CONSENT TO TAKE PART IN A RESEARCH STUDY

This is a research study for people who voluntarily choose to take part. Please take your time to make a decision, and discuss the study with your personal doctor, family and friends if you wish.

STUDY TITLE: Tai Chi for pain management of knee osteoarthritis

INVESTIGATOR(S): Chawn-Li (Leslie) Shen, PhD, CCRP; Volker Neugebauer, PhD; Jean-Michel Brismée ScD, PT; Mimi Zumwalt, MD; Jaehoon Lee, PhD; Ming-Chien Chyu, PhD; Hui-Ying Luk, PhD; Michael O'Boyle, PhD; Rui Wang, PhD; Jeff Roark

CONTACT TELEPHONE NUMBERS: Dr. Shen: 806-743-2815; Clinical Research Institute: 806-743-4222 (office) or 806-543-8994 (cell)

You may contact the investigators at the numbers listed above during normal business hours if you develop any of the conditions listed in Question #7 of this form or if you have any unexpected complications.

INSTITUTION(S): Texas Tech University Health Sciences Center, Lubbock, TX; Texas Tech University, Lubbock, TX; University of California at Davis, Davis, CA

1. **Taking part in this study is your choice.**
   You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make; you will not lose access to your medical care or give up any legal rights or benefits.

   This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered. See the “What if I have questions?” section for other places you can get answers if necessary.

2. **What is the purpose of this study?**
   This study is being done to see if Tai Chi can help control joint pain and swelling. Tai Chi is a mind-body moderate-intensity work out that uses gentle synchronized and flowing movements.

3. **What is the usual approach to my knee osteoarthritis?**
   Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil) or naproxen sodium (Aleve) are commonly used to control joint pain and swelling.

4. **How many people will take part in this study?**
   Up to 36 people will take part in this study.
5. **Why am I being asked to take part in this research study?**
   You are being asked to take part in this study because you are postmenopausal women with knee osteoarthritis.

6. **What are the study groups?**
   There will be two groups: those who agree to have 2 MRIs, and those who choose not to have 2 MRIs.

   If you agree to have 2 MRIs, the MRIs will be to measure the connectivity of white matter in your brain. All other procedures are the same for both groups.

   We will study this because prior studies have shown that chronic pain can lead to changes in the brain. We want to see if Tai Chi affects the brain in relation to managing knee osteoarthritis pain.

7. **What will happen if I decide to take part in this study?**
   You will have 7 study visits that will include 8 surveys, MRI safety screenings (if you agree to have MRIs), 2 MRIs of your brain (optional, but if you agree to have MRIs, both must be done), and 3 blood draws, plus 3 Tai Chi classes per week for 8 weeks. You will be on the study for at least 8 weeks, and up to 8 months depending upon MRI appointment availability. This will end your study involvement.

   **Study Visit 1 (Information Visit):**
   This visit will take place at the Clinical Research Institute at TTUHSC.
   This visit will take about 30-45 minutes of your time.
   - After you have signed this consent form, if you agree to have 2 MRIs (Optional), you will be asked to complete an MRI Safety Screening Sheet.
   - You will then be asked to complete surveys to tell us about yourself, including: your age, health, medical history, medications, menstrual history, and physical activity level, etc.
   - You will also be asked to complete a survey about your osteoarthritis, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).
   - You will be notified whether or not you qualify, and if you do qualify, your second study visit will be scheduled.

   **Study Visit 2 (Baseline Functional/Clinical Outcome Measures):**
   This visit will take place at the Center for Rehabilitation Research at TTHUSC.
   This visit will take about 45 minutes of your time.
   - You will be asked to complete the WOMAC.
   - You will also be asked to complete a questionnaire about your pain level, Brief Pain Inventory (BPI).
   - You will complete the Quantitative Sensory Test including windup (QST).
Study Visit 3 (Baseline MRI, optional):
This visit will take place at the Texas Tech Neurological Institute (TTNI) at TTU. This visit will take about 1 hour of your time.
- You will sign a TTNI MRI consent form.
- You will complete a TTNI Safety Screening sheet.
- You will have an MRI of your brain done.

