CBT-I for Psychosis: Guidelines, Preliminary Efficacy, and Functional Outcomes

NCT02535923

Informed Consent Form

Date of upload: 4/19/2022; Informed consent form approval date: 3/27/2020

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: CBT-I for Psychosis: Guidelines, Preliminary Efficacy, and Functional Outcomes-Trial

Principal Investigator: Elizabeth Klingaman, PhD, 410-637-1875 VA Facility: Baltimore 512

RCT

STUDY No: HP- 00074686

SPONSOR: VA Rehabilitation Research and Development Service

- This is a research study. Your participation is voluntary; you can ask questions at any time.

- This study is taking place at the VA Maryland Health Care System (VAMHCS). Your participation in this study will take place entirely at the VAMHCS.

PURPOSE OF STUDY

- People with mental illness often experience trouble sleeping, such as insomnia. The purpose of this study is to evaluate a new program designed to help people with mental illness develop skills identify and replace thoughts and behaviors that cause or worsen sleep problems with habits that promote sound sleep.

- You are being invited to volunteer for this study because: a) you have a psychotic disorder or bipolar disorder, b) you reported having sleep problems, and c) you are currently receiving mental health treatment at the VA.

- A total of 60 Veterans with psychotic or bipolar disorders will be asked to participate in this portion of the study. You will be one of approximately 60 Veterans to be asked to participate at this location. Your participation in this study is voluntary.

PROCEDURES

- This study has two parts. You may be eligible for one or both of them.

- If you agree to participate in this study, you will begin by completing Part One of the study. In Part One, you will be asked to complete a questionnaire about your background

and a brief questionnaire about your sleep habits. These questions should take approximately 10 minutes to complete. Your responses to these questions will determine if you are eligible to continue in the study. If you are found not to be eligible, you will be paid $5 for your time, and will not have to complete any other study tasks.

- If you are eligible to continue in the study, you will be asked to wear an activity wristwatch to monitor how much activity you get and also to keep a log of your sleep for two weeks. After the two weeks, you will be required to return the watch and the sleep log to study staff. You will be asked to complete an assessment including 1) questions about your feelings, thoughts, and behaviors, and 2) an assessment of your thinking and memory. This interview will take approximately 2.5 hours and you will be paid $30 for your time. Your responses to these questions will help to determine if you are eligible to continue to Part Two of the study. If needed, questionnaires about thoughts, feelings, and behaviors can be completed over-the-phone. If you complete them over the phone, you will be sent a portion of the payment ($20). Since the assessment of your thinking and memory must be completed in person, you will receive the additional $10 payment once you attend and complete this portion.

- You will be asked to complete a home sleep screening test to also help determine if you are eligible to continue to Part Two of the study. The home sleep testing involves wearing a small lightweight device on your wrist and finger which collects information such as breathing and blood oxygen level while in the comfort of your own home. A research staff member will explain how to use the device, show you how to use it, let you practice, and answer any questions you have before you take it home. You will be asked to use it for 1 night and will be required to return the equipment to study staff the following day. Typically, 1 night of use is needed, but you may be asked to repeat the test. You will be paid $75 after your participation in the home sleep screening test is complete.

- If you are eligible to participate in Part Two of the study, you will be placed in one of two study groups through random assignment. Random assignment means your group assignment will be determined by chance, like picking the name out of a hat. The two groups are: (1) Cognitive Behavioral Therapy for Insomnia (CBT-I) or (2) Health and Wellness (HW).

- If you are assigned to CBT-I, you will be asked to come to approximately 10 individual CBT-I treatment meetings with a study therapist, each of which will last approximately 1 hour. If needed, you may participate in sessions over the phone. During these meetings: (1) your study therapist will ask you questions about your sleep problems and day/nighttime habits, (2) you will learn and practice strategies to improve your sleep, and (3) you will receive help in setting goals for improving your sleep. We will help you learn these skills by giving you worksheets and pamphlets to take home to read and complete. You may also be asked to wear an activity wristwatch to monitor how much activity you get during the course of the treatment. You will be required to return the watch to study staff at the end of the treatment. **These meetings will be audio recorded in order to provide ongoing supervision and feedback to the staff that are running the meetings.** If you refuse to be audio recorded, you will not be able to partake in this study.

  Up to 30 participants in the CBT-I intervention will be invited to complete an additional interview shortly after completing the treatment sessions. If you are asked to participate in this extra interview your participation will be entirely voluntary. This extra interview will take place at the VAMHCS or via telephone. If you agree, during it you will be asked questions about your experiences while in CBT-I, as well as your opinion of how this treatment could be improved upon. We will also ask for your input to help us think about how to best offer this intervention to others. The interview will take about 1 hour and will be audio recorded. **Audio recordings of this interview will be sent securely to a VA-approved transcription agency that is outside the VA, so that they can transcribe the interview for us.** Participants who complete this additional interview will be paid $40. If you complete this interview over the phone, your payment will be sent to you.

- If you are assigned to HW, you will be asked to come to approximately 10 individual HW treatment meetings with a study therapist, each of which will last approximately 1 hour. If needed, you may participate in sessions over the phone. During these meetings: (1) your study therapist will ask you questions about your health and wellness, (2) you will learn ways to better manage your health, (3) you will receive help in setting goals for improving your health. We will help you learn these skills by giving you worksheets and pamphlets to take home to read and complete. You may also be asked to wear an activity

wristwatch to monitor how much activity you get during the course of the treatment. You will be required to return the watch to study staff at the end of the treatment. **These meetings will be audio recorded in order to provide ongoing supervision and feedback to the staff that are running the meetings.** If you refuse to be audio recorded, you will not be able to partake in this study.

- If you are eligible to participate in Part Two, you will also be asked to complete 2 assessments regardless of the group you are assigned to. The first assessment will be completed at the end of your treatment meetings and the second assessment will be completed about 3 months later. These assessments will include questions 1) about your feelings, thoughts, and behaviors, and 2) to assess your thinking and memory. For two weeks prior to each assessment, you will be asked to keep a log of your sleep and may be asked to wear an activity wristwatch to monitor how much activity you get. You will be required to return the watch to study staff at the end of each assessment. Each assessment will take approximately 2.5 hours to complete and for each assessment you will be paid $30 for your time, for a total of $60 for both assessments. If needed, questionnaires can be completed over-the-phone. If you complete them over the phone, you will be sent a portion of the payment ($20 per assessment). Since the assessment of your thinking and memory must be completed in person, you will receive the additional $10 payment per assessment once you attend and complete this portion.

- If you would like, we can use VA email to communicate with you during your study participation in order to send electronic copies of resources and/or blank worksheets for you to complete at a later time during phone-based assessment and/or treatment sessions. We will only send these materials at your request and staff will discuss proper procedures for communication via email with you ahead of time. No completed forms or personal identifying information should be returned to the study staff via email correspondence. All emails sent by study staff will be deleted upon receipt to ensure security.

- All in person meetings and assessments for this study will take place at the VAMHCS. If you are completing sessions over the phone, research staff will conduct all procedures in a private, secure space and will ask you questions to ensure that you are also in a private space in order to protect your privacy.

- You may request the overall results of this study when the study is complete.

- **We may have additional studies in the future related to sleep problems in Veterans. If another study about sleep becomes available, we would like permission to contact you to tell you about it and see if you would like to participate.**

  Please indicate whether or not you agree to be re-contacted for future studies about sleep problems:

  _____ Yes, I agree to be re-contacted for future studies about sleep problems.

  _____ No, I do not want to be re-contacted for future studies about sleep problems.

POTENTIAL RISKS/DISCOMFORTS:

- The tasks that you will be asked to complete during this study have been used in many other research studies. They are not harmful or unpleasant. You may feel some discomfort with discussing your thoughts or with restructuring your routines to improve your sleep, health, and wellness. However, the intervention is not generally considered unpleasant and severe reactions are uncommon based on prior studies using CBT-I and HW. You may feel a little embarrassed while first being audio recorded or when personal topics are being discussed; however, most people get used to the situation and relax after a few minutes. It is possible that some of the questions the therapist asks you may lead you to think of upsetting experiences. You are free to not answer any question or discontinue your participation at any time you wish. The wristwatch you will be asked to wear has caused some skin irritation in some people. You are free to remove the watch and stop wearing it at any time if this were to happen to you. Please feel free to contact study staff and/or your physician should you have any concerns while wearing the watch.

- Other unlikely risks include a breach of confidentiality. We have several procedures in place for minimizing these risks. All data and test results and audio recordings will be kept in locked cabinets in the researcher's offices at the Baltimore VAMC (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201),

and accessible only by individuals directly involved in the research project. Consent forms and any forms with your name on them will be kept separately at the Baltimore VAMC (MIRECC Offices, VA Annex, 209 W. Fayette Street, 7th floor, Room 733, Baltimore, MD 21201). Materials will only be available to project staff as needed. Paper copies of testing data and computer files will be labeled by code; this means they will not have your name on them. Audio recordings will be labeled by code; this means they will not have your name on them. All project staff will be thoroughly trained in issues relating to confidentiality. Statistical analyses will be based on group data; no individual data will be reported.

- Your audio recorded meetings will be shared with Dr. Philip Gehrman, an expert in the field of sleep at the Philadelphia VA. Dr. Gehrman is a member of this research team. He will listen to the recordings and will provide study staff feedback on their treatment delivery.

- There may be risks in this study which are not yet known.

POTENTIAL BENEFITS

- You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. However, you may learn strategies/tools and receive resources to reduce or better cope with your insomnia symptoms.

- Your participation in this study could also lead to knowledge that may benefit other Veterans who experience sleep problems.

ALTERNATIVES TO PARTICIPATION

- You may choose to not participate in this study.

- If you choose not to take part in this study, you may ask the study team to provide you with information regarding other types of insomnia treatments not associated with the

research study. Your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected regardless of your decision to participate in the study.

COSTS TO PARTICIPANTS

- There are no costs to you as a consequence of your participation in this research study.
- Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

PAYMENT TO PARTICIPANTS

- For Part One of the study, if you are ineligible after you complete the initial screening questionnaires, you will be paid $5. If you are eligible to continue and complete the initial assessment battery, you will be paid $30. You will be paid $75 for the home sleep apnea screening test and then $30 for the initial assessment battery for a total of $105.
- Participants who are eligible for Part Two of the study will be paid $30 for each of the two assessments for a total of $60 for Part Two. CBT-I participants who complete the additional interview after completing the treatment sessions will receive an additional $40, for a total of $100 for Part Two.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA Maryland Health Care System (VAMHCS) will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Dr. Elizabeth Klingaman at 410-637-1875 and AFTER HOURS: Dr. Elizabeth Klingaman at pager number 410-447-1275.

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

- This study will involve confidential information. In order to learn about how to help you improve your sleep, we will ask you questions and review your medical records. We have several procedures in place to help protect your confidentiality. Your name will not be included on the collected data. Instead, a code will be placed on the data, and through the use of an identification key, the researchers will be able to link your survey to your identity. Only the researchers will have access to the identification key. The information we collect from you will be stored at the VAMHCS (MIRECC Offices, 209 W. Fayette Street, Baltimore, MD 21201- VA Annex Building). Electronic files with your information will be kept in secure computers in a locked room. The electronic data files with your information will be password protected and behind the VA firewall. All records and audio recordings will be stored in locked cabinets in a locked room. Coded information will only be accessible to members of the research team and individuals involved in our data management process.

- It may be necessary for us to contact your VA medical providers to coordinate the delivery of this intervention with the rest of your medical care. We will share information about how you are doing with your clinical team if it may be helpful to you.

- Confidentiality is not absolute (perfect). There are several situations in which we would tell information that would identify you without your consent. If the research interviewer hears about or sees that you intend to harm yourself or someone else, s/he will tell a doctor or some other authority so that you can get some help, even if it means telling the authorities without your permission. In such a situation, the researchers would only disclose information that would prevent harm to you or other people believed to be in danger. If we hear about or see something that would immediately endanger you or

others, such as child abuse, we will seek help, to protect the child. In addition, we must follow legal requirements concerning child abuse and neglect. If you tell us information about child abuse, we must disclose this information to the appropriate individuals and/or authorities. We must report this information regardless of when the child abuse occurred (whether it is occurring now or happened in the past) or who was the victim of the abuse (whether it was you or someone else). Also, the researchers will report certain diseases that can be given to other people.

- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, the VAMHCS Office of Research Compliance and other representatives of this organization. Study records can be reviewed by federal agencies, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP).

- Your research records and/or identifiers will be destroyed in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

- If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

- If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Elizabeth Klingaman at 410-637-1875.

- There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research.

- If you withdraw from this study, already collected data may not be removed from the study database.

- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, you may contact Dr. Elizabeth Klingaman at 410-637-1875.

Please read the University's statement below.
The University of Maryland, Baltimore (UMB) is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland Baltimore. The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the UMB Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Office of Academic Affairs Regulatory Compliance
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO)**.** The contact information for the HARPO is:

VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56512
Room 3D-158

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date:_____

Title of Study: CBT-I for Psychosis: Guidelines, Preliminary Efficacy, and Functional Outcomes-Trial

Principal Investigator: Elizabeth Klingaman, PhD, 410-637-1875 VA Facility: Baltimore 512

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.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____