Cognitive Behavioral Therapy to improve work and wellness in veterans with mental illness

NCT04504903

July 11, 2022

Study Information Sheet
Veterans
CIRB 20-08, [Site Name]

VA Central IRB
VA Institutional Review Board for Multisite Studies

You are being invited to take part in a research study that is being funded by VA Health Services Research and Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn more about the effects of cognitive behavioral therapy on competitive work, health, and recovery outcomes in Veterans with serious mental illness. Your participation in this research will last about 12 months in total.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The Cognitive Behavioral Therapy for Work Success (CBTw) intervention in this study may benefit Veterans with serious mental illness. Specifically, potential benefits could include: enhanced functioning, recovery, and health, as well as increased competitive work success with potential long-term benefits, such as longer periods worked, higher wages earned, more opportunities for career advancement, and less health changes.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you have previously participated in cognitive behavioral therapy related research or have a severe medical or cognitive impairment that will prevent participation in the study, then you may not wish to participate. If you would feel uncomfortable sharing any personal information at all during group sessions or with a research assistant, then you may choose to not volunteer for this study. If the possible risk of loss of confidentiality or being audio recorded is an especially important concern, then you may choose to not participate in this study.

There are exceptions in which we have to break confidentiality, like if are if you are about to harm yourself or others, or in other instances required by law

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [PI Name] at the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact her at [phone number].

The project manager for this study is [PM Name]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact her at [phone number].

Your Local Site Investigator is Insert LSI Name and contact information.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn the effects of a cognitive behavioral therapy intervention designed to target competitive work, health, and recovery outcomes in Veterans with serious mental illness. We will compare two groups, each lasting 12 weeks. One group will receive Cognitive Behavioral Therapy for Work Success (CBTw) plus supported employment services. The second group will receive psychoeducation (learning information about your mental illness and how to manage it) plus supported employment as well. You were selected as a possible participant because you are not currently employed in a competitive job, have a serious mental illness, are receiving supported employment services, and have a competitive work goal. Before starting group, you will be asked to complete a baseline assessment. You will be asked to complete follow-up assessments at 12 weeks (right after group ends), 6 months, and 9 months .

HOW LONG WILL I BE IN THE STUDY?

If you chose to participate, you will be one of XXX participants from Local Site Name, and among 276 total participants across all three VA sites: Richard L. Roudebush VA, Edward Hines Jr. VA Hospital, and VA St. Louis Health Care System. This research study is expected to take approximately 4 years in total. However, your individual participation in the project will take 12 months (3 months in group and 9 months of periodic follow-up).

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will first be asked to complete a baseline assessment with a research assistant. This will involve asking you questions about your self, your health, and your work history. Then you will be randomly assigned (like flipping a coin) into one of two groups; cognitive behavioral therapy intervention or psychoeducation control. Each group will meet for one-hour a week, for 12 weeks total, and group sessions will be audio recorded to observe the group leader. You will be asked to state your consent to be audio recorded at the start of each audio-recorded group. These groups will involve learning material and concepts about mental health, participate in discussions, and complete worksheets or other writing exercises. You will receive standard supported employment services during the entire study period regardless of which group you are assigned to. Groups may be help remotely (via phone or video) or in person, in order to minimize any unnecessary in-person contact. In the instance that you miss a group session, group leaders may provide individual booster sessions, as their schedule allows. You will also be asked once a month for updates regarding your current work status. If you decide to withdraw from the study, then you will not be able to continue in group sessions or complete any further assessments; your regular supported employment services will not be affected. If necessary, group will be held remotely according to local SOPs for remote groups, as developed by local Service Line Leadership. If requested upon withdrawal, your data will be removed from the study in the extent possible.

Both the intervention and control group participants will be asked to complete 4 assessments during the study: one before group starts, one after group has ended, one at 6 months, and one at 9 months. Each assessment will involve answering questions about demographics, employment history and status, mental health symptoms, quality of life, suicidality, and recovery attitudes. Each assessment will take approximately one hour and will be given by a research assistant. Assessments may be done in person or by phone, in order to minimize any unnecessary in-person contact. During the assessments, you may skip any questions that you would prefer not to answer.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you agree to participate in this study, you are expected to:

- Attend all group sessions for one-hour a week, for 12 weeks
- Complete all 4 assessments. If you miss an appointment, please contact research staff to reschedule as soon as you know you will miss or have missed the appointment
- Fill out your monthly work update form
- Ask questions as you think of them
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any research study has possible risks and discomforts. What you will be doing in this study may cause all, some, or none of the risks or side effects as listed.

Risk of being uncomfortable during group sessions and/or assessments: Personal sharing during group sessions is not mandatory, and participants have the right not to disclose information and/or speak during groups at their discretion. During individual assessments, all participants will be instructed that they may refuse to answer any question that they are uncomfortable answering.

Risk of loss of confidentiality: We cannot guarantee absolute confidentiality. You will be required to share your name and the fact that you have serious mental illness with others in this study. The sharing of any other personal information will be determined by what you and your group leader(s) are comfortable with.

