Using factorial design to examine efficacies of technology-based augmentations for improving treatment adherence and skills utilization in a self-help CBT program for binge eating (CONQUER)

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INSTRUCTIONS:

Protocol Title: Using factorial design to examine efficacies of technology-based augmentations for improving treatment adherence and skills utilization in a self-help CBT program for binge eating.

1) IRB Review History

Does not apply.

2) Sponsor/Funding:

National Institutes of Mental Health funded the proposed project on 09/01/2022

3) Objectives

(1) Test the independent efficacy of Advanced Digital Data Sharing (DDS) with Coaches and Just-In-Time, Adaptive Interventions (JITAIs) in producing improvements in treatment adherence and skills utilization when used in conjunction with self-help CBT program for binge eating
(2) Test the feasibility and acceptability of Advanced DDS with Coaches and JITAIs as adjuncts to self-help CBT program for binge eating
(3) Test the initial efficacy of Advanced DDS with Coaches and JITAIs in producing greater improvements in binge eating frequency at post-treatment, and 3 months follow-up
(4) To confirm that improvements in treatment adherence and skills utilization will be associated with reductions in binge eating.
(5) To quantify the interaction effects of Advanced DDS with Coaches and JITAIs, which may be partially additive, fully additive, or synergistic.

4) Background

Binge eating (i.e., eating large amounts of food within a discrete-time period, characterized by a sense of loss of control) is associated with serious health consequences and places a substantial burden on the nation's health care system. Unfortunately, the first-line treatment, cognitive behavioral therapy (CBT), is intensive (1620 sessions), expensive ($1,882 per patient), and requires access to clinicians with specialized training. In an effort to disseminate CBT, a number of self-help CBTs for binge eating have been evaluated including both 'pure' self-help (PSH, i.e., purely self-directed by the patient), and 'guided' self-help (GSH, i.e., largely self- administered along with periodic contact with a highly trained clinician). Self-help CBTs can produce abstinence from binge eating in 20-35% of patients, suggesting that a considerable number of individuals with binge eating could benefit from self-help CBT programs.

Extant meta-analysis has shown that rates of abstinence from binge eating at post-treatment are superior in CBT-GSH (i.e., 35%) compared to CBT-PSH (i.e., 16%) suggesting that self-help CBTs are maximally effective when they include involvement of a clinician as part of the treatment program. Clinician involvement in CBTGSH likely enhance outcomes as clinician

likely supports positive clinical outcomes via two key pathways 1) better treatment adherence (i.e., use of self-help treatment over time and self-monitoring compliance), and 2) higher rates of therapeutic skills utilization (i.e., practice of CBT skills). Improvements in these two treatment targets likely occur because clinicians are highly trained in how to implement specific behavior change techniques designed to improve treatment targets and clinical outcomes (e.g., identify areas for intervention, provide targeted feedback on behavioral progress and offer guidance on improving target behaviors). Recent technological advancements may have the potential to closely emulate some of the behavior change techniques utilized by expert clinicians to improve treatment adherence and skills utilization during self-help CBT program for binge eating. Emerging evidence have shown promise of two technology-based interventions in approximating behavior change techniques typically implemented by expert clinicians in self-help treatments including 1) Advanced Digital Data Sharing (Advanced DDS) with Coaches, and 2) Just-in-time Adaptive Interventions (JITAIs). Advanced DDS systems can mimic an expert clinician's ability to 1) gather digitally monitored data on target behaviors, 2) synthesize the collected data, 3) flag data to increase salience of behaviors needing improvement, and 4) use sophisticated algorithms to generate recommendations about how to intervene based on identified data patterns. Critically, by accomplishing key tasks typically performed by skilled clinicians, Advanced DDS systems may allow less trained coaches (i.e., individuals with bachelor's degree in health-related fields) to function like expert clinicians during a self-help CBT program without needing extensive training in behavior change techniques. Coaches could simply use the recommendation generated by Advanced DDS system to provide feedback and support to patient for improving target behaviors during self-help CBT program. An additional way to improve treatment targets in self-help CBTs is through the provision of targeted and personalized micro-interventions known as just-in-time adaptive interventions (JITAIs). JITAIs are a smartphone intervention design that can synthesize patterns of digital data (self- monitored data or data collected from a self-helpapp) and use sophisticated algorithms to determine the timing and content of interventions to improve 1) treatment adherence and 2) skills utilization during a self-help CBT program. Understanding which technology-based augmentations can independently and synergistically enhance treatment adherence, skills utilization, and clinical outcomes could allow for the development of more effective and disseminable self-help CBTs for binge eating without clinician involvement.

Proposed Study. In the current study, we will use a 2 x 2 full factorial design in which 76 individuals with BN or BED are assigned to one of four treatment conditions, i.e., representing each permutation of Advanced DDS with Coaches (Advanced DDS with Coaches ON vs. Advanced DDS with Coaches OFF) and JITAIs (JITAIs ON vs. JITAIs OFF) as an augmentation to self-help CBT program. Self-help CBT program will deliver an evidence-based program based on Dr Chris Fairburn's Overcoming Binge Eating self-help book via a smartphone application. The application will deliver treatment via 12 learning modules over 12 weeks. The app will also allow for electronic self-monitoring (or, tracking) of eating and eating disorder behaviors. This study is being conducted to test novel approaches to delivering an evidence-based treatment that is delivered in routine clinical setting. The primary aims of the study will be to (1) Test target engagement, i.e., that each factor including Advanced DDS with Coaches and JITAIs produces greater improvements in treatment adherence and skills utilization, (2) Test the feasibility and acceptability of two intervention factors as adjuncts to self-help CBT program for binge eating; (3) Test the initial efficacy, i.e., that each factor including Advanced DDS with Coaches and

JITAIs will produce greater improvements in binge eating frequency at post-treatment, and 3 months follow-up; and (4) Test target validation, i.e., that improvements in treatment adherence and skills utilization will be associated with reductions in binge eating. Exploratory aim will be to quantify the intervention factors interaction effects, which may be partially additive (because intervention factors overlap and/or there is diminishing return), fully additive, or synergistic (in that intervention factor may partially depend on each other).

5) Inclusion and Exclusion Criteria

For the study we will recruit participants from the community. Information needed to determine whether research participant meets eligibility requirements will be obtained during an initial phone-screen (see attached – using questions drawn from the Mini International Neuropsychiatric Interview (MINI). If research participants meet the inclusion criteria based on the phone screening, they will be scheduled for an in-person or remote initial clinical assessment. Trained assessors will go through each criterion and document whether the research participant is eligible for the study using a standardized assessment checklist. If research participants meet the inclusion criteria based on the clinical assessment, they will be scheduled for an in-person or remote clinical intake. Research participants will be included if they meet the following criteria:

Individuals will be included if they:

1. Are 18 to 70 years old
2. Have experienced 12 or more loss of control episodes within the previous 3 months
3. Have a BMI above 18.5
4. Are located in the US and wiling/able to participate in remote treatment
5. Are able to give consent

Individuals will be excluded from the study if they:

1. Are unable to fluently speak, write and read English
2. Are already receiving treatment for an eating disorder (e.g., research participants cannot be receiving concurrent eating disorder treatment from another provider)
3. Have a mental handicap or are currently experiencing severe psychopathology that would limit their ability to engage in study (e.g., suicidality, substance use disorder, active psychotic disorder, severe depression with suicidal intent)
4. Are purging and/or using laxatives 3 or more times per week and are not deemed safe for outpatient treatment by a primary care provider
5. Are unwilling to receive medical clearance and/or medical monitoring as requested by the study to ensure they are medically safe to participate
6. Are pregnant or planning to become pregnant within the next year
7. Are individuals who are not yet adults (infants, children, teenagers)
8. Are currently taking any of these medications: Haldol, Loxitane, Mellaril, Moban, Navane, Prolixin, Serentil, Stelaxine, Trilafon, Thoraxine, Abilify, Clozaril, Geodon, Risperdal, Seroquel, Zyprexa
9. Are adults unable to consent

10. Are prisoners

We will tell subjects verbally at the end of the Phone Screen if they are found to be ineligible for the study. If the subject asks, we will tell them the specific exclusion criteria that made them ineligible for the study.

