Project Title:	**Novel Interventions for Gulf War Veterans' Illnesses**	
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1. OVERVIEW OF THE RESEARCH STUDY:

We are asking you to be in a research study that is being supported by Veteran Affairs' Clinical Science Research and Development (VA CSR & D). Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to evaluate two telehealth treatments for Gulf War Veterans' Illness: Tai Chi and Wellness Education. If you agree, you will be invited to complete 24 sessions of either Wellness Education or Tai Chi classes and complete four different assessments. You will be in the study for approximately 12 months (one year) if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because you are interested in treatments that may help symptoms of Gulf War Veteran's Illnesses. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because you may find the assessments or treatments to be uncomfortable or difficult. You will find more information about these risks later in this form.

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

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

2. WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study to find out more about treatments that can help Veterans with Gulf War Illness. You are being asked to participate in this study because you are: (1) a Veteran of the 1990-91 Persian Gulf War, and (2) have symptoms of Gulf War Veterans' Illness. We plan to enroll up to 120 participants for this study (60 in each of the two treatment groups). The two treatments we are studying are Wellness Education and Tai Chi.

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 and have symptoms similar to Gulf War Veterans' Illness.
Wellness Education provides information about topics, such as pain, fatigue and mood, which are related to Gulf War Illnesses. The Wellness Education corresponds to the VA Whole Health Program to educate Veterans about different types of wellness (such as physical, emotional, and spiritual lives.) Each session will include a video clip and a brief mindfulness meditation.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS 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 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 a total of 12 months (28 remote sessions) and will be divided into five parts:

- baseline assessment (1 remote session)
- group Tai Chi or Wellness sessions (24 remote sessions)
- post-treatment assessment (1 remote session)
- 3-month assessment (1 remote session)
- 9-month assessment (1 remote session)

You will complete the baseline assessment today, and then, 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 hours and will help us find out whether you are eligible to be in this study. You will fill out some paper and pencil questionnaires that will ask questions on different topics such as psychological issues, physical symptoms, and your health habits. You do not have to answer any questions that you do not feel comfortable answering. We will also review your VA Medical Record to document the medications that have been prescribed for you. At the end of the session, whether or not you are eligible to participate further, you will be compensated $50 for your time.

Tai Chi and Wellness Education Groups
If you are eligible to participate in the remainder of the study, you will be invited to attend the 24 online group sessions (Tai Chi or Wellness Education). The study interventions will take place via telehealth on a secure VA-approved platform (e.g. VVC, WebEx). All 24 sessions of both the Wellness Education and the Tai Chi group will be approximately 60 minutes long. For each of the 24 groups you attend, we will compensate you $10 for use of video devices and inconvenience.

During the 12-weeks of the intervention you may asked to complete short questionnaires about your symptoms and experiences with the group and practice assignments. During the days between each group session, you will be asked to fill out a practice log that tracks how often you practiced exercises. These questionnaires and practice logs will be collected either by mailing, via telephone or telehealth, or in person by study staff.

Post-treatment Assessment

You will be asked to complete a post-treatment assessment. This assessment will be very similar to the baseline assessment with many of the same questionnaires. In addition, you will be asked to complete a questionnaire and a brief interview with a study staff member that asks how you felt about various aspects of the Tai Chi program or the Wellness Education course. If you agree, this interview may be audio-recorded. You may still participate in the study if you choose not to be audio-recorded for this interview. The post-treatment assessment should take approximately two hours.

3-month Follow-up Assessment

3 months (approximately 12 weeks) following the post-treatment assessment, you will be asked to complete another assessment. This follow-up assessment will be very similar to the post-treatment assessment with many of the same questionnaires and should take approximately two hours. If you agree, the interview may be audio-recorded.

9-month Follow-up Assessment (Final)

6 months (approximately 24 weeks) following the 3-month follow-up assessment, you will be asked to complete the final assessment. This final assessment will be very similar to the 3-month follow-up assessment with many of the same questionnaires and should take approximately two hours. If you agree, this interview may be audio-recorded.

We will mail paper and pencil questionnaires to you and provide a self-addressed stamped with instructions for mailing back the forms.

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

Yes (initials) _____

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

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 an audio-recording of interviews at their post-treatment assessments. The audio recordings will help researchers analyze the information collected about how veterans may respond to the Tai Chi or Wellness Education programs. Your name and identifying information will not be on the digital recordings, only your participant number. You may still participate in the study if you choose not to be audio-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.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study. However, you may experience less pain, fatigue, or a reduction in other symptoms of Gulf War Illness.

6. 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.

7. 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.

8. 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.

9. 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 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 audio recorded, audio recordings will be transferred from the recorders to the password protected research drive and then deleted from the audio recorder. All digital audio recordings also will be coded with an identification number and will be kept separately from your name. However, your voice may be identifiable.

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.

We will record information from this study in your medical record, such as information related to your medical care. Please ask us if you have any questions about what information will be included in your medical records.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). 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 (audio 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, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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.

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the 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.

10. WHO ELSE MIGHT SEE MY DATA?

You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Institutional Review Board and Research & Development Committees of VABHS, the VA, Federal agencies, or national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

11. 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.

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

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated be compensated $50 for the baseline and immediate post-treatment assessments, $75 for the 3-month follow-up assessment, and $100 for the 9-month follow-up (final) assessment. You will also be compensated $10 for use of video devices and inconvenience for each group session you attend, for a total of up to $240. Your total compensation will be $515 if you fully complete every part of the study, for your time and effort taking part in this study.

We will mail paper and pencil questionnaires to you and provide a self-addressed stamped with instructions for mailing back the forms. We will conduct the interviews over the telephone.

To process the payments, you consent to the release of personally identifying information about you including your name, address, and the last 4 digits of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you. Since payment will be made to you by the VA by check, an IRS Form 1099 will be generated regardless of the amount you are paid.

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

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

14. 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, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research; obtain information; or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

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.

I understand that, if at any point during this study I have any questions about my rights as a research participant, I may contact the Employee Relations Specialist at (857) 364-5564.

16. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have 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 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.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

_____

Participant's Signature **Month Day Year** **Name (print)**