Increasing the Effectiveness of CBT for Anxiety in Veterans by Involving Family Members

NCT05340478

August 9, 2022

Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: [redacted] **VAMC:** _____

H-51655 - INCREASING THE EFFECTIVENESS OF CBT FOR ANXIETY IN VETERANS BY INVOLVING FAMILY MEMBERS

Anxiety Treatment for Veterans with Participation from Family Members (Veteran Version)

Concise and Focused Presentation

Participants will be enrolled in the study for approximately 4 months. Participants will attend a weekend workshop for anxiety. Family members of Veterans will complete a two-session class to learn ways to support the Veteran in coping with anxiety. Veteran participants will complete a conjoint session with their family member and three assessments during their enrollment in the study. Risks of participating in this study are that you may experience minimal or no symptom improvement. Benefits are that you may experience improvement in your symptoms and quality of relationships. If you decide not to participate in this study you can receive different treatments for anxiety that are not part of research.

Background

Many Veterans experience anxiety that can interfere with their everyday lives. Anxiety can make it difficult to enjoy life and do things such as going to work and school. Anxiety can also lead to feelings of sadness. Anxiety comes in many forms, including general nervousness, panic attacks, fear of social situations, and uncontrollable worry. Fortunately, helpful treatments are available. But these treatments usually require attending weekly appointments over several months, which interferes with Veterans' daily schedules. This is a common reason why Veterans may not complete treatment. Also, many people experience a combination of anxiety problems and sometimes depression, but existing treatments only target one problem at a time. This means that a person would spend much of their time in treatment. To address this, investigators at the MEDVAMC have been examining a brief, intensive treatment that can address a range of anxiety problems. This treatment can target multiple anxiety related concerns including feelings of sadness at one time. This treatment can also be completed in one weekend. Results show that this treatment is effective. Specifically, Veterans report lower anxiety and a better quality of life after completing the weekend treatment. Based on feedback from Veterans who completed the treatment, we are now studying a way to include family members of Veterans in the treatment process. This is because many Veterans have shared that they would like their family members to attend a class where they can learn more about anxiety so that they can better understand the Veteran's experience of anxiety. Family members can also learn more about the treatment Veterans receive so they can help support the Veteran in their recovery process.

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

This research study is funded by VA Rehabilitation Research & Development

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Purpose

The purpose of this study is assess a program designed to help Veterans with anxiety. The program entails Veterans receiving a treatment for anxiety that can be completed in one weekend and family members receiving a brief class to help them better understand and support the Veteran's recovery process.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.
If you agree to take part in this study, you and your family member will complete a brief assessment together today. This visit will last about 2 hours. You will also be asked to attend two additional assessment appointments. These appointments will occur before treatment and 1-month after treatment. At each of the these visits you will be given a few self-report measures to complete that will ask how you have been feeling. These measures will ask about your levels of anxiety, depression, and stress. You will also discuss your symptoms with a clinician. Each of these assessments will last approximately 2.5 hours. All activities will be supervised by a licensed psychologist at the MEDVAMC. Study staff will need to access your medical records at times to track your health information that is related to the study. Specifically, we will be tracking the medications you are taking and the number of individual and group treatments you attend during the study period. Only approved members of the study staff may access this information. Research personnel conducting quality assurance checks may also access your information collected in this study. This includes measures of mood, anxiety, and related symptom ratings you complete during the course of the study.

You will be asked to meet with a clinician and to complete an assessment (review of your anxiety symptoms) approximately 2 weeks before you receive the weekend treatment. The treatment will be provided in a small group format and can be delivered in a virtual format. Weekend treatment is conducted over Saturday and Sunday and lasts about 8 hours on each day. Your family member will also be asked to attend a separate anxiety class within approximately 1-2 weeks of your scheduled weekend treatment. The class for your family member consists of two 2-hour long sessions and will be provided in a small group format made up of family members of other Veterans. Trained clinicians will conduct the treatment and all assessments.