6) Study-Wide Number of Subjects

We will be enrolling 76 research participants.

7) Study-Wide Recruitment Methods

Does Not Apply

8) Study Timelines

The research received receipt of application from the NIMH in 1st September 2022. The current study will use the first 7-months (September 2022-April 2023) of the study for synchronous development of technology-based intervention systems including Advanced DDS and JITAIs along with self-help CBT program for binge eating. We also conservatively allow 25 months (May 2023-July 2025) of active recruitment time; recruitment rates in our previous seven NIH-funded clinical trials for BN, BED, and/or obesity suggest we can reach our target of 76 research participants within this time period. Treatment will consist of 12 weeks of the self-help CBT program delivered via smartphone app for binge eating over a period of approximately 4 months.

9) Study Endpoints

The expected outcomes from the curret study will include the following:
1) The Advanced DDS with coaches will independently produce greater improvements in treatment adherence and skills utilization.
2) JITAIs system will independently produce greater improvements in treatment adherence and skills utilization.
3) Advanced DDS with coaches and JITAIs systems as adjuncts to self-help CBT program for binge eating will be feasible and acceptable. Specifically for feasibility of Advanced DDS with coaches and JITAIs, there will be a high number of patients screened per month, high % of eligible patients enrolled, low treatment attrition, high study retention, high treatment adherence, high treatment fidelity. Specifically for acceptability of Advanced DDS with

coaches and JITAIs, there will be high adherence and competency ratings from the feedback questionnaires of 20% of the sessions for each group treatment.

4) The Advanced DDS with Coaches and JITAIs will produce greater improvements in binge eating frequency at post-treatment, and 3 months follow-up.

5)Improvements in treatment adherence and skills utilization will be associated with reductions in binge eating.

10) Procedures or Methods Involved

Aims and Design. The primary aims of the study will be to (1) Test target engagement, i.e., that each factor including Advanced DDS with Coaches and JITAIs produces greater improvements in treatment adherence and skills utilization, (2) Test the feasibility and acceptability of two intervention factors as adjuncts to self-help CBT program for binge eating; (3) Test the initial efficacy, i.e., that each factor including Advanced DDS with Coaches and JITAIs will produce greater improvements in binge eating frequency at post-treatment, and 3 months follow-up; and (4) Test target validation, i.e., that improvements in treatment adherence and skills utilization will be associated with reductions in binge eating. Exploratory aim will be to quantify the intervention factors interaction effects, which may be partially additive (because intervention factors overlap and/or there is diminishing return), fully additive, or synergistic (in that intervention factor may partially depend on each other). This study is being conducted to test a novel approach to deliver evidence-based treatment in a routine clinical setting. The proposed study will use a factorial (2 x 2) design to evaluate the independent and interactive efficacy of two intervention factors (Advanced DDS with Coaches and JITAIs) when added to a self-help CBT program at improving treatment adherence, skills utilization and clinical outcomes. The self-help CBT program will be delivered through the smartphone application. Both intervention factors have two levels, either ON or OFF (Assignment is not dynamic, i.e., the ON versus OFF assignment at baseline remains as such for the entirety of the program) producing 4 possible treatment combinations.

Randomization. Participants will be randomized into one of the 4 treatment conditions and will receive 12 weeks of treatment. Of note, the treatment conditions being offered in the current study are superior than standard of care for binge spectrum eating disorders. The standard of care for binge spectrum eating disorder and bulimia nervosa is behavioral treatment. In this project, all the participants will receive self-help CBT program, which is an evidence based-treatment program for binge spectrum eating disorders and is superior to standard of care. As such, there is no potential of randomizing subjects into a condition that is less than standard of care for their eating disorders.

Treatment Conditions.

Base self-help program. All participants will receive 12 weeks of the self-help CBT program delivered via a self-help smartphone application (app). Participants will access the self-help applicationthat will guide them through the treatment and goals setting. Participants will also use the base self-help app during the week to self-monitor all eating and ED

behaviors. Below we describe the programin detail and how the treatment will be deployed via this program.

Self-help CBT app. The self-help CBT program will be delivered through the smartphone application. The application will deliver treatment via 12 learning modules that will be based on Chris Fairburn's "Overcoming Binge Eating" self-help book, the most widely used self-help resource for binge eating, that has shown to produce moderate-to-large effect size reductions in binge eating. Treatment modules will aim to 1) provide psychoeducation on maintenance factors for binge eating, 2) teach CBT skills designed to interrupt these maintenance factors, and 3) coach participant to set personalized goals each week. Modules will be completed in succession over the course of 12-weeks and a new module will be made open each week. Consistent with standard self-help CBT for binge eating, the app will allow for electronic self-monitoring (or, tracking) of eating and eating disorder behaviors. A list of the data to be collected via self-monitoring forms can found in the *Data collected through self-help app document.*

Addition of intervention factors to self-help CBT program to accomplish factorial design. As mentioned above, participants will be randomized to one of the 4 treatment combinations. The standard of care for binge spectrum eating disorder and bulimia nervosa is behavioral treatment. In this project, all the participants will receive self-help CBT program based on Dr. Chris Fairburn's evidence-basedtreatment program for binge spectrum eating disorders, and is superior to standard of care. As such, there is no potential of randomizing subjects into a condition that is less than standard of care for their eating disorders. Below, we describe the treatment when each of the two intervention factors are turned ON and OFF and when synergies occur between both intervention factors, as applicable.

Advanced Digital Data Sharing with Coaches When Advanced DDS with Coaches is turned ON, coaches having a bachelor's degree in health-related fields (e.g., psychology, nursing, nutrition etc.) will have access to a secure web portal called the digital data portal. Our team has successfully developed and used a digital data portal for ED treatments in a recent CBT+ clinical trial (R34MH11602). This portal will accomplish four key functions including, 1) gather data on target behaviors from the base self-help app (i.e., uptake of weekly module, self-monitoring compliance and skills utilization), 2) synthesize participants' behavioral data on treatment targets, 3) flag data to increase salience of behaviors needing improvement and 4) use sophisticated algorithms to generate recommendations for intervening on the identified data patterns. Using the information from the digital data portal, the coaches will send weekly emails to facilitate improvement in treatment targets. Coaches will send one email a week for a total of 12 emails over the course of treatment.

When Advanced DDS with Coaches is turned OFF, participants' will not have their data shared and will not receive emails from the coaches.

