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Design of the CHARGE study: A randomized control trial evaluating a novel treatment for Veterans with binge eating disorder and overweight and obesity

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Abstract

A large number of Veterans experience binge eating and overweight or obesity, which are associated with significant health and psychological consequences. The gold-standard program for the treatment of binge eating, Cognitive Behavioral Therapy (CBT), results in decreases in binge eating frequency but does not result in significant weight loss. We developed the Regulation of Cues (ROC) program to reduce overeating and binge eating through improvement in sensitivity to appetitive cues and decreased responsivity to external cues, an approach that has never been tested among Veterans. In this study, we combined ROC with energy restriction recommendations from behavioral weight loss (ROC+). This study is a 2-arm randomized controlled trial designed to evaluate the feasibility and acceptability of ROC+, and to compare the efficacy of ROC+ and CBT on reduction of binge eating, weight, and energy intake over 5-months of treatment and 6-month follow-up. Study recruitment completed in March 2022. One hundred and twenty-nine Veterans were randomized (mean age=47.10 (sd = 11.3) years; 41% female, mean BMI=34.8 (sd = 4.7); 33% Hispanic) and assessments were conducted at baseline, during treatment and at post-treatment. The final 6-month follow-ups were completed in April 2023. Targeting novel mechanisms including sensitivity to internal cures and responsivity to external cues is critically important to improve binge eating and weight-loss programs among Veterans.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Keywords

Veterans; binge eating; weight management; appetitive traits; food responsiveness; satiety responsiveness

Introduction

Binge eating disorder (BED) is the most prevalent eating disorder in the United States and is accompanied by a sense of loss of control without the use of compensatory behaviors and is associated with overweight or obesity (OW/OB) and multiple medical and psychiatric comorbidities.[1-4]

Cognitive behavioral therapy (CBT) is considered a first-line treatment for BED.[5-7] CBT focuses on disrupting the dietary restraint/binge-eating cycle by encouraging healthy eating behaviors and improving maladaptive thoughts and behaviors related to eating, shape, and weight. Data indicate that significantly more participants in CBT, compared to waitlist controls, achieve abstinence from binge eating and report improved eating-related psychopathology.[8] However, CBT does not produce significant weight loss,[9] bringing into question changes in eating behavior and leaving individuals to cope with the medical and psychological difficulties associated with having OW/OB.

The behavioral susceptibility theory (BST)[10, 11] suggests that genetically determined appetitive traits interact with the current food environment, leading to overeating and weight gain. The BST focuses on two important aspects of appetite: eating onset driven by food responsiveness (FR) and eating offset driven by satiety responsiveness (SR). Research suggests that higher food cue responsiveness and lower satiety responsiveness are associated with overeating and OW/OB cross-sectionally and longitudinally.[12] We've developed a novel treatment model, Regulation of Cues (ROC), based on the BST to target both FR and SR. Our pilot data show that ROC is feasible, acceptable, and facilitates decreases in weight and binge eating in adults.[13, 14] We conducted a randomized trial among 271 community adults comparing ROC, behavioral weight loss (BWL), ROC+ (ROC+BWL) and an attentional control (AC) and showed that patients randomized to ROC, ROC+, and BWL had significantly lower BMI at the end of treatment and follow-up compared to AC. We found that FR was a significant moderator, and participants who scored higher on FR lost more weight in the ROC and ROC+ groups than in the BWL or AC groups.[14] We also found that all four groups had reduction in eating disorder symptoms and binge eating during treatment.[15]

Rates of binge eating are higher among military Veterans than the general population, with over 65% of female and 45% of male Veterans reporting one or more current symptoms of BED [16] and approximately 77% of Veterans have OW/OB.[17, 18] To our knowledge, no studies have specifically examined FR and SR in an experimental paradigm with active-duty service members or Veterans. However, there is a small but growing body of research reporting that Veterans' previous military experiences and norms, such as eating quickly, strict mealtime regimens, eating in response to periods of deprivation, repeated exposure to stressors, and others, put veterans at greater risk of binge eating, binge eating,

and disordered eating patterns,[19-22] which typically are related to FR and SR. Based on our previous studies in which targeting FR and SR did positively impact eating patterns, we anticipated that Veterans would respond positively to the ROC intervention explicitly because of the eating patterns developed over their years of military experience. Thus, changing eating patterns by increasing SR and decreasing FR could result in a significant advancement in clinical care for Veterans with both binge eating and OW/OB.

