Weight Loss Treatment for Veterans with Binge Eating

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1. Study Protocol

Potential participants were Veterans with recurrent binge eating seeking weight loss were recruited from VA's Weight Management Program, MOVE! at two VA sites: West Haven, CT and Northampton, MA between January 2018 and May 2022. As recruitment for this study was underway during the COVID-19 pandemic, Veterans were first recruited from in-person MOVE! orientation sessions between January 2018 and March 2020 and then additionally from VA's remote TeleMOVE! program starting in July 2020. Eligibility required age 21+, Body Mass Index (BMI)>=25, and DSM-5 clinical/subclinical BED. Exclusions were: attendance of more than 4 MOVE! group sessions in the prior year, active psychosis or suicidal ideation, medical or psychiatric illness or cognitive deficits that interfere with providing consent or completing assessments, and pregnancy or lactation. The study received IRB approval by the VA Connecticut Healthcare System, which provides oversight for both West Haven, CT, and Northampton, MA facilities.

1.1 Measures

Participant assessments were conducted by blind assessors at baseline, post-treatment (3-months), and 6- and 12-month follow-ups (9- and 15-months after randomization). Primary outcomes included eating pathology and binge eating, secondary outcomes included measures of mental health, quality of life, and other eating behavior. Weight outcomes were explored. Participants were compensated $25 for baseline, $40 for post-treatment, and $50 and then $60 for follow-up assessments.

1.2 Diagnostic and Primary Outcomes: Eating Pathology and Binge Eating

Eating Disorder Examination-Interview 17.0th Edition (EDE)[1] is the structured diagnostic interview that is considered the gold-standard to diagnose, and assess the symptoms of, eating disorders including binge eating and eating disorder pathology. Binge Frequency was defined as the average number of monthly binge episodes for the past three months at baseline, and average number of monthly binge episodes for the past month at post-treatment and follow-up assessments. Binge Remission was defined as zero binge episodes in the previous month.

Eating Disorder Examination-Self-report Questionnaire (EDE-Q)[2] is the self-report version of the more intensive EDE interview. Research has documented that the EDE-Q performs well as a measure of change in treatment trials[3] and has adequate convergence with the interview format[4, 5]. The EDE-Q generates the same frequency data for binge eating in the past 28 days, as well as a total score for overall eating pathology and subscale scores for dietary restraint, weight concern and shape concern, and eating concern.

1.3 Secondary Outcomes: Mental Health, Quality of Life and Other Eating Behaviors

The Patient Health Questionnaire-9 (PHQ-9)[6] is a 9-item self-report questionnaire used to assess for the presence and severity of the symptoms of depression. The PHQ-9 has been shown to be a reliable and valid measure of depression severity [7]. The PTSD Checklist (PCL-5)[8] is a 20-item self-report measure assessing the 20 DSM-5 PTSD symptoms. The Weight and Eating Quality of Life (WE-QOL)[9] is an 8-item self-report instrument for measurement of the impact weight and eating has on quality-of-life outcomes [9]. The European Quality of Life (EQ-ED-5L)[10] is a 5-item self-report instrument for measurement of quality of life outcomes that has specifically been used in weight loss trials with Veterans[11]. The Loss of Control Eating Scale (LOCES)[12] is a 7-item scale assessing the sense of loss of control overeating, an important BED characteristic. The LOCES has proven to be valid and is significantly correlated with eating disturbances, general distress, functional impairment, and general self-control [12]. The Night Eating Questionnaire (NEQ)[13] is a 14-item self-report questionnaire used to measure the severity of Night Eating Syndrome. Finally, the Modified Yale Food Addiction Scale 2.0 (mYFAS 2.0)[14] is a 13-itme self-administered scale used to assess the features of food addiction. Lower scores reflect better functioning on mental health, WE-QOL, and eating behavior measures; higher scores reflect better functioning on the EQ-ED-5L measure.

1.4 Weight Outcomes

Weight Control Strategies Scale (WCSS)[15] is a self-report instrument that assesses the use of specific weight loss behaviors. The measure has been shown to be valid, reliable, and predictive of weight loss [15]. Percent

Weight Loss and 5% Weight Loss. Height at baseline, and weight at every assessment point, were measured with clinic scales for the in-person cohort and at home for the virtual cohort. Veteran MOVE! participant self-report of heights and weights have been shown to be reliable [16]. Percent weight loss was calculated with baseline weight minus the assessment weight and then dividing that number by the baseline weight. This percentage was dichotomized to create a 5% weight loss variable.

1.5 Treatment Fidelity

Treatment Satisfaction for all participants was assessed with an 11-item measure asking patients about their ability to manage aspects of their eating, weight and mental health after treatment, and satisfaction with the treatment, materials, clinician and overall results. Items were rated on a 5-point scale from strongly agree to strongly disagree with higher scores representing greater satisfaction. CBT Treatment Session Attendance for the experimental condition was determined by the number of the nine offered clinician-led CBT treatment sessions attended. CBT Therapist Adherence for the experimental condition was determined by independent assessors who listened to every session of a therapist's first case and then randomly selected audio recordings for 10% of CBT sessions thereafter. Recordings were rated on 13 dichotomized items covering therapeutic alliance, session content (skills), homework and goal setting, and session management. Mean scores resulted in totals ranging from 0 to 1 with higher scores representing greater adherence.