Just-in-time, adaptive interventions (JITAIs) The proposed JITAIs system will use machine learning algorithms to intervene on 1) treatment adherence, and 2) skills utilization during the 12 weeks of treatment. When JITAIs are turned ON, the base self-help app will be used to deliver targeted, personalized and automated interventions during machine learning

algorithm-identified moments when participant could benefit from receiving an intervention for improving two key areas including 1) treatment adherence, and 2) skills utilization based on responses (or lack thereof) in self-help app. For example, JITAIs will be delivered during times when treatment adherence is low (e.g., when participant has missed tracking for several days in a row, when participant has not updated weekly goals on the self-help app). JITAIs may deliver an intervention educating about relationship between low adherence and poor outcomes and suggest strategies to make progress in the following days. JITAIs will also be delivered during times of machine learning algorithm-identified moments when treatment skills use may be beneficial (e.g., participant reports an urge to binge, report skipping a meal/snack). In this case JITAIs may deliver interventions encouraging use of specific skills with brief instruction for skills implementation. For example, if a patient reports having an urge to engage in binge eating, the machine learning algorithm will identify that this patient is at risk for a binge episode in the near future. As a consequence, the JITAIs system will send automated interventions to coach a person on using urge management skills to prevent binge eating occurrence.

When JITAIs are turned OFF, participants will not receive interventions in real-time on the base self-help app.

When Advanced DDS with Coaches and JITAIs are both ON, while participants will continue to receive machine learning informed interventions, coaches will also have the ability to create and send interventions via the digital data portal to provide additional support. For instance, coaches will have the ability to write an intervention and schedule its delivery at a time when they believe participant will be at high risk for ED symptoms.

Consent procedures.

Interested parties will be provided with a telephone number and electronic mailing address to contact study personnel for more information regarding the study. A verbal consent form followed by a brief telephone screen will be used to assess initial eligibility; if research participants meet inclusion criteria based on the screening, the research participant will be scheduled for an initial clinical assessment with a trained assessor. If the research participant reports use of compensatory behaviors 3 or more times per week (i.e., purging and/or using laxatives), or endorses medical symptoms related to their eating disorder on the phone screen, we will ask the research participant to receive medical clearance from his or her PCP prior to enrollment in the study to ensure the research participant is safe to receive outpatient treatment. If the research participant refuses to obtain medical clearance or receive medical monitoring as requested by the study, they will be informed that they will not be eligible for participation in the study. Materials for their PCP will be mailed or emailed to research participants so they can obtain medical clearance for participation prior to their initial clinical assessment visit. Written or electronic informed consent will be obtained at the clinical assessment. The consent form will contain all pertinent details of the study procedure. Research participants will be clearly informed of the voluntary and confidential nature of their participation, and their right to terminate treatment at any time without penalty. After

research participants read the consent form, the program staff will paraphrase each segment of the consent form and will answer any questions. If the research participant agrees to participate, the consent form will be signed and witnessed. If the research participant chooses not to participate, they are given the option to be added to our study database to be contacted for other studies they might be eligible for at the WELL Center in the future. They will also be offered referral lists for other resources if they are interested. If they choose not to be entered into the database, all their information will be destroyed upon the completion of the study.

All assessments will be conducted remotely using the Drexel Medicine HIPAA-compliant Zoom software. Research participants must provide consent for engaging in remote assessment. Research participants will be sent the Zoom consent form via email. Research participants are offered an opportunity to set up a phone call if they had any questions about the use of Zoom for assessment. Research participants then either 1) print out the form, sign it, and scan it or take a photo and emailed that back to the study coordinator, 2) e-signed the form and emailed it back to the study coordinator, or 3) typed their first and last name in the document and emailed it back to the study coordinator. Once the research participant consents to Zoom assessments, study coordinator will send Zoom meeting invitations to their research participants at each assessment point using Drexel Outlook. Research participants who are not willing to participate remotely will be provided with referrals for other treatment providers.

Screening. Should the prospective research participant be interested in being pre-screened for this research study, they will be invited to complete a brief general interest survey and universal eligibility screener utilizing the WELL Center Screening and Registry Study (#2112008968). The WELL Center Screening and Registry Study is a screening and enrollment tool utilized by the WELL Center to determine a prospective research participant's preliminary eligibility for WELL Center research studies and will match the prospective research participant with the study that best fits their needs. The 4 phases of the WELL Center Screening and Registry Study that are utilized by the current study include (1) the General Interest Survey, (2) WELL Center Informed Screening Consent Form, (3) Universal Eligibility Screener, and (4) the Eating Disorder Phone Screen. The phone screen will have two components including, 1) determining preliminary eligibility check for basic aspects of eligibility for WELL Center research studies that can be assessed over the phone, such as age, condition of pregnancy, loss of control eating, compensatory behaviors, and suicidal ideation for the purpose of triaging prospective participants, and 2) for determining eligibility specific to current study. The first component of the phone screen will use questions from the Mini-International Neuropsychiatric Interview (MINI) to assess psychiatric comorbidity and will be conducted by trained graduate students, similar to procedures used successfully in our teams for other NIH trials. The second component will assess for eligibility the current project based on the questions asked related to study's inclusion and exclusion criteria. If the participant preliminarily appears eligible for this research study, they will then be read a brief description of the study, and, if they are interested, will be invited to sign up

for a baseline assessment. This assessment will be conducted by a trained master's level clinician and the assessment will be used to determine final eligibility.

Patients with frequent or and intense eating disorder pathology, or medical symptoms related to their eating disorder must receive clearance from their primary care physician (PCP) before they can be considered eligible for participation in this study. PCPs will be asked to provide measurements of height, weight, vital signs, and blood draws. PCPs will be notified via letter of their role in determining eligibility for the study and will be provided contact information for the study PI if they have any questions or concerns. Individuals who are or become medically unstable for outpatient treatment will be referred for appropriate medical treatment. Patients must also agree to allow study staff to communicate with their PCP throughout the study and to be reassessed for medical stability if there is a worsening in symptoms. Once a participant is enrolled in the study, study therapists/staff and the PCP will jointly determine the appropriate level of medical care outside of study visits to ensure the participant remains medically stable for outpatient treatment. If patients become medically unstable for outpatient treatment or show a significant and continued worsening in symptoms, they will be removed from the study and referred to a higher level of care. The procedures for medical management of the study patients described above have been successfully utilized by our lab in prior studies of patients with binge eating spectrum disorders. After potential participants are deemed eligible a baseline assessment will be completed. If participants are found to be ineligible at any stage of the process, participants will be given referrals if desired.

Following the baseline assessment, participants will be randomized to receive one of the four treatment conditions and will recive 12 weeks of treatment.

Plans for assessing and/or intervening on suicidal ideation or risk for serious self-harm.

Eating disorders are associated with suicidality and studies utilizing eating disorder samples have a plan to ensure the adequate assessment and treatment of suicidality. If study staff or clinicians become aware of a clinically significant increase in depression or the emergence of suicidal ideation or self-harm behavior, the participant will undergo a comprehensive assessment of suicide ideation, plan, and intent with Dr. Paakhi Srivastava (a Licensed Clinical Psychologist), and the necessary precautions will be taken to ensure safety or medical attention as appropriate. If high acute risk for suicidal ideation is discovered, Dr. Srivastava will make a telephone connection to a crisis resource (i.e., 24-hour crisis lines at 800-273-8255) while maintaining contact with the participant in order to make a direct transfer. In addition, Dr. Srivastava will also immediately connect these participants with mental health emergency for hospitalization. These participants will be removed from the study so their suicidal ideations can be fully addressed. If intermediate acute risk and low acute risk for suicidal ideation is discovered, Dr. Srivastava will provide participants with contact information for mental health care provider and will be instructed to use mental health resources in case of psychiatric emergency or suicidality (i.e., 24-hour crisis lines at 800-273-8255) that occurs outside of standard business hours when Dr. Srivastava could not be reached. These participants will be allowed to continue their study participation. Dr. Srivastava will maintain contact

mental health provider to determine acuity of referral. This method for assessing and intervening on suicidal ideation or risk for serious self-harm is currently standard practice in the WELL clinic and has been used successfully in our other clinical trials for BN and BED.

