Participant Name: _____ Date:_____

Title of Study: Feasibility of Remote-Delivery Interventions: Tai Chi and Wellness for PTSD and Pain in Veterans

Principal Investigator: Barbara L. Niles, Ph.D._____ VA Facility: VA Boston Healthcare System

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NCT05693805

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the National Center for Complementary and Integrative Health (NCCIH). 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 hope to develop integrative treatments for posttraumatic stress disorder (PTSD) and pain. Specifically, we are developing both a Wellness group and a Tai Chi group that will be delivered over videoconference for Veterans with PTSD and pain. We hope to learn about what Veterans think about these programs and use that feedback and other information to help develop treatments that could have an impact on quality of life for Veterans with PTSD and chronic pain. Participation in this program will last between 6 and 7 months.

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

You might choose to volunteer in the study because you are interested in treatments that may help symptoms of PTSD and chronic pain. For more information of benefits, refer to the Detailed Information section of this form.

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

You may choose not to volunteer to be in the study because you may find the assessments or treatments to be uncomfortable or difficult. For a complete description of risks, refer to the Detailed Consent section, below.

Healthcare providers in your clinic might also be investigators in this research study. Being an investigator means your clinician is interested in both you and the study. Your clinician may tell you about the study and answer questions you may have. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another clinician who is not an investigator can give you a second opinion about being in the study. Further, another research staff member who is not your clinician will go through the informed consent process with you. Your clinician will not be the research staff member to consent you.

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You do not have to agree to be in this study even though it is offered by your doctor or another clinician.

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 volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Barbara Niles, Ph.D., Principal Investigator, at the VA Boston Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 857-364-4128.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn about the how Veterans respond to two remotely delivered treatments for PTSD and pain: Tai Chi and Wellness Program. Tai Chi is an ancient Chinese exercise that combines deep breathing and relaxation with slow and gentle movements to improve health of the body and mind. Tai Chi has been found to improve health in disorders that last a long time. The Wellness condition uses the VA Whole Health Program to improve wellness in various health domains (e.g., physical, emotional, and spiritual lives.) Each group session will focus on a different domain. Veterans will discuss the information, watch videos, and set goals about things that are important to them.

HOW LONG WILL I BE IN THE STUDY?

Approximately 36 veterans are expected to participate in this phase of the study. The entire study is expected to take approximately 3 years to complete. Your individual participation in the project will take approximately 6 to 7 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

In this study you will be randomly placed into one of two groups, either Tai Chi or Wellness Education. You have a 50% chance of being offered Wellness Education, and a 50% chance of being offered Tai Chi. It's like a flip of a coin which treatment you would be offered. Both study

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treatments consist of 24 group sessions that meet online for about an hour two times every week. For both groups, the study will last for approximately 6-7 months (27 to 30 remote sessions) and will be divided into four parts:

- baseline assessment (2 remote sessions and questionnaires filled out online)
- group Tai Chi or Wellness sessions (24 remote sessions twice weekly for 12 weeks)
- post-treatment assessment (1 or 2 remote session(s) and questionnaires filled out online)
- 3-month follow-up assessment (1 or 2 remote session(s) and questionnaires filled out online)

You will complete the first session of the baseline assessment today. After the second baseline assessment, if you are eligible, you will be enrolled into the study.

Baseline Assessment

First, you will complete the baseline assessment. This session will last approximately two and a half hours and will be administered in two remote sessions. The baseline assessment will help us find out whether you are eligible to be in this study. During the first baseline session, you will be asked to do a sit to stand task that measures strength and endurance. In between the two baseline sessions, you will fill out some questionnaires on your computer or tablet using a program called Qualtrics. It will ask questions on different topics such as psychological issues, physical symptoms, and your health habits. During your second baseline session, you will complete an interview about psychological symptoms related to trauma. You do not have to answer any questions that you do not feel comfortable answering. If there is a delay before the second baseline session, you may be asked to complete the sit to stand task another time. We will also review your VA Medical Record to document the medications that have been prescribed for you and treatments you are getting.

