

wHOPE ICF Cover Page

Official Title: Implementation of a Pragmatic Trial of Whole Health Team vs. Primary Care Group Education to Promote Non-Pharmacological Strategies to Improve Pain, Functioning, and Quality of Life in Veterans

Acronym: wHOPE

Study Type: Interventional

Brief Title: Pragmatic Trial of WHT vs. PC-GE to Promote Non-Pharmacological Strategies to Treat Chronic Pain in Veterans

NCT Number: NCT04330365

Unique Protocol ID: UH3AT009765

Combined Informed Consent and HIPAA Authorization Template



KEY SUMMARY INFORMATION ABOUT THIS STUDY

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

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST? By doing this study, we are testing different approaches to pain management aimed at reducing pain and improving overall functioning and quality of life in Veterans. Your participation in this research will last about 1 year, but the majority of research visits will be completed within the first 3 months after you join the study.

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

Possible benefits may include improvement of your pain and reduction in your pain medications. You do not need to come to the VA for study visits and can participate in wHOPE entirely from home through video telehealth or even telephone, which is especially important during the coronavirus pandemic. For a complete description of benefits, refer to the Detailed Information section of this consent.

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

This study will involve a time commitment on your part. In addition, some of the questions asked concern sensitive issues and may make you feel uncomfortable; however, these questions are similar to those asked in regular clinical treatment. For a complete description of risks, refer to the Detailed Consent section of this document.

DO YOU HAVE TO TAKE PART IN THE STUDY?

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

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is _____ *[Principal Investigator, Local Site Investigator as applicable]* at the *[insert name of VA facility.]* If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: *[PI or LSI contact information as applicable].*



Participant Name: _____ Date: _____

Title of Study: Implementation of a Pragmatic Trial of Whole Health Team vs. Primary Care Group Education to Promote Non-Pharmacological Strategies to Improve Pain, Functioning, and Quality of Life in Veterans

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Karen Seal MD, MPH; William Becker, MD

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This research study aims to help improve pain management in veterans. The institution and investigators are receiving a grant from the National Institutes of Health (NIH) to support this research. There are no conflicts of interest to report between the investigators and NIH.

The Principal Investigators for this study are Karen Seal, MD, MPH, from the San Francisco VA Health Care system (SFVAHCS) and William Becker, MD, from the VA Connecticut Healthcare System (VACHS). They have prepared this consent form so that you can learn what our study is about and, if you are eligible, so you can decide if you want to participate. Participation in research is completely voluntary, and only those who really want to should participate. You don't have to participate, and you may end your participation in this study at any time.

Why is this study being done? The overall purpose of this study is to test pain management approaches aimed at reducing pain symptoms and improving overall functioning and quality of life in veterans.

How many people will take part in this study? We expect that about 155 veterans will be enrolled at this VA facility and we expect that approximately 765 veterans will take part in this study across 5 different VA sites in the United States.

You are being asked to take part in this study because you:

- Are a patient of a VA Primary Care Provider at an enrolling VA facility.
- Report that you experience pain every day or nearly every day for 6 months or more and have pain that is moderate to severe.
- Are available to participate for 12 months.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the study will occur over the course of 1 year, but the majority of research visits will be completed within the first 3 months after you join the study.

This research study overall is expected to take approximately 4 years.

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WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

1. You will participate in 5 phone study assessments where you will answer a series of questions at baseline (today), 3, 6, 9, and 12 months. All outcome assessments will be conducted as telephone interviews by the research staff. Interviewers are “blinded” meaning the research staff member who conducts the assessment does not know which treatment group you are assigned to. *Full-length* outcome assessments will be conducted at baseline, 6 months, and 12 months. An abbreviated version of these assessments will be conducted at 3 and 9 months. The duration of outcome assessment interviews will be approximately 60-75 minutes at baseline, 6, and 12 months, and 30-45 minutes at 3 and 9 months.
2. If you are determined to be eligible after you complete the baseline assessment, the study coordinator will randomly assign you to one of three groups, the Whole Health Team (WHT), Primary Care Group Education (PC-GE), or Usual Primary Care (UPC).
 - You will be placed into a group based on a computer randomization program (like a flip of a coin, but computerized). Neither you nor the study coordinator can choose a specific group.
 - You, your primary care team and the study team at [local VA facility] will know which group you are assigned to.
 - Participation time will vary depending on which intervention you receive.
- a. If you are randomly selected to be in the Whole Health Team intervention arm, you will have one initial telephone or video telehealth Whole Health coaching session. Following this, you will have one initial visit with your Whole Health Team, followed by at least 3 follow-up visits, and one final visit (either in-person, through video telehealth, or by telephone). In addition, you will be asked to participate in at least 8 telephone coaching sessions (~30 minutes each) with your assigned Whole Health Coach. Please note that you can choose to complete all study visits from your own home via telehealth (telephone or video conferencing).