Ensuring participants receive high-quality interventions.

Coaches will be individuals with bachelor's degree in health-related fields (e.g., psychology, nursing, nutrition etc.) working at the WELL clinic. Coaches are research personnel and have been trained in human subject research through CITI. Coaches will receive training from Dr. Srivastava on reviewing participant's treatment adherence, skills utilization, and self-monitored data and to provide support to participants for improving treatment adherence and skills utilization via emails. Coaches will attend weekly group meetings with Dr. Srivastava to jointly review participants' treatment adherence, skills utilization, and self-monitored data and discuss ways to offer support for improving behaviors related to treatment targets via emails. All assessors will already have had prior training and experience working with individuals with eating disorders. Study personnel will receive specialized training in the administration of assessments. Training will be conducted by Dr. Srivastava will include, but not be limited to, review and discussion of interviews, role playing, and dry runs with practice individuals with live supervision. The project statistician will conduct randomization to prevent the assessor from being a source of bias. The content of the base self- help CBT program will be based on Chris Fairburn's evidence-based Overcoming Binge Eating book.

The standard of care for binge spectrum eating disorder and bulimia nervosa is behavioral treatment. In this project, all the participants will receive self-help CBT program based on Dr. Chris Fairburn's evidence based-treatment program for binge spectrum eating disorders and is superior to standard of care. As such, there is no potential of randomizing subjects into a condition that is less than standard of care for their eating disorders.

Participants will continue in their current medical treatment at time of enrollment. Medical status will be closely monitored throughout the intervention. Participants will be required to sign consent to contact their PCP throughout the study to ensure coordination in care. The PCP will be provided with a letter describing enrollment in the study. Participants will be informed that the research team will inform the PCP if there is a change in symptom status such as notable weight loss, increase in restrictive eating behavior or increase in purging behavior that may require additional medical management. Concurrent psychotherapy for eating pathology will not be permitted during the study as this could confound data. Pharmacological management will be permitted for psychiatric co-morbidities. Any prescribed medications or dosage changes will be carefully tracked through the study.

Assessment Procedure. Assessments will occur at at baseline, mid-treatment, post-treatment, and at 3-month follow-up. In order to maximize assessment completion, we

will increase compensation across assessments ($20, $30, $50 and $75). At the beginning of the assessment at the baseline, the assessor will review the IRB approved Consent Form with the prospective participant. Of note, none of the assessments within the proposed study requires prospective participants to provide their signatures except for the Consent Form. Assessments will be conducted by Independent Evaluators (IEs), IEs will be trained until they reach 100% agreement on diagnosis and acceptable reliability (>.80) on EDE scoring. Assessments will be audio recorded for review. Twenty randomly selected tapes will be reviewed to compute reliability statistics. All measures listed below have acceptable psychometric properties.

Assessments will be conducted by unblinded assessors at baseline, mid-treatment, post-treatment, and at 3-month follow-ups. Assessments will be for a total of 3 hours in length. Assessors for the baseline, mid-treatment, post-treatment, and 3 month follow up will be research coordinators employed and paid by the WELL Center and Ph.D students at Drexel University. Three hours of the assessment is a semi-structured interview in which the participants will be using a zoom link via Drexel's HIPAA compliant Zoom platform the assessor sent prior to the interview to meet with the assessor who conducts the interview with the participant. Total length of participation in this study will be about 7 months from the baseline assessment to the 3-month follow-up assessment. As the study continues, the status of the trial will be updated on http://www.ClinicalTrials.gov as different phases of the study start and end (including but not limited to "not yet recruiting", "recruiting", "active not recruiting", and "completed").

This study will have 2 kinds of blind assessors. One type of blind assessor is the study coordinator. The study coordinator is a full-time paid employee on the study. As part of their job responsibilities, they will conduct assessments for this current study. The other type of assessors is graduate students. Students serve as assessors on clinical trials being conducted in a research lab to receive specialized training and supervision in conducting clinical interviews for assessing eating disorders. Typically, graduate students are obligated to fulfill 8 hours of training time in the specialized research lab without getting paid. Graduate students will be asked to conduct assessments within these 8 hours of free lab time and hence, will not be paid for conducting the assessments. In the conditions with Advanced DDS with Coaches, coaches will be unblinded throughout the 12-week program. Coaches will know the study condition and diagnosis of the specific patients they've been assigned in order to facilitate improvement in treatment targets of the patients they've been assigned. Coaches will be blinded to the clinical outcomes from treatment for the patients they are assigned to. They will be blinded to all clinical outcomes data collected at different assessment time points.

Blood Draws. As is standard, blood testing to assess for medical complications associated with purging is conducted based on severity of purging behavior. If participants demonstrate purging 3 or more times per week and are deemed unsafe to continue study participation by their PCP, they will be removed from the study to receive medical care of worsened purging behavior, and thus, will not undergo anymore blood testing for the study assessments. If the severity of purging is low (i.e., less than 3

episodes per week), participants may undergo blood testing once during the study for medical monitoring and to receive PCP clearance to continue study participation in addition to study assessments.

Feasibility and Acceptability. Assessment of feasibility will include number of patients screened per month, % of eligible patients enrolled, treatment attrition (% of patients that prematurely terminate treatment), study retention (% of patients that complete all study assessments), treatment adherence, treatment fidelity. Acceptability will be assessed using the Feedback Questionnaire. During treatment each session will be audio-recorded and 20% of the sessions for each group treatment will be randomly selected for adherence and competency ratings by a blinded IE.

Outcome Measures

Rater-Administered Measures:

- ***Eating Disorder Examination (EDE).*** The EDE is a widely utilized, semi-structured interview for the assessment of eating disorder symptoms. The EDE interview will be audio recorded and will be used to confirm research participant's eligibility. The EDE has been updated to the newest version of this measure.

- ***Mini International Neuropsychiatric Interview (MINI).*** The MINI is a structured psychiatric diagnostic interview.
- ***Body Mass Index (BMI).*** For BMI, height (via stadiometer) and weight (via medical-grade, digital scale) will be assessed in the clinic prior to treatment onset and at each assessment point. This data will be used to calculate BMI. In the case of remote assessments, research participants will weigh themselves at home using digital scales and take their heights using yard sticks or measuring tape.

- ***Eating Disorder Diagnosis.*** This measure will be used to determine a research participant's eating disorder diagnosis based on the presence, frequency, and duration of pathological behavioral symptoms a research participant endorses at the assessment point.

- ***Feedback Questionnaire.*** This measure will be used to assess research participant's overall enjoyment and perceptions of the treatment and assessments. The measure

will be conducted as an interview at mid-treatment (after 6 weeks of treatment) and post-treatment (after 12 weeks of treatment).

Self Report Measures

- ***Demographics Questionnaire (DQ).*** The Demographics Questionnaire will assess information such as age, sex, gender, sexual orientation, ethnicity, and SES.

- ***Dieting and Weight History Questionnaire (DWHQ).*** The DWHQ evaluates weight suppression, weight history, current and previous dieting history.

- ***Beck Depression Inventory-II (BDI-II).*** The BDI-II measures depression symptomatology over the past 2 weeks.

- ***Quality of Life Inventory (QOLI).*** The Quality-of-Life Questionnaire assesses quality of life across several life domains

- ***Short Positive and Negative Affect Scale (PANAS).*** The PANAS assesses positive and negative affect over a specified period of time.

Other measures

- ***Treatment adherence*** will be indicated by number of completed modules within 12 weeks of treatment, number of pages visited, number of worksheets completed, and goals setting each week using the appand self-monitoring compliance (i.e., number of days when self-monitoring was completed).

- ***Skill utilization*** will be assessed using data from the self help app. Because participants will be recording eating behavior via app multiple times per day throughout the duration of the study in all conditions, electronic monitoring forms will be a valuable source of data on real-time skills use for the three skills related to reducing dietary restraint. Because skill use related to effectively coping with cues that trigger binge eating cannot be as easily identified from self-monitoring records, we will obtain self-reported data on frequency of skill use and success of skill use from pre-module surveys that participants will be asked to complete prior to each week's module using questionnaire that was developed for use in R34MH116021. These items were adapted from the Difficulties in Emotion Regulation Scale (DERS)

to assess skills related to internal experiences such as urges that contribute to ED behaviors.

Assessment Schedule

Assessment	Baseline	Mid-tx	Post-Tx
Eating Disorder Examination	X	X	X
Mini International Neuropsychiatric Interview	X		
Body Mass Index	X	X	X
Feedback Questionnaire		X	X
Demographics Questionnaire	X		
Beck Depression Inventory-II	X	X	X
Dieting and Weight History Questionnaire	X		
Quality of Life Inventory	X	X	X
Short Positive and Negative Affect Scale	X	X	X
Treatment adherence		X	X
Skill utilization		X	X
Condition of Pregnancy	X	X	X

11) Data Banking

Dr. Srivastava will administer a data collection and storage training to all project staff who must demonstrate competence in interviewing and administration before commencing their responsibilities. Staff will be assigned to review assessment data for accuracy and completion, and to pursue missing data by re-contacting research participants. Specialized validity tools (e.g., customized spreadsheets and data entry software) will be used to maximize data accuracy. Double entry will be utilized where appropriate. As per IRB policy, all research participant data, including the fact of participation, will be treated confidentially and will be safeguarded according to the practices described above. Research participants will sign HIPAA authorizations specifying the use of their protected health information (PHI). The research team will collect and retain any PHI from the medical records obtained through the HIPAA authorization. Permission to release information pertaining to mental health diagnosis or treatment collected in the current

study to other providers, if needed will also be collected. Any PHI collected will be stored for 7 years. Confidentiality will be strictly maintained during each of the research activities. All identifying information will be kept confidential by project staff. Citation and data entry will be made using research participant numbers only. All research data will be kept separate from identifiers and linked with research participant numbers. Only Dr. Srivastava and her study staff will have access to the file linking names and research participant numbers, which will be stored securely in a password protected excel database using Drexel's virtual private network (VPN) and on Drexel's secure REDCap system. If applicable, any physical documentation of research data will be stored in locked cabinets in locked offices at Drexel University. All electronic files containing research data will be password protected and stored on a secure network. All research assistants will be instructed not to discuss research participants outside of the research team. All statistical analyses will focus on aggregate data, all interview data will be appropriately disguised, and no individual research participants will be identified in research reports. The Data Safety Officer will monitor data-management processes, and Dr. Srivastava will randomly check data storage and management throughout the course of the study. Only if required by law will subject identifiable data be disclosed to persons or organizations not directly involved in this research. With the exception of release of information required by law, no subject identifiable information will be released without the subject's explicit permission. The data collected by the smartphone application will not be shared with other smart devices, third parties or specified organizations. All the data you entered in the app will be saved on an encrypted back-end server, which will be linked to the unique research participant identifier assigned to you. No personal health information will be linked to this data collected from the smartphone application and saved on the back-end server. This back-end server will only be accessed by the study team using a secure password.

Participant Confidentiality. As per policy of the IRB, all research participant data, including the fact of their participation, will be treated confidentially and will be safeguarded according to the practices described above. To ensure research participant confidentiality, training will be provided to all staff regarding responsibilities for maintaining and protecting research participant confidentiality. Unique identifiers will be used to identify research participants in the database, and all written measures and transcripts will be solely identified with a research participant identifier. All data will be housed in locked files to which only the study staff will have access. The master list linking research participant names and unique identifiers will be securely stored in a password protected excel database that can only be accessed when connected to Drexel's VPN. The data collected by the smartphone application will not be shared with other smart devices, third parties or specified organizations. All the data you entered in the app will be saved on an encrypted back-end server, which will be linked to the unique research participant identifier assigned to you. No personal health information will be linked to this data collected from the smartphone application and saved on the back-end server. This back-end server will only be accessed by the study team using a secure password.

If applicable, any physical data will be stored in a locked file cabinet in a location physically distant from the data. Drexel-owned computers used for data collection will be password protected and, if we are not operating remotely, they will be stored in locked file cabinets when

not in use. Baseline and follow-up measures will be linked by the unique identifiers employed (which will be stored in the password protected excel database, only accessible when connected to Drexel's VPN and Drexel's secure REDCap system). Research participant consent forms will stipulate the research activities and treatment services they can anticipate and the protections they will receive. Study findings will make use of aggregate data only and no publication or presentation will involve any use of individual or personalized information. All physical copies of medical information collected as part of the medical clearance process will be kept confidential by project staff and stored in locked cabinets in locked offices at Drexel University. All electronic copies of medical information collected as part of the medical clearance process will be received from research participants through Drexel's secure Outlook system and the information will be password protected and stored on a secure network.

12) Data Management

Data collection, storage, and quality control. Data for those who fail screenings and do not meet inclusion criteria will be destroyed or, with consent from the participant, participants may be screened for another study or added to the WELL Center database to be contacted for future studies.

All data will all be de-identified and code numbers will be used to integrate the various data collected from each subject. The pre and post study self-report questionnaires will be completed on the research participant's computer using a secure survey collection website (Drexel's REDCap system). Unidentifiable data will be downloaded and entered into SPSS. Data files will not contain personal health information. Name and contact information will be stored in a separate password-protected Excel database, only accessible when connected to Drexel's VPN and Drexel's secure REDCap system, to enable the researchers in facilitating remuneration and future contact. Names will not be linked to data. All electronic files will be stored on a Drexel-owned computer in an encrypted password protected directory that can only be accessed by specific, trained users. Data is de-identified and will not contain PHI including information pertaining to mental health diagnosis or treatment, and is stored on an encrypted backend server(a unique subject identification number will be used in place of participants names to identify
input from the app). Our server utilizes industry-standard encryption techniques (e.g., secure sockets layer; SSL) to facilitate secure data transfer from subject device to study repository). For data analysis purpose, data from our server will be downloaded to Drexel-owned computers. All data will be stored on research lab computers with encrypted storage in password-protected files. All paper surveys (if any) will be labeled with non-identifiable information and stored in a locked filing cabinet in a limited access, password protected office at the Drexel University Center for Weight, Eating, and Lifestyle Science (WELL Center). All data will be erased or shredded in the standard 3 years after publication of results. The data collected by the smartphone application will not be shared with other smart devices, third parties or specified organizations. All the data you entered in the app will be saved on an encrypted back-end server, which will be linked to the unique research participant identifier assigned to you. No personal health information will be linked to this data collected from the smartphone application and

saved on the back-end server. This back-end server will only be accessed by the study team using a secure password.