2. Study Objectives

The CHARGE (Controlling Hunger and ReGulating Eating for Veterans) study randomly assigned 129 Veterans with binge eating and OW/OB into one of two group-based 5-month treatments: ROC+ and CBT. The primary objectives of the study are: 1) to evaluate the feasibility and acceptability of ROC+ in Veterans, 2) to compare the efficacy of ROC+ and CBT on reduction of binge eating over the duration of the study period, and 3) to compare the efficacy of ROC+ and CBT on weight loss and reduction of energy intake over the duration of the study period. The secondary objectives include determining the extent to which ROC+ and CBT affect underlying mechanisms to reduce weight and binge eating, including FR, SR, and reward-based eating. The exploratory objective of the study is to evaluate potential moderators of treatment (age, gender, binge eating, FR, SR, reward-based eating; military service variables) and mediators of treatment outcomes (FR, SR, reward-based eating, physical activity).

3. Study Design

3.1. Trial design

CHARGE is a parallel group, randomized controlled trial for Veterans with binge eating and OW/OB. Veterans were randomly assigned to ROC+ or CBT stratified using a permuted block randomization procedure[23] by gender and the number of loss of control eating episodes on the Eating Disorder Examination interview.[24, 25] All randomized participants attended group treatment over 5 months. Cohort 1 was provided in person and cohorts 2-5 were provided remote due to the COVID-19 pandemic restrictions. Assessments were conducted at four time points: baseline, during treatment, post-treatment (month 5), and 6-month follow-up (month 11). The primary outcome measures were feasibility and acceptability, body mass index (BMI), binge eating episodes, and energy intake through follow-up assessments.

3.2. Participants

Participants are male and female Veterans (N=129; mean age=47.1 (sd= 1.3) years; 41% female, mean BMI=34.8 (sd=4.7); 33% Hispanic).

3.3. Inclusion and exclusion criteria

Inclusion criteria are: Veterans aged 18 to 65 years; BMI ≥25 and ≤45; Diagnostic and Statistical Manual-5 (DSM-5) criteria for BED or subclinical BED (see section 3.6.2); willing and able to participate in assessments and treatment at UC San Diego; willing and able to maintain contact with the study team for the 11-month study period; and

English language skills at the 5th grade reading level. Exclusion criteria are: serious or unstable medical (e.g., current symptoms of angina, stroke, heart disease or other serious medical condition that would make physical activity or weight loss unsafe or impossible at a moderate level), psychiatric (i.e., active suicidal ideation, history of suicide attempt within 1 year, current unmanaged psychosis, manic episode, anorexia nervosa, bulimia nervosa, or substance abuse within the past year) or psychosocial instability (e.g., homelessness) that could compromise study participation; pharmacotherapy for OW/OB or BED (e.g., Orlistat or Meridia) or pharmacotherapy that could impact weight; bariatric surgery within the past 6 months; participation or planned participation in another organized weight loss or binge eating program; or pregnancy or lactation.

3.4. Recruitment and retention

Recruitment occurred between March 2019 and March 2022. Participants were recruited from the VA San Diego Healthcare System (VASDHS) and the San Diego Metropolitan community. Recruitment of participants at VASDHS was made through multiple clinics (e.g., weight control, primary care, and mental health clinics) using letters, flyers, tabling events, and physicians' referrals. The VASDHS recruitment team conducted a brief screening interview with potential participants from VASDHS and reviewed the medical records of Veterans who received their healthcare at the VASDHS to facilitate the eligibility prescreening process. Veterans who appeared eligible from this prescreening process signed the VASDHS consent form to share participants' prescreening and contact information with UC San Diego. Veterans were also recruited from the community through flyers, email listservs, magazines for Veterans, physician, and study participant referrals, clinicaltrials.gov, online recruitment ads, and tabling events. Those who appeared eligible based on their prescreening responses were invited to the study orientation at UCSD and complete the consent process.