Study Visit 4 (Baseline Blood Draw):
This visit will take place at the Clinical Research Institute at TTUHSC. This visit will take about 45 minutes of your time.
- We will take about 2 tbsp. of your blood via needle stick.
- You will be asked to complete a questionnaire about your physical activity, quality of life, and food intake.

Tai Chi Intervention Visits:
The Tai Chi classes will take place at the Department of Kinesiology and Sport Management at TTU. Each of these 24 visits will take about one hour of your time.
- After your 4th study visit, you will begin taking 24-form Tai Chi classes.
- You will be asked to participate in 3, 60-minute session per week, each on non-consecutive days, for 8 weeks.

Study Visit 5 (Final Visit for Blood Draws):
This visit will take place at the Department of Kinesiology and Sport Management at TTU. This visit will add about 15 minutes of time to your last Tai Chi class.
- We will take about 2 tbsp. of your blood right before you begin your last Tai Chi session.
- We will then take about 2 tbsp. of your blood right after you finish your last Tai Chi session.

Study Visit 6 (Final Visit for MRI, if Baseline MRI was done):
This visit will take place at the Texas Tech Neurological Institute (TTNI) at TTU. This visit will take about one hour of your time.
- You will sign a TTNI MRI consent form.
- You will complete a TTNI Safety Screening sheet.
- You will have an MRI of your brain done.

Study Visit 7 (Final Visit for Functional/Clinical Outcome Measures):
This visit will take place at the Center for Rehabilitation Research at TTUHSC. This visit will take about one hour of your time.
- You will be asked to complete the WOMAC.
- You will also be asked to complete the BPI questionnaire.
- You will complete the Quantitative Sensory Test including windup (QST). You will also be asked to complete a questionnaire about your physical activity, quality of life, and food intake.
8. **What are my choices if I decide not to take part in this study?**
   You may choose to have the usual approach described above. You may choose to take part in a different research study, if one is available.

9. **If I decide to take part in this study, can I stop later?**
   Yes, you can decide to stop taking part in the study at any time.
   
   Your study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

10. **Are there other reasons why I might stop being in the study?**
    Yes. The study team may take you off the study if:
    - Your health changes and the study is no longer in your best interest.
    - New information becomes available and the study is no longer in your best interest.
    - You do not follow the study rules.
    - The study is stopped by Institutional Review Board (a committee that reviews and approves research), or the Food and Drug Administration.

    **It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don’t understand, be sure to ask your study team.

11. **What are the risks and benefits of taking part in this study?**
    There are risks and may be benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

    **Benefits**
    There is no guarantee that you will benefit from taking part in this study. However, we hope that it may help reduce the pain in your knee(s).

    **Risks**
    **Possible Risks of Tai Chi Exercises:**
    - Shortness of breath
    - Muscle soreness during and/or after exercise
    - Joint injury
    - Falls and other health related injuries

    You should talk to your doctor before starting Tai Chi, especially if you have a health condition, injury, or have not exercised in a while.

    You should **not** replace your regular medical care with Tai Chi.
Possible Risks of a Blood Draw:
- Pain, discomfort, bleeding, redness, bruising, or infection where the needle enters the skin
- Lightheadedness, dizziness, or fainting at the sight of blood

Possible Risks of MRI (If you agree to have MRIs):
- Feeling discomfort due to the enclosed space or noise from the scanner

There is also a possible risk of loss of confidentiality. We will do all we can to protect your personal information. There may be other risks that are unknown.

12. What are my responsibilities in this study?
   If you choose to take part in this study you will need to:
   - Keep your study appointments.
   - Tell your study team about:
     - all medications and supplements you are taking
     - any side effects
     - any doctors’ visits or hospital stays outside of this study
     - if you have been or are currently in another research study.