Data for this study will be entered into REDCap , a secure data collection tool , which uses a MySQL database via a secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. The MySQL database and the web server will both be housed on secure servers operated by Drexel University College of Medicine Information Technology. The servers are in a physically secure location on campus and are backed up nightly, with the backups stored in accordance with the retention schedule of daily, weekly, and monthly tapes retained for 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The servers provide a stable, secure, well-maintained, and high-capacity data storage environment, and both REDCap and MySQL are widely used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password.

Blinding of Data. All data will be blinded, and therefore, will contain no identifying information, except as required when reporting adverse events. All research data will be kept separate from identifiers and linked with a participant number. Only Dr. Srivastava and her study staff will have access to the file linking names and participant numbers, and this file will be stored in an encrypted backend secure server.

Protected health information storage and privacy in self-help CBT program. The research team will generate unique user ID and password that will not include any personal identifiable information (PII) to allow participants to access the self-help CBT program. De-identified data pertaining to eating behavior, (e.g., food consumed, binge eating, context for eating episodes) will be automatically transmitted through end-to-end transmission from the base self-help app to an encrypted backend server. End-to-end transmission of digital data will be encrypted over HTTP using TLS1.2 enforced. Our database server utilizes industry-standard encryption techniques (e.g., secure sockets layer; SSL and Transparent Data Encryption; TDE) to facilitate secure data transfer from subject device to study repository). In order to safeguard these data and participants' privacy, the following steps will be taken: (1) Informed consent will be conducted prior to the study screening procedures. The informed consent procedure will fully and in plain English explain which data are shared, the manner of sharing and the potential risks (e.g., another individual gaining access to their mobile device, theft or loss of their mobile device, interception of transmission); (2) participants will be provided with clear instructions for safeguarding data (e.g., setting a password for entry to the smartphone or laptop, setting an automatic timer to lock the device after a certain number of seconds of non-use, keeping the device on their person at all times); (3) data will regularly be downloaded from the encrypted and secure web server by study staff and subsequently removed from the web server; and 4) self-help app will have its own sandbox environment and no data will be shared outside the app.

Protected health information storage and privacy in treatment conditions when Just-in-time, adaptive interventions (JITAIs) are turned ON. In addition to above measures to

safeguard participants' data and privacy, in treatment conditions when JITAIs are turned ON, following steps will be taken. 1) Intervention messages will only be accessible via smartphone app which will be password protected, 2) Intervention messages will be nondescript and will not include participant's PHI including information pertaining to mental health diagnosis or treatment, and 3) Push notifications will not contain any sensitive information.

13) Provisions to Monitor the Data to Ensure the Safety of Subjects

Participants will continue in their current medical treatment at the time of enrollment. Medical status will be closely monitored throughout the intervention. Participants will be required to sign consent to contact their PCP throughout the study to ensure coordination in care. The PCP will be provided with a letter describing enrollment in the study. Participants will be informed that their study staff will inform the PCP if there is a change in symptom status such as notable weight loss, increase in restrictive eating behavior, or increase in purging behavior that may require additional medical management. If the study team becomes aware of worsening levels of disordered eating symptoms that could pose an acute danger to the research participant's health, we will work with them to get touch with their primary care physician and encourage additional medical monitoring to ensure they are safe and stable enough to be receiving outpatient treatment based on their primary care physician's discretion. If they do not have access to a primary care physician, we will help them locate one. We will also provide referrals for treatment. Concurrent psychotherapy will not be permitted during the study as this could confound data. Pharmacological management will be permitted for psychiatric comorbidities. Any prescribed medications or dosage changes will be carefully tracked through the study.

14) Withdrawal of Subjects

Research participants will be withdrawn from the study if they no longer meet the study criteria and/or they experience any acute life-threatening incident (precipitous drop in weight, change in electrolyte balance, etc.), hospitalization, suicidal or homicidal ideation, or serious self-harm behavior, failure to comply with study procedures. Condition of pregnancy will be assessed during the baseline, mid-treatment, post-treatment, and 3 month follow-up. If the research participant finds out that they are pregnant or plan on becoming pregnant within the next year during their time in the study, they must notify the project coordinator immediately. They will no longer meet study criteria and will be withdrawn from the study immediately. If termination is found necessary, the research participant will be contacted by the project coordinator immediately and the necessary precautions will be taken to ensure safety or medical attention as appropriate. The research participant will then be provided with referrals to other programs or studies if applicable and the data will be destroyed/barred from use. If, at any time, the treating physician determines that the health of the research participant precludes continuation of outpatient treatment, a meeting will be scheduled with the treating physician, research participant, and study staff to assist in locating referrals for appropriate levels of care. If a higher level of care is sought, research participants will be removed from the trial. Research participants are given the option to be added to our study database to be contacted for other studies they

might be eligible for at the WELL Center in the future. If they choose not to be entered into the database, all their information will be destroyed.

15) Risk to Subjects

Eating disorders can be medically dangerous, particularly if the individual is of low weight or engaging in frequent or severe compensatory behaviors. Thus, careful monitoring of treatment progress is essential. It is possible that some research participants may develop Anorexia Nervosa or display dangerous electrolyte imbalances due to purging. In this case, the research participant will be removed from the study and referred to a more appropriate level of care (e.g., intensive outpatient, inpatient treatment). The process for tracking this information and making referrals to a higher level of care is described below.

Some research participants undergoing treatment may become uncomfortable or anxious. Research participants will be asked to abstain from binge eating and purging, a process that is difficult given the nature of the illness. Research participants will also be asked to provide information regarding a number of significant health behaviors during the assessments. However, all assessment instruments have been used in past research without incidence and research participants will be informed that they can skip questions or discontinue participation at any time. Although we expect most research participants to show a reduction in disordered eating symptoms, it is possible that some research participants could experience a worsening of eating disorder symptoms during the study period. If a worsening of symptoms is identified, we will follow the protocol described below to ensure the safety of research participants. This protocol is based on those used in our team's current NIH funded trials for BN and BED. If a coachidentifies worsening binge eating symptoms or compensatory behaviors, the principal investigator and research coordinator will be notified. If the increases in disordered eating symptoms are determined to be transient, mild, and unlikely to result in adverse health consequences, efforts will be made to keep the research participant enrolled in the current study and treatment condition consistent suggestions will be made to address current symptoms. If the increases in eating disorder symptoms are sustained, clinically significant, or likely to cause health consequences, we will consult with the research participant's PCP to discuss whether medical management is needed. Research participants with frequent and intense eating disorder pathology will be medically monitored by their PCP throughout the trial and will only be allowed to participate if it is deemed medically appropriate by their PCP. Research participants will be informed that research personnelwill inform the PCP if there is a change in symptom status such as an increase in restrictive eating behavior or increase in purging behavior that may require additional medical management. It is expected that these research participants will have regular appointments with their PCP, the frequency of which will be determined by the treating physician. In order to facilitate care, consent will be obtained prior to treatment onset for two-way communication between study staff and the treating physician. As part of the trial, treating physicians will also be provided current practice guidelines as set forth by the American Academy of Psychiatry regarding eating disorders. Research participants without a PCP, with limited access to their PCP, or with a PCP that is unable to effectively monitor their eating disorder symptoms, will be assisted in locating a PCP that better fits their needs. We will not be

covering any costs for PCP visits or related fees. Ongoing participation in the trial will be contingent upon continued medical management. If, at any time, the treating physician determines that the health of the research participant precludes continuation of outpatient treatment, a meeting will be scheduled with the treating physician, research participant, and study staff to assist in locating referrals for appropriate levels of care. If a higher level of care is sought, research participants will be removed from the trial.

