Complete Title: Targeting Relationship Domains in Community-Based Treatment of Binge-Eating Disorder

Short Title: Uniting Couples in the Treatment of Binge-Eating Disorder (UNITE)

Sponsor: National Institute of Mental Health

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Short Title: Uniting Couples in the Treatment of Binge-Eating Disorder (UNITE)

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I confirm that I have read this protocol and understand it.

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Principal Investigator Signature: 

Date: 8/29/18

ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
BED	Binge-eating disorder
NIMH	National Institute of Mental Health
DSM	Diagnostic and Statistical Manual of Mental Disorders
NIMH	National Institute of Mental Health
ED	Eating disorder(s)
UNITE	Uniting Couples in the Treatment of Eating Disorders (a couple-based intervention for Binge-eating disorder)
CBT-E	Cognitive-Behavioral Therapy – Enhanced (an individual-based psychological treatment for eating disorders)
CBCT	Cognitive-Behavioral Couple Therapy
PCP	Primary Care Provider
CBT	Cognitive-Behavioral Therapy
PI	Principal Investigator(s)
RC	Research Coordinator
UNC	University of North Carolina
IRB	Institutional Review Board
DSMG	Data and Safety Monitoring Group
MLM	Multi-level modeling
AN	Anorexia nervosa
BN	Bulimia nervosa
EDE-Q	Eating Disorder Examination-Questionnaire
BES	Binge Eating Scale
YBOCS-BE	Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating
BE Frequency	Binge Eating Frequency
SCID	Structured Clinical Interview for DSM-IV
BDI-II	Beck Depression Inventory-II
BAI	Beck Anxiety Scale
DERS	Difficulties in Emotion Regulation Scale
DERS-Partner	Difficulties in Emotion Regulation- Partner Version
DAS	Dyadic Adjustment Scale
DAS-4	Dyadic Adjustment Scale-4 Item Version
CPQ-SF	Communication Patterns Questionnaire-Short Form
R-BISF	Brief Index of Sexual Functioning, Revised
MSI-R (AFC, PSC)	Marital Satisfaction Inventory-Revised (Affective Communication, Problem-Solving Communication Subscales)
EDQOL	Eating Disorders Quality of Life
CSQ	Client Satisfaction Questionnaire

Study Title	**Targeting Relationship Domains in Community-Based Treatment of Binge-Eating Disorder**
Funder	**NIMH**
Study Rationale	Clinicians' options for BED treatment are inadequate. Treatments for BED have demonstrated efficacy in controlled settings with specialist therapists and expert supervision, but much less in known about the effectiveness of BED interventions and whether the transition of evidence-based treatments to the community results in poorer outcomes. UNITE activates a key resource by incorporating an important part of the patient's social environment (the partner) into treatment. The investigators hypothesize that UNITE will show preliminary evidence of being superior to CBT-E in achieving binge abstinence via engaging ED-related relationship targets, including improved (a) communication around the disorder, (b) disorder-specific interpersonal problem-solving/ behavioral change skills, and (c) partner-assisted emotion regulation. The investigators will assess targeted relationship domains with observational and speech prosody measures during clinic interactions and self-reports reflecting experiences outside of the clinic. Because the couple is learning how to work together to address BED, the investigators hypothesize that maintenance of gains will show evidence consistent with superiority in UNITE.
Study Objective(s)	**Primary** • To compare the effectiveness of UNITE versus CBT-E in achieving abstinence from binge-eating. **Secondary** • To compare the effectiveness of UNITE versus individual CBT-E in decreasing ED-related psychopathology, depression, and anxiety. • To compare target relationship domains in patients and partners. • To compare treatment satisfaction and ED-related quality of life in UNITE versus CBT-E
Study Design	38 couples will be enrolled over 18 months (to aim for 34 couples who complete the intervention). Each couple will be randomly assigned to UNITE or CBT-E and will undergo 16 weeks of study treatment. Preliminary efficacy (e.g., changes in binge-eating frequency, depression, anxiety, and relationship functioning) of UNITE will be assessed in comparison to the control group (CBT-E). Treatment gains will be assessed including observational and self-report measures.
Subject Population key criteria for Inclusion and Exclusion:	**Inclusion Criteria** 1. Subjects age 18 – 99 2. Current DSM-5 criteria for BED (one partner per couple) 3. English speaking and able to read 4. In a committed relationship for at least 6 months (regardless of sexual orientation)

