned to. The final phase will consist of one final assessment 6 months after the completion of the intervention. This final assessment will also take place in Rawl 301 or Rawl 303 or Rawl 123.

What will I be asked to do?

You will be invited into the lab or clinic (Rawl 123 or 301 or 303) in order to receive materials for the intervention and complete the first assessment. At this time, you will be given a weight loss manual, and you will be randomized to: 1) receiving treatment with just the weight loss manual and weekly online group counseling or 2) receiving treatment with the DPP and weekly online group counseling along with additional self-compassion exercises. You will be engaged in this weight loss program for a total of 10 months. Four months of active treatment and six months of non-treatment contact. You will complete 3 assessment sessions ranging from 15 minutes to 2 hours depending on the assessment.

What might I experience if I take part in the research?

Other people who have taken part in this type of research have experienced successful weight loss results. By participating in this research study, you may also experience these benefits. All changes in eating and physical activity are voluntary. Nevertheless, you may experience discomfort as you reduce your caloric intake or increase your physical activity. Risk of more serious potential harms is minimal.

Will I be paid for taking part in this research?

We will be unable to pay you for the time you volunteer while being in this study. However, you will receive the weight loss manual and weekly weight loss counseling free of charge.

Will it cost me to take part in this research?

It will not cost you any money to be part of the research. It will however cost your time and effort. Committing to this research means committing to completing experimental protocols and measures and doing your best to attend and complete follow-up assessments, and counseling should it be necessary. These are all things to take into consideration when deciding whether or not to participate.

Who will know that I took part in this research and learn personal information about me?

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- The study staff and Principal Investigator.

How will you keep the information you collect about me secure? How long will you keep it?

Coded or identified data will never be released to anyone outside of the IRB for the purposes of an audit or study staff. Following the completion of the study, the identified data used to communicate with study participants will be erased from the hard drive and backup flash drive that it was stored on. This will leave study staff with unidentified data. Paper data will be kept for 7 years in a locked file cabinet per APA ethics requirements. At that point it will be shredded and discarded.

Audio or video will be utilized during online weight loss counseling sessions for the purpose of supervising the doctoral-level clinicians only, and will be destroyed after viewing. Data will be discarded per item 2.0. There is no anticipated further use of this data beyond the 7 years. We use Cisco Webex as a secure video-conferencing platform, allowing for face-to-face video and it is HIPAA compliant. For more information about WEBEX security and privacy, please see: https:// www.cisco.com/.

What if I decide I don't want to continue in this research?

You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. We understand there are a variety of situations that may necessitate withdrawal from the study and will gladly assist you should you decide that you do not wish to continue. You will not lose any benefits that you have already received.

Who should I contact if I have questions?

The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-737-5070 (Monday-Friday, between 9am and 5pm).

If you have questions about your rights as someone taking part in research, you may call the University & Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914.

I have decided I want to take part in this research. What should I do now?

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

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Participant's Name (PRINT) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

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Person Obtaining Consent (PRINT) **Signature** **Date**