Tai Chi and Wellness Groups

If you are eligible to participate in the remainder of the study, you will be randomly assigned to attend one of two online group programs: Tai Chi or Wellness. Each group program will run for 12 weeks, twice weekly for a total of 24 60-minute sessions. The study interventions will take place via telehealth on a secure VA-approved platform (e.g., WebEx). In both groups, the study staff and other Veterans in the group will be able to see you and you will be able to see them on your video screen. Therefore, we will ask you to join the group from a private place to protect confidentiality. We will also ask you to provide an emergency contact in case there is an emergency during the group. Between groups, we will ask you to practice some of the skills you are learning in the group and keep weekly logs of your practice. The Tai Chi group will be led by a qualified Tai Chi instructor. The Wellness group will be run by study staff and supervised by a credentialed VA psychologist.

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During the 12-weeks of the intervention you will be asked to complete short questionnaires about your symptoms and experiences with the group and practice assignments. These questionnaires and practice logs will be filled out on your computer or tablet using Qualtrics. In addition, you will receive phone calls each week where you will report on your home practice in the Tai Chi Group, or report on the goals you have set for yourself in the Wellness group. During these calls, you will have the opportunity to provide feedback that may be used to improve the group experience.

Post-treatment and Three-month Follow-up Assessments

You will be asked to complete a post-treatment assessment and a three-month follow-up assessment. Each assessment will be completed in one or two sessions. These assessments will be very similar to the baseline assessment with interviews and many of the same questionnaires. You will fill out some questionnaires on your computer or tablet using Qualtrics, complete interviews with a study staff member about psychological symptoms related to trauma, and do a sit to stand task. In addition, you will be asked to complete a brief interview with a study staff member that asks how you felt about various aspects of the Tai Chi program or the Wellness group.

If you agree, the interview parts of the baseline, post-treatment and follow-up assessments may be video-recorded. You may still participate in the study if you choose not to be video-recorded for this interview. The post-treatment and follow-ups assessment should take approximately two and a half hours each.

(Optional) I agree for the interviews to be video-recorded:

Yes (initials) _____

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

If you enroll in this study, we will ask that you agree to:

- Attend 24 sessions in either the Wellness or Tai Chi group and keep your study appointments. If you are unable to attend an appointment, please contact the research staff to let them know.
- Complete your assessments, questionnaires, and home practice logs as instructed.

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- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators. 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.
- While participating in this research study, we also ask that you do not start psychotherapy or mindfulness-based treatments for PTSD, pain or other related problems. Exceptions will be made if another provider prescribes treatment, or treatment is necessary for other reasons.

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

Any treatment 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.

This research involves answering questions about both mental and physical health which some people feel uncomfortable discussing. In addition, this study asks questions about traumatic experiences you may have had, as well as reactions to traumatic events, which may be upsetting. You may also experience some disruption of daily routines due to the scheduling of study intervention sessions and assessments.

Some participants may feel uncomfortable about having a video-recording of interviews at their assessments. The video recordings will help researchers analyze the information collected from veterans, including how veterans may respond to the Tai Chi or Wellness programs. You may still participate in the study if you choose not to be video-recorded for this interview.

Some people may experience distress or become uncomfortable being asked questions about personal experiences. You do not have to answer any questions that you do not wish to answer, and you are free to stop the session at any time. If you feel it would be helpful to talk with a mental health clinician after participating in this study, we can arrange a referral.

There is some potential for pain or discomfort following the exercise and stretching, including muscle pain, strain, sprains, and joint pain. In order to minimize these risks, the group instructors will advise you to stop or modify the activity if something causes pain. The study intervention may involve risks that are currently unforeseeable.

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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?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your condition(s).