Approximately 2 weeks after your family member completes their anxiety class, you will be asked to attend a booster session together. This session will last about 90 minutes. A study clinician will check in on your progress and provide you and your family member with suggestions and support in using what you learned in treatment. Once your family member completes their anxiety class, you both will be asked to complete a 1-month follow-up assessment. During this follow-up visit, you both will be interviewed by a member of the study team to share your experience with the anxiety class and weekend treatment. These interviews will be audio recorded and transcribed so that we can examine common themes

expressed among study participants.

The weekend treatment has been shown to be effective for people with anxiety. It provides education about anxiety and teaches you to identify the types of thoughts that lead to your anxiety. The treatment also includes exercises that will help you better understand and manage your anxiety symptoms. The anxiety class for your family member provides education about anxiety, teaches skills that they can use to support you, and helps with improving communication between you and your family member.

While participating in this study you agree not to receive transdiagnostic CBT for anxiety outside of this study at the same time for your anxiety symptoms. You may receive treatment for any other psychological problems. You may continue taking prescribed medications.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Confidentiality

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Partial Social Security # (Last four digits)
- Photographs, videotapes, and/or audiotapes of you

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

As with any type of treatment for anxiety disorders, there is a chance that you will not experience noticeable improvement in your symptoms; and some may find their symptoms worsen during treatment. At times, some patients may experience discomfort or embarrassment in sharing personal information or in discussing issues typically addressed in therapy. While participating in various exercises, you may experience momentary discomfort (when talking about events that cause you anxiety, tensing parts of the body). You will be monitored closely by a trained clinician and will not be asked to engage in potentially anxiety-provoking exercises for prolonged periods of time or do more than you are willing. If a participant remains distressed or upset after a therapy or evaluation session, that individual will be encouraged to speak to the therapist/interviewer or another mental healthcare professional.

If you or your family member are experiencing symptoms after a session, you should talk to your therapist or interviewer. If you need immediate attention and your therapist is not available, arrangements will be made for you to meet with a mental health professional at this facility. In any event, you will have access to services at the MEDVAMC 24 hours a day, 7 days a week.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: People who participate in the study may experience symptom improvement related to their anxiety symptoms and improvement in the quality of their relationships. This intervention will be among the first to incorporate family members directly into the recovery process. Information learned from this study will be used to continue research on this intervention. If effective, many other Veterans and their family members may benefit from this study. . However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: People can get different anxiety treatment that is not research. A member of the study team can discuss other treatment options with you.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will receive $50 for every completed assessment. If you complete both assessments at baseline and 1-month follow-up, you will have received a total of $100, which will be directly deposited into your account.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, [redacted], and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: [redacted] at [redacted] during the day and the Emergency Department at [redacted] after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is [redacted]. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Subject Name: _____ **Date:** _____

Subject Initials: _____

Principal Investigator: [redacted] **VAMC:** _____

H-51655 - INCREASING THE EFFECTIVENESS OF CBT FOR ANXIETY IN VETERANS BY INVOLVING FAMILY MEMBERS

Under Federal Regulations, the VA Medical facility shall provide necessary medical treatment to you as a research subject injured as a result by participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Michael E. DeBakey VA Medical Center. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You do not waive any liability rights for personal injury by signing this form.

You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMC. If you would like to verify the validity of the study and authorized contacts, you may speak with the Michael E. DeBakey Veterans Affairs Medical Center Research Office at [redacted] or [redacted].

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness	Date

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

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Principal Investigator: [redacted] **VAMC:** _____

H-51655 - INCREASING THE EFFECTIVENESS OF CBT FOR ANXIETY IN VETERANS BY INVOLVING FAMILY MEMBERS

Anxiety Treatment for Veterans with Participation from Family Members (Family Member Version)

Concise and Focused Presentation

Participants will be enrolled in the study for approximately 4 months. Family members of Veterans (who attend a weekend workshop for anxiety) will complete a two-session class to learn ways to support the Veteran in coping with anxiety. Family members will also complete a conjoint session with the Veteran and three assessments during their enrollment in the study. Risks of participating in this study are that you may not find the brief class useful in helping you support the Veteran's recovery from anxiety. Benefits are that you may find the brief class useful in helping you support the Veteran's recovery from anxiety. You may also experience improvement in the quality of your relationship with the Veteran. If you decide not to participate in this study, you may be able to receive supportive therapy from a community provider.

Background

Many Veterans experience anxiety that can interfere with their everyday lives. Anxiety can make it difficult to enjoy life and do things such as spending time with their family and going to work or school. Anxiety can also lead to feelings of sadness. Anxiety comes in many forms, including general nervousness, panic attacks, fear of social situations, and uncontrollable worry. Although effective treatments for anxiety are available, most of them focus only on the patient. However, some studies show that it can be helpful for family members to be involved and informed about their Veteran's anxiety treatment. Also, many Veterans who completed our weekend anxiety treatment have shared that they would like their family members to attend a class where they can learn more about anxiety. This can help family members better understand and support the Veteran as they apply skills to overcome their anxiety. We are now studying a way to include family members of Veterans in the treatment process.

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

This research study is funded by VA Rehabilitation Research & Development

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this study is to see if offering an anxiety class to family members of Veterans who receive anxiety treatment can help them better support the Veteran's recovery process.

Procedures

The research will be conducted at the following location(s):

Baylor College of Medicine and Michael E. DeBakey Veterans Affairs Medical Center.

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Subject Initials: _____

Principal Investigator: [redacted] **VAMC:** _____

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If you agree to take part in this study, you and your Veteran will complete a brief assessment together today. This visit will last about 2 hours. You will also be asked to attend one additional assessment appointment. This appointment will occur 1-month after you complete the anxiety class and will last about 2.5 hours. During the assessment visits you will be given a few self-report measures to complete that will ask about your experiences with supporting your Veteran in recovery. You will also discuss these experiences with a clinician. All activities will be supervised by a licensed psychologist at the MEDVAMC. Research personnel conducting quality assurance checks may also access your information collected in this study. This includes measures and symptom ratings you complete during the course of the study. Only approved members of the study staff may access this information.

As a part of this study, your Veteran will complete a weekend treatment for anxiety. Weekend treatment is conducted over Saturday and Sunday and lasts about 8 hours on each day. You will be asked to attend an anxiety class within approximately 1-2 weeks of your Veteran's scheduled weekend treatment. The class consists of two 2-hour long sessions and will be provided in a small group format made up of family members of other Veterans. The class can be delivered in a virtual format. Trained clinicians will conduct the class and assessments.

Approximately 2 weeks after you complete the anxiety class, you will be asked to attend a booster session with your Veteran. This session will last about 90 minutes. A study clinician will check in on your Veteran's progress and provide both of you with suggestions and support in using what you learned in treatment. Once you complete the anxiety class, you both will be asked to complete a 1-month follow-up assessment. During the follow-up visit, you both will be interviewed by a member of the study team to share your experience with the anxiety class and weekend treatment. These interviews will be audio recorded and transcribed so that we can examine common themes expressed by participants.

The anxiety class provides education about anxiety, teaches skills that you can use to support your Veteran, and helps with improving communication between you and your Veteran.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Confidentiality

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Partial Social Security # (Last four digits)
- Photographs, videotapes, and/or audiotapes of you

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

At times, some participants may experience discomfort or embarrassment in sharing personal information. If you remain distressed or upset after a class or evaluation session, you will be encouraged to speak to the therapist/interviewer or another mental healthcare professional.

If you or your Veteran are experiencing symptoms after a session, you should talk to your therapist or interviewer. If you need immediate attention and your therapist is not available, arrangements will be made for you to meet with a mental health professional at this facility. In any event, you will have access to services at the MEDVAMC 24 hours a day, 7 days a week.

There are certain situations in which study staff may need to break confidentiality in order to protect you or others from direct harm. These situations include reports of abuse or neglect of a minor or vulnerable adult and plans to harm yourself or others.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

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Potential Benefits

The benefits of participating in this study may be: The benefits of participating in this study may be: Family members who participate in the study may learn helpful information about anxiety and how treatment works. They may also see their Veteran experience symptom improvement related to their anxiety symptoms. Also, family members may experience improvement in the quality of their relationships with their Veterans. This intervention will be among the first to incorporate family members directly into the recovery process. Information learned from this study will be used to continue research on this intervention. If effective, many other Veterans and their family members may benefit from this study.. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be paid for taking part in this study.

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