	5. Live with partner (or interact with each other daily) 6. Partner willingness to participate in treatment 7. Able to travel to Chapel Hill, NC weekly for treatment (N.B. Changed in 3/20 to "in North Carolina" due to pandemic) **Exclusion Criteria** 1. Alcohol or drug dependence in the past year 2. Current anorexia nervosa; current bulimia nervosa 3. Current significant suicidal ideation with active suicidal intent 4. Severe depression that would seriously interfere with functional capacity 5. Developmental disability that would impair the ability to benefit from the intervention 6. Any psychosis, schizophrenia, or bipolar I disorder, unless stably remitted on maintenance therapy for at least 1 year 7. Moderate to high reported levels of physical violence from either partner 8. Unwillingness to forgo non-protocol concurrent couple therapy 9. Previously participated in the UNITE pilot trial
Number of Subjects	76 (38 couples)
Study Duration	Each subject's participation will last approximately 20-30 hours over 10 months. The entire study is expected to last two years.
Study Phases **Screening** **Study Treatment** **Follow-Up**	**(1) <u>Screening</u>:** After consenting to participate and completing an initial phone screening, potential participants will be asked to complete a pre-treatment assessment consisting of electronic questionnaires and an in-person interview in order to determine eligibility for the study. These assessments will ask questions about a range of relationship concerns and interaction patterns as well as eating behaviors. The participant with BED in each couple must provide written certification from their PCP that their health status is suitable for this study. After determining eligibility, patients will be randomized to either UNITE or CBT-E and receive 16 approximately one-hour sessions of the respective treatment. **(2) <u>Intervention</u>:** ● **UNITE** is a manualized CBCT intervention that engages the couple to address the core psychopathology of BED and targets improved: o Communication around the ED o Interpersonal problem-solving and behavioral change skills o Partner-assisted emotion regulation ● **CBT-E** is a manualized CBT intervention for ED with four stages of treatment: o Psychoeducation and symptom self-monitoring o Review progress and formulate plans for future

	○ Reducing ED behaviors and improve mood tolerance ○ Maintaining progress and minimizing relapse risk **(3) <u>Follow-Up</u>:** Participants will complete follow-up assessments: ● at the end of treatment ● 3 months after the completion of treatment ● 6 months after the completion of treatment
Efficacy Evaluations	Recruitment, enrollment, retention, and follow-up targets met.
Safety Evaluations	The clinical status of all participants will be monitored closely by the study team. If information about a participant is generated that warrants concern (such as participant suicidality or danger to self or others), the research team will follow an established safety protocol to assess for immediate participant danger or safety. Participants will be provided with appropriate crisis resources if needed at the time of assessment. If concerns are identified that require additional support (for either the patient or the partner), the research team will work to find the participant an appropriate professional referral from an internal referral list of therapists, psychiatrists, nutritionists, and other mental health professionals.
Outcomes	**Primary outcome**: *<u>Eating Disorder Examination-Questionnaire</u>* (EDE-Q) abstinence from binge eating (Fairburn & Beglin, 1994). **Secondary outcomes** will **i**nclude ED symptoms, depression and anxiety, couple-based measures, treatment satisfaction, and quality of life. ED symptoms will be measured with the *<u>Eating Disorder Examination-Questionnaire</u>* (EDE-Q; 28 items) binge frequency and global score (Fairburn & Beglin, 1994), the *<u>Binge Eating Scale</u>* (BES; 16 items) which measures binge eating severity (Gormally et al., 1982), and the *<u>Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating</u>* (Y-BOCS-BE; 10 items) which measures the obsessiveness of binge-eating thoughts and compulsiveness of binge-eating behaviors (Deal et al., 2015). *<u>Beck Depression Inventory-II</u>* (BDI-II; 21 items) and *<u>Beck Anxiety Inventory</u>* (BAI; 21 items) will measure severity of current depressive and anxiety symptoms, respectively (Beck et al., 1988; Beck et al., 1996). *<u>Difficulties in Emotion Regulation Scale</u>* (DERS; 36-item) and the partner version (DERS-Partner; 8 items) will measure emotion regulation in oneself and one's partner, respectively (Gratz & Roemer, 2004). *<u>Dyadic Adjustment Scale</u>* (DAS; 32 items) and DAS-4 (4 items) will measure relationship satisfaction. *<u>Communication Patterns Questionnaire-Short Form</u>* (CPQ-SF; 12 items (Christensen & Heavey, 1990) modified for BED has two scores that will be calculated to assess how the couple communicates about the ED. These are a total score made up of the Self Demand/Partner Withdraw and Partner Demand/Self Withdraw subscales (6 items) and the Constructive Communication subscale (3 items). *<u>Marital Satisfaction Inventory</u>* (MSI-R; 32 items) affective communication (AFC) and problem-solving/communication (PSC) subscales will be used (Snyder, 1997). Treatment satisfaction will be measured with the *<u>Client Satisfaction Questionnaire</u>* (CSQ; 18 items). (Nguyen et al., 1983). *<u>Eating</u>*