16) Potential Benefits to Subjects

All efforts will be made to minimize the risk to research participants in this study, with medical monitoring occurring on a regular basis and research participant data being securely stored. The proposed treatment includes elements that have been shown to lead to decreased symptomatology in research participants with clinically significant binge eating and comorbid syndromes, and to improve quality of life and associated distress. Thus, it is expected that research participants will directly benefit from the study intervention. Also, the standard of care for binge spectrum eating disorder and bulimia nervosa is behavioral treatment. In this project, all the participants will receive self-help CBT program based on Dr. Chris Fairburn's evidence-based treatment program for binge spectrum eating disorders, which is superior to standard of care. Indirect benefits include increased knowledge regarding treatment for clinically significant binge eating, which will improve interventions for future research participants and could decrease the impact of this illness on society by way of decreased health care costs and disability. As such, the benefits of this study far outweigh the potential risks.

17) Vulnerable Populations

Does not apply

18) Multi-Site Research

Does not apply

19) Community-Based Participatory Research

Does not apply

20) Sharing the Results with Subjects

Participants will have access to their own personal survey and interview results upon request; however, researchers will not share data with each participant as part of study protocol. If participants request their data, they will be provided with a password protected excel file with their own response. A password will be sent in a separate email to ensure protection of data. If the research participant doesn't have access to a computer, they can be provided a paper copy of their responses.

Additionally, information will be shared with the subject's primary care physicians. Medical status will be closely monitored throughout the intervention by the PCP and patients will be required to have additional medical evaluations if they show a deterioration in symptoms. Participants will be required to sign consent to contact their PCP throughout the study to ensure coordination in care. The PCP will be provided with a letter describing enrollment in the study

and provide detailed information on the medical management of transdiagnostic binge eating. Participants will be informed that their coach/study staff will inform the PCP if there is a change in symptom status such as an increase in restrictive eating behavior or an increase in purging behavior.

21) Setting

The study will take place remotely via Drexel's HIPAA compliant zoom. This study spans the research side of the Center for Weight Eating, and Lifestyle Sciences (WELL Center) clinic, an outpatient treatment facility located on Drexel University's campus that provides empirically supported treatment of eating disorders, feeding disorders, and obesity to the Philadelphia-area community. Research participants with transdiagnostic binge eating will be specifically recruited to the WELL clinic using a number of referral sources and advertising methods successfully employed by our team in the past. Dr. Srivastava has already established a steady flow of referrals for her existing trials recruiting research participants with binge eating disorder (BED) and bulimia nervosa (BN) from the connections she has made in the Philadelphia region and we believe these sources will continue referring research participants at a suitable rate during the course of the current study. Find more information regarding referrals in the "Recruitment Methods" section.

Remote assessments will be conducted through the Drexel Medicine HIPAA-compliant Zoom software. Research participants must provide consent for engaging in remote assessments through zoom consent form.

All assessments will be provided remotely. Research participants who are not willing to participate remotely will be withdrawn from the study and will be provided with referrals for other treatment providers.

22) Resources Available

Research and support staff. A co-investigator, study coordinator, and graduate students will be able to dedicate 40 hours a week to the project. Access to ample support staff (including support for grant administration, budgeting, teaching, general administration, and ordering of equipment and supplies) will be readily available due to several other studies being conducted in the lab.

WELL Center. The investigators on the project are experts in the area of the development of acceptance-based treatments for health-related behavior change, related to eating disorders and obesity. The lab has several NIH-funded research grants related to eating behavior, including a recent grant to develop a smartphone app for the treatment of binge eating disorder, a multi-site trial testing an eating disorder prevention program, and two R01s investigating acceptance-based treatments for obesity.

Department of Psychology. The Department of Psychology is actively engaged in research initiatives to advance the science and practice of psychology. The faculty is highly collaborative, frequently cooperating on research projects, co-mentoring doctoral students, and providing consultation to one another as needed. Faculty and students collaborate on a great deal of

research; a total of 110 conference presentations and 61 publications (including four books) resulted from these efforts during the past few years. Extramural funding totaling over $10 million (including the full number of ongoing awards) support this work in 2011. The department currently houses several prominent research laboratories that focus on research similar to the proposed study, including acceptance-based behavioral treatment and eating pathology.

Laboratory Space. Because this study will occur remotely, no laboratory space will be required.

Computing Facilities. At present, all personnel have desktop and laptop computers with broadband Internet connections and necessary word processing and statistical software. The system is protected by firewalls and password protection for security of sensitive data.

Independent Evaluator Training, Supervision, and Integrity. Outcome assessments will be conducted by independent evaluators (IE). IEs will be highly trained and closely supervised clinical psychology doctoral students. IEs will be trained until they reach 100% agreement on eating disorder diagnosis and acceptable reliability (> .80) on EDE scoring. Assessments will be audio-recorded for review. The identity of participants will not be discussed to prevent the possibility of this information influencing feedback and rating decisions. If reliability falls < .80, retaining procedures will be implemented. If this is insufficient, the IE will be replaced. Twenty randomly assigned selected tapes will be reviewed to compute reliability statistics for diagnoses and ratings.

23) Prior Approvals

Does not apply.

24) Recruitment Methods

Research participants with BN and BED will be specifically recruited to the WELL clinic using a number of referral sources (including, physicians, dentists, university counseling centers, eating disorders providers and psychiatrists) successfully employed by our team during in the past. Dr. Srivastava has already established a steady flow of referrals for their existing trials recruiting research participants with BN and BED from the connections they have made in the Philadelphia region and we believe these sources will continue referring research participants at a suitable rate during the course of the current study.

In addition to these methods, we will also recruit research participants through flyers distributed throughout the greater Philadelphia area, social media advertisements, and radio ads throughout the Philadelphia area. We will ensure to distribute flyers in areas where permission is not required (including locations that have established and strong connections with the Well Clinic and thus do not require anything beyond verbal permission for our flyers to be distributed there). In all of these recruitment methods, the participant will be directed to the interest survey on the WELL Center website. Anyone who lands on the WELL Center website will be asked if they are interested in participating in one of the WELL Center's ongoing clinical trials or research

studies. If they are interested, they will complete the general interest survey, which will direct them to complete a universal phone screen that determines their eligibility for any active study or clinical trial. All advertisement methods will be approved by Drexel's communication office prior to be administered.

Research participants will receive up to $175 in compensation for completing the study. They will receive $20 for completing the baseline assessment, $30 for completing the mid treatment assessment, $50 for completing the post-treatment assessment, $75 for completing the 3-month follow-up assessment.

Participants will receive compensation for their participation after each assessment point through QuickPay, a remote-payment electronic system at Drexel, which is administered by JPMorgan Chase Bank. This system allows us to compensate participants in the study through a secure electronic payment system (ACH) that is used by most major banks. This system securely sends direct payments from an account associated with this study to the participant's account, immediately upon study completion. The use of this system as a payment option allows for remote payment and helps us protect the privacy and safety of the participants and the research staff.

To use this form of payment, the participant number ID and your email and phone number will be provided to JPMorgan Chase Bank. Participants will receive an invitation to receive payment either as an email or a text message. Once you accept the invitation the funds will be disposed to your account by the next business day. Drexel University and the researcher team do not have any access to your account information, and they are not directly involved in the disbursement of the funds. If participants cannot or do not want to receive a direct, electronic payment through this system, they have the option of receiving a check from Drexel University. Alternatively, if participants do not want a check, we can send them an electronic Amazon gift card to their provided email.

