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

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

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University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Subjects: Patients
Biomedical Form

IRB Study # 18-1379
Consent Form Version Date: November 28, 2018

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

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Sponsor: National Institute of Mental Health

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What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to compare two different treatments for binge-eating disorder – couple-based therapy (UNITE) and individual enhanced cognitive behavioral therapy (Individual CBT-E). UNITE (UNiting couples In the Treatment of Eating Disorders) is a couple-based program that helps patients with binge-eating disorder and their committed partners address eating disorder symptoms and unique stresses that binge-eating disorder places on the relationship while enhancing support for the couple during the recovery process. We plan to deliver both **UNITE** and **Individual CBT-E** in this research study to compare outcomes on a number of areas including the eating disorder, mood, and relationship functioning.

In this study, 38 adults with a diagnosis of binge-eating disorder and their partners will participate. Therefore, 76 adults total will be recruited. If you choose to participate, you and your partner will be randomly assigned (like the flip of a coin) to either **UNITE** or **Individual CBT-E**.

UNITE: You and your partner will participate in 16 couple therapy sessions led by a couple therapist. Couple sessions will last approximately 60 minutes. You and your partner will both complete weekly questionnaires as well as assessments in the middle of treatment, after the treatment has ended, and at two follow up periods (3- and 6-months after treatment has ended).

Individual CBT-E: You will participate in 16 individual therapy sessions that will last approximately 60 minutes each. Your partner will not participate in therapy sessions if you and your partner are randomized to this condition. You will complete weekly questionnaires and you and your partner will complete assessments in the middle of treatment, after the treatment has ended, and at two follow up periods (3- and 6-months after treatment has ended).

You are being asked to be in the study because you have a diagnosis of binge-eating disorder, are in a committed relationship, and you are over the age of 18 years.

Are there any reasons you should not be in this study?

Patients whose symptoms are unresponsive in an outpatient setting or who are medically unstable should be considered for a higher level of care, such as residential or inpatient treatment. In order to participate in the study, you must have a primary care physician (PCP) and verification that you have health insurance coverage. Your PCP must approve you for participation in the study prior to your beginning the study. Also, your PCP and the principal investigators must continue to approve both your safety and appropriateness for receiving outpatient care in order for both you and your partner to remain eligible for participation. If the treatment team determines that outpatient care is no longer the appropriate level of care for you, the treatment team will recommend that your participation in this study be put on hold while you seek a higher level of care. If you choose not to follow-through with a recommendation for higher level of care, your study-related treatment may be terminated on the basis of safety.

You should not be in the study if you are under the age of 18, cannot read and speak English, or do not live within driving distance of Chapel Hill, NC. Also, only couples who live together or who are in daily interaction with each other and have been in a committed relationship for at least six months can participate in the study, and both partners must consent to participate.

It is essential that all of our sessions are audio and video recorded to assure that you are receiving appropriate care. Therefore, you can participate only if both you and your partner are willing to have all sessions recorded and retained for supervision and research purposes.

How many people will take part in this study?

There will be about 76 people (38 couples) in this research study.

How long will your part in this study last?

Participation in this study will last approximately 4 months, plus two additional follow-up assessments at 3- and 6-months after treatment has ended. First, you will have an eligibility assessment session (approximately 2-3 hours) to determine whether you are eligible for the study.

If you are randomized to the **UNITE** condition, you and your partner will have 16 couple-therapy sessions (one initial 90-minute session and 60 minutes for each subsequent session) with a couple therapist.

If you are randomized to the **Individual CBT-E** condition, you will have 16 individual therapy sessions (one initial 90-minute session and 50 minutes for each subsequent session) with an individual therapist.

Your partner will not participate in therapy sessions if you and your partner are randomized to this condition.

In addition, all participants in this study will complete a mid-treatment assessment (30 minutes), a post-treatment assessment (2-3 hours), and two follow-up assessments at 3- and 6-months after treatment has ended (approximately 30 minutes and 2-3 hours, respectively).

What will happen if you take part in the study?
During the course of the study, the following will occur:

First you will have an eligibility assessment. You will be asked to complete an assessment interview and electronic questionnaires that ask questions about a range of relationship concerns and interaction patterns as well as eating behaviors. Your height, weight, and vital signs (heart rate, blood pressure) will also be measured. You also will have audio and video recorded conversations with your partner. In addition, your PCP must provide written certification that your health status is suitable for this study.

If you are eligible, you and your partner will be randomly assigned (like a flip of a coin) to either **UNITE** or **Individual CBT-E**. If you are assigned to the **UNITE** condition, you will receive 16 couple-therapy sessions together with your partner and a couple therapist. These sessions will be scheduled once a week. Sessions will be held at the UNC Psychology Community Clinic. Parking will be free of charge.