The study used several strategies to maximize the retention of participants such as birthday cards, holiday cards, sympathy cards, and emails to honor Veterans and Memorial Days. When participants missed treatment sessions, interventionists offered make-up sessions. The study also collected the contact information of two individuals who could assist with contacting participants.

3.5. Measures

Table 1 details the measures collected at all study timepoints. Assessments began in April 2019 and the final assessment was completed in April 2023.

3.5.1. Demographics and screening measures.—Demographics. Participants respond to questions regarding age, gender, years of education, socioeconomic status, branch of service, years and position in military, highest rank at discharge, exposure to combat (yes/no), and years since actively serving in the military.

Participants report their medical and psychiatric history and current medication use at baseline to determine whether any exclusionary criteria were met. Veterans report any changes in medical status and medications throughout treatment and at follow-up.

Mini International Neuropsychiatric Interview Version 7.0.0.[26] (MINI). The MINI is a structured clinical interview that assesses any psychiatric conditions that warranted study exclusion.

3.6.2. Clinical and subclinical binge eating—Eating Disorder Examination (EDE Version 17.0).[24, 25] The EDE is a structured clinical interview that assesses binge eating and other disordered attitudes and behaviors related to eating, body-shape and weight. Only the binge eating sections were administered at baseline and follow-up timepoints. Clinical binge eating included at least 12 objective binge eating episodes. Subclinical binge eating was defined as: 1) a minimum of three objective binge eating episodes (OBEs); 2) a minimum of six subjective binge eating episodes (SBEs); 3) a minimum of two OBEs and two SBEs; or 4) a minimum of one OBE and four SBEs over the past 3 months.

Eating Disorder Examination-Questionnaire 6.0 (EDE-Q).[27] The EDE-Q is a 28-item questionnaire adapted from the EDE interview that assesses eating disorder behaviors and attitudes.

Binge Eating Scale (BES).[28] The BES is a 16-item questionnaire that assesses binge eating severity.

3.5.3. Anthropometry—Body Mass Index (BMI). Height is measured using the Seca 222 wall-mounted stadiometer in triplicate to the nearest 0.1 cm, and the average of the three values is recorded. Body weight in kilograms is measured on a calibrated Tanita Digital Scale (Model WB-380S) and recorded to the nearest 0.1 kg. Participants remove their shoes for height and weight measurements. Height and weight are converted to BMI (kg/m^2). After March 2020, participants were provided Bluetooth scales (Withings) which allows the study team to access their weight data throughout the study.

3.5.4. Energy intake—24-hour dietary recalls.[29-31] Dietary intake is assessed with three 24-hour dietary recalls on three non-consecutive days, via telephone interview, two during the week and one on a weekend day. All interviews use the Nutrition Data Systems for Research (NDS-R) nutrient calculation software. All dietary interviews are administered by trained assessment staff from the UCSD Nutrition Shared Resource, blinded to study group assignment.

3.5.5. Food Responsiveness and Satiety Responsiveness—Adult Eating Behavior Questionnaire (AEBQ).[32] The AEBQ consists of 35 questions and 8 subscales. The 4-item Food Responsiveness subscale (FR) measures an individual's reactivity to food cues in the environment and the 4-item Satiety Responsiveness subscale (SR) measures an individual's ability to respond to satiety signals.

Heart Rate Variability. Veterans participate in a laboratory-based assessment protocol to generate measurable changes in psychophysiological responses to food cues. [33] There are three 6 min phases in the paradigm - baseline, exposure, and recovery. During the baseline phase, the participant was asked to sit quietly and remain still. During the exposure phase, the participant's preferred food was put in front of them, and they were prompted by

a research assistant to hold and smell the food at alternating 30 s intervals. The final phase was a recovery phase, where the food was removed and the participant sat quietly again, identical to the baseline phase. Heart rate (HR) and heart rate variability (HRV) are measured continuously during the food exposure tasks.[34]

Reward-Based Eating-13 (RED-13).[35] The RED-13 is a 13 item questionnaire that assesses reward-based eating, including lack of satiety, preoccupation with food, and lack of control over eating.