Risk of being audio recorded: Since your group sessions will be audio recorded, there is a risk of loss of anonymity, which means you may be identifiable. However, audio files will be stored on a password-protected computer. At any time, you may tell the researcher or group leader that you feel uncomfortable or do not wish to continue.

There are exceptions in which it is necessary to break confidentiality, like if you are about to harm yourself or others, or if the law requires. However, every effort will be made to ensure all information collected about you remains secure and is viewed only by study staff.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive at VA or in supported employment services are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will specifically get any benefits from taking part in this research study. However, the CBTw intervention examined in this project may have potential widespread benefits to Veterans with serious mental illness. Specifically, potential benefits to participants could include improved functioning, recovery and health, and socioeconomic outcomes, including increased competitive work success with potential long-term benefits, such as longer periods worked, higher wages earned, more opportunities for career advancement, and a reduction in health differences. You may also experience more of an understanding of the impact of your thoughts and feelings on work related behavior, greater work-related self-worth, more motivation, better self-esteem, and improved problem-solving ability and healthy coping.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

This study will collect and use, but not disclose, your Protected Health Information (PHI). Data will not be banked. Biological specimens are not utilized in this study.

Prior to the start of research, study investigators will have completed required VA R&D committee training (i.e., VA's Cyber Security Awareness course and Overview of Good Clinical Practice and Human Subjects Protection course) as well as other required trainings by IRB. Research staff and all site investigators will complete all required VA R&D and IRB research trainings, such as Collaborative Institutional Training Initiative courses on responsible practice of research and protection against risk.

To protect against the potential loss of confidentiality, all electronic data will be de-identified to the extent possible, or identified with a study code, and stored on a secure, password-protected VA server. There will be a file that connects your name to your participant ID for the study; this file will be stored behind the VA firewall in a password protected folder that is only accessible to the study team. Any paper documents collected will be kept in a locked cabinet in secure (locked) office space at each VA site. Computerized files will be protected by the electronic firewall at the Roudebush VAMC and will be password protected (Roudebush servers behind VA firewall will be accessible to and used by study personnel at all sites, including Hines and St. Louis). Passwords are created according to guidelines set by the VA Office of Cyber and Information Security.

Further, "group rules" will be laid out at the beginning of the CBTw and psychoeducation groups during the first group session in which confidentiality and respect for the privacy of other veterans will be discussed and agreed upon by all participants. Specifically, information discussed in the group will stay in the group and is not to be discussed with other persons outside of the group. Forming these "group rules" is also standard practice in research and clinical group therapy and psychoeducation settings.

WILL MY INFORMATION BE USED IN FUTURE RESEARCH?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you would not be asked for additional consent.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no costs to you for any of the group sessions or assessments that are part of this research study. You will continue to receive all VA care and rehabilitation services (including supported employment) as usual, regardless of your study status. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are <u>not</u> part of this study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

WHAT PAYMENT IS OFFERED TO ME IF I PARTICIAPTE IN THIS STUDY?

1. You will be compensated $20 for each completed assessment: baseline, 12 weeks (after group end), 6 months, and 9 months. Each assessment will take approximately one hour. If you complete all the assessments you would receive $80.
2. You will <u>NOT</u> be compensated for attendance in weekly group sessions (CBTw or psychoeducation). You will <u>NOT</u> be compensated for transportation costs.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. Financial compensation for research-related injuries is not available. By signing this form, however; you do not give up your legal rights or release the VA from any liability.

DO I HAVE TO TAKE PART IN THE STUDY?

Alternative to participation:
You can receive supported employment services without participating in this study.

You have the option to not participate in the study. You do not have to participate in this study. Your participation is entirely voluntary. If you refuse to participate in this study, this will involve no penalty or loss of benefits to which you are entitled. If you are a VA employee or student and refuse to participate in the study, this will in no way effect your employment, ratings, subsequent recommendations, or academic progress as applicable.

At any point if you decide you no longer wish to continue your participation in this research study, you may withdraw from the study at any time without any repercussions. You will continue to receive all VA care and rehabilitation services (including supported employment) as usual, regardless of your study status. If you withdraw from the research study, you will not be able to continue your participation in the study's groups or complete any further assessments. If requested upon withdrawal, your data will be removed from the study to the extent possible. If you wish to withdraw, you will be directed to contact the research assistant at your research study site to provide a reason for withdrawal.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

If you are no longer receiving supported employment services at any point during the study, your participation in the study will be terminated. It is not anticipated that this circumstance will occur.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

The person in charge of the study is [PI Name] at the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact her at [phone number].

The project manager for this study is [PM Name]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study you may contact her at [phone number].

Your Local Site Investigator is Insert LSI Name and contact information.

Please direct questions about the consent process and the rights of research subjects to the VA Customer Service Office at 317-988-2602. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The research assistant has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By verbally stating your consent, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent.