Cover Page

Thorco-Lumbar Fascia Mobility (TLFM)

NCT03916705

Approval date: 7/21/2020

ICD-INFORMED CONSENT

Name of Participant:

_____
(First Last)

Study contact information:
Robert Vining: Research study Principal Investigator (PI) 563-884-5690
Research clinic staff phone: 563-884-5153
Research clinic staff email: TLFM@palmer.edu

Key information about this study

- We will use ultrasound to measure movement of muscles and tissues in your low back
- In this study you will have 7 ultrasound measurements of your low back
- We will ask you to avoid treatment to your back between joining the study and your next visit with us (1 month later)
- Once you start the treatment part of the study, we ask you to come in 2 times per week for 8 weeks
- You will receive 16 chiropractic treatments to your low back over 8 weeks
- Common chiropractic treatments will be used in this study
- Common risks of taking part in the study include minor muscle soreness and stiffness
- You may not benefit from taking part in this study

We invite you to take part in this research study funded by Palmer College of Chiropractic. This form describes what you will be asked to do. It tells you the risks and benefits of the research. You will also learn about your rights as a research participant.

- You do not have to decide now if you want to participate.
- Before you decide, you may take this form and talk with others about the study.

If you don't understand something about this study at any time, please ask any of our research team.

Please do not agree to take part in this study until your questions are answered and you are comfortable with your choice.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The purpose of this study is to:

- Use ultrasound to measure the movement of muscles and tissues of the back before and after chiropractic treatment.
- Use ultrasound to measure muscle and tissue movement of the lower back over time and when muscles are tight and relaxed.
- Measure pain and function.

WHAT IS EXPERIMENTAL ABOUT THIS STUDY?

All treatments in this study are commonly used by doctors of chiropractic to manage back pain. No treatment is experimental. The experimental part of this study involves measuring movement of tissues in your back. We will also compare these measurements to any changes you report with your low back pain.

For this study we will collect protected health information (PHI) such as past/present conditions, information on your low back pain and other information like sex and age that can relate to your health.

Your health information will help the research team to know if you are eligible and if it is safe for you to join the study.

Information gathered for research will help the study team better understand treatments for back pain.

WHO IS ELIGIBLE TO TAKE PART IN THIS STUDY?

You may qualify for this study if :
- You are 21 - 65 years old
- Have low back pain
- follow the study procedures outlined in this form
- You are the right type of person we need to answer our research questions

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We will enroll about 30 people in this study.

I have had the opportunity to discuss key information in the previous section with a study member ☐

HOW LONG WILL I BE IN THIS STUDY?

- If you qualify for phase 1 of this study, you will have an exam of your low back and ultrasound measurements taken (today).
- It will take 4 weeks to determine if you qualify for phase 2 of the study.
- If you qualify for phase 2 of the study, you will be asked to come to our clinic for 2 visits per week for 8 weeks.

This means that you will spend around 11 hours (total) over the next 12 weeks at this clinic.

WHAT WILL HAPPEN DURING THE STUDY?

During this study, you will be asked to complete some or all the following activities:

==> This baseline visit (around 3 hours long)

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This includes:
• Vital Signs:
We will measure your typical vital signs (i.e. height, weight, temperature, heart rate, blood pressure and breathing rate) and ask about your medication use.

• Questionnaires:
You will be asked to answer research questions about your past health, your low back pain, and other background information.

• Interview:
We will ask you some questions to help us know if you are eligible for this study.

• Examination:
We will conduct an exam to see if you can receive treatment and do testing for this study. We will collect information about your back, joints and muscles and your general health status.

• X-Rays:
A Doctor of Chiropractic may order and perform x-rays for you at the baseline visit, or at other times during the study as clinically appropriate. If you have had recent x-rays of your spine, they may be requested to avoid more x-rays.

• Ultrasound measurement:
At this baseline visit we will collect ultrasound measurements. You will be in a room with 3 study personnel during these measurements. You will lie face down on a special table. Study personnel will strap your ankles in place and make sure you are on the table properly. A hand-held ultrasound probe will touch one side of your low back. The table will move your legs up and down in a precise way while ultrasound measurements are recorded. The recording lasts about 20 seconds. It will be repeated on the other side of your back. You may stop the table from moving with a handheld switch if you feel uncomfortable at any time.

If we have problems collecting the ultrasound image, we may attempt to re-position you, we may need to shave your low back, or repeat the ultrasound measurement.

During the first ultrasound measurements, we will take repeat measurements after
1) a 5-minute rest period and 2) while you lift your head slightly off the table.

==> A phone call in the next 4 weeks

This call will include:

• A discussion with a doctor of chiropractic about the results of your exam.

• Another chance to ask questions you have about the study.

==> Your next visit to our clinic will occur 4 weeks from now (1-2 hours long).