Research participants who discontinue their participation in treatment will be encouraged to continue to participate in assessments for compensation. In order to facilitate completion of assessments and increase quality of data, all the assessments will be completed electronically and remotely. This will be via the secure on-line data collection site "REDCap". All data will be downloaded and stored in password protected files on Drexel-owned computers.

25) Number of Subjects

The current study is seeking to recruit 76 subjects to complete the treatment program. We plan to screen 150 subjects over the phone and conduct baseline assessments until 76 eligible participants are enrolled in the study.

26) Confidentiality

Confidentiality will be strictly maintained during each of the research activities. All identifying information will be kept confidential by project staff. Citation and data entry will be made using participant numbers only. All research data will be kept separate from identifiers and linked with participant numbers. Only Dr. Srivastava and her study staff will have access to the file linking names and participant numbers, and this file will be stored cabinets in locked offices at Drexel University for 3 years and then shredded. Electronically collected data (e.g., audio recordings, electronic surveys, databases) will be stored on a research lab computer within an encrypted password protected directory (using Sophos SafeGuard Enterprise) maintained and implemented by Drexel University. All research assistants will be instructed not to discuss research participants outside of the research team. Data will not contain PHI including information pertaining to mental health diagnosis or treatment and is stored on an encrypted backend server (a unique subject identification number will be used in place of participants names to identify input from the app). All statistical analysis will focus on aggregated data, all interview data will be appropriately disguised, and no individual participant will be identified in research reports. Except for release of information required by law, no subject identifiable information will be released without the subject's explicit permission. Dr Srivastava will monitor the data management process and randomly check data storage and management throughout the course of the study.

27) Provisions to Protect the Privacy Interests of Subjects

This study is designed in order to maximize the privacy interest of research participants. Data will be collected from research participants continuously throughout the study by remote assessment (e.g., pre- and post-intervention period) and through continuous contextual assessment methods (e.g., treatment). Survey responses will remain anonymous, and all data will be de-identified with unique subject identifiers. Identifiable information will only be used for payment and scheduling and will be kept separate from all data. Participant contact information may be stored on Calendly, an online booking system vetted by Drexel's Information Security team. All assessments scheduled via Calendly are synced to the corresponding Drexel employee's Outlook calendar and are only visible to those currently on the research team and the research participant. Research participants are invited to use Calendly for scheduling purposes, however, if research participants do not want to use Calendly, they will be offered alternative scheduling methods (i.e., scheduling via email or phone call). Using Calendly is not required to participate in the research study. If a research participant chooses to schedule an assessment via Calendly, they are instructed to only use their first name and the last initial for assessments (i.e., phone screens and clinical assessments) or their unique participant id number to schedule

assessments. All questions are worded as to minimize stress and anxiety for research participants. Researcher contact information will be provided and research participants will be encouraged to contact if they have any questions regarding the research process.

Protected health information privacy in self-help CBT program. The research team will generate unique user ID and password that will not include any personal identifiable information (PII) to allow participants to access the self-help CBT program. De-identified data pertaining to eating behavior, (e.g., food consumed, binge eating, context for eating episodes) will be automatically transmitted through end-to-end transmission from the base self-help app to an encrypted backend server. End-to-end transmission of digital data will be encrypted over HTTP using TLS1.2 enforced. Our database server utilizes industry-standard encryption techniques (e.g., secure sockets layer; SSL and Transparent Data Encryption; TDE) to facilitate secure data transfer from subject device to study repository). In order to safeguard these data and participants' privacy, the following steps will be taken: (1) Informed consent will be conducted prior to the study screening procedures. The informed consent procedure will fully and in plain English explain which data are shared, the manner of sharing and the potential risks (e.g., another individual gaining access to their mobile device, theft or loss of their mobile device, interception of transmission); (2) participants will be provided with clear instructions for safeguarding data (e.g., setting a password for entry to the smartphone or laptop, setting an automatic timer to lock the device after a certain number of seconds of non-use, keeping the device on their person at all times); (3) data will regularly be downloaded from the encrypted and secure web server by study staff and subsequently removed from the web server; and 4) self-help app will have its own sandbox environment and no data will be shared outside the app. However, the research team will collect and retain any PHI from the medical records obtained through the HIPAA authorization. Any PHI collected will be stored for 7 years.

Protected health information privacy in treatment conditions when Just-in-time, adaptive interventions (JITAIs) are turned ON. In addition to above measures to safeguard participants' data and privacy, in treatment conditions when JITAIs are turned ON, following steps will be taken. 1) Intervention messages will only be accessible via smartphone app which will be password protected, 2) Intervention messages will be nondescript and will not include participant's PHI including information pertaining to mental health diagnosis or treatment, and 3) Push notifications will not contain any sensitive information.

28) Compensation for Research-Related Injury

Does not apply. This research does not involve more than minimal risk to subjects.

29) Economic Burden to Subjects

Does not apply. This research will be conducted remotely via Drexel HIPAA-Compliant Zoom software.

30) Consent Process

The Institutional Review Board of Drexel University will have approved the protocol, advertisements, and consent form prior to initiation of the study. Interested parties will be provided with a telephone number and electronic mailing address to contact study personnel for more information regarding the study. A verbal consent form followed by a brief telephone

screen will be used to assess initial eligibility. If the research participant reports use of compensatory behaviors 3 or more times per week (i.e., purging and/or using laxatives), has a BMI <18.5, or endorses medical symptoms related to their eating disorder on the phone screen, we will ask the research participant to receive medical clearance from his or her PCP prior to enrollment in the study to ensure the research participant is safe to receive outpatient treatment. If the research participant refuses to obtain medical clearance or receive medical monitoring as requested by the study, they will be informed that they will not be eligible for participation in the study. Materials for their PCP will be mailed or emailed to research participants so they can obtain medical clearance for participation prior to their initial clinical assessment visit. If participants meet inclusion criteria based on the screening, the participant will be scheduled for an intake interview and initial assessment via Drexel HIPAA-Compliant Zoom software.. Materials for their PCP will be mailed so that participants can obtain medical clearance for participation prior to their intake interview. Written informed consent will be obtained at the clinical interview. The consent form will contain all pertinent details of the study procedure. Participants will be clearly informed of the voluntary and confidential nature of their participation, and their right to terminate treatment at any given time without penalty. After participants read the consent form, the program staff will paraphrase each segment of the consent form and will answer any questions. If the participant agrees to participate, the consent form will be signed and witnessed. If, during the study period, new study procedures are added (e.g., new assessment measures are added), written consent addendum will be obtained by participants. The consent addendum will allow already enrolled participants to agree to additional study procedures not disclosed in the initial consent form.

Non-English Speaking Subjects

Does Not Apply

Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

Does Not Apply

Subjects who are not yet adults (infants, children, teenagers)

Does Not Apply

Cognitively Impaired Adults

Does Not Apply

Adults Unable to Consent

Does Not Apply

Adults Unable to Consent

Does Not Apply

31) Process to Document Consent in Writing

Consent will be obtained in writing after an individual has been deemed eligible to participate in the study. After a research participant has read the consent form, they will be asked if they have any questions regarding the research and a member of the research team will be present to read through the consent and answer questions. They will then be asked to sign the consent and initial each page as they review it. Researchers will sign the document as well. They will be given a copy of consent and are encouraged to contact the PI at any time if they have any questions or concerns.

Consent form is attached.