	Disorders Quality of Life (EDQOL; 26 items) will measure the extent to which the ED affects quality of life (Engel, 2003). ED-related measures will be given to patients only and all other measures will be given to patients and partners.
Statistical and Analytic Plan	Intent-to-treat or modified intent-to-treat, if appropriate, will comprise the primary approach. Differential treatment effects will be analyzed with multilevel mixed-effects models with fixed effects and interactions for Time, Treatment, and (where appropriate) Participant Status (i.e., patients/partners), and with random effects to address clustering.
Data and Safety Monitoring Plan	The DSMG will be responsible for data quality management and ongoing assessment of participant safety.

1 BACKGROUND AND RATIONALE

1.1 Introduction

Clinicians' options for EDs (ED) treatment are inadequate. EDs challenge caregivers and strain relationships (Van den Broucke & Vandereycken, 1988; Van den Broucke et al., 1994, 1995, 1995; Whisman et al., 2012). Partners are typically excluded from treatment. Family involvement improves outcomes in youth (le Grange et al., 2010) and in adults with anorexia nervosa (AN) (Baucom et al., 2017). Engaging partners improves weight gain in AN, reduces high drop out in AN (Baucom et al., 2017) and binge-eating disorder (BED) (Runfola et al., 2018), and may lead to greater binge-eating abstinence (Runfola et al., 2018). As BED awareness and treatment demand increases post DSM-5, the field will benefit from scalable interventions.

- Name and Description of Intervention: The experimental treatment, UNITE, is a manualized cognitive-behavioral couple therapy (CBCT) intervention that engages the couple to address the core psychopathology of BED. It includes three stages: early treatment (psychoeducation and understanding the couple's experience of BED within the relationship); mid-treatment (effective communication, interpersonal problem-solving, and emotion regulation skills), and late treatment (relapse prevention). Additional relevant topics may be covered including body image, weight stigma, weight and health concerns, and intimacy and sexuality issues.

The active comparator, CBT-E, is a trans-diagnostic cognitive behavioral individual therapy treatment for eating disorders. It has been shown to be effective in numerous controlled and open trials. It includes four stages: an introductory stage (psychoeducation, normalization of eating patterns, and symptom self-monitoring); a second, brief stage (review progress and formulate plans for the subsequent treatment phase); a third stage (elimination of dieting, reducing shape checking and avoidance behaviors, educating about mood tolerance, and targeting over-evaluation of shape and weight); and the fourth stage (maintaining progress and minimizing relapse risk).