Activities at this visit include:

• Interview:
We will ask you some questions to ensure you are still eligible.

★ If you are not eligible at this visit, you will not continue as a study participant.

★ If you are still eligible:

• Questionnaires:
you will answer research questions

• 2 separate ultrasound recordings to your low back:
One before treatment, and one after treatment

• Study treatment:
At each visit, we will assess your health status and spine to determine if you will receive a chiropractic treatment.

• The study treatments will be delivered by the study doctor to your low back, mid or upper back.

• The treatments and the equipment used in this study will be based upon your specific needs. If you have had chiropractic care in the past, some treatments used in this study might be familiar; other treatments might be new to you. Please tell us about any treatments you received in the past that worked well as well as those that did not.

• During most treatments, you will lie or sit on a treatment table. You may lie with your face down, with your face up, or on your side. The chiropractor will move you and/or the table into position and ask you to relax for the exam and treatment. You will feel the chiropractor touch, support or move your neck, back, hips, arms or legs with his or her hands. The chiropractor will push along your spine and other joints to look for areas that do not move with ease or that move too much. He or she will ask you if these areas are tender to touch or painful with movement. Prior to treatment, the doctor of chiropractic will explain what you can expect to happen.

★ Your chiropractic treatments may include one or more of the following:

• High velocity-low amplitude (HVLA) treatment. During a HVLA treatment, the chiropractor will make a quick and controlled thrust to move your joints. This treatment often includes a soft popping or cracking sound. HVLA treatment will be provided to your upper back with you lying face down or sometimes while lying on your back. HVLA treatment to your lower back will occur while you lie on your side or face down. Only HVLA treatment and advice will be used during the 1st visit of Phase 2. Other treatments (described below) may be added over the remaining 15 visits. Your condition, how you respond to treatment, and other factors that you can discuss with the study doctor will determine how other treatments are used.

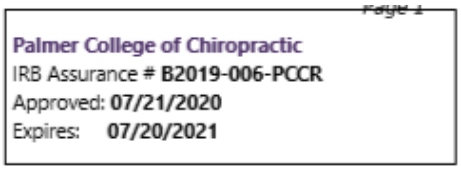
• Stretching and/or slowly moving your back, hips, or torso area.

• Light or deep pressure applied to muscles in the back hip or torso area.

• Specific exercises to perform between study visits

• Self-care advice designed to help you self-monitor and reduce the negative impact of your low back pain

• Treatment will be focused on your low back pain. Treatment designed for other symptoms such as shoulder or arm pain, knee pain, neck pain, or headache is not part of this study



==> You will then be scheduled for 2 visits per week over the next 8 weeks
This includes:
• 2 ultrasound and treatment visits, which last about 45 minutes:
Treatment visits 8 and 16 include an ultrasound measurement before treatment.
You will also complete questionnaires on these 2 visits.

• Treatment visits with no ultrasound or questionnaires last about 30 minutes:
This occurs at visit 2-7 and 9-15,
You will have the study treatment described above to your low back and/or upper back region.
During any treatment or measurement, if you feel too uncomfortable, tell us and we will modify or stop the procedure.

Missing Visits
In the event you are not able to attend a scheduled visit, we will attempt to reschedule you as much as we are able. However, if we cannot reschedule you within 4 business days, we will continue with the next scheduled visit.

If you need to miss more than 2 weeks (14 consecutive days) of appointments, your participation in this study will end.

Other study considerations
Clothing: When we obtain ultrasound recordings (at your first visit, in 4 weeks and on visits 8 and 16) we will ask you to wear a special top (provided by the clinic) that opens in the low back area.

Manual Therapy Avoidance: During your participation in this study, we ask that you avoid all other forms of chiropractic care and manual therapy, such as physical therapy or massage to your lower back. If you visit a healthcare provider who is not part of this study, please let us know so we can include this information in your record.

Tape: We will use a piece of tape to secure the ultrasound probe to your skin. Some discomfort may occur when the tape is removed.

Skin marking: We will mark your skin with a skin marking pen. We attempt to remove these marks, but often a slight mark will remain on the skin for a day or two.

Shaving: If you have body hair in the low back area that interferes with the ultrasound recordings, we may need to shave the area (about 2-3 square inches) with an electric razor. There is a very slight chance of receiving a cut or abrasion from the shaving procedure. Study personnel are trained and able to bandage the cut if this occurs.

X-rays: your doctor of chiropractic may preform x-rays at any of your study visits based on how you are responding to care. The x-ray exam will be done at the research center. This should only add around 30 minutes onto your appointment time.

Other study considerations (Cont,d)
Due to the COVID 19 pandemic, Palmer is taking many steps to keep individuals safe. We are requiring all individuals visiting and working on our campus to wear face masks. If you do not have one of your own, one will be provided for you.
We are also implementing screening prior to all visits to the research clinic. This screening will include:
• A call prior to every clinic appointment

• Screening questions and a temperature check when visiting the research clinic.

