# Improving the Assessment and Treatment of Chronic Pain in Veterans with Serious Mental Illness

NCT04118283

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Department of Veterans Affairs

# Research Consent Form

Participant Name: _____ Date:_____

Title of Study: Improving the Assessment and Treatment of Chronic Pain in Veterans with Serious Mental Illness

Principal Investigator: Letitia Travaglini, PhD Facility: VA Maryland Health Care System

**IRB Study Number:** HP-00088491
**Sponsor:** VA Office of Rehabilitation Research & Development (RR&D)

**INTRODUCTION:** You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS). 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.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, that will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

## CONCISE SUMMARY

The purpose of this research is to determine the feasibility and acceptability of Cognitive Behavioral Therapy for Chronic Pain (CBT-CP) for Veterans with serious mental illness (SMI). Participants will have gone through an initial screening to determine study eligibility, including an assessment of current pain severity. Once screening is complete, participants will complete a questionnaire several times over the course of one week before meeting with a study team member to complete pre-treatment assessments. Participants will then be assigned to one of two different individual treatments, which will take place every week for 10 weeks. Each visit will take approximately 60 minutes. At the end of treatment, participants will complete post- treatment assessments (usually 1-2 weeks after the end of treatment) and another assessment approximately three months after they finish treatment. Participants may also be asked to participate in a one-time interview about their experience with the treatment. Total study duration is about 6 months. Participants will be compensated up to $163 for their participation.

The greatest risks of this study include boredom, embarrassment, and potential loss of confidentiality. The potential benefit is that participants may learn strategies and receive resources to improve pain-related functioning and quality of life.

If you are interested in learning more about this study, please continue to read below.

Participant Name: _____ Date:_____

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## RESEARCH DETAILS

### PURPOSE OF THE STUDY

- People with mental illness often experience chronic pain that can have a significant impact on functioning and quality of life. The purpose of this study is to evaluate a behavioral pain management treatment designed to help people with chronic pain develop skills to identify and replace thoughts and behaviors that can worsen pain with strategies that can help someone better manage pain and improve related functioning.
- You are being invited to participate in this study because: a) you have a psychotic or bipolar disorder; b) you have a chronic pain condition noted in your medical record; and c) you are currently receiving outpatient care through the VAMHCS.
- A total of 50 Veterans with comorbid chronic pain and serious mental illness will be asked to participate in all study procedures. Your participation is voluntary.

### STUDY PROCEDURES

- This study has two parts. All study parts take place over the phone or via telehealth appointment in private rooms.
- For Part One, you will be asked to complete a series of questionnaires over the course of 7 days. Three times per day for 7 days in a row, you will receive prompts/reminders from the research team asking you to complete the Part One questionnaires. Your first prompt would occur between 8am-12pm, the second between 12pm-4pm, and the third between 4pm-8pm, during each of the 7 days. You can earn up to $48 for participating in Part One of this study.
    - If you have a phone on which you can receive text messages and can connect to the internet, the prompt will come as a text message with a link to an online questionnaire that you can complete on your phone.
    - If your phone cannot receive texts or you cannot connect to the internet, you will receive a phone call prompt, with one of our study staff asking you the questions over the phone.
    - Study staff will provide you with instructions on how to complete the Part One questionnaires , and will have you practice responding to the prompts and



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answering the questions before you attempt them on your own at home. Study staff will also be available throughout the 7-day Part One period either over the phone should you have any issues with the surveys.

- **Please indicate whether you prefer to be contacted via text message or phone call for the survey by agreeing to one of the options below:**

  **_____PHONE CALL: I prefer to have a study staff member call me to complete the surveys.**

  **_____TEXT MESSAGE: I prefer to have a text message with a survey link sent to me to complete the survey.**

- For Part Two of the study, you would be placed into 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. Neither you nor study staff will be able to pick which group you are assigned to. The two groups are: (1) Cognitive Behavioral Therapy for Chronic Pain (CBT-CP) or (2) Health and Wellness (HW). Participants are twice as likely to be assigned to CBT-CP as they are to HW. You will be told what group you are assigned to at the first treatment session.

- If you are assigned to CBT-CP, you will be asked to come to approximately 10 individual CBT-CP treatment meetings led by a study therapist, each of which will last approximately 1 hour. These sessions will be conducted over the phone or via telehealth (video sessions). During these meetings: (1) your study therapist will ask you questions about how your pain affects your life, (2) you will learn and practice strategies to manage your pain, and (3) you will receive help in setting goals for reducing how much chronic pain interferes with your life. We will help you learn these skills by giving you worksheets and handouts to read. You may also be asked to wear a pedometer (step counter) to monitor how much activity you get during the course of the treatment. You will be able to keep the this pedometer after the study ends for your own personal use. **The CBT-CP treatment 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 participate in this study.

  Up to 15 participants (out of approximately 30) in the CBT-CP treatment group will be invited to complete an additional interview shortly after completing all CBT-CP treatment sessions. If you are asked to participate in this extra interview your participation will be entirely voluntary. This extra interview will also take place over the phone or via telehealth. The post-treatment interview will consist of questions about your experiences while in CBT-CP, as well as your opinion of how this treatment could be improved . We will also ask for

your input to help us think about how to best offer this intervention to other Veterans with serious mental illness. 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 (i.e., put the spoken words on to a written page). Participants who complete this additional interview will be paid $20.

- If you are assigned to the HW treatment group, you will be asked to come to approximately 10 individual HW treatment meetings led by a study therapist, each of which will last approximately 1 hour. These sessions will be conducted over the phone or via telehealth. 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 read and complete. You may also be asked to wear a pedometer to monitor how much activity you get during the course of the treatment. You will be able to keep this pedometer after the study ends for your own personal use. **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 3 separate assessment visits regardless of the group you are assigned to (CBT-CP or HW). These visits are used to determine how the Part Three treatment period affects your pain, thinking, behavior and quality of life. The first assessment will be completed one week after the initial screening meeting, prior to starting either CBT-CP or HW treatment meetings. The second assessment will occur at the end of your treatment meetings. The third assessment will be completed about 3 months after the CBT-CP or HW treatment meetings end. These assessment visits will involve answering questions about 1) your current experience with chronic pain, 2) your feelings, thoughts, and behaviors, and 3) functioning and quality of life. Each assessment visit will take approximately 2 hours to complete. You will also complete a small survey at mid-point treatment, and you would be paid $5 for that. You will be paid $30 for completing each assessment visit, for a total of $95 if all four assessment visits are completed. Your payment may be emailed or mailed to you.

- 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 or telehealth assessments and/or treatment sessions. We will only send these materials at your request and staff will discuss proper procedures for communications 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 visits will be done over the phone or via telehealth. For all sessions, 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.

Occasionally, participants may find it helpful to have a significant person in their lives (e.g., friend, family member) involved in treatment sessions in order to obtain support from this person in practicing CBT-CP strategies and working toward treatment goals. You can let the study therapist know at any point if you are interested in including a significant person in your sessions and the study therapist will discuss options for involving this person(s) in treatment sessions.

**WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?**

- Clinically relevant research results will be disclosed to participants and their providers, as applicable to well-being.
- You may request the overall results of this study when the study is complete.

**FUTURE USE OF DATA AND RE-CONTACT**

- Information collected from you for this research 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, we cannot ask for your additional consent.



- Materials will only be available to project staff as needed. All audio recordings will be kept on the MIRECC Restricted Share Drive behind the VA computer firewall for added security.

**WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?**

- If you take part in this research, you will be responsible to:
  - Show respect for study staff and other study participants in and outside of study appointments.
  - Plan to attend all scheduled study appointments and call research staff if you will be late or need to cancel a scheduled appointment.
  - Contact research staff if you have any difficulty accessing and/or completing phone-based questionnaires.

**POTENTIAL RISKS/DISCOMFORTS**

- The tasks that you will be asked to complete during this study have been used in many other research studies.
- You may feel embarrassed or uncomfortable answering questions that are personal to your health and wellness during assessment sessions. You are free to not answer any questions that make you uncomfortable. Additionally, you may feel bored or tired while completing assessments. You have the option of taking a break during assessment sessions, or completing assessment sessions over the course of two days.
- You may feel some discomfort with discussing your thoughts or with restructuring your routines to better manage chronic pain and improve your overall health and wellness. As you increase physical activity, you may notice some initial muscle soreness; it is important to note that "hurt" does not necessarily mean "harm," but that your body is starting to strengthen muscles. If you have any concerns about potential injury or acute pain, please notify research staff and your primary care physician. The interventions are not generally considered unpleasant and severe reactions are uncommon based on prior studies using our two treatments (CBT-CP 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. You can also ask that recording devices be turned off at any point during the research visit.

- Other unlikely risks include a loss of confidentiality, when research records are accidently disclosed to people who are not authorized to see the information. We have several procedures in place for minimizing these privacy risks. 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.
- Another unlikely risk includes loss of privacy, when you may be identified as a research participant. All study procedures will take place in private rooms that are equipped with sound machines to minimize the likelihood of anything being overheard by other building occupants. Additionally, as study procedures take place private rooms, it would be unlikely others would identify you as someone participating in this particular study.
- There may be other risks associated with 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 better cope with your chronic pain symptoms and improve pain-related functioning.
- Your participation in this study could also lead to knowledge that may benefit other Veterans who experience chronic pain.

**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 chronic pain management resources 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**

- It will not cost you anything to take part in this study.
- You will not be charged for any treatments or procedures that are performed for research purposes in this study. 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 not part of this study.

**PAYMENT/REIMBURSEMENT TO PARTICIPANTS**

- You can earn up $163 for participating in this study, depending upon how many study components are completed, and as detailed below:
    - $10 for attending this consent session
    - $10 for attending the meeting to learn about the phone-based questionnaires
    - Up to $28 for completing the phone-based surveys during the 7-day Part One period; $4 per day ($2 for one completed survey per day, $1 for each additional survey completed)
    - $30 for each of the three study Part Two treatment-related assessments, totaling $90
    - $5 for mid-point treatment satisfaction survey
    - $20 for the one-time interview if you are assigned to CBT-CP and invited to participate
- If you are unable to complete the full assessment at any point, we will prorate your payment based on the amount of assessment you completed.
- You will not be paid for attending CBT-CP or HW treatment sessions.
- You will receive the payments at the end of your schedule study visits. Your payment for participating in the phone-based surveys will be provided during the pre-treatment assessment session. You will be mailed or emailed your payment for assessment sessions.

- There are times, during your participation in this study, when we may run into problems with having payments available at the completion of your scheduled study visits. The end of the fiscal year (September 30) is a time when this problem may arise because the release of VA research funds can be put on hold. We do not anticipate this to happen often. We will notify you before your visit should this problem come up. If at the time of your appointment we do not have access to funds in order to pay you, we will pay you as soon as possible following your appointment, or we may pay you in cash. All payments will be mailed to you.

**MEDICAL TREATMENT AND COMPENSATION FOR INJURY**

- The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). 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 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 Dr. Letitia Travaglini at 410-637-1867.
- The VA does not normally provide any other form of compensation for injury. You have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

**CONFIDENTIALITY AND ACCESS TO RECORDS**

- All information collected during the study will be kept confidential to the fullest extent permitted by law. However, if the research staff hears about or sees that you intend to harm yourself or someone else, s/he will need to tell your treatment provider or some other authority so that you can get help, even if that means telling them without your permission. In this situation, research staff would only disclose information that would prevent harm to you or other people that might 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.

- This study will involve confidential information. We have several procedures in place to help protect your confidentiality. Your name will not be included on the collected data. Instead, a code number will be placed on the data, and through an identification key, the researchers will be able to link your study questionnaire assessments to your identity. Only the researchers will have access to the identification key. Electronic files with your identifying information will only be accessible through computer accounts behind the VA firewall. No electronic study data containing VA sensitive information will ever exist outside the VA firewall, with only de-identified, coded electronic data sent outside the confines of VAMHCS. Similarly, only coded, de-identified paper study records will exist outside of VAMHCS, with the identifying codes retained securely within VAMHCS. The electronic data files with your information will be password protected. Audio recordings will be stored electronically, behind the VA firewall and labeled by code. Coded information will only be accessible to members of the research team and individuals involved in our data management process.
- We will include information about your study participation in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law. The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include an outside approved transcription agency.
- The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medication information, diagnoses relevant to this study (schizophrenia spectrum, bipolar disorder, major depression with psychotic features; chronic pain condition) and pain numeric ratings.
- 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.
- 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 University of Maryland Institutional Review Board (IRB) and the VAMHCS Office of Research Compliance. The study records can also be reviewed by federal agencies, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), VAMHCS Office of Research Compliance (ORC), Office of Human Research Protections (OHRP), the Government Accountability (GAO),Office of Human Research Protections (OHRP). The monitors, auditors, and the IRB, will be granted

direct access to your medical records for verification of the research procedures and date.

- Your research records and/or identifiers will be retained 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 However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information.
- 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.
- 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.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

- Information collected from you for this research 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, we cannot ask for your additional consent.

**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. Letitia Travaglini, at 410-637-1867.

- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's 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, or if you have any questions, concerns, complaints, you may contact:

**University of Maryland Baltimore**
**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)**.**

**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 56582 or 56568

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

Participant Name: _____ Date:_____

Title of Study: Improving the Assessment and Treatment of Chronic Pain in Veterans with Serious Mental Illness

Principal Investigator: Letitia Travaglini, PhD Facility: VA Maryland Health Care System

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Your verbal agreement to participate indicates that the research team member obtaining consent 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.

You are voluntarily agreeing to participate in this study. You are also confirming that you have read this consent, or it has been read to you. You will receive a copy of this consent.