Brief Cognitive Behavioral Therapy for Chronic Pain to Improve Functional Outcomes among Primary Care Veterans

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Study Overview

Title of Research Study: Brief Cognitive Behavioral Therapy for Chronic Pain to Improve Functional Outcomes among Primary Care Veterans

Sponsor: This study is being sponsored by the VA Office of Rehabilitation Research and Development. The investigators have been approved to complete this study by the Facility Conflict of Interest Administrator. There are no conflicts of interest to report.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to volunteer for a research study by the VA Western New York Healthcare System (VAWNYHS) being funded by the VA Rehabilitation Research and Development service. The purpose of this study is to test a brief behavioral intervention that teaches you new ways to cope with chronic pain. You are being asking to take part in this study because you indicated that you have experienced chronic pain and pain-related functional impairment. This summary is intended to give you key information to help you decide whether to participate. We have included detailed information after this section. Please ask the research team questions you might have. Taking part in this study is completely voluntary.

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

To expand treatment options for Veterans in primary care, our research team has developed a brief cognitive behavioral intervention for chronic pain. This study will help us evaluate the intervention's effectiveness for use with Veterans in VA primary care settings. By participating in this study, we hope to learn whether this new brief treatment is helpful for Veterans experiencing chronic pain and pain-related disability. Your participation in this research will last about 24 weeks.

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

You may choose to volunteer for this study if you experience chronic pain and pain-related disability. Your participation in this study will help us understand if a brief, non-medication treatment is helpful to Veterans who experience chronic pain. All study appointments can be completed over the phone or through video telehealth. In-person appointments will be offered when it is safe to do so. For a complete description of benefits, refer to the detailed summary below.

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

This study will require you to attend up to 11 study appointments with staff from the VA Western New York Healthcare System (by phone, video telehealth, or face-to-face). You should not participate if you will not be available to attend these appointments. We also ask that you avoid starting new mental health or pain treatment services during the study. You may continue taking any psychiatric or pain medications you are prescribed but avoid changing the dose during the study. You should not participate if you feel that this treatment would interfere with your mental health or pain care. Responding to questions during study assessments may cause distress. Examples of distress include anxiety symptoms (e.g., shortness of breath, fear) or feeling down. For a complete description of risks, refer to the detailed summary. If you choose not to participate, study staff can refer you to regular VA services for any health concerns you have. For a complete description of alternate treatments, refer to the detailed summary below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

You should only be in this study if you want to volunteer. You do not need to be in the study to please the study doctor or the research staff. If you decide not to take part, you will not lose any services, benefits, or rights you would normally have. It is also important to tell the study team if you are taking part in another research study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The Principal Investigator for this study is at the VA Center for Integrated Healthcare, located at the VA Western New York Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, he can be contacted by phone. Alternatively, you can contact the study coordinator for questions or to withdraw from the study at any time.

DETAILED SUMMARY

WHAT IS THE PURPOSE OF THIS STUDY?

This study will help us evaluate the effectiveness of a brief cognitive behavioral therapy intervention for chronic pain and assess its suitability for VA primary care settings. With this research, we hope to learn if the brief treatment is effective at reducing functional impairment from chronic pain. Treatment involves meeting with a behavioral health provider up to 6 times over a period of approximately 12 weeks.

Using a process like a flip of a coin, you will have a one in two chance of receiving the brief cognitive behavioral therapy intervention. The brief intervention will include 6 individual sessions lasting about 30 minutes which focus on techniques for improving pain and functional impairment. If you are randomized into the treatment as usual condition, you will continue your regular primary care at the VA.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years to complete. Your individual participation in the project will take 24 weeks. In addition to the interview today, you will be asked to complete 3 interviews by telephone or video telehealth. If you are randomly selected to receive the brief cognitive behavioral therapy intervention, you will be asked to complete 6 sessions with a study therapist (either in person or by phone/video telehealth). A subgroup of participants who received the brief intervention will also be asked to complete a fifth interview to ask about their experience with treatment.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 190 people will participate in this research study from the VA Western New York Healthcare System, Rochester VA Community Based Outpatient Clinics, or Syracuse VA Healthcare System.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Here is what you can expect if you decide to participate in this study.