Water Load Task (WLT).[36, 37] The WLT assesses gastric sensitivity. Participants drink room temperature, non-carbonated water ad libitum from an unmarked flask hidden from their view until reaching the first signs of fullness (step 1). Participants then drink water from another hidden flask until they feel the signs of maximum fullness (step 2). The volume of the water consumed in both steps is recorded and total volume is calculated. Participant's gastric interception is calculated as percentage of fullness (step 1) and maximum fullness (step 2).

3.5.6. Physical activity—Godin Leisure-time exercise questionnaire (GLTEQ).[38, 39] The GLTEQ includes 3 questions that assess the frequency and occurrence of leisure time physical activity.

Global Physical Activity Questionnaire (GPAQ).[40-42] The GPAQ includes 16 questions and assesses engagement in physical activity in three settings: activity at work, travel to and from places, and recreational activities.

3.5.7. Feasibility and acceptability—Feasibility is assessed by weekly attendance data and retention. Acceptability is assessed using a self-report questionnaire designed by the study staff to assess overall liking and helpfulness of the program.

4. Intervention

All randomized participants attended group treatment that included 18, 90-minute visits over five months. Groups met weekly for the first 16 weeks and twice a month for 1 month. Both treatments included didactic teaching, discussion, and activities. Both groups also recommended physical activity (see section 4.3). See Table 2 for session topics.

4.1. Regulation of Cues (ROC+)

ROC+ is based on the BST[10, 11] and includes psychoeducation, coping skills, experiential learning and self-monitoring. Psychoeducation in ROC+ targets the improvement of satiety responsiveness and the management of food responsiveness to decrease overeating and binge eating. Physiological, neurobiological, and environmental models of overeating and binge eating are presented in lay language to identify and manage vulnerabilities to overeating and binge eating. "Tricky Hungers" are presented during sessions as a way of presenting how the environment "tricks" the body into overeating and binge eating. Coping skills are taught to assist in mastery and toleration of FR. Additionally, ROC+ includes some components of BWL to help change energy balance.

The first phase of ROC+ focuses on managing overeating and binge eating through improving SR and reduction in caloric intake. Participants are taught models of hunger and satiety dysregulation. In phase one, participants learn to identify their hunger level as an internal management strategy for the management of overeating and binge eating. Participants self-monitor their hunger in a self-monitoring booklet or an app, on a 1–5 scale, with 1=“starving” and 5=“stuffed” before, during and after each meal or snack consumed each day. Starting at session two, participants are taught to also self-monitor their caloric intake (as an external management strategy) and are provided a calorie range goal starting at session three to achieve a 1-2 lb. weight loss/week. Psychoeducation in phase one teaches participants about high-risk situations for overeating or binge eating, including getting too hungry, getting too thirsty, eating out of boredom, eating due to other emotions, and eating due to social contexts. Skills are provided for prevention of or to use during these circumstances. Participants are also taught about strategies to reduce energy intake, including stimulus control, reading food labels and healthy eating. Participants bring a meal and consume dinner in group and are prompted to monitoring their hunger before, during and after the meal as well as their caloric intake after the meal. Conditions are manipulated to simulate eating and monitoring hunger under different conditions.

The second phase of ROC+ focuses on management of FR through toleration and response inhibition. Participants learn about basic learning theory and how physiological responses to food cues develop and can be reduced and/or inhibited to manage FR. Cravings are introduced as a urge to eat when not physically hungry and are markers of food responsiveness. Psychoeducation in this phase focuses on identifying specific cues in the environment, prediction error, habituation, acceptance vs tolerance of cravings, and habit learning. Strategies to resist urges and increase inhibition are provided. Participants learn to assess and rate their cravings (defined as urges to eat when not physically hungry) and bring their own highly craved foods to group each week. Using these foods, they complete two exposures at each session when physically sated. During the exposure, participants rate their cravings from 1 to 10 with 1= “not at all” and 10= “highest possible” at 30-second intervals while looking at the food, holding the food, smelling the food, after taking two small bites of the food for the duration of the exposure. After 5 minutes, the participants dispose of the food without eating it. Participants rate their expectations prior to the exposure and then process the outcomes after the exposure, to provide expectancy violation. Participants are encouraged to complete out of session exposures and monitor their practice on paper or using an app.

The last two sessions of ROC+ include a meal and exposures. Participants monitor their hunger, energy intake and cravings in session. During these sessions lapse and relapse are defined, and participants review their progress and the skills learned.

4.2. Cognitive Behavior Therapy (CBT)

CBT follows an adapted manualized protocol[43, 44] which has been delivered in groups.[45] CBT for BED is based on the premise that binge-eating patterns develop as a response to repeated restrictive dieting attempts as well as behavioral reinforcement. CBT treatment consists of three phases. The first phase focuses on reducing binge eating frequency by

normalizing eating patterns to reduce dietary restraint, consuming regular meals and snacks, and incorporating a variety of foods into the diet. During initial sessions, participants are educated about binge eating and begin detailed self-monitoring of their eating behavior including binge eating. Phase I also emphasizes the importance of identifying precipitants and consequences of binge eating behaviors, as well as using stimulus control techniques targeting binge eating behavior. Self-monitoring focuses on contextual factors associated with binge eating including location, stress, and mood. By identifying the links between these precipitants, as well as the consequences, of binge eating behavior, participants learn to use behavioral strategies including alternative behaviors to substitute adaptive responses for binge eating.

The second phase focuses on addressing problematic cognitions related to eating behavior as well as shape and weight. Participants self-monitor their thought patterns and learn cognitive restructuring techniques targeting problematic cognitions including dichotomous, all-or-none thinking. In the third phase, participants practice relapse prevention techniques including in vivo exposure to high-risk foods and situations. Specifically, they create lists of foods and situations that have been associated with binge eating in the past and gradually reincorporate these high-risk stimuli through practice to promote behavioral extinction. The distinction between a “lapse” and a “relapse” is emphasized, along with the importance of using strategies to get back on track if a lapse occurs. Participants identify potential situations in which a lapse might occur in the future as well as specific behavioral and cognitive strategies they can use to get back on track and prevent a full relapse. The third phase of CBT also includes topics relevant to BED including self-esteem, body image, and problem solving. In one session, information is provided about weight regulation and maintenance, but weight loss is not emphasized. The final phase of CBT also focuses on reviewing participant progress and facilitating continued improvement following the end of treatment.

4.3. Physical activity across both groups

Participants in both groups received the same goal of engaging in at least 250 minutes of moderate or high intensity physical activity and strategies to increase physical activity. In the ROC+ group, physical activity was recommended to improve self-regulatory strength to master and tolerate physiological and psychological arousal, resisting cravings, and preventing overeating. Physical activity was also recommended to burn calories and produce a calorie deficit. In the CBT group, physical activity was encouraged to promote general health, stress management, and to improve mood.

4.4. Treatment fidelity

Group interventionists for the CHARGE program included a registered dietitian, postdoctoral clinical psychology fellows, advanced graduate students in clinical psychology, and licensed clinical psychologists. Separate interventionists provided the ROC+ and CBT arms. All interventionists completed a day-long training course in their assigned treatment and attended weekly supervision with a licensed psychologist.