1.2 Non-Clinical and Clinical Study Findings

- Potential Benefits: This is a treatment research study in which all patients enrolled will receive an intervention for BED (regardless of the treatment group to which they are randomized). Although the investigators cannot guarantee that patients will derive any benefit from the study, the likelihood is fairly high that patients will benefit to some degree from the study. Results of this study could enhance treatment of BED. If implementation of the couple program is feasible and efficacious, couple treatment may show promise in increasing treatment response rates and maintaining engagement after formal treatment. Training for a couple-based approach to the treatment of BED could also then be implemented in other non-specialty settings, thus increasing patient access to care.

- Risk /Benefit Assessment: Participants may find participation in clinical interviews or the videotaped assessments to be unpleasant or distressing. Similarly, any psychotherapeutic intervention may be associated with discomfort consequent to discussion of painful symptoms or problems. Some participants may find the couple format uncomfortable. A number of steps will be taken to protect participants against possible risks. All study personnel will be trained to be sensitive to participants' concerns and will make it clear to participants that participation in the study is voluntary and that they may withdraw from the study at any time. Participants will be directed to alert study personnel if there is a change in their psychological condition. Strict confidentiality will be maintained with any use of participants' medical records or claim files in accordance with federal, state, and local policies. Research data will be maintained in separate charts and identified by participant number only. Clinical supervision of UNITE and CBT-E study treatment will each be conducted by a licensed psychologist with a one-hour weekly group supervision meeting. Thus, through initial training and weekly supervision, the investigators will provide supervision commensurate with the practice of the community clinic.

1.3 Relevant Literature and Data

Treatments for BED and bulimia nervosa (BN) have demonstrated *efficacy* in controlled settings with specialist therapists and expert supervision (Brownley et al., 2016; Shapiro et al., 2007). Much less is known about the *effectiveness* of BED/BN interventions and whether the transition of evidence-based treatments to the community results in poorer outcomes. One strategy to bolster the effectiveness of BED/BN treatment in real world conditions is to **activate resources in the patient's environment** (Grawe, 2007). Including partners in treatment is one such resource and is defensible, as 22-46% of BN patients (Carter et al., 2003; Ghaderi, 2006; Poulsen et al., 2014) and 60-77% of BED patients (Safer & Jo, 2010; Schlup et al., 2010) are married or co-habiting, comparable to healthy controls (Maxwell et al., 2011). Partners are eager to help yet unsure what to do (Kirby et al., 2015). Relationships can also be a source of stress, as BED/BN patients report higher levels of relationship distress, negative interactions, and poorer communication than those with other psychiatric disorders (Van den Broucke & Vandereycken, 1988; Van den Broucke et al., 1994, 1995, 1995; Whisman et al., 2012). The transdiagnostic theory of EDs highlights adverse interpersonal environments as illness-maintaining factors (Fairburn et al., 2003), and interpersonal theory targets interpersonal stressors as binge/purge triggers via their contribution to negative affect (Arcelus et al., 2013). Patients also cite interpersonal stressors as common binge/purge triggers, as confirmed by ecological momentary sampling (Goldschmidt et al., 2014; Hilbert et al., 2011). **Including a partner in treatment facilitates transformation of the relationship from a stressor into an agent of positive change.**

The investigators have incorporated partners in the treatment of adult psychiatric disorders, using adaptations of cognitive-behavioral couple therapy (CBCT) (Abramowitz et al., 2013; Baucom et al., 2017; Baucom et al., 1998; Sher et al., 1990). The investigators demonstrated initial efficacy of our couple-based ED treatments in a university hospital specialist setting (Baucom et al., 2017; Bulik et al., 2011; Kirby et al., 2015). The investigators developed a CBCT intervention for BED/BN (UNiting couples In the Treatment of Eating disorders [UNITE]). Here the investigators test the preliminary comparative effectiveness of UNITE versus individual CBT-enhanced (CBT-E) (a transdiagnostic treatment for EDs) in a small randomized controlled trial (RCT) of 28 couples in a community clinic. Because UNITE activates a key resource by incorporating an important part of the patient's social environment (the partner) into treatment, the investigators hypothesize that UNITE will show preliminary evidence of being superior to CBT-E in achieving binge/purge abstinence via engaging ED-related relationship targets, including improved (a) communication around the disorder, (b) disorder-specific interpersonal problem-solving/ behavioral change skills, and (c) partner-assisted emotion regulation. Targeted relationship domains will be assessed with observational and speech prosody measures during clinic interactions and self-reports reflecting experiences outside of the clinic. Because the

couple is learning how to work together to address BED/BN the maintenance of gains are hypothesized to show evidence consistent with superiority in UNITE.

2 STUDY OBJECTIVE

2.1 Primary Objective: The purpose of this study is to test the feasibility, acceptability, and preliminary effectiveness of a novel couple-based intervention for BED (UNITE) relative to an established evidence-based individual treatment (CBT-E) in a community clinic setting.

3 INVESTIGATIONAL PLAN

3.1 Study Design

Type of design: Randomized controlled trial

Brief overview of the study phases: see Protocol Synopsis "Study Phases"

3.2 Study Duration, Enrollment and Number of Subjects

38 couples will be enrolled over 18 months (to aim for 34 couples who complete the intervention). Each couple will be randomized to either UNITE or CBT-E and will undergo 16 weeks of treatment, followed by follow-up assessments at the end of treatment and 3- and 6-months after the end of treatment.

3.3 Study Population: see Protocol Synopsis "Subject Population"

4 STUDY PROCEDURES

4.1 Screening/Baseline Visit procedures

Pre-Treatment

1. Patient and partner come in for pre-treatment visit, which includes the following:
    - Consent with both patient and partner
    - Videotaped couple interaction
    - Interviews
    - Self-report Questionnaires
2. Eligibility is determined
3. Couple is randomized to UNITE or CBT-E condition
4. Therapist is assigned and notified

- Baseline (Pre-Treatment)
    - Consent
    - Background information
        - *Background Information* (1 min)**.** This questionnaire asks questions about age, sex, race/ethnicity, socioeconomic status, and relationship history.
    - Couple Interaction
        - Couple is recorded having two 10-minute conversations:
            - For the first conversation ("sharing thoughts and feelings") the couple is given the prompt: Please select an issue in your relationship related to [patient's] eating disorder, sharing your thoughts and feelings with each other about this issue. Don't attempt to resolve it, just let each other know what you think and feel. Try to select something that you view as being of a moderate level of concern or intensity.
            - For the second conversation ("problem-solving"), the couple is given the prompt: I will again ask you to select an issue in your relationship related to [patient's]

eating disorder, but this time you will discuss ways you could resolve or improve this issue. Try to select something that you view as being of a moderate level of concern or intensity. That is, don't select something trivial, but also don't select the most difficult concern that you have."

- For each conversation, the interviewer may assist the couple in identifying a topic for conversation. Then, the interviewer leaves the room during the 10-minute recorded conversation.

- Vitals (Patient, Partner)
  - Self-reported height, weight, BMI
- Questionnaire (Patient, Partner)
  - ED100K, EDE-Q, BES, BE frequency, BDI-II, BAI, DERS, DERS-Partner, DAS, CPQ-SF, R-BISF, CTS-2, MSI-R, EDQOL
- Interview (Patient, Partner)
  - Videotaped couple interaction
  - MINI, YBOCS-BE

4.2 Intervention/Treatment procedures (by visits)

Both UNITE and CBT-E have 16 treatment sessions
Weekly questionnaires to be completed by the participants in treatment
Weekly Questionnaires consist of binge eating frequency assessment, DAS-4
For UNITE, Patient and Partner fill out questionnaires. For CBT-E, only Patient.
Mid-treatment assessment after session 8 is completed
End-treatment assessment after session 16 is completed

Mid-Treatment (after Session 8)

