

Kaiser Permanente Washington Members
Cohort 1

TAI CHI STUDY Consent Form

R34AT009052

**Tai Chi for Chronic Low Back Pain in Older Adults: A Feasibility Randomized
Clinical Trial (Back Tai Chi)**

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Sponsored by:

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Kaiser Permanente Washington Health Research Institute
University of Washington
Elder Tai Chi Study
Consent Form

| Researchers | | Project Manager | |
|------------------------|----------------|-----------------|----------------|
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**University of Washington

We are asking you to take part in a research study. This form explains what the study is about and what we'll ask you to do. We will go over this information with you in person to find out if you're interested in the study. Please ask our staff to explain anything in this form that you don't understand.

What is the study about?

Not much is known about which treatments are safest for people 65 and older who have chronic low back pain. Tai Chi is a gentle form of movement that has been proven safe for people 65 and older in previous studies. Tai Chi has never been tested to see if it can help with chronic low back pain in older adults. This current study is designed to gather information needed to see if a large clinical trial testing the value of Tai Chi in older adults would be feasible. This study is funded by the National Institutes of Health. We plan to enroll 64 people in this research 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.

What will happen if I decide to be in this study?

This study will last about 12 months. During that time, we will ask you to take part in the study activities described below.

Activities for Everybody:

If you decide to be in this study, we will review this consent form. You will be asked to take part in a brief physical assessment to measure your gait and balance and to complete the first of 4 surveys. The survey will be completed on paper. The physical assessment and survey will take about 20-35 minutes. The first survey includes questions about you, your back problem, your physical and mental health, education, marital status, race, and work status. You may skip any questions you don't want to answer.

Once you have completed the first survey and physical assessment today, if you are still willing to participate, you will be randomly assigned by the computer into one of two groups: Tai Chi

classes or continued Usual Medical Care. You will have an equal chance of being assigned to each group.

Surveys and in-person visits

We will ask you to come to 4 in-person visits to complete 4 surveys during this study—the first one will take place today after we review the consent form. The second one is in about 12 weeks, the third happens about 6 months from now, and the last one is in about 1 year. The physical assessment and surveys will last about 20-35 minutes each and will ask about you, your back problem, your physical and emotional health, care you may have received for your back pain and information about changes in your health. We will send you a reminder letter about a week before each survey. We will pay you \$25 in cash for each survey that you complete except the first one after you enroll in the study.

Focus groups

Soon after the completion of your 1-year in-person visit, you may be invited to take place in a group discussion so that we can learn about your thoughts, experiences, and feelings about participating in this study. The information you provide will help us to develop the next phase of this research, which is a much larger clinical trial. A court reporter will attend the discussion groups so that an accurate transcript of the discussion group will be available for analysis. No names will be included in the transcripts.

Study Groups:

Tai Chi:

If you are assigned to the Tai Chi group, you will attend a series of 36 classes over a 36-week time period. You will attend classes twice a week for the first 12 weeks, once a week for the next 6 weeks, 1 every-other week for the next 6 weeks, and then attend classes once a month for the final 3 months of classes. Each class will last about 60 minutes. In addition, you will be expected to practice regularly Tai Chi outside of class. You will be asked to keep a daily log of practice done outside of class. All Tai Chi sessions will be paid for by the study. The groups will be held at a Kaiser Permanente Clinic. We ask that you agree to attend each class. We will record all group sessions on a digital audio recorder for quality purposes. We won't collect any information about the people in the group from these audio recordings. You can ask that the recorder be turned off at any time during the session. We will destroy all audio files 3 years after the end of the study (4/30/2023).

Home practice

If you are assigned to the Tai Chi Classes, we will ask you to practice the techniques you learn in class for up to 15 minutes per day on your non-class days. At each class, you will be given suggested home practice exercises and it will be up to you to decide how much time and effort you spend on home practice each day. You will be provided with study-created videos of each home practice technique sequence accessible on YouTube or on a DVD, whichever is most convenient to you.

Home practice logs

If you are assigned to the Tai Chi group, we will ask you to keep track of your daily home practice and turn these logs into the study Research Specialist at the start of each class. The information on your home practice log will not be shared with your instructor.

Attendance information

If you are assigned to the Tai Chi Classes, we will collect attendance information so that we know how many classes you attended.

Usual Medical Care:

If you are assigned to the Usual Medical Care group, you will continue to take care of your lower back pain as you usually do. In addition, we will provide you with a stainless steel Kaiser Permanente-branded water bottle to thank you for your participation in the study. You will not receive any additional treatments as a part of this study.

Will you look at my medical record?

We will check your Kaiser Permanente medical record for information about care you get for your back. This would include visits you make to the doctor and medicines you are prescribed. We will look at your medical record from 5/1/2016 through 5/1/2020. This will let us know if there any changes in the type of care you receive for you back during and after you participate in the study. We may also look at your medical record if you have a health problem during the study that could be related to study procedures. We will not put any information into your medical record and your doctor will not be told that you participated in this study.