1.6 Randomization

Stratified randomization (clinical BED (n=101) and subclinical BED (n=8)) to the two conditions was performed with a computer-generated sequence.

1.7 Treatment Conditions

MOVE! (Treatment-as-Usual)

All participants received VA's Weight Management Program, MOVE!, as administered at their site, without research staff involvement. MOVE! is an evidence-based behavioral weight management program that includes treatment procedures, clinical algorithms, patient and provider information, and instructional materials. The program was widely disseminated and implemented beginning in January 2006 [17]. The 60-minute groups cycle every 16 weeks and are led by trained and monitored MOVE! clinicians who are from the following disciplines: primary care, psychology, nutrition, and physical therapy. Clinicians utilize materials available in hard copy or on-line, and encourage the use of, but do not require or provide, food diaries. Due to the COVID-19 pandemic, MOVE! modalities offered for the present study were expanded to include VA's virtual MOVE! and TeleMOVE! programs. Virtual MOVE! involves synchronous delivery of MOVE! groups via VA Video Connect (i.e., telehealth). TeleMOVE! involves asynchronous delivery of MOVE! content via home-based technology and as needed clinician phone contact. Thus, MOVE! in the present study involved two cohorts: 1) ***in-person*** MOVE! (n=40), and 2) ***virtual*** MOVE! or TeleMOVE! (n=69).

Brief, Clinician-led Cognitive-Behavioral Therapy for BED

One-half of participants received CBT in addition to MOVE!. The CBT was administered via 9 hourly individual sessions over a three-month treatment period. The treatment was led by a licensed clinical psychologist or social worker following a CBT for BED manual specifically developed for this project. Based upon a manual from previous studies [18, 19], the manual was adapted for the VA healthcare user population using iterative input from VA clinicians experienced with Veteran and eating disorder care, a Veteran Engagement Group paid to provide investigators with feedback about the design of Veteran research, and a Veteran who served as one of the study clinicians for this project. The most notable adaptions included person-first language, Veteran-centered examples, graphical representation of concepts, and writing at the seventh-grade reading level. Four clinicians received training from the Principal Investigator (PI; RM), feedback on videorecording of every session for clinicians' first two cases, feedback and adherence ratings of 10% of sessions thereafter, and weekly supervision from the PI (RM). Participants completed daily records of food intake and binge episodes, and these were reviewed and checked weekly by clinicians. The treatment consisted of three overlapping phases. The first phase involved building a collaborative therapeutic relationship, educating the patient about the diagnosis of BED and maintaining factors of binge eating, and utilizing

behavioral strategies (self-monitoring and goal setting and problem-solving to achieve structured patterning, timing and settings for eating). The second phase integrated cognitive skills such that patients learned to identify and challenge maladaptive thoughts and emotional triggers related to eating/restriction and weight/shape. The final phase focused on the maintenance of change and relapse prevention. Brief clinician-led CBT was conducted in-person before the onset of the COVID-19 pandemic and by phone after.

2. Statistical Analysis Plan

Baseline characteristics were compared between the treatment groups using ANOVA and chi-squares as appropriate in order to determine the level of success of the randomization. Distributions of outcomes were examined to determine if assumptions of specific model types were met. Change of model type as well as transformation of the data were considered if model assumptions were not met. Mixed-effects models, a method for statistical modeling that uses both fixed effects and random effects, were used to examine continuous outcomes such as eating pathology binge eating frequency, mental health symptoms, and percent weight loss for completer, as well as intent-to-treat (all randomized persons), analyses. Logistic regression models were used for categorical outcomes such as binge remission and achieving clinically meaningful weight loss (i.e., 5% weight loss or greater). The outcomes were transformed to approach normality as needed and models controlled for treatment, time, gender, age, and baseline BMI.

2.1 Cohort (in-person vs remote) analyses. There were 40 (37%) subjects in cohort 1 and 69 (63%) in cohort 2. All the analyses with cohort (categorical variable) added to the models were run and conclusions were substantively the same.

2.2 Missing Data. Missing data was minimized by having participants complete with assistance of research assistants. The mixed-effects models addressed missing data for continuous outcomes as the modeling makes use of all available data for each participant, even when there are different numbers of observations. [79]

2.3 Missingness analyses. We focused on the missingness of the primary outcome averages binge per month (over past 3 months). Outcome was missing for 11.9% of subjects at month 3, 19.3% at month 9, and 24.8% at month 15. Overall, these 3 timepoints, 35.8% of subjects had incomplete outcome data (missing outcome at any of timepoints). There was no evidence of a difference between groups in missingness at any timepoint or overall (all p-values>=.10).

2.4 Variables predictive of missingness. Those with incomplete outcome data were more likely to be male (p=.05) and younger (p=.01), and have higher baseline BMI (p=0.03), greater highest weight (p=0.01), better weight quality of life at baseline (p=0.03) and lower food addiction at baseline (p=.03). Gender, age, and baseline BMI were already covariates in the models. We repeated the primary analyses to include the other three variables associated with missingness in the models and conclusions stayed the same.

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