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- b. If you are randomly selected to be in the Primary Care Group Education (PC-GE) intervention arm, you will be asked to participate in a series of weekly group treatment sessions (either in-person, through video telehealth, or by telephone) based in Cognitive Behavioral Therapy for Chronic Pain (CBT-CP). First, you will join the next available orientation session, which is about 90 minutes. There will then be 5 weekly group sessions that will last approximately 90 minutes each. Once the 5 weekly group sessions are completed, you will be asked to participate in a 90-minute discharge session. Thereafter, you are free to attend Booster sessions, but these are optional. Please note that you can choose to complete all study sessions from your own home via telehealth (telephone or video conferencing)
 - c. If you are randomly selected to be in the Usual Primary Care group, you will continue seeing your primary care team with no additional study visits required.
3. All study participants, regardless of which intervention you are assigned to, will be oriented and have access to the web/mobile Whole Health Resource Directory. This directory identifies Complementary and Integrative Health pain-related resources both at your VA and in your community.
4. Regardless of the group you are assigned to, you may also be invited to participate in a telephone interview asking your opinions and experiences about participating in this research study. If you are selected for the telephone interview asking your feedback, you will be contacted by one of our researchers and will verbally consent to those study procedures separately.

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

1. Keep all scheduled study appointments: This includes:

- a. Attending all scheduled telephone or video research appointments.
- b. Attending all scheduled clinical appointments with your study providers (the number of appointments varies depending on your assigned group) and may be in-person, by telephone or by video telehealth, based on preference and availability of these alternative services.
- c. Having a working telephone.

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2. Letting the research staff know if you need to miss an appointment and rescheduling as close to the original study appointment as possible.
3. Asking questions of the study team as you think of them.
4. While participating in this research study, you will be asked to not take part in other research studies without checking in with the study staff first. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

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

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. For Veterans, some of the questions asked concern sensitive issues (such as questions about mental health symptoms, including drug use) and possibly illegal activities involved. Being asked some of these questions may make participants feel uncomfortable, however the questions asked do not fall outside what would normally be asked during a health care appointment.

There is always a chance that any procedure can harm you. The procedures in this study are not different from those you might experience in usual VA health care. 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?

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may result in improvement of your chronic pain, functioning and quality of life and improved safety of your medication regimen, if you are taking pain medications when you enter the study. In addition, by participating in this study you will be helping VA clinicians learn new approaches to managing pain that may help other Veterans who deal with moderate to severe chronic pain. Depending on the treatment group that you are randomized to, you may

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also receive chronic pain care from providers at your local VA without having to leave your home.

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

You are free to choose to not to participate in this study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits and you can still get your care from the VA and other healthcare facilities the way you usually do. Whether you decide to participate in this research or not you can receive standard care outside of this research study. You may discuss these options with your health care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The information collected for this study will be kept confidential. We will include information about your study participation in your medical record. All electronic files containing any information about you (such as your phone number and address) will be kept on a password protected VA server behind a secure firewall. A research record will be created because of your participation in this study, but your personal information, such as your name and any other identifying information, will be separated from the information you provide as part of the study assessments. No individual identities will be used in any reports or publications resulting from this study.

There are times when we might have to show your records to other people, therefore complete confidentiality cannot be guaranteed. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Additionally, identifiers might be removed from your identifiable private information or identifiable biospecimens and the information or biospecimens 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.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The

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Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

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.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as medication history, HIV status, COVID-19 status, drug, alcohol or STD treatment, genetic test results or mental health treatment.

The research team may also need to disclose the information to others as part of study oversight. Others may include the following: our affiliated non-profit corporation Northern California Institute for Research and Education (NCIRE), the Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office, the VA Institutional Review Board, the National Institutes of Health and the local VA medical facility Human Research Protections Program.