- Vitals (Patient, Partner)
  - Self-reported height, weight, BMI
- Questionnaire (Patient, Partner)
  - EDE-Q, BES, BE frequency, BDI-II, BAI, DERS, DERS-Partner, DAS, CPQ-SF, R-BISF, MSI-R, EDQOL
- Check BDI for suicidality
- YBOCS-BE Interview (Patient)

Post-Treatment (after Session 16)

- **Couple Interaction**
- Vitals (Patient, Partner)
  - Self-reported height, weight, BMI
- Questionnaire (Patient, Partner)
  - CSQ, EDE-Q, BES, BE frequency, BDI-II, BAI, DERS, DERS-Partner, DAS, CPQ-SF, R-BISF, MSI-R, EDQOL
- YBOCS-BE Interview (Patient)
- Therapist Feedback (Therapist)

4.3 Follow-up procedures (by visits)

*N.B.: virtual after 3/20.

- 3-Month Follow-Up
  - Vitals (Patient, Partner)

        - Height, weight, BMI, blood pressure, heart rate
    - Questionnaire (Patient, Partner)
        - EDE-Q, BES, BE frequency, BDI-II, BAI, DERS, DERS-Partner, DAS, CPQ-SF, R-BISF, MSI-R, EDQOL
    - $50 visa card upon completion
- 6-Month Follow-Up
    - Vitals (Patient, Partner)
        - Self-reported height, weight, BM
    - Questionnaire (Patient, Partner)
        - EDE-Q, BES, BE frequency, BDI-II, BAI, DERS, DERS-Partner, DAS, CPQ-SF, R-BISF, MSI-R, EDQOL
    - YBOCS-BE Interview (Patient)
    - $50 visa card upon completion

4.4 Subject Withdrawal procedures

Decisions regarding study withdrawal will be made by the investigators. Factors to consider include:
(a) physical deterioration or escalation of symptoms requiring prolonged hospitalization
(b) couple separates and is no longer in a committed relationship.
(c) significant risk of suicide in the judgment of the treatment provider
(d) development or exacerbation of a severe comorbid psychiatric disorder, such as a psychotic disorder or severe major depressive disorder, making it unlikely that they would benefit from outpatient treatment.

4.5 Screen Failure procedures

Participants who are ineligible for this study will be provided with treatment referral information.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Efficacy Evaluation

Preliminary efficacy (e.g. changes in binge-eating frequency, depression, anxiety, and relationship functioning) of UNITE will be assessed in comparison to the control group (CBT-E). Treatment gains will be assessed including observational and self-report measures. The primary outcome is abstinence from binge eating over the past 28 days measured with the EDE-Q. Secondary outcomes include EDE-Q binge frequency and global psychopathology, BES, Y-BOCS-BE, BDI-II, BAI, DERS, DERS-Partner, DAS, DAS-4, CPQ-SF, MSI-R (AFC and PSC), CSQ, and EDQOL.

5.2 Safety Evaluations

Weekly reports from therapists to supervisors on therapy progress and from staff on assessments and follow-up visits. Discussed by investigators at weekly team meetings.

STATISTICAL CONSIDERATIONS

5.3 Statistical Methods

- **Baseline Data.** Sociodemographics and baseline clinical characteristics will be summarized with descriptive statistics.
- **Efficacy Analysis.** Study hypotheses will be tested using intent-to-treat or modified intent-to-treat methods, as appropriate. For patient-only outcomes, differential treatment effects will be tested with multilevel mixed-effects models with fixed effects and two-way interactions for Time and Treatment and a random effect for Patient. For outcomes assessed in both patients and partners, differential treatment effects will be tested with multilevel mixed-effects models with fixed effects and two- and

three-way interactions for Time, Treatment, and Participant Status (i.e., Patient or Partners) and random effects for Participant and Couple. Linear, logistic, and Poisson distribution functions will be used to model outcome variables. Treatment satisfaction, assessed at post-treatment only, will be compared between patients in UNITE and CBT-E with linear regression.

- **Safety Analysis.** Adverse events will be summarized as a numerator (total affected) and denominator (number at risk) for patients and partners in each treatment arm using the ClinicalTrials.gov categories of all-cause mortality, serious adverse events, and other (not including serious) adverse events.

5.4 Sample Size and Power

While there is not universal agreement about the minimum number of higher-level groups required to produce stable estimates in multilevel models, Maas and Hox's (2005) definitive simulation study of bias in higher level effects demonstrates that a sample size of 20 groups (which are couples in this case) is sufficient to produce unbiased estimates of standard errors. Thus, while the sample size of 38 couples does not result in power to test all study hypotheses, the sample size of 38 couples is adequate to perform unbiased analyses using multilevel mixed-effects models.

5.5 Interim Analysis

Problems with participant recruitment, dropouts, or data management would be most likely to trigger the need for stopping the protocol. However, adverse events also would be a possible reason as would a clear finding of superiority for one treatment arm prior to the completion of the protocol. It is unlikely that any new information will become available that would necessitate stopping the trial. It is possible that excessive study dropouts and missing data would limit the data analysis. The investigators have powered the study expecting dropouts. The investigators acknowledge that there may be situations that occur that might warrant stopping the trial that are not covered here.

6 STUDY INTERVENTION (intervention details)

- **Description:** see Background and Rationale "Name and Description of Intervention"
- **Treatment Compliance and Adherence**
  Given the substantial interruption to the trial due to the Covid-19 pandemic (i.e., initial couples receiving face-to-face care; some couples having a portion of treatment face to face and transitioning to virtual, other couples having fully virtual treatment) our adherence measures were limited to assurances by the supervisors (who reviewed audio-recordings of all sessions) that therapists were adhering to the treatments as laid forth in the manuals. As funding for personnel continued even when the trial was interrupted, adequate funds for extensive compliance/adherence assessments were not available.

7 STUDY INTERVENTION ADMINISTRATION

- **Randomization**: The study statistician will write a computer program to perform a stratified random assignment to the initial two conditions on a 1:1 basis using a permuted block algorithm.

8 SAFETY MANAGEMENT

-Adverse Event Monitoring and Reporting

Any unanticipated problems, or adverse events, or new safety concerns will be promptly reported to the UNC IRB and discussed by the PIs and DSMG.

-See Protocol Synopsis "Data and Safety Monitoring Plan"

9 DATA COLLECTION AND MANAGEMENT

The DSMG will standardize data collection, management, and analysis, evaluate the progress of the study, and monitor participant safety and data quality. Privacy will be ensured for all participants in several ways. All potential participants will call the RC if interested in the study. Should potential

couples pass the telephone screening, they will be scheduled for an in-person interview, which will be conducted in a private room by one of the study personnel. During this interview, couples will be asked to complete measures pertaining to eating behavior and weight loss. They will be instructed that they are allowed to leave any answer blank if they do not want to complete the question. All participants and partners will be assigned a study number, which will be used in place of their name. The key linking study numbers to names will be kept in a locked filing cabinet and in a password protected excel file, only accessible to the PI. Participants will not be identified by name in any analysis or publication resulting from this study. Electronic files containing participant data will be password protected and stored on a secure server. Digital video and audio files of treatment sessions and assessments will be handled with extreme care, given that visual and audio information can identify participants. Audio and video recordings will be password protected, encrypted. The digital video recordings from the assessment sessions will be coded by trained research assistants who are well trained in the importance of participant confidentiality. Assessment sessions will be viewed only in confidential research settings where no one other than the coders, their trainers, and their supervisors can see the video monitor or hear the participants' voices. Recordings of assessment interviews and therapy sessions will be listened to and viewed only in confidential settings by the project staff supervising the therapists and assisting with treatment development, and the therapists themselves.

10 RECRUITMENT STRATEGY

Participants will be recruited from local physician offices, social media, advertisements, and local listservs. Potential participants will be asked to contact the study RC for more information. Potential participants will complete a screening questionnaire by phone with the RC, which will determine if they meet general study criteria.