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

Your alternative is to not participate in this study. If you do not meet the eligibility criteria for the study, if you decide to withdraw from the study, or if you would like to pursue additional treatment after completion of the study, then we can provide you with a list of treatment providers or make referrals as indicated.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following ways:

We will store your information in ways we think are secure. All data collected for this study on paper forms will be stored in secure, locked file cabinets in locked study offices. Paper and electronic data will be identified only by the study participant number that has been assigned to you. Electronic data will be kept in a shared drive on a secure server. Only study staff will have access to this drive. Additional password protection will be used for any electronic files that include identifying information (e.g., your name, address, telephone number, etc.).

If you consent to be video recorded, the digital video recordings also will be coded with an identification number and will be kept separately from your name. However, your image and voice may be identifiable.

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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.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule. Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved
- Digital images and recordings will be destroyed in a manner such that they cannot be retrieved.

Your research records and the information within them will not be used for any purpose other than that described in this study as approved by the IRB.

However, identifiers might be removed from the identifiable private information that are collected. After that removal, data may be shared outside of VABHS for data analysis purposes. Such information could also 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.

To comply with laws and regulations, we may need to share safety-related information such as that relating to child abuse or neglect; elder or disabled person abuse; specific reportable diseases; harm to yourself or others.

This research is covered by 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 or elder abuse or neglect as defined by regional authorities; or if you are deemed at immediate risk of suicide; or if you are deemed to be at risk of doing bodily harm to a specifically identifiable individual. The 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 Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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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.

You will be compensated for your time and inconvenience at a rate of $25 for each of the two sessions of the baseline assessment, $65 for the post-treatment assessment, and $80 for the three-month follow-up assessment. You will also receive $5 for completing the weekly measures, $5 for the weekly phone calls with study staff who track home practice/goals, and $5 for each intervention group session you attend for a total of up to $435.

Payment will be provided in one of three ways:

1) Gift cards to a national chain store (e.g., Target or Walmart) which would be mailed to you.

2) Electronic funds transfer to your bank accounts. In this case, you consent to the release of personally identifying information about you including your name, address, social security number and bank information (bank name, routing number, and account number) to the VA so that we may provide compensation to you. You will receive payment within 7 to 10 days.

3) Debit card payments using Direct Express. In this case, you consent to the release of personally identifying information about you including your name, address, and social security number to the VA so that we may provide compensation to you. You can expect to receive a debit card within 2-6 weeks. The government may garnish the compensation against outstanding debts a veteran has to the federal government.

If payment is made to you by the VA (whether by direct deposit, or a VA issued debit card), an IRS Form 1099 may be generated regardless of the amount you are paid.

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 or if the research is conducted for VA under contract with an individual or non-VA institution.

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Principal Investigator: Barbara L. Niles, Ph.D._____ VA Facility: VA Boston Healthcare System

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DO I HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

If you are 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 as applicable. You may discontinue taking part at any time without any penalty or loss of benefits.

You may also withdraw and still receive the same standard of clinical care at VA that you would otherwise have received. If you withdraw from the study, the study team will use the data collected from your participation in the study but will not collect additional information from you.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The study investigators may terminate your participation in this research if you are not able to participate in the group treatments or assessments due to disruptive behavior.

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

The study person named below has explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that if I have any medical questions about this research study, I can call **Dr. Barbara Niles at (857) 364-4128** during normal working hours.

I understand that if I have any general questions about this research study, I can call **Dr. Barbara Niles at (857) 364-4128** during normal working hours.

I understand that if I have any medical problems that might be related to this study that during the day, I can call **Dr. Barbara Niles at (857) 364-4128 after hours** I can call the **Medical Center operator at (617) 323-7700** and ask for **the fellow on call for psychiatry.**

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

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If you have questions about your rights as a study participant or any other questions, complaints, concerns or suggestions about this study, you may contact the Institutional Review Board at (617) 637-3794. This is the Board that oversees all human research at VA Boston Healthcare Systems and has the responsibility to ensure the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

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	_____ Participant's Signature	_____ Date

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