13. Will I receive anything for taking part in this research study?
   You will receive a $25 gift card at the end of visit 4.

   You will receive another $25 gift card at the end of visit 7.

   If you agree to have both MRIs, you will receive an additional $25 gift card to compensate you for your time and travel after each MRI has been completed.

   Payment for participation in this research is considered taxable income. In order for you to receive payment for this research, we will need to collect your name, address, and social security number. If you are not able to provide this information, 30% of the amount being paid for this research study will be automatically deducted and sent to the Internal Revenue Service (IRS).

   If you receive payments that total more than $600 in one calendar year, Texas Tech University Health Sciences Center is required to report this information to the IRS. A Miscellaneous Income form (1099-MISC) will be sent to you and to the IRS.

14. What are the costs of taking part in this study?
   It will not cost you anything to take part in this study. We will pay for all activities.

15. What happens if I am injured because I take part in this study?
   Texas Tech University and Texas Tech University Health Sciences Center do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such
injury or illness unless specifically stated.

If you have a research related illness or injury, care will be available to you as usual, but you and/or your medical or hospital insurance company will be responsible for the cost of treatment. Before entering this study, you should check whether your insurance company might limit your insurance coverage if you take part in a research study.

16. **What will happen to my blood samples when the research study is over?**
   In this study, we will be collecting some of your blood. When the study is done, we will make sure that the blood samples cannot be identified as belonging to you.

   We will keep the blood samples to use in our future research, or in research done by our colleagues. If your unidentifiable blood samples are used in future studies, we will not ask for your consent again before using them. You will not know when or if those samples are used for research, and no one will be able to tell you any results of research that used your samples.

   It is possible that these samples will be used in research that could profit the investigator or others. If the sample is used in that way, you will not share in any of the potential profit.

17. **What about confidentiality and the privacy of my records?**
   We will keep your involvement in this research study confidential to the extent permitted by law. In addition to the staff carrying out this study, others may learn that you are in the study. This might include federal regulatory agencies such as the Food and Drug Administration (FDA) and the Office for Human Research Protection (OHRP), Texas Tech University (TTU) representatives, representatives from any hospital or site where the research takes place, and the TTU Institutional Review Board (a committee that reviews and approves research). These people may review and copy records involving your participation in this research. A copy of this document may be placed in your medical record.

18. **Does anyone on the research staff have a personal financial interest in this study?**
   No one on the research staff has a financial interest in this study.

19. **What if I have questions?**
   For questions about this study, contact the Investigator, Dr. Leslie Shen at 806-743-2815 or email at Leslie.Shen@ttuhsc.edu

   If you would like to speak to someone who is not involved in the study about your rights as a participant, research-related injuries, or any other matter related to the study, you can call the TTU EthicsPoint Hotline: 1-866-294-9352.

   Or, you can file an EthicsPoint report online:
A description of this clinical trial will be available on [www.ClinicalTrials.gov](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.

Your signature indicates that:
- this research study has been explained to you;
- you have been given the opportunity to ask questions and have received answers;
- you accept your responsibility to follow the instructions given to you by the research team regarding study participation and, if applicable, research medication;
- you agree to take part in this study.

You will be given a signed and dated copy of this form.

Printed Name of Subject

__________________________________________
Signature of Subject                                       Date

Time

I have discussed this research study with the subject and his or her authorized representative, using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Signature of authorized research personnel who

conducted the informed consent discussion

__________________________________________
Date

Time
Optional Participation Activities

MRI Agreement (OPTIONAL)
You will have the option to participate in the portion of the study to have MRI’s. This will add at least 2 additional hours to your participation. You also may be in the study for more than 10 weeks due to limited MRI Scheduling. You do NOT have to have MRI’s to be in this study. This is for research purposes. This is your choice. We will pay for the MRI’s and procedures at these visits. Your care will not be affected based on your decision.