11 CONSENT PROCESS

Patients responding to advertisements for participation will be asked by the RC if they are interested in hearing about the research study. Verbal consent must be obtained prior to obtaining any information about the participant other than contact information. After receiving information by phone and completing a phone consent screener in order to determine initial eligibility, they will be provided with written descriptions of the investigation, and the study will be explained in person by the RC before consenting. Participants will be provided an opportunity to have questions addressed by the PIs. Finally, participants will be required to sign a consent form approved by the IRB at UNC to participate in the proposed study. As detailed above, informed consent will be obtained by the research coordinator and not by a person with perceived authority, such as a treating physician.

12 PLANS FOR PUBLICATION

The primary outcome paper will include post-treatment, 3-month, and 6-month data on primary and secondary outcomes. Secondary papers will include coding of couple interactions and other secondary analysis results.

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Table 1.

Comparison of Intervention Arms

Table 1: Comparison of Intervention Arms		
Discipline	**UNITE (16 sessions)**	**Individual CBT-E (16 sessions)**
Medical	Psychiatrist (1)	Psychiatrist (1)
	Medical consults (as needed)	Medical consults (as needed)
Psycho-therapy	UNITE Couple Sessions (one 120-minute intro session, one 90-minute second session and fourteen 60 minute sessions) ***1050 minutes***	Individual CBT-E (one 120-minute intro session, one 90-minute second session and fourteen 60 minute sessions) ***1050 minutes***

Table 2.

UNITE Manual Components

Table 2. UNITE Manual Components	
Session	Topic
Early Treatment	
1	Introduction to UNITE and Relationship Assessment
2	Understanding BED in a Couples Context: Symptoms and Course of Illness
3	BED Etiology, Treatment Goals, and Recovery
Mid-Treatment	
4-14	Target 1: Communication around BED
	• Emotional expressiveness communication skills
	Target 2: Problem-solving/Behavioral Change Skills
	• Problem-solving communication skills
	• Balanced eating
	• Mealtimes, food purchasing and preparation
	Target 3: Partner-Assisted Emotion Regulation
	• BED triggers and recovery cues
	• Managing emotions effectively as a couple
	• Effective self-care (i.e., physical activity, sleeping, relaxation)
	*Additional topics as needed:
	• Body image, weight stigma
	• Weight and health concerns
	• Physical affection and sexuality
	• *Flex session (incorporated anytime in treatment)
	• *Flex session (incorporated anytime in treatment)
Late Treatment	
15	Relapse Prevention
16	Relapse Prevention and Termination
** Topics selected according to patient/couple needs*	

Table 3.

Assessment Instruments and Schedule

Table 3. Assessment Instruments and Schedule						
Assessment	Screen	Pre	Mid	Post	3 mo	6 mo
Phone Screen	1					
Background Info		1,2				
Eating Disorder Pathology						
EDE-Q		1	1	1	1	1
BES		1	1	1	1	1
YBOCS-BE		1	1	1		1
BE Frequency*		1	1	1	1	1
Height/Weight, Vitals		1,2	1,2	1,2	1,2	1,2
Mood/Psychological Functioning						
SCID		1,2				
BDI-II		1,2	1,2	1,2	1,2	1,2
BAI		1,2	1,2	1,2	1,2	1,2
DERS		1,2	1,2	1,2	1,2	1,2
DERS-Partner		1,2	1,2	1,2	1,2	1,2
Relationship Adjustment and Communication						
DAS*		1,2	1,2	1,2	1,2	1,2
MSI-R						
CPQ-SF		1,2	1,2	1,2	1,2	1,2
BISF		1,2	1,2	1,2	1,2	1,2
EDQOL		1	1	1	1	1
CTSR		1,2				
Videotaped Interactions		1,2		1,2	1,2	1,2
CSQ				1,2		
Therapist Feedback				3		

1 = Patient, 2 = Partner, 3 = UNITE Therapist
Pre = Pre-treatment, Mid = Mid-treatment, Post = Post-treatment, 3 mo = 3-month follow-up
**Binge eating and purging frequency, weekly*