Can anything bad happen to me from being in this study?

Some people may be uncomfortable answering personal questions about their physical and mental health. You may skip any question you do not want to answer. There have been no serious adverse effects attributed to Tai Chi reported in the literature. As with any type of stretching or movement exercise, there is a small risk for falls (comparable to walking) and a possibility of minor strains and sprains that may result in increased pain, although this risk is low.

A risk of participation in this study is a breach of confidentiality. We have strong safeguards in place to minimize this risk. Some participants prefer to get study appointment reminders sent to them using email. If you want to be contacted by our study staff via email, the study team will use their Kaiser Permanente Outlook email address to contact you. Please note that Kaiser Permanente cannot guarantee the confidentiality of email communication. Study staff will use the minimum amount of identifying information in email communications, usually just your first name.

If you feel like you have been harmed as a result of participating in this study, please contact Project Manager, Rene Hawkes. Kaiser Permanente will provide treatment to the extent of your coverage as long as you remain an enrollee, but will not be provided if you are no longer enrolled at KP. You will be responsible for paying any co-pays, co-insurance, and deductions related to your care.

Will being in this study help me?

For people assigned to Tai Chi, there is the possibility of improvement in physical or mental health. For people assigned to Usual Medical Care, there are no direct benefits to participating in this study. However, information from this study may help improve care for back pain.

Will you keep my information confidential?

We will keep all information we collect confidential, as provided by law. In this study, we will collect information about you during the in-person appointments and from the interviews and surveys. We will collect information from you when you submit your home practice logs to the study research specialist at the start of each class. We will not share this information with your doctor or put it in your medical record.

Are there rules you follow to protect my privacy?

Your health information is protected by a federal privacy law called HIPAA. Kaiser Permanente must follow this privacy law. According to HIPAA, the information collected by the researchers for this study is part of that protected health information. HIPAA requires that the researchers tell you the following:

By agreeing to be in this study, you are giving Kaiser Permanente permission to allow the researchers to collect, use, and share the following information about you for this study:

1. Your survey answers.
2. Information collected from study logs as described above.
3. Your medical record information as described above.
4. Class Attendance information

It is possible that staff from Kaiser Permanente and the National Institutes of Health, who is funding this study, may need to look at study records to make sure the study is following the correct procedures. We will not share the information we collect for this study with anyone else except as allowed by law.

The HIPAA privacy law does not always apply to those who are given protected health information. Once Kaiser Permanente has given out health information, the person who receives it may re-disclose it. Privacy laws may no longer protect the information.

In order to be in the study, you must agree to this use of your health information. This permission for the researchers to obtain your health information for this study ends when the study ends, which is 5/1/2020.

Permission to use your health information:

We will use your health information from this study indefinitely. But, 3 years after the study ends, 4/30/2023, we will destroy all study records that include your name or information that could identify you. After that time, we will no longer be able to link your health information to your identity. This means that no one will be able to tell that you took part in this study.

You may take back your permission for us to use your health information at any time. If you do this, you may no longer be allowed to be in the study. The researchers may keep and use the health information they have already collected.

To take back your permission, write to:

 Karen Sherman, PhD
Kaiser Permanente Washington Health Research Institute
1730 Minor Avenue, Suite 1600
Seattle, WA 98101

Do I have to be in this study?

No, being in this study is up to you.. You may stop being in this study at any time without penalty or loss of benefits to which you are entitled.

Other Information:

If you are injured as a result of this study, please contact Rene Hawkes at 206-287-2073. Treatment for any injury will be paid by Kaiser Permanente to the extent of your Kaiser

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Permanente insurance, as long as you are still a Kaiser Permanente member. You may remain in the study if you are no longer a Kaiser Permanente member. You will be responsible for paying any co-pays, co-insurance, and deductions related to your care.

As always, if your back symptoms become severe, call your Kaiser Permanente physician or consulting nurse.

For general information about the study, you may call Project Manager **Rene Hawkes at (206) 287-2073.**

If you have any bad effects from this study, call your doctor and let the study staff know.

What if I have questions or concerns?

 If you have questions or concerns about the study, please call the project manager, Rene Hawkes, at 206-287-2073. If you have questions about your rights as a research participant, please call the Kaiser Permanente Human Subjects Review Office at 206-287-2919.

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I understand that I may stop participating at any time without affecting my Kaiser Permanente care or benefits. I have had a chance to ask questions. If I have questions later about the research, I can call the Principal Investigator Sherman at (206) 287-2426 or Co-Investigator Thakral at (206) 287-2108. The Human Subjects representative at (206) 287-2919 will answer any questions I have about subjects' rights. I will receive a copy of this consent form for my records.

Please **PRINT** your name

Signature

Date