Optimizing Psychotherapy for Older Veterans With Chronic Pain

NCT03918642

05/21/2020

CONSENT TO BE PART OF A RESEARCH STUDY

Participant Name: _____ **Date:** _____

Study Title: Optimizing Psychotherapy for Older Veterans with Chronic Pain

Principal Investigator: Brandon C. Yarns, MD, MS **Phone:** (424) 279-8439

INVITATION and KEY INFORMATION

We invite you to take part in a research study about psychotherapy for older Veterans with chronic pain. We are inviting you because you are an older Veteran (age 60-95 years) who has had at least three months of musculoskeletal pain.

The following information is provided to help you decide whether to participate in this study:

This study is being done to compare the effects of Emotional Awareness and Expression Therapy (EAET)—which focuses on how stress and emotions relate to pain—with standard VA psychotherapy, Cognitive Behavior Therapy (CBT)—which focuses on learning pain coping skills—for older Veterans with chronic musculoskeletal pain.

If you agree, you will be in this study for about 39 weeks and will need to visit the research site about 11 times. You do not have to take part in this research. If you decide not to take part in this study, there is no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

There are risks to taking part in this research. Here are some of the main risks: inconvenience, frustration with questions, discomfort disclosing personal information, worsening of symptoms, nonresponse, or limited response to treatment. There may be additional risks, and these risks are listed later in this document.

We cannot promise any benefits to you or others if you decide to join this research, but we hope that this research will benefit your pain and other symptoms, such as mood, anxiety, PTSD symptoms, fatigue, and sleep.

Here are some reasons you **may or may not** want to participate in this research:

- Psychotherapy is an evidence-based treatment (a treatment that has been demonstrated to be successful through extensive scientific research) for chronic pain, but only one of the study treatments, CBT, is currently available to Veterans outside this study.
- All participants in this study will receive one 90-minute individual psychotherapy session and eight 90-minute group psychotherapy sessions, which aim to help with pain and associated symptoms. Homework assignments will take approximately 30 minutes per week during the eight weeks of the group sessions.
- You will be eligible to receive up to $150 for participating in this study and will not be billed for any study visits.
- You will be randomized into one of the two treatments, so you do not get to choose which treatment you receive.
- To participate, you will need to fill out three (3) rounds of questionnaires: at enrollment, immediately following the last psychotherapy session, and at 6-month follow-up.
- While participating in this study, you may continue all your other treatments for pain, including medications, physical therapy, or other treatments, and may continue psychotherapy if you are receiving it for a condition other than chronic pain.
- While participating in this study and through the final 6-month follow up, you must refrain from participating in any psychotherapies for pain as part of clinical care. You may not participate in this study if you have received CBT for pain within the past 3 months.
- There are no medications provided as part of this study, nor any other FDA-regulated products.

We expect about 160 people at VA Greater Los Angeles will participate in this research.

BACKGROUND AND PURPOSE

This study is being performed to compare the effects of two alternate types of psychotherapy for chronic musculoskeletal pain in older adults, to evaluate which patients respond better to each treatment, and to investigate how each treatment works. The first treatment approach we are studying is cognitive behavior therapy (CBT), which focuses on improving coping skills for pain. This treatment is the standard psychotherapy treatment offered at VA. The second psychotherapy is called emotional awareness and expression therapy (EAET). This is a newer treatment, which focuses on understanding how life stress, relationships, and emotions may

cause and perpetuate pain. Each treatment uses a standardized treatment manual and consists of one 90-minute individual psychotherapy session and eight 90-minute group psychotherapy sessions for small groups of eight Veterans. Both treatments involve comparable amounts of discussion, handouts, and between-session homework assignments. Homework assignments will take approximately 30 minutes of your time per week during the eight weeks of the group treatment.

You will be randomized to one of these two treatment approaches, and every participant will receive one of the two forms of psychotherapy.

We are performing the study because pain is a large problem among Veterans. Studies show that chronic pain affects as many as 50% of male Veterans and 75% of female Veterans. We are focusing on older adult Veterans because they have the highest rates of chronic pain at VA, perhaps as high as 80%. We are looking at psychotherapy in this study because VA, the Department of Defense, and the CDC recently recommended psychosocial treatments, such as psychotherapy, as first treatments for chronic pain, along with medications other than opioids (e.g., oxycodone). However, only one form of psychotherapy (CBT) is currently available in clinical practice at VA, and this study may provide evidence for introducing an alternative (EAET) for Veterans who do not benefit from CBT.

To be eligible for this study, you must be age 60-95 years, and you must have had musculoskeletal pain for at least 3 months (i.e., chronic pain). Musculoskeletal pain that would make you eligible for this study includes regional pain syndromes (e.g., low back, neck, leg, or pelvic pain, or temporomandibular joint disorders), widespread pain syndromes (e.g., fibromyalgia), whiplash, tension headaches, or any combination of these disorders.

In addition, patients with uncontrolled severe psychiatric disorders, active suicide or violence risk in the past 6 months, substantial cognitive impairment or dementia, active alcohol or substance use disorder that will inhibit the ability to participate in psychotherapy, those with pain-related legal proceedings or applying for service-connection, service-connection increase, service-connection re-evaluation or other compensation related to pain, those unable to fluently read or converse in English, those who have received CBT for pain within the past 3 months, and those planning to move from the area in the next 6 months (before the completion of the study) will not be eligible. As long as you are in the study, you may not be enrolled in any psychotherapy for pain by your clinical provider.

We will enroll up to 160 participants for this study. All participants will be from the West Los Angeles VA Medical Center.

INVESTIGATOR DISCLOSURE

Sponsor
VA Clinical Science Research and Development (CSR&D) is providing financial support and/or material for this study.

No investigator is receiving any payment that could be construed as a potential conflict of interest.

If any of the doctors listed on this consent form is your treating physician, he (or she) is also an investigator for this study. As an investigator, he (or she) is interested not only in your clinical welfare, but also in the results of this study. It is possible that occasionally these two goals may be in conflict. At any time during this study, you may ask for a second opinion from another doctor who is in no way associated with this study.

DURATION OF THE RESEARCH

Your participation in this study will take approximately 39 weeks. This study is expected to take up to 5 years for the researchers to complete.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

We will first complete a questionnaire called the Mini-Mental State Examination (MMSE) with you, which has questions about your memory and thinking. This questionnaire is for screening purposes, lasts about 5 minutes, and is the final step to make sure you continue to be eligible for the study. If you continue to be eligible, the following will occur as part of the study:

You will first be asked to complete some paper-and-pencil and computerized questionnaires on pain and other related symptoms and psychological processes that may account for the improvement in pain. This will take place today if you decide to take part in the study and will last about 45 minutes.

Next, you will be randomized to one of the two psychotherapy treatments described above, either Emotional Awareness and Expression Therapy (EAET) or Cognitive Behavior Therapy (CBT) for chronic pain. This is like flipping a coin, and you have an equal 50/50 chance of entering either treatment.

Once you have been randomized, you will receive a phone call from a member of the research team indicating which treatment group you have been assigned to, and you will also be scheduled for a one-on-one (individual) psychotherapy session with one of the study therapists. This individual psychotherapy session will last approximately 90 minutes and take place in Building 401 in one of the following rooms: A123, A203, A238, or B129.

The following week, you will receive the first of 8 once-weekly group psychotherapy sessions. There will be 8 participants in each group. Each group is led by an experienced psychologist or psychiatrist; you should have the same therapist for all 8 group sessions. Each group session will last 90 minutes and take place in Building 401 in either room B123 or B125. With either treatment, during the sessions you will be asked to speak up and participate. As a key part of the treatment, you will also be asked to complete written assignments both during the sessions and at home between the sessions for homework. Please complete all written assignments as instructed.

Some individual and group therapy sessions will be video and audio recorded to ensure the treatments are being performed correctly. Please see more details on session recordings in a section below.

Immediately after the final group therapy session, you will be asked to complete more paper-and-pencil and computerized questionnaires that are like the ones you completed at the beginning of the study. This should take 45 minutes. This is primarily to see how the treatments affect the measures that are represented by the questionnaires.

Finally, you will be scheduled to come in and complete one more round of paper-and-pencil and computerized questionnaires 6 months after the completion of the psychotherapy sessions

for us to determine the effects of the treatment after this time. This visit should take about 45 minutes.