Greenphire is the company we will be working with to support this debit card reimbursement process. In order for Greenphire to support this reimbursement process, Greenphire will need to process certain personal information about you. This information will be collected from you by the project coordinator and entered into the Greenphire ClinCard registration system. In order to assign a physical ClinCard to you and load funds onto the ClinCard, Greenphire will need your Subject ID, Name, Address, and Date of Birth. Greenphire has administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of your personal information. Your personal information will be used and disclosed only to support the described activities, including to service providers who assist us in managing, administering, or delivering the Services. Your personal information will not be shared by Greenphire or sold, used or distributed for any other purpose. Your information will be

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retained for as long as necessary to provide the described activities and for compliance with applicable laws.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research-related health records.

Your participation will not affect your VA healthcare, including your health care provider's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization in writing at any time. To revoke your authorization, you must write to the Release of Information Office at your facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VA patient to treatment or benefits outside of the study.

If you revoke this authorization, **(insert name of Site Investigator)** and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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

Costs to Participants:

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 while in the study. If you chose to take time off work to attend treatment visits you will be responsible for the time you incur. You will also be responsible for your own transportation costs to the VA (not travel pay eligible). You may also

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ask the study team about telephone and telehealth options to reduce travel to the VA. If you choose to seek services outside the VA you may incur those additional costs.

Payment Offered for Participation:

For your participation in this research you will be compensated \$50 for completion of each full-length masked assessment (baseline, 6, and 12 months) and \$25 for each brief masked assessment (3 and 9 months). Total compensation for completing all the assessments is \$200 over the course of the one-year study period. We will mail the payment to you in the form of a physical debit card (ClinCard).

The registered ready-to-use ClinCard will be sent to the address you provide after each completed assessment, and it may take 4-5 weeks for you to receive it in the mail. You may also receive an additional payment of \$50 if you are contacted for and complete a telephone interview about your opinions and experiences during this research study.

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

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to your not following the study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

Should you have a medical concern or get hurt or sick as a result of taking part in this study, you may call the following numbers:

NON-URGENT

[INSERT LOCAL SITE INVESTIGATORS]

**Karen Hope Seal, MD, MPH, San Francisco VA Health Care System
(415) 221-4810 extension 24852**

**William Becker, MD, VA Connecticut Healthcare System,
203-932-5711 ext. 2427**

URGENT

National Veterans Crisis Line Number: 1-800-273-8255

Emergency and ongoing medical treatment will be provided as needed.

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DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether to take part in this study. If you decide to participate, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part in this study, you can still receive all usual care that is available to you. Your decision to not to take part will not affect the relationship you have with your health care provider or other staff at the VA or in the community and it will not affect the usual care that you receive as a VA patient.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

You may be withdrawn from this study if it is determined that you are actively suicidal or otherwise experiencing very serious medical or psychological problems (requiring hospitalization). In this case, we will work with your treating provider and referrals will be made. If you are withdrawn you can continue to receive all VA health care benefits and services.

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

If you have any further questions, you may call

[INSERT Local Site PI and local site coordinator name and contact information]

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

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

AUDIO RECORDING

If you are assigned to the Whole Health Team you may be audio-recorded as a part of this study (audio recording only, no photographs or video recordings will occur). You can still participate in this study if you do not wish to be audio recorded.

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Monthly Whole Health coaching telephone sessions will be recorded for the Whole Health Team participants. As part of the study, the research team wants to ensure that the coaches are following a similar protocol for these sessions. Researchers who are experts in counseling techniques will listen to the recording of the sessions. If needed, the researchers may give feedback to the Whole Health coaches to improve their techniques. We will record only coaching sessions and not Whole Health Team appointments. Your coaches will notify you at the beginning of the sessions if it will be audio-recorded.

Prior to recording any study sessions, you will be reminded to avoid using your name or any other information that would personally identify you.

Do you consent to be audio recorded?

- ☐ Yes
☐ No

FUTURE USE OF DATA

If you agree to take part in this study, the data that we gather will be analyzed and published. Identifiers, such as name, dates, and addresses will be removed and the de-identified information will be used for future research without additional informed consent. In addition, these de-identified datasets may in the future contribute to a central database accessible to other researchers. Your data will be combined with data from other people taking part in this study and other studies. Your identity cannot be determined from these shared datasets. Any papers, presentations or reports of the results of this study will not identify you in any way.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study staff 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 signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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RESEARCH CONSENT FORM

Version Date: 04/25/2022

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I agree to participate in this research study as has been explained in this document.

Participant's Name

Participant's Signature

Date

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