Self-Administered Acupressure for Veterans with Chronic Back Pain: A Multisite Evaluation of Effectiveness and Implementation

NCT05423145

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Principal Investigator:	[redacted]	VAMC: VA Ann Arbor Healthcare System
Participant Name:		Date:

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This study's goal is to help the VA is move from using medications to treat chronic lower-back pain (CLBP) to using non-pharmacological options, such as acupressure. Acupressure is a Traditional Chinese Medicine technique derived from acupuncture and has been shown to be a potentially effective approach for treating several chronic pain conditions and could prove beneficial in helping Veterans manage their chronic lower-back pain (CLBP).

By conducting this research project, we hope to learn how effective self-administered acupressure is in treating CLBP and determine whether it would be feasible to offer the treatment at VA healthcare facilities.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 4 years. Your individual participation in the project will last approximately 10 weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Here is a description of what will occur if you decide to participate in this study.

We will ask you to complete a web-based survey that will take 30-40 minutes. The survey questions are mostly about your back pain, although there are also some questions about your general physical and mental health. If you don't have any access to the internet, a study staff member will contact you so you can complete this survey by phone.

Then, we will use a computer to assign you to one of two groups. It is like flipping a coin. You will have an equal chance of being in either group. No matter which group you are placed in, you will continue to receive the same care from the VA that you receive now. Taking part in the study will not change that in any way.

No matter which group you are assigned to, we will collect some information about your use of pain-related medications or other healthcare services you may have received from your electronic medical record. You will also be asked to complete surveys, similar to the first survey, at approximately 6-weeks and 10-weeks. After completing the 10-week survey your participation in the study will be complete. The differences between the groups are explained below.

Group A

If you are placed in Group A:

- After you complete the 10-week survey your active participation in the study will be complete. We will mail you a Kindle tablet that you may keep. It will have an app that shows you how to self-administer acupressure for low back pain. The app will show you Acupoints, the places on your body to apply pressure, using a diagram of the human body. Each acupoint will have a

more detailed picture of where the acupoint is located and contain written directions. Another feature of the app is the ability to watch videos that demonstrate how to locate the acupoints and describe the amount of pressure used. This is the same program that the participants in Group B will be using during their participation in the study.

Group B

If you are placed in Group B:

- After completing the first survey you will be mailed a Kindle tablet with an app that shows you how to self-administer acupressure for low back pain and a plastic Acuwand to apply the acupressure if you wish. The app will show you Acupoints, the places on your body to apply pressure, using a diagram of the human body. Each acupoint will have a more detailed picture of where the acupoint is located and contain written directions. Another feature of the app is the ability to watch videos that demonstrate how to locate the acupoints and describe the amount of pressure used.
- You will be asked to do the acupressure session daily for the next 6 weeks and note how long it takes you to perform each session using a paper log that you will receive in the same package as the Kindle and Acuwand. Each session will take approximately 30 minutes.
- Within two weeks after you receive the Kindle and begin your acupressure sessions, you will be contacted by a member of the study team and asked to demonstrate how you have been performing your acupressure sessions. This check will be done via video call or by phone if you aren't able to do a video call.
- After you have performed the acupressure sessions daily for 6 weeks, we will ask you to stop doing the acupressure for the next 4 weeks, and return the Acuwand, so we can learn if any benefits you experience might continue.
- After completing a final survey at approximately 10 weeks your active participation in the study will be complete and you may resume the acupressure sessions if you choose.

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

- Group A:
  - Complete 3 surveys over the course of the approximately 10-week study period.
- Group B:
  - Complete 3 surveys over the course of the approximately 10-week study period.
  - Perform self-administered acupressure daily for 6 weeks.
  - Keep a log of all acupressure sessions.

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- Demonstrate how you perform your acupressure sessions during a check-in video or phone call with study staff.

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

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

- Psychological discomfort:
  - While the surveys do not ask about especially sensitive topics, you might become uncomfortable at being asked questions about their health. You may choose to skip any questions you don't wish to answer. You may also decide not to complete the survey.
  - We may be asking you to show how to locate the places on their body to apply pressure. This could cause mild anxiety and feel like you are being "tested". The study staff will be sensitive to your concerns and, if you are too uncomfortable, you will be offered the option of completing the procedure verbally over the phone.
- Health concerns:
  - There is small risk of bruising if too much pressure is applied at any one acupressure site. This occurs in less than 1% of all applications. The study staff will make sure that all participants are taught the correct amount of pressure to use.
- Inconvenience:
  - You may find it time-consuming and inconvenient to practice daily self-administered acupressure and then note it in your log.
  - You may also find it inconvenient to complete the 3 surveys.
  - Participants are free to withdraw at any time without penalty or prejudice.
- Loss of confidentiality:
  - Information will be collected about you for this study. There is a small possibility that someone outside the study team could obtain access to your study data, although we will work hard to prevent this from happening. Steps will be taken to protect your identity. All electronic files will be stored in secure study folders on VA computer servers. Printed copies of all study information, including this document, will be kept in a locked file cabinet in a locked office at the Ann Arbor VA Health Services Research and Development Center (HSR&D). Only approved research staff will have access to the information. All research data collected as part of this study will be stored according to the privacy and security guidelines set by the Veterans Health Administration (VHA). We will never use your name in reports about this study. Despite these safeguards, the information collected about you can never be 100% secure.

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In addition to the risks described above, you may experience a previously unknown risk or side effect.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may or may not experience direct benefit as a result of being in this study. Some participants asked to perform acupressure on a daily basis may derive benefit from having access to a treatment that is not generally available to most Veterans with CLBP. In addition, you will be contributing to medical knowledge about how to manage CLBP in Veterans. It has the potential to add to the treatment options offered in the VA system, and might benefit those Veterans who have long gaps between medical visits.

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

If you decide not to participate in this study, you can speak with your primary care physician about other possible alternatives as part of your usual healthcare. The options might include things like physical therapy, manual or manipulative therapy, injections or medications.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

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

- Paper study records will be kept in a locked filing cabinet in a locked VA office.
- Electronic study records will be stored in secure study folders on VA computer servers.
- Only approved research staff will have access to the information.
- If the results of this study are reported in medical journals or at meetings, you will not be identified by name or by any other means.

Your information collected as part of the research will not be used or distributed for future research studies, even if information that identifies you is removed. By law, study records must be kept in a secure location for about six years after the study has ended, at which time they will be destroyed.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor'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.

There are times when we might have to show your records to other people. 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 Institutional Review Board (IRB), our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you

A description of this study 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.

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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 medications you use and diagnoses you have received.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Data Safety Monitoring Board, Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program. 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. This will not affect your VA healthcare, including your doctor'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 Principal Investigator at this 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 Study Team 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 VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and 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 do not depend 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?

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.

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WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

In addition to the Kindle, which is valued at approximately $90, you will receive $10 gift cards from retail stores for each survey assessment completed online, by phone or on paper (baseline, 6-wks and 10-wks). We will mail the card to your home within 5 days of assessment completion.

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 non-compliance by a study participant with study procedures. Emergency and ongoing medical treatment will be provided as needed.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call [redacted] at [redacted].

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you whether to take part in this study. You may decide not to be in the study at any time. If you choose not to take part or choose to stop taking part at any time, you will still receive the same health care and benefits from the VA you currently receive. Your decision will not change that in any way.

If you choose to take part in the study but then change your mind, [redacted] and her research team can continue to use the information collected from you up to that point. The research team will not collect information about you after you let them know you no longer wish to take part in the study, though they may still collect information about you that is available from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Principal Investigator may end your participation in the study without your consent for one or more of the following reasons:

- If you are verbally abusive or inappropriate with study staff during study follow-up assessments.
- She believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- The study is suspended or canceled.

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

If you have any questions, complaints, or concerns about this study, please contact [redacted] at [redacted]. 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 IRB Coordinators at [redacted] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

The researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible you may be asked to sign a new consent form that includes the new information.

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.

By signing this document below, you voluntarily consent to participate 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.

I agree to participate in this research study as has been explained in this form.		
_____	_____	_____
Participant's Name (Printed)	Participant's Signature	Today's Date

Person Obtaining Informed Consent:		
_____	_____	_____
Study Team Member Name (Printed)	Study Team Member's Signature	Today's Date