Also, please remember the following:

- If you decide to participate, you will be expected to attend the individual psychotherapy session and all 8 group psychotherapy sessions, as well as the 6-month follow-up appointment to complete questionnaires. If you need to miss any of these appointments, please call Dr. Yarns directly at 424-279-8439 or your therapist as soon as you know you will miss.
- Please complete all questionnaires as instructed. However, you are free to skip any questions that you would prefer not to answer.
- Please ask questions as you think of them.
- There will be verbal check-ins at the beginning of each session to monitor for safety and your symptoms. However, if your symptoms get worse between sessions or you have other urgent concerns, please contact Dr. Yarns at any time directly at 424-279-8439. If you become suicidal or believe you will act on violent impulses, call 911 or report to the nearest emergency room at once.
- Please remember that whatever is said during therapy sessions is confidential, except that information will be shared with your primary care provider in the event you express suicidal ideation or aggressive behavior. Although we have no way to enforce confidentiality, we request that you do not share any information expressed by group members during group therapy sessions outside the group.
- You may also call Dr. Yarns if you change your mind about staying in the study.
- If you would like to see your results from questionnaires or the overall results of the study, please contact Dr. Yarns after the completion of the study.

There is no single standard treatment for chronic pain. As part of their regular health care, people with chronic pain might get medications, injections, surgery, physical therapy, psychotherapy, or no treatment at all. People who take part in this study will all get psychotherapy. This study is not part of your health care. All procedures in this study are being done for research purposes.

Use of Photography, Video and/or Audio Recording (Include if Applicable)

Some individual and group psychotherapy session will be video and audio recorded using an encrypted laptop that has been approved for use in research by the VA. All recordings will be

stored on the encrypted VA research service. Video and audio recording are solely for the purpose of quality assurance of the treatments. No recordings will be shared with anyone outside of our research team at the West Los Angeles VA Medical Center.

POSSIBLE RISKS OR DISCOMFORTS

This study involves the following risks, discomforts, and possible inconveniences:

- Sadness, distress, or discomfort discussing emotional experiences and disclosing personal information to the therapist and other group members;
- Worsening of symptoms, nonresponse, or limited response to treatment;
- Frustration or boredom with study questionnaires;
- Inconvenience in scheduling psychotherapy sessions; and
- Breach in confidentiality.

If you have worsening of symptoms, which is infrequent but not rare, you may call the study's Principal Investigator, Dr. Yarns, at any time at 424-279-8439, or tell your therapist at the next session during the check-in period. Remember you are always free to end participation in the study and pursue alternate treatment if you choose.

We do not expect these treatments to result in anyone becoming suicidal or violent, but in the rare event that this does occur, call 911 or report to the nearest emergency room at once.

POTENTIAL BENEFITS

You might benefit from being in this study because psychotherapy is an evidence-based treatment for chronic pain. Thus, the psychotherapy you receive may result in improvements in in your pain and related symptoms, including mood, anxiety, sleep, fatigue. However, we cannot promise that you will get any benefits from taking part in this research study.

This study may also have benefits in that it will inform future research on psychotherapy interventions for chronic pain and contribute to understanding the psychological change processes involved in improvements in chronic pain. We hope that ultimately this research leads to future benefits for Veterans with chronic pain.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

There may be other ways of treating your condition if you do not wish to be in this research. These include medications, injections, physical therapy, mindfulness classes, acupuncture, and other complementary or alternative medicine approaches. Some types of chronic pain may also be eligible for surgery.

Cognitive Behavior Therapy (CBT), one of the study treatments, is also available at VA Greater Los Angeles in an individual format and as part of the VA comprehensive pain rehabilitation program, which also includes physical and occupational therapy. Emotional Awareness and Expression Therapy (EAET) is not available at VA Greater Los Angeles outside this study.

You may discuss these options with your doctor.

CONFIDENTIALITY – DATA PROTECTION DURING RESEARCH STUDY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- When you begin the study, all your private information will be labeled with a code.
- Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project.
- Records will be locked in filing cabinets in Bldg. 401, Rm. A236, or Bldg. 158, Rm. 154-169.
- Video/audio recordings will be stored on a password-protected research server.

We are collecting the last 4 digits of your Social Security number, but this will be stored in a locked filing cabinet. For payment, we will need your Social Security number. You may elect to withhold your Social Security number, but we will not be able to provide you with payment.

We will keep your name and all the information about you used in this study as confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, telephone number,

or any other direct personal identifier. Also, other federal agencies as required, such as the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Greater Los Angeles Institutional Review Board (IRB), our local Research and Development Committee, the study sponsor (VA Clinical Science Research & Development – CSR&D), and the VA CSR&D Data Monitoring Committee may have access to your information, may have access to your information.

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.

SHARING OF INDIVIDUAL AND OVERALL RESEARCH RESULTS

There is a possibility that during the research we could learn things about you that could affect your health. If this occurs, the finding will be reviewed by the study team to determine if it is in your best interest to contact you. Sometimes during a research study, an incidental finding is made. This is a situation where we are studying one thing and we learn something else about you. If an incidental finding is made, it will be reviewed by the study team to determine if it is in your best interest to contact you. Additionally, information will be shared with your primary care provider in the event you express suicidal ideation or aggressive behavior.

Aggregate data will be available to you from this research project. Aggregate data combine all data from the participants into a report, which describes the findings of the study. This report will be published in research journals when the study is completed. It is anticipated that results from this study should be publicly available in 5 years. If you would like to be contacted about when results are posted, you may contact the research team at 424-279-8439.

DATA USE/SHARING WITH RESEARCHERS

After this study is complete, we would like to keep your study information in a locked cabinet in the geriatric psychiatry research center for future research questions in this area. This includes questions on psychotherapy, aging, psychological processes, and chronic pain. If you allow us to keep information from your interviews, questionnaires, and video recordings of your psychotherapy sessions, please check below. Your information will be labeled with a code that

does not contain your name or other ways that identify who you are. The research we conduct with your information is being done for research purposes only and we will not tell you or your doctor about the results of the research.

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you.

_____ Yes, I give permission for my interview, questionnaires, and video recordings of my psychotherapy sessions to be saved for future research, as set-forth above.

_____ No, I do not give permission for my interview, questionnaires, and video recordings to be saved for future research.

WITHDRAWAL FROM PARTICIPATION

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled, and your decision will not affect your ability to receive medical care for your condition.

If you want to stop being in the study you should tell the principal investigator. You can do this by phone by calling Dr. Brandon C. Yarns at 424-279-8439. You should ask for a HIPAA revocation form, which you can sign in order to revoke any data collection, which does not require your participation. Dr. Yarns can provide this to you, upon request.

If you withdraw from the study:

- There are no anticipated adverse effects; however, you would likely not have the benefits of full participation described above.
- You will be asked to come in to complete a final round of questionnaires upon your exit from the study; however, it is not a requirement that you do so.
- Any data already collected prior to your withdrawal from the study may be used by the investigators, but no further information will be collected after your withdrawal from the study.

The investigators may also withdraw you from the study for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff,
- Excessive absences (>4) from psychotherapy sessions,
- Extreme disruptiveness during psychotherapy sessions,
- The investigators decide that continuing your participation could be harmful to you,
- You need treatment not allowed in the study,
- The study is cancelled.

PARTICIPANTS RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this research 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. You will not have to pay anything to be in this study.

PAYMENT OFFERED FOR PARTICIPATION

You will be paid in return for your time, transportation to complete questionnaires, and inconvenience for your participation in this study. Upon completion of baseline questionnaires, you will receive $50. If you complete post-treatment questionnaires, you will receive $50. If you

return at 6 months to complete the follow-up questionnaires, you will receive $50. You will be mailed a check approximately three (3) weeks after the study has ended but it could take up to 2 months. Note that we will require your social security number to process the check.

With few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A Form 1099 will be sent to you if your total payments for research participation are $600.00 or more in a calendar year.

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 will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. No other form of compensation for injuries is available. However, by signing this form you have not released the VA from liability for negligence.

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. Brandon C. Yarns at 424-279-8439 and

AFTER HOURS:

Dr. Brandon C. Yarns at 424-279-8439.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints, or concerns about the research or related matters, please feel free to call the principal investigator, Dr. Brandon Yarns at any time at 424-279-8439.

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 Greater Los Angeles 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 Greater Los Angeles IRB at 1-310-268-4437 if you have questions, complaints or concerns about the study, or if you would like to obtain information or offer input.

RE-CONTACT for FUTURE STUDIES

The research staff would like to contact you in the future about participation in other studies. The reason you would be contacted are that you meet basic inclusion/exclusion criteria for another study we are conducting. If you are agreeable to this, we need your permission.

Please let us know if you are willing to be contacted about any future research by the research team:

_____ Yes, I give permission to be re-contacted about future research.

_____ No, I do not give permission to be re-contacted about future research.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____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.

The California Bill of Rights of Human Subjects in Medical Experiments is provided.

California Bill of Rights
RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

CONSENT TO BE PART OF A RESEARCH STUDY

Study Title: Optimizing Psychotherapy for Older Veterans with Chronic Pain

Principal Investigator: Brandon C. Yarns, MD, MS Phone: (424) 279-8439

SIGNATURES

By signing, you are agreeing to volunteer for 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. Your signature also confirms that The California Bill of Rights of Human Subjects in Medical Experiments has also been given to you. A copy of this signed consent will be retained in the investigator's research records.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date