During the rest of today's session, which will take approximately 60 minutes, you will be asked to respond to a few questionnaires regarding your pain, pain-related thoughts and feelings, activity limitations, and other health related behaviors such as:

a) Demographics, medication, and treatment history

b) Depressed mood and well-being

c) Quality of life

d) Engagement in social activities

e) Expectations about the brief cognitive behavioral therapy treatment

A portion of today's session will be audiotaped for supervision and training purposes. A detailed description of the research procedures that follow today's session is outlined below.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

During the initial appointment, which will take about 60 minutes, a study staff member will ask you to complete some questionnaires and surveys regarding:

- Your background, demographics, and health care use
- Chronic pain and how it impacts different areas of your life
- Your overall health and subjective well-being
- Symptoms related to your mood
- Your expectations for treatment

Our team will then review your responses to determine if you are eligible to proceed in the study. We will let you know once we have reviewed your responses.

If you are eligible, you will be assigned to one of two treatment conditions using a process like flipping a coin. You will have a one in two chance of receiving the brief cognitive behavioral therapy intervention. The brief intervention will include 6 individual sessions lasting about 30 minutes which focus on techniques for improving pain and functional impairment. If you are randomized into the treatment as usual condition, you will continue your regular care at the VA.

If you are randomized to the brief cognitive behavioral therapy condition, you will be asked to participate in six individual treatment sessions across a 6 to 12-week time period. You will be scheduled to meet with a study therapist by phone, video telehealth, or in-person (pending pandemic safety requirements). We will work with you to accommodate your schedule if need be. If we are not able to schedule your first treatment appointment today, a member of our team will follow-up with you by phone.

During treatment appointments, you and your study therapist will cover the treatment materials about non-drug approaches to chronic pain management and ways to improve pain and functional impairment. These meetings will last about 30 minutes. A brief checklist will be used to help track how you are doing. Sessions will be audiotaped for supervision and training purposes as well as to ensure delivery of high quality treatment.

If you are randomized to the treatment as usual condition, you will continue your regular treatment at the VA. You will only be asked to complete three additional interviews during the study period.

You will be asked not to start any new mental or behavioral health treatment or other treatment for chronic pain during the study. After the final assessment, you and your healthcare provider may make any changes you deem necessary. If you are already engaged in medical treatment for chronic pain, you will be encouraged to continue that treatment as appropriate.

You will be asked to complete 3 additional assessments in person or via telephone/video conference over the course of the study. These assessments will occur at 6, 12, and 24 weeks and will take up to 60 minutes each. A portion of these assessments will be audiotaped for supervision and training purposes. If you are randomized to the brief cognitive behavioral therapy condition, you may also be asked to complete an additional brief (about 30 minutes) telephone interview about your satisfaction with this treatment. This interview will be audio recorded to help us collect and analyze your feedback accurately. If you are randomized to the treatment as usual condition, you will not be asked to complete the additional telephone/video telehealth interview.

Research staff conducting the assessment sessions will not know whether you are assigned to the brief cognitive behavioral therapy intervention or treatment-as-usual. This helps them treat everyone the same and not give special treatment to one group or another.

Furthermore, we also ask permission to obtain the following information about you from your medical records: information about any treatment that you have received for behavioral and/or medical disorders, including the number of treatment visits, medications prescribed, treatment diagnoses, recommendations, and duration.

Your privacy will be carefully protected (see below). Both your own reports at follow-up and the information we get from your medical records are important ways of evaluating chronic pain outcomes.

Since this study involves asking you for further information about your pain, mood, and issues pertaining to your safety, we want you to know that at any time if we are concerned about your safety, we will discuss it with you, if possible, or seek help from VA providers or emergency services. At the discretion of the study investigators, participants may be taken out of this study due to unanticipated circumstances, such as extreme distress. In other words, we may withdraw you from the study, should we judge your participation not to be in your best interest.

As a research participant, you will not be required to pay for the chronic pain intervention received in this research study.

At any time, you can choose to discontinue the entire study, including all assessment sessions, or you can choose to discontinue the brief cognitive behavioral therapy intervention and continue to participate in the assessment portion of the study.

While participating in this research study, we ask the following:

• Complete surveys and interviews as instructed. Please know that answers to certain questions are required to determine your eligibility to participate. You are however free to skip any questions that you would prefer not to answer.

• Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

• Do not start a new mental health treatment or change your psychiatric medication while you are attending study treatment sessions. If you would rather seek other mental health services instead of completing the study, please let us know. If you would like to initiate other mental health services after completing your final treatment session, please also let us know. We will help make referrals that may be necessary.

• Do not start a new treatment for your pain or change your pain medication while you are attending study treatment sessions. If you would rather seek other pain services instead of completing the study, please let us know. If you would like to initiate other pain services after completing your final treatment session, please also let us know. We will help make referrals that may be necessary.

• Do not take part in any other research project without approval from the investigators. This is to protect you from possible injury and to prevent treatment interactions. 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.

• Ask questions about the study or procedures when you think of them.

The surveys, interviews, and treatment described above will be performed for research purposes only by members of the study team. Dr. Beehler (a licensed psychologist) will oversee the study team.

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

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

Most individuals will experience little, if any, risks from their participation in this study. Responding to questions that are sensitive in nature (i.e., about distress associated with experiencing chronic pain) during interviews may cause some minor discomfort. Examples of distress include anxiety symptoms (e.g., shortness of breath,

fear) or feeling down. If you experience distress during the interview, please discuss this with your interviewer. You may decide to stop the interview or talk to the on-call clinician. The interviewer will discuss with you what to do if you experience distress after the interview, which will include calling the on-call clinician or the Veterans Crisis Line. In addition, there may be unknown or unforeseen risks associated with study participation.

For the behavioral intervention, it is possible that some patients may find the assessments and intervention provided as part of the trial uncomfortable or emotionally sensitive. There is minimal risk that participation in this protocol will produce psychological distress (i.e., embarrassment, discomfort) when asked to share sensitive information about yourself (e.g., distress associated with experiencing chronic pain) with the research staff. Your therapist will discuss with you safety precautions to take if this does occur. Finally, your therapist will discuss with you steps to take to minimize any other distress that may occur. It is possible that you might not feel this treatment is a good fit for you, or that you would prefer to seek other services. If that is the case, please let us know and we will help make other referrals.

You may find it inconvenient to make time for study contact. We will make efforts to arrange treatment appointments and other contact at a time that works for your schedule.

Some people feel uncomfortable knowing that their voices will be recorded. This recording is necessary for the supervision and training of study therapists, and to ensure quality control for study data. Recording also ensures that we have accurately collected your responses for analysis. Your voice recording will not be disclosed outside of the VA.

By providing your consent to participate in this study, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating. You will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used.

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 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?

You may or may not be helped by being in this study. However, by participating in the study, you may help us learn how to benefit patients in the future.

You will be receiving behavioral care for chronic pain. Previous studies using similar types of non-medication treatments for chronic pain in Veterans have demonstrated that the risks associated with this type of study are minimal and that the benefits can be significant. Without conducting research studies such as this one, we cannot identify which non-medication interventions can improve pain, functional impairment, and health of those Veterans who experience chronic pain.

Possible benefits include:

- Learning more about chronic pain and how it impacts your life
- Learning new skills and techniques to minimize pain and improve functional disability
- Learning new symptom management skills

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as continuing with your current treatment or medication regimen or seeking other care. Options for other care may include seeking behavioral health services to help manage life stress or mood symptoms; pain services such as chiropractic, physical therapy, acupuncture, or behavioral pain management to help with your symptoms; or talking with your medical providers about medications to help manage chronic pain or other physical health concerns you may have. You may discuss these options with your primary care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Any information obtained about you in this study will be treated as confidential and will be securely stored as stated in the Privacy Act of 1974. In order to follow federal regulations, records identifying you may be inspected by sponsors of this study and others including, but not limited to:

- **The VAWNYHS Medical Center Research and Development Committee and its Subcommittees**
- **VAWNYHS Research Staff and Research Compliance Officer**
- **The Office for Human Research Protections (OHRP)**
- **VA Office of Research Oversight (ORO)**
- **Office of the Inspector General (OIG)**

All data will be assigned a study-specific identification number and paper data will be stored in locked file cabinets in secure offices of the Center for Integrated Healthcare to which only IRB-approved research staff will have access. All electronic data will be stored on a secure VA network to which only IRB-approved research staff will have access.

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are. Only approved study staff or the inspectors outlined above will have access to your identifiable information.

The study team may include additional information about your study participation in your medical record if it becomes necessary. For instance, if you opt for or require additional mental health treatment during or following the study or experience a personal crisis. It is possible that additional disclosures may be required by law, for instance if evidence of elder abuse or child abuse emerges, or evidence emerges that you pose a danger to yourself or another person.

Identifiers might later be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

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

You will not be charged for any treatments or procedures that are part of 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.

WILL I BE PAID FOR PARTICIPATING?

You will receive $50 for completing today's baseline visit.

You will receive $50 for each of the assessments at 6, 12, and 24 weeks that you complete. If you are randomized to the brief cognitive behavioral therapy treatment and asked to participate in an interview about treatment satisfaction, you will receive an additional $50 for completing this interview.

If you complete all of the scheduled parts of the study, you will have received a total of $200. If assigned to the brief cognitive behavioral therapy treatment and asked to complete an additional interview about treatment satisfaction, you will have received a total of $250 for completing all scheduled parts of the study.

Compensation will be offered by direct deposit. The principal investigator or their designee will review this process with you at the end of today's assessment and assist with processing your payment. To process your payment by direct deposit, your bank account information (bank name, address, and account number) is requested.

Should you choose to withdraw, or be withdrawn from the study, you will be paid for the portion of procedures you complete.

Payments will be scheduled following each completed study visit and will be made by direct deposit. Identifying information, including your Social Security Number, is needed to make these payments. Direct deposit will be processed from a central location. Study staff will review this with you at the end of today's assessment and assist with processing your payment.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

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

The VA Western New York Healthcare System will provide necessary medical treatment at no cost to you if you are injured as a result of taking part in this study. This does not apply to treatment for injuries that occur because you did not follow study procedures. If you usually pay co-payments for VA care and medications, these co-payment requirements will apply to medical care and services provided by the VA that are not part of this study. Except in limited circumstances, the necessary care will be provided in VA medical facilities. Any expenses not covered by your insurance may be covered by the VA, consistent with applicable law, regulation, and policy. If you should have a medical concern or get hurt or sick as a result of taking part in this study, call the principal investigator during normal business hours. Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is completely voluntary. Refusing to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you are also a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may withdraw from the study at any time without any penalty or loss of benefits.

If you withdraw, you will still receive the same standard of care that you otherwise would have received. Our team may continue to review and use data that were collected prior to your withdrawal but will not collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

• We find out it is not safe for you to stay in the study. For example, your health may worsen.
• You are not coming for your study visits when scheduled or completing study tasks as needed.
• The funding for the study is stopped.
• At the discretion of the primary investigators, participants may be taken out of this study due to unanticipated circumstances, such as extreme distress. In other words, we may withdraw you from the study should we judge your participation not to be in your best interest.

If we feel that it is necessary for you to withdraw from the study, we will let you know. We are not aware of any adverse effects of discontinuing this treatment early. We will instruct you how to stop the treatment and help make referrals for any necessary follow-up mental health care.

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

If you would like more information about this study, please call the study coordinator.

If you have any questions, complaints, or concerns about the research or related matters, please contact one of the following individuals:

- Principal Investigator

- The Patient Advocate

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 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 Human Research Protections Program Coordinator if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

Data collected as part of this study may be retained for future research in accordance with the Veterans Health Administration (VHA) Records Control Schedule. Any relevant hard copies of study data will be stored in a locked file cabinet in the office of the VA Center for Integrated Healthcare, located at the VA Western New York Healthcare System. Relevant electronic data will be stored on a secure VA network. Only authorized personnel will have access to the data.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Principal Investigator, or his designee, 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 providing your verbal consent, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that

you have read this consent, or it has been read to you. A copy of this summary has been provided to you.