5. Statistical analyses

5.1. Sample size and power consideration

We selected a sample size of 120 to detect a moderate sized effect (d≥0.50) of the ROC+ intervention when compared with CBT. However, we over-recruited and randomized 129 participants to compensate for measurements that were not collected during the COVID-19 restrictions. The sample size was selected to ensure detection of expected improvements over CBT using moderate effect sizes reflecting a between groups difference in counts of binge eating episodes (d=0.50), decrease in post-treatment BMI (d=0.62, ~ −2.5 BMI or >5% loss),[46] and energy intake (d=0.75), and a clinically significant improvement of ~5% weight loss. Empirical power estimates were assessed by generating multivariate random samples that were matched to the expected outcome for each condition at each planned assessment mirroring the correlation structures of assessments over time as observed in our pilot study. The percentage of datasets with significant effects for the primary hypothesis comparing ROC+ vs. CBT (i.e., $p < .05$) provided a simulation-based estimate of power for the primary hypothesis. Given the median treatment effect of condition on binge eating in GLME was −0.07 (SD = 0.03) and for BMI over time was −0.06 (SD= 0.02) across 1000 data sets, the planned design would provide greater than 0.82 power for detecting the treatment differences with allowance for up to 20% lost to follow up. Empirical power analyses suggested this sample of 60 participants for each group (n=120) also would allow mediation analyses to sustain power >0.80 given expected medium effect of ROC+ on primary mediators and small to medium effects of primary mediators on changes in BMI.[47]

5.2. Data analyses

All analyses will include an intention to treat approach and missing data will be evaluated prior to testing primary aims. All models will include planned covariates (age, gender, loss of control episodes) and baseline BMI.

5.2.1.1. Primary Objective 1—Feasibility will be evaluated through the assessment of attendance and retention rates of individuals in the ROC+ and CBT treatments for treatment completers, dropouts and number of sessions attended. Logistic regression models will be used with planned covariates and baseline BMI to estimate between-group difference in odds of treatment completion, defined by receiving a sufficient dose of treatment (i.e. >70% of sessions). Cox proportional hazards models will evaluate differences in time to dropout defined as missing four or more consecutive treatment sessions. To assess acceptability, we will use linear models to estimate between-group differences in satisfaction and liking of the treatment they received.

5.2.1.2. Primary Objective 2—Efficacy of ROC+ and CBT on changes in binge eating episodes at mid-treatment, post-treatment, and 6-months post-treatment timepoints will be assessed with generalized linear mixed effects (LME) models with corresponding baseline values for each outcome. Interactions of between-group indictor and time will assess whether differences in binge eating dissipate from active treatment compared to the 6-month post-treatment timepoint.

5.2.1.3. Primary Objective 3—Efficacy of ROC+ and CBT on changes in weight loss (BMI) and energy intake (kcal/day), at mid-treatment, post-treatment and 6-months post-treatment time points will be evaluated with generalized LME models using corresponding baseline values for each outcome.

5.2.2. Secondary outcomes

5.2.2.1. Secondary Objective 1: The extent to which ROC+ and CBT affect FR (FR scale, psychophysiological responding to food, RED-13), SR (SR scale, WLT), and reward-based eating (RED 13) will also be evaluated with generalized LME.

5.2.3. Exploratory analyses: A series of analyses will explore whether individual factors including baseline age, gender, binge eating status, SR, FR, or reward-based eating, and Veteran-specific variables (e.g., combat exposure) moderate the impact of ROC+ vs CBT on improvements in binge eating and weight. Exploratory analyses also will evaluate whether improvements in responsivity to food cues, satiety responsiveness, reward-based eating or physical activity mediate improvements in binge eating and weight using a multiple mediator model.[48] Significance tests of indirect effects will be assessed using a product of coefficients method with bootstrap estimation of 95% confidence intervals.

5.3. Missing data

Prior to testing primary hypotheses, we will conduct exploratory analyses to determine if baseline characteristics predict patterns of missingness. Any significant ($p<0.10$) predictors of missingness will be used with multiple imputation methods[49, 50] to pool final model estimates using multiply imputed data during primary outcome, exploratory examination of candidate moderators of ROC+ vs CBT and mediation analyses.[51]

6. Discussion

This paper reviews the rationale, design, and methodology of a fully powered parallel group randomized controlled trial comparing the ROC+ program with CBT among Veterans with binge eating and OW/OB over 11 months. ROC+ is a novel intervention based on a robust model identifying potential mechanisms to impact both binge eating and OW/OB. The CHARGE study will provide critical knowledge regarding the feasibility and acceptability of ROC+ in Veterans and whether the ROC+ program will provide greater reductions in binge eating, weight, and energy intake compared to CBT. This study also will evaluate changes in key mechanistic variables, including food cues, satiety responsiveness, and reward-based eating, and explore potential mediators and moderators of treatment effects on binge eating, BMI and energy intake. By targeting underlying mechanisms such as sensitivity to hunger and satiety cues, external food cue responsiveness, and inhibitory control, we hope to inoculate Veterans against the ubiquitous food cues in the current environment as well as increase their responsiveness to internal cues.

The CHARGE study is the first to our knowledge to target satiety responsiveness and food responsiveness to address binge eating and OW/OB among Veterans. Given the widespread problem of binge eating and OW/OB in Veterans and the significant impact on their health

and functioning as well as healthcare systems, ROC+ can serve as a novel intervention approach for this population. Further, examining mediators of treatment effect can facilitate refining the intervention for increased efficacy. Data on potential moderators will allow for tailoring treatments to individual level factors in Veterans and others. Therefore, the CHARGE study and data are critical to advancing the development of targeted programs for binge eating that can also produce clinically significant weight loss for Veterans and civilians.

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Table 1.

Measurements table and assessment time points

	Instrument	Timepoint			
		Baseline	During tx	Post tx	6-mon FU
Demographics & military characteristics	Age, gender, years of education, socioeconomic status, and military service	x			
Anthropometry	Height and Weight (BMI)	x	x[1]	x	x
Medical and psychiatric history	MINI	x			
	Medical history questions	x		x	x
Binge eating	Eating Disorder Examination	x	x[3]	x	x
	Eating Disorder Examination questionnaire	x	x[2]	x	x
	Binge Eating Scale	x	x[2]	x	x
Satiety responsiveness	Adult Eating Behavior Questionnaire	x	x[2]	x	x
	Water Load Task	x		x	x
Food responsivity	Adult Eating Behavior Questionnaire	x	x[2]	x	x
	Psychophysiological measurement	x		x	x
	Reward-Based Eating-13	x	x[2]	x	x
Energy intake	24-hour dietary recalls	x		x	x
Physical activity	Godin Leisure-time exercise questionnaire	x	x[2]	x	x
	Global Physical Activity Questionnaire	x	x[2]	x	x

[1] weekly

[2] monthly

[3] mid treatment

Tx = treatment; FU = follow-up

Table 2.

ROC+ and CBT topics during the 5-month intervention period.

Session	ROC+	CBT
1	Introduction	Introduction
2	Hunger, calories, and tracking *h*	Tracking food intake
3	Ignoring fullness and physical activity *h*	Dieting and overeating Physical activity
4	Ignoring hunger and stimulus control *h*	Cues and triggers of overeating
5	Eating for entertainment Increasing fruits and vegetables and healthy substitutions *h*	Reinforcement and consequences of overeating
6	Eating due to stress and sadness *h*	Thinking styles
7	Eating too fast, mindless eating, high-risk situations *h*	Examining and restructuring thoughts
8	Motivation and review *h*	Understanding cues and chains of behaviors
9	Cravings and Exposures	Strategies for eating wisely and reducing food intake
10	Eating because it's there How context affects cravings Goal setting *e*	Identifying high-risk foods and situations
11	Eating due to anticipation Prediction error & revising predictions Restaurants and dining out successfully *e*	Understanding the link between emotions and overeating
12	Habituation and extinction Urge surfing *e*	Problem solving to prevent overeating
13	Acceptance and tolerance of cravings *e*	Thoughts and beliefs related to self-esteem
14	Eating due to social cues Behavioral chains *e*	Improving body image
15	Eating due to habit Habit learning & habit reversal *e*	Difference between a "lapse" and a "relapse"
16	All-or-nothing eating Awareness of dichotomous thinking *e*	Factors that can lead to relapse
17	Lapse vs relapse *h, e* Relapse prevention planning	Recognizing and maintaining progress
18	Review and wrap up *h, e*	Review and wrap up

h=hunger monitoring in session while eating a meal

e=exposure session with highly craved foods