If you are assigned to the **Individual CBT-E** condition, you will receive 16 individual therapy sessions with an individual therapist. These sessions will be scheduled once a week. Sessions will be held at the UNC Community Psychology Clinic and parking will be free of charge.

In order to provide optimal care and meet requirements of the research investigation, members of your treatment team will discuss your care and progress with each other. We may also discuss your care and progress with your primary care provider and other providers to facilitate transition into our program and to ensure optimal care throughout study participation. Also, at their discretion, members of the treatment team will talk with your partner who is participating with you in this investigation about your care and progress, including, for example, your medical, psychological, and nutritional status, along with recommendations for changes in your treatment plan. Also, at their discretion, members of the treatment team will talk with you about communication between your partner and the treatment team.

Halfway through your treatment, you will complete questionnaires that are similar to the ones you completed at the first assessment and will have your weight measured and vital signs taken.

At the end of treatment, you will complete a post-treatment assessment. You will be asked to complete questionnaires similar to the ones filled out at the first assessment, and your weight will be measured. You will also participate in an audio and video recorded conversation with your partner.

At 3- and 6-months after the end of treatment, you will complete two additional assessments. You will be given the option of completing the 3- and 6-month follow-up assessment questionnaires online at a secure website. The 6-month follow-up also includes an assessment interview which you will have the option of completing by phone with a member of the research study staff. These will also be similar to the initial assessment.

If at any point during study participation you or your partner identify concerns that pose risks to your safety or to the safety of others, we will take additional steps to assess your safety and may provide you with referrals for additional counseling or other support if needed.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. If you take part in this study, you may benefit by receiving a form of psychotherapy specifically designed to address the symptoms of binge-eating disorder. You may also benefit by achieving control over symptoms in the context of your relationship.

What are the possible risks or discomforts involved with being in this study?
You may find participation in clinical interviews or assessments to be unpleasant or distressing. They study may make you feel embarrassed, uncomfortable, or emotionally distressed when discussing challenges surrounding your own or your loved one's eating disorder. Although unlikely, it is possible that through discussion of binge-eating disorder and your relationship, you or your partner could become distressed in the relationship or the relationship could deteriorate.

Although there are a number of steps that will be taken to maintain confidentiality, there is also always the possibility that identities could become known in which case you may experience stress, anxiety, stigmatization, or embarrassment.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. The other procedures or treatments that are available include treatment services in the community or those routinely available at the UNC Center of Excellence for Eating Disorders.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy and confidentiality be protected?
All personal information about you and your partner will be kept strictly confidential. Participants will not be identified in any report or publication about this study. We will code all data, which means your identifiable information will be replaced with a unique identification number, and store all study materials in locked filing cabinets only accessible to research staff to protect your confidentiality. Immediately following the treatment sessions, we will encrypt, password-protect, and upload the audio-recorded session to a secure server that is only accessible to the study staff. The original digital files will be deleted from recording devices immediately after uploading. Only your assigned identification number (and not name) will be on consent forms, assessment forms, audio files, and session transcripts. We will maintain a list linking names and identification numbers that include contact information for you and your partner in a separate location. Only research study staff will have access to the list linking subject names with identification numbers.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state,

or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

How may my data be archived and shared?

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at

Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, we are concerned about your safety or the safety of others, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will receive a payment of $50 if you and your partner complete the 3-month follow-up assessment. You will receive a second payment of $50 if you and your partner complete the 6-month follow-up assessment, for the opportunity to receive $100 total if both you and your partner complete all aspects of both assessments.

Will it cost you anything to be in this study?
We do not have funds to reimburse gas needed for driving to and from the study site. Also, to be in the study, we do require that the participant with binge-eating disorder have physical exams (as medically indicated by their PCP) outside of the study covered by their insurance or out of pocket funds. Examples of some of the medical care that will be provided by and covered by the study include regular assessments of your height and weight. Any other routine medical procedures outside of the scope of the protocol will not be covered.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by National Institutes of Mental Health. This means that the research team is being paid by the sponsor to conduct the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form (contact information provided as well).

If a medical or psychiatric emergency should occur or if you are feeling unsafe and need immediate assistance, you may go to the emergency room nearest to you. Emergency services are also available at UNC 24 hours a day. If you are unable to go to the emergency room, please call 911 to receive immediate support.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Patient Participant

Consent Form Version Date: May 25, 2018
IRB Study # 18-1379
Title of Study: Targeting Relationship Domains in Community-Based Treatment of Binge-Eating Disorder
Principal Investigator: Cynthia Bulik, PhD
UNC-Chapel Hill Department: Psychiatry
UNC-Chapel Hill phone number: 984-974-3233
Co-Investigators: Donald Baucom, PhD, Jennifer Kirby, PhD, Camden Matherne, PhD, Brian Baucom, PhD
Sponsor: National Institute of Mental Health

Study Contact phone number: 984-974-3802
Study Contact email: unite@unc.edu

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent