

Study Title: Dismantling the Components and
Dosing of CBT for Co-Occurring Disorders

NCT #: 02161211

Form Date: April 2019

CONSENT FORM

ALCOHOL AND ANXIETY DISORDER RESEARCH STUDY

INTRODUCTION

We are conducting a clinical study (a type of research study) to examine whether a psychological (cognitive-behavioral therapy; CBT) treatment for individuals being treated for alcohol problems who also have a co-occurring anxiety disorder can improve the effectiveness of standard alcohol treatment.

You were selected as a possible participant because you are a patient in the Fairview chemical dependency program (Lodging Plus; LP) seeking treatment for problematic alcohol use and you were determined to be eligible for this protocol based on the Consortium of Addiction Research screening process.

This study is being conducted by Dr. Matt Kushner, a licensed clinical psychologist and faculty member of the Department of Psychiatry at the University of Minnesota. The research study is funded by the *National Institute on Alcohol Abuse and Alcoholism* (NIAAA), a branch of the *National Institutes of Health* (NIH) that is devoted to the study of alcohol problems and disorders. This study has been reviewed by the director of Fairview's Chemical Dependency Programs, who determined that it meets Fairview's standards for research conducted in this program.

This Consent Form provides information on the purpose, procedures and risks involved in this study. Please read this form carefully so that you can decide if you want to take part in the study. You will have time to discuss your decision with others and speak to a study staff member who will answer any questions you might have and will also review key elements of what your participation will involve before you decide whether or not to participate.

PURPOSE OF THE STUDY

It has been shown in multiple studies that individuals with anxiety disorders who are being treated for alcohol problems relapse to drinking following treatment at a higher rate than do those who do not have anxiety disorders. In a previous study we conducted with Lodging Plus patients, we showed that adding a CBT program we developed provided modest improvement in the alcoholism treatment outcomes of patients with co-occurring anxiety disorders, but this improvement was not as great as we had hoped. Therefore, we are conducting this study to see if several different variations of the original CBT program could be more helpful in improving the alcohol treatment outcomes in those with co-occurring anxiety disorders. To do this, we will recruit Lodging Plus patients being treated for alcohol dependence who have any of several common anxiety disorders and then place them in one of three treatment groups where each group receives a different version of the CBT program while also attending the Lodging Plus program. We will then compare the

three groups of patients in terms of their drinking status one month and four months following treatment.

PROCEDURES

All study activities while you are a patient in Lodging Plus will take place during free-time from Lodging Plus (i.e., when there is no other Lodging Plus programming). This allows you to participate in the study without missing any Lodging Plus programming. We will ensure that you will not miss any meals in Lodging Plus or other evening activities. The study activities while you are a patient in Lodging Plus will take place in the same building as the Lodging Plus program. However, after you are discharged from Lodging Plus, participation in the study will involve your returning to Fairview for a follow-up assessment on two occasions. Parking and/or transportation will be arranged ahead of time by the study staff.

All of the procedures described here may be videotaped or audiotaped for the purpose of quality assurance and training purposes. However, in no cases will your image or other information that could identify you be included in the recordings. For example, if we are using video recording, the camera will include images of the therapist or the therapy materials but will not include you other than your voice. (This is discussed further in the general discussion of information confidentiality a little later in this Consent Form.)

You may be asked to take a Breathalyzer test (breath into a straw attached to a small device) prior to each of the study tasks. The results of this test will not be retained but if it reveals you are intoxicated, the study that day may be rescheduled.

If you are a participant in this study, we would ask you to do the following things:

	Baseline	CBT (6 sessions daily sessions)	Post- Treatment	1 Month follow- up	4 Month follow- up
Consent	X				
Interviews	X		X	X	X
Questionnaires	X		X	X	X
Talk therapy		X			
Subject Payments	\$25	\$5 per session	\$25	\$50	\$100
Time	1-2 hours	1-1.5 hours per session	2-2.5 hours	2-2.5 hours	2-2.5 hours

Baseline Assessment (1-2 hours, paid \$25 upon completion)

If you are interested in participating in this study, you will first review this Consent Form with a study staff member who will ask you questions about your understanding of the study and its procedures. After you have signed the Consent Form, you will complete the Baseline appointment for this study. This involves several questionnaires that you fill out on your own and questionnaires administered by an assessor. The questions focus primarily on your anxiety symptoms/problems and alcohol use habits and related problems. You will also be asked about other psychiatric or substance abuse treatment and problems you may have now or had in the past. If you are a woman you will be asked to fill out a brief questionnaire on the duration and regularity of your menstrual cycle. The assessment will take place in one of our private offices

(either on the Lodging Plus ward or in the ARC) during your free time from Lodging Plus (i.e., no other Lodging Plus programming).

CBT Therapy (one to one and a half hour session per day for six days paid \$5 upon the completion of each session)

The therapy sessions will take place in the ARC (second floor of Fairview hospital) during your free time from Lodging Plus (i.e., no other Lodging Plus programming). The first therapy session typically takes place after you have been in the Lodging Plus program for about 1 week and then continues every business day (one one-hour session per day) at the same time and place until you've completed the six sessions.

There are three therapy conditions (or groups) in this study but you will be assigned (randomly, like flipping a coin) to participate in only one of the three conditions. We currently do not know if any of the three conditions will be more beneficial than the others, which is the reason we are conducting the study in a way that allows us to compare the outcomes of the three therapy groups.

Several elements are the same for all three therapy groups as follows:

- Psycho-Education in which you will learn how CBT works
- Cognitive Coping Skills in which you will learn how thoughts affect feelings and behaviors and learn to modify dysfunctional and inaccurate thoughts and beliefs
- Behavioral Coping Skills in which you will learn safe behaviors for coping with and reducing negative emotions
- Coping Skills Practice with Guided Imagery in which you will practice applying cognitive and behavioral skills while imagining a recent mildly to moderately stressful situation related to your anxiety symptoms. The therapist will help you identify one or more recent stressful situations you encountered and will aid you in vividly imagining being in that situation while practicing the cognitive and behavioral coping skills you've learned in the therapy.

Extremely upsetting thoughts like those associated with a trauma will not be used in these exercises. Before, during, and after these exercises your heart rate and blood pressure will be measured using a cuff placed on your arm that inflates with air so that it is tight but not painful. These measures will provide us with important information on how you are responding to the exercise.

- Post therapy session knowledge quiz in which you complete a brief quiz to ensure that you understood the major points covered at the end of each session. If this quiz reveals that you did not understand one or more important points that were covered, the therapist will spend some additional time with you to review those points.

- Between session practice and monitoring in which you will be asked to practice the skills you learned in each session and keep track of the intensity of your anxiety symptoms and drinking urges between the sessions.

Several elements are different for the three therapy groups as follows:

"Anxiety Reduction" therapy group: Those assigned to this group will undergo all of the CBT elements outlined above but with all six sessions focused on helping you to reduce your anxiety symptoms without specific reference to your alcohol use.

"Anxiety-Alcohol Interaction" therapy group: Those assigned to this group will undergo all of the CBT elements outlined above but with all six sessions focused on helping you to break the association between your anxiety symptoms and alcohol use/urges/problems.

"Combination CBT" therapy group: Those assigned to this group include all of the CBT elements outlined above but with three of the six sessions focused on helping you reduce your anxiety symptoms without reference to alcohol use and the other three sessions focused on

helping you break the association between your anxiety symptoms and alcohol use/problems/urges.

Post-Treatment Assessment (1-2 hours, paid \$25 upon completion)

After you complete your final therapy session, but before you are discharged from Lodging Plus, you will be asked to complete another assessment that will be nearly identical to the Baseline Assessment (see description above). If this assessment reveals significant clinical problems, the study staff may refer you for additional treatment at that time.

One-Month Assessment (1-2 hours, paid \$50 upon completion)

Prior to your leaving Lodging Plus, a study staff member will set up an appointment with you for you to return to Fairview for the one-month follow-up assessment. One to two weeks prior to this appointment, a study staff member will contact you using the contact information you provided us for that purpose to confirm that the time and date still work for you to return to the Fairview ARC for the 1-2 hour assessment. Once the date and time are confirmed, we will mail material to you with parking information and driving routes and public transportation routes from different parts of the Twin Cities to Fairview. You will be able to park at Fairview for these assessments at no cost to you.

The one-month assessment will include the same interviews and questionnaires given at the post-treatment assessment but will focus on the time since you completed the therapy. You will also be asked for information about any additional psychiatric or substance abuse treatment you received since completing the study treatment. If any assessments reveal significant clinical problems, the study staff may refer you for additional treatment at that time.

Four-Month Assessment (1-2 hours, paid \$100 upon completion)

The four month assessment will be identical in content to the one-month assessment but will focus on the time since your last assessment. At the time of your one-month assessment, a study staff person will set up an appointment with you for you to return to Fairview for the four-month assessment. One to two weeks prior to this appointment, a study staff member will contact you using the contact information you provided us for that purpose to confirm that the time and date still work for you to return to the Fairview ARC for the 1-2 hour assessment. Once the date and time are confirmed, we will mail material to you with parking information and driving routes and public transportation routes from different parts of the Twin Cities to Fairview. You will be able to park at Fairview for these assessments at no cost to you.

If you missed your one-month assessments, we will still attempt to contact you to complete the four-month assessment using the contact information that you provided us for this purpose.

Payment Method

You will be given a Greenphire ClinCard, which is a specially made debit card for clinical research payments. After you have completed a visit, the specific payment for that visit will be added onto your card. It can be used wherever MasterCard's are accepted. You will be given additional information on how the card works.

Certain types of transactions made with your ClinCard may incur usage fees (similar to the fees you pay when using an ATM that is not your bank's). These fees are determined by Greenphire, and you will be responsible for them. A detailed notification of the potential fees will be given to you to assist you in assessing when you may be charged a fee. You will never be

charged a fee for making in store or online purchases with your ClinCard.

Lost or Stolen ClinCards: If your card is lost or damaged, please contact the study coordinator for assistance. If the card is stolen, please call (866) 952-3795 for ClinCard's Customer Service immediately and also notify the study coordinator. Available funds on the card **at the time of notification** will be frozen and transferred to a new card. Customer Service will mark the card "stolen" and will assist you in contacting MasterCard to open a case.

If you receive more than \$600 in compensation/stipends in a calendar year for participating in a research study, you will be required to fill out an IRS form W-9. Your name, address, and social security number will be collected as part of that form. You will receive an IRS form 1099-MISC and those monies will be taxed as income and reported to the IRS. You would be responsible for the payment of any tax that may be due.

RISKS AND BENEFITS OF BEING IN THE STUDY

The study has several risks:

First, it may be stressful, embarrassing or otherwise make you feel uncomfortable when asked to provide personal and potentially sensitive information regarding your experiences with anxiety, worry, and drinking behavior and other psychiatric/substance abuse history in the assessments. Because these questions are highly similar (in some cases identical) to issues discussed in Lodging Plus, we believe that participants are typically reasonably comfortable answering such questions; however, this may not be true for you. In order to minimize this risk, you will not be required to answer questions that make you too uncomfortable.

Second, some of the CBT therapy elements are designed to make you feel temporary discomfort and alcohol cravings, usually lasting no more than 20 minutes following the exercise. Specifically, in the course of the CBT therapy, you will be asked to imagine a recent moderately stressful situation related to your anxiety symptoms to practice the coping skills you are being taught. You may also (depending on your group assignment) be asked to vividly imagine a recent stressful situation related to your anxiety symptoms in which you drank alcohol to cope. Again, the purpose of this is to allow you the opportunity to practice the coping skills you are being taught under an imagined "high risk" situation. While the exercises are designed to induce temporary anxiety and/or alcohol craving, the coping skills you are taught will be used to reduce the anxiety and craving back down to the pre-exercise level (or lower). In our experience, and the experience of other researchers who have used this approach, the anxiety or alcohol craving is unlikely to last more than 20 minutes and the likelihood of this anxiety or craving lasting beyond the exercise is low. We base this on our prior work in the Lodging Plus patient population using this CBT approach in which no participants discontinued treatment because of anxiety or craving caused by the therapy or reported prolonged discomfort or cravings that they believed resulted from the CBT therapy. In order to minimize this risk further, your therapist is trained to interrupt the exercise if they perceive you are experiencing significant discomfort or craving and to ask you if you feel you can continue. The exercise can be discontinued completely if either you or the therapist believes that your anxiety or alcohol craving level is reaching an unsafe or intolerable level. Under these circumstances standard relaxation techniques would be used to help you recover quickly. You will also be given an opportunity to stay in the therapy room after the session to further recover if necessary and the Principal Investigator (Dr. Kushner) or the study physician (Dr. Specker) will be available to intervene further if the efforts of the therapist are not satisfactory. If an elevated level of alcohol craving or anxiety persists after the above precautions are taken we will also recommend that you not leave the Lodging Plus premises during the evening following the exercise.

The benefits to participation are:

There are no direct benefits to participation in the study.

COSTS/COMPENSATION

If you participate in all elements of the study described above, including the two follow-up assessments conducted in person at Fairview, you would be compensated by a total amount of \$230. Table 1 above lists the individual payments per activity. Payments will be given within one business day upon completion of each of the study elements listed. Additionally, free parking for your one- and four -month assessments will be available. Also, if approved ahead of time by Dr. Kushner, ground transportation can be arranged in some circumstances; otherwise, you would be responsible for your transportation to Fairview for the assessments.

There are some circumstances in which you would not receive the full amounts for participation listed in Table 1 above.

- Failure to participate in some elements of the study. You will only be paid for those study elements you complete.

- Drop out. If you do chose to discontinue your participation in the study, you would only be paid for the study activities you had completed up to that point.

NEW FINDINGS

If appropriate, you will be given any new significant information that is discovered by the investigators during the course of this study, which may influence your willingness to continue in this study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a subject. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality. As noted earlier, video or audio tapes that do not contain your image will be made for quality control and training purposes. These recordings will be digital and also stored securely using encryption according to current University policy for protection of confidentiality. Also, only researchers will have access to these recordings. After retaining the recordings and other study data securely for the period of time recommended by professional bodies such as the American Psychological Association, the tapes will be destroyed.

ALTERNATIVE TREATMENTS

Whether or not you choose to participate in this study, you will continue to have at your disposal the full range of health care services typically available to you at the Fairview Hospital and the University of Minnesota.

VOLUNTARY NATURE OF THE STUDY

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota or Fairview Hospital, including the Lodging Plus program. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

CONTACTS AND QUESTIONS:

The researchers conducting this study are Matt Kushner, Ph.D and Sheila Specker, M.D.. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact them at the University of Minnesota Department of Psychiatry, 612-273-9800 (adult psychiatry), kushn001@umn.edu or speck001@umn.edu.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the Research Subjects' Advocate Line, 350-2 McNamara, 200 Oak St. SE, Minneapolis, MN 55414; (612) 625-1650; z.umn.edu/participants.

You will be given a copy of this information to keep for your records.

STATEMENT OF CONSENT

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Participant's Name (Please Print)

Date

Participant's Signature

Date

Signature of Investigator

Date