I agree to have MRI scans. I understand that if I agree, I will be required to have 2 MRIs for this part of the study.

[ ] [ ] NO
Initial in the box above

Contact for Future Research (OPTIONAL)
We would like to be able to contact you to participate in future research studies. This is optional, you do NOT have to agree. Your care and participation will not be affected based on your decision.

I agree that someone on the study team may contact me to see if I wish to participate in other research studies in the future.

[ ] [ ] NO
Initial in the box above
STUDY TITLE: Tai Chi for pain management of knee osteoarthritis

This form is intended to tell you about the use and/or disclosure (sharing) of your personal Protected Health Information (PHI) if you decide to participate in the research study described on the previous pages. The health information about you that may be used or disclosed is described below. This information is usually found in your medical records. Only the health information about you that is needed for this research study will be used or disclosed. When you consider taking part in this research study, you are also being asked to give your permission for your Protected Health Information to be released from your doctors, clinics, and hospitals to the research personnel approved for this research study. This Authorization specifically relates to the research study described in the attached Informed Consent document.

1. This Authorization is valid indefinitely or until such time as legal requirements will allow this Authorization to be destroyed.

2. If you choose to cancel this Authorization, please give notice in writing to:

Institutional Privacy Officer
Office of Institutional Compliance
3601 4th St MS 8165
Lubbock TX 79430

If you sign this Authorization, the following persons, groups or organizations may rely on this Authorization to disclose your Protected Health Information to the Principal Investigator and other research personnel who are conducting this Study:

• your treating physicians and healthcare providers and their staff,
• associated healthcare institutions and hospitals where you have or may receive care.

While this research study is in progress, the Principal Investigator or research personnel working on this study will inform you whether or not you will be allowed to see the research related health information that is created about you or collected by the research personnel prior to the end of the study. After the study is finished you may request this information as allowed by the TTUHSC Notice of Privacy Practices.

The Protected Health Information that you authorize to be used or disclosed for research purposes may include your current or future health information from some or all of your health records, including:
• hospital records and reports
• admission history, and physical examination
• X-ray films and reports; operative reports
• laboratory reports, treatment and test results
  (including sexually transmitted diseases, HIV or AIDS)
• any other Protected Health Information needed
  by the research personnel listed above.

(* use separate form for disclosure of
psychotherapy notes)

• immunizations
• allergy reports
• prescriptions
• consultations
• clinic notes
• mental health records
• alcohol / substance abuse
  records

For the purposes of this study, your Protected Health Information may need to be reviewed or
disclosed to individuals or organizations within and/or outside of TTUHSC who sponsor,
approve, assist with, monitor or oversee the conduct of research studies. This includes, but is
not limited to, the TTUHSC Institutional Review Board, TTUHSC compliance reviews, the US
Food and Drug Administration (FDA) or governmental agencies in other countries. Some of
these individuals or organizations may share your health information further, and your health
information may not be protected by the same privacy standards that TTUHSC is required to
meet.

If you choose to sign this Authorization form, you can change your mind about this later. If you
change your mind, send a letter to the person identified above telling us to stop collecting and
sharing your Protected Health Information. When we receive your request, you may be asked to
leave the research study if all the necessary information has not been collected. We may still
use the information about you that we have already collected. We need to know what happens
to everyone who starts a research study, not just those people who stay in it.

You have the right to refuse to sign this form. If you choose not to sign this form,
your regular health care will not be affected. However, not signing this form will
prevent you from participating in this research study and prevent you from
receiving research related health care services provided under this study.

I have had the opportunity to review and ask questions regarding this Authorization to use or
disclose my personal health information, and I will receive a copy of this form. By signing this
Authorization, I am confirming that it reflects my wishes.

Printed Name

______________________________  ______________________________
Signature of Individual or Authorized Representative   Date

If applicable, Relationship of Authorized Representative
or Authority to Sign