• If you feel ill, have been diagnosed with COVID-19 illness, or been in contact with someone diagnosed with COVID-19, we ask that call us before your visit, we will discuss options for re-scheduling your appointment(s).
At any of your visits, the study clinician may need to update or perform a physical exam.

I have had the opportunity to discuss key information in the previous section with a study member ☐

WHAT ARE THE RISKS OF THIS STUDY?

The exams and treatments used in this study involve minimal risks. Risks in this study include treatment side effects or injuries, discomfort during the measurements and other occurrences listed below. In addition to these, there may be other unknown risks we did not anticipate.

• Treatment Side Effects or Injuries:
Some possible side effects include muscle or joint pain or stiffness, or mild radiating symptoms caused by the exam or chiropractic treatment. These symptoms are most likely to occur at the beginning of the study and are usually self-limiting and last less than 24 hours. Sometimes they last longer. Some treatments where deep pressure is used can result in mild bruising. Other risks can include fatigue, light-headedness or dizziness, sweating and a flushed feeling. These symptoms may occur right after a treatment and usually last only a few minutes.

Extremely small but more serious risks linked to chiropractic care of the back include bone fracture or muscle and ligament strains or sprains.

If our doctors identify you as high risk for any safety concern and our doctors of chiropractic are unable to treat you in a manner that reduces your risk, you will not be eligible for the study or study participation may be stopped.

• Discomfort during measurements:
Some participants may experience soreness or stiffness from moving the body during ultrasound measurements. When this occurs, symptoms usually go away within a short time.

Ultrasound waves have been known to cause slight tissue heating. You may experience a slight warming sensation under the ultrasound probe.

Ultrasound can cause tiny air bubbles in the tissue under the ultrasound probe. These are very small air bubbles that you should not feel. The air bubbles will naturally dissolve within a few minutes.

Though rare, itching or redness can occur after tape is placed on the skin. Please let us know if you are sensitive to tape.

• Other Occurrences:
As part of the exam, the study doctor may order x-rays of your spine. If this is the case, you will be exposed to a very small amount of radiation. This radiation may be potentially harmful, but the risks are small and well accepted within healthcare.

There is a risk of your personal health records or personal data to be compromised. However, the research team has measures in place to prevent this from occurring.

We will conduct all procedures in a safe and ethical manner. We will follow the best available practice procedures during this study.

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WHAT PROTECTIONS ARE USED TO DECREASE MY RISK IN THIS STUDY?

• We screen participants carefully to make sure that only people who meet the research criteria and safety guidelines are enrolled in this study.

• If other tests are needed to determine the cause of your low back pain, you will not be included in this study. In this case, we may refer you to another healthcare provider .

• If you are enrolled in this study and we think that it is harmful for you to continue, study participation will be stopped. In this case, we may refer you for follow-up care.

• We will let you know if information is found during this study that may affect your decision to participate.

•We use procedures consistent with recommendations from the Centers for Disease Control and Prevention to reduce the risk of COVID-19 transmission.

WHAT ARE THE BENEFITS OF THIS STUDY?

There may be no direct benefit to you from taking part in this study. On the other hand, you may experience an improvement in your back pain. In either case, the research community and the public may benefit from the knowledge gained from this study.

I have had the opportunity to discuss key information in the previous section with a study member ☐

WILL IT COST ME ANYTHING TO PARTICIPATE IN THIS STUDY?

During this study, there are no charges for the exam, x-rays, or study treatment provided to you at the Palmer Research Clinic. You will spend time and effort to complete the study. You will also be responsible for the transportation to and from the research clinic.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

No, you will not be paid for taking part in this study.

IS BEING IN THIS STUDY VOLUNTARY?

Yes, your participation is entirely voluntary. You may refuse to take part in this study, and you have the right to quit at any time without any penalty.

WHAT ARE MY ALTERNATIVES TO PARTICIPATING IN THIS STUDY?

You can seek care from your primary care provider, a medical specialist, a doctor of chiropractic, or other healthcare provider.

WHAT HAPPENS IF I AM INJURED DURING THIS STUDY?

In the unlikely event that you are injured during your visit at our clinic, research clinic staff can provide first aid to you without cost. However, other treatment costs are not available from the Palmer College of Chiropractic. You and/or your insurance provider are responsible for any medical costs related to illness or injury.

It is important to tell us if you feel you have been injured because of taking part in this study. Let us know if you have any changes to your health that you think are related to this study.

HOW IS MY PERSONAL INFORMATION KEPT CONFIDENTIAL?

The information that you share during this study is kept private.

Your research records will be identified with a study ID number. Only select research personnel will have access to your name and ID number.

Under special conditions, other people may be able to view the information collected for this study. This includes protected health information. They include radiologists and interns from Palmer College of Chiropractic, members of the Palmer College of Chiropractic Institutional Review Board (IRB), Palmer College of Chiropractic Office of Compliance, and federal agencies that oversee human research.

If by law your healthcare information is required to be shared, the research team cannot guarantee that the shared information will still be protected under HIPAA.

If information is published or presented at scientific meetings, your name and personal information will not be used.

During and after the study, all paper forms are stored in locked cabinets. Computer records are stored on Palmer College of Chiropractic secured networks.

We will be sharing the ultrasound images of your low back with a specialist for study analysis. These will be sent using a secure cloud-based file sharing network called Microsoft OneDrive. The images will be sent using a coded ID number. They will not contain your name or other information that can be used to identify you.

The Palmer Research Clinic keeps healthcare records with your personal identifiable information for seven years. Upon request, you may obtain reports summarizing your exam and x ray findings and treatment. Copies of the actual treatment records from the Palmer Research Clinic may not be obtained until after manuscripts for this study have been released. This time period may last several years beyond your participation in this study.

Research data without your name or other identifiable information will be kept indefinitely by Palmer College of Chiropractic. This can include data that is collected even if you later choose not to continue participation in the study or are not eligible at a later point. These data are sometimes used for studies other than this one. You will not be contacted about this future use of study data from which you cannot be identified.

If you do not agree to the use of your healthcare information for this project, you should not sign this consent document. If you do not agree to the use of your healthcare information for this project, you will not participate in this research study.

WHERE CAN ADDITIONAL INFORMATION ABOUT THE STUDY BE FOUND?

A description of this study is available on www.ClinicalTrials.gov. This Web site will not include information that can identify you.

The study team will not be able to provide results of the research specifically to you, but this website will include information about the study and a summary of the results after the study is complete. You can search this Website at any time.

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WHO CAN I CONTACT FOR INFORMATION ABOUT THIS STUDY?

Please ask study personnel questions about the study at any time.

You may also contact:
Dr. Robert Vining, Principle Investigator at (563)884-5690 if you have questions about this study.

Palmer College of Chiropractic Institutional Review Board Office for Human Research Protections at support.irbmanager@palmer.edu or (563) 884-5757 if I have questions about your rights as a research participant.

WHAT IF I WOULD LIKE TO CANCEL MY PERMISSION TO USE MY HEALTH DATA

You may cancel this release of authorization.
If you cancel, the research team will still use the information that was collected as part of the research project between the date you signed this form and the date you cancel your permission. This is to protect the quality of the research results.
Canceling this permission will end your participation in this study. If you choose to cancel this authorization, you must notify the Principal Investigator for this study in writing at:

Robert Vining, DC, DHSc
Palmer Center for Chiropractic Research
741 Brady St.
Davenport, IA 52803

I have had the opportunity to discuss key information in the previous section with a study member ☐

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----- Office use only-----
Please give this device to the study team member to complete the form.

SPECIAL PROCEDURE PERMISSIONS

Voicemail Message Permission

We may call you to remind you of appointments or give you updates during this study. Sometimes, we may need to leave you a message on voicemail.

With a voice message, others may see or hear a message we leave. This can link you to participation in this research study. We will leave a voicemail only if you give permission.

This decision will not affect your eligibility for this study.

◯ I give my permission for voicemail messages during this study.
◯ I do not give my permission for voicemail messages during this study.

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STATEMENT OF CONSENT
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part or quit at any time without any penalty.

I understand that I will be given a signed copy of this consent document for my records.

I have read through this document and discussed the research with study personnel.

I feel I understand the information presented to me and agree to participate in the Thoraco-Lumbar Fascial Mobility study.

I agree to participate in this research with the understanding that I am authorizing researchers from Palmer Center for Chiropractic Research to use my protected healthcare information for this study.

Do you agree to consent?:

◯ Yes
◯ No

Participant Signature:

_____
(Please click on the link to the right to add your signature)

Participant Full name:

_____
(First Last)

Today's Date:

_____

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Please give this device to the study team member to complete the form.

STATEMENT OF PERSON WHO OBTAINED CONSENT
1. I have discussed the above points related to the Thoraco-Lumbar Fascial Mobility study with this participant.

2. The study purpose, risks, benefits, and procedures were described in detail.

3. The participant was given opportunity to read the Informed Consent form and ask questions.

4. The Participant verbalized understanding of the study and related visits and procedures.

5. No procedure was performed prior to obtaining informed consent

☐ I attest that all these required actions have occurred.

Signature of person who obtained consent:

_____
(Signature of Study Person who obtained Consent)

Study staff full name who obtained the Consent:

◯ Elissa Twist
◯ Anna-Marie Schmidt
◯ Anna Walden-Cobb

Today's Date:

_____