TITLE: Effectiveness of Intense Therapeutic Ultrasound in the Management of Patients with Plantar Fasciitis

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Sponsor: Guided Therapy
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The University of Arizona Consent to Participate in Research

Study Title:	**Effectiveness of intense therapeutic ultrasound in the management of patients with plantar fasciitis**
Principal Investigator:	**L. Daniel Latt, MD PhD**
Sponsor:	**Guided Therapy Systems**

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious, depending on the nature of the research.

1. Why is this study being done?

Plantar Fasciitis is a painful, inflammatory condition occurring where the plantar fascia attaches to the heel bone. Plantar Fasciitis is usually treated with stretching exercises, anti-inflammatory medication (NSAIDS), and heel cups. Despite these treatments, 5% - 20% of patients will still have symptoms at 1 year. The purpose of this study is to determine if the investigational therapy, Intense Therapeutic Ultrasound (ITU), can promote healing of plantar fasciitis. ITU is a noninvasive way to heal tissues with sound waves. ITU helps the body make more collagen. Because the plantar fascia is made of collagen, this study will determine if ITU can also speed the healing of plantar fasciitis. Every subject will receive the standard treatment which is anti-inflammatory medication, a viscoelastic heel cup, and physical therapy. Subjects receiving just these treatments will be compared to those also receiving ITU treatments.

2. How many people will take part in this study?

Approximately 50 people may participate in this study.

3. What will happen if I take part in this study?

If you decide to be a part of this study, you will be asked questions and have x-rays taken to determine whether you have chronic plantar fasciitis and do not have other conditions which will prevent you from being able to participate in the study such as pregnancy, diabetes, infections, other foot problems, or plantar fasciitis in both feet. If you are 18 or older and have been diagnosed with chronic plantar fasciitis in one foot without any other complications, you will receive standard treatment and either ITU or fake-ITU.

As part of standard treatment you will receive non-steroidal anti-inflammatory medications called NSAIDS, heel cups, and be asked to see a physical therapist twice a week for six weeks who will assist you with the home exercises. As part of the research we will want to know how often you see the physical therapist and will ask you to keep track of how frequently you do the home exercises. We will give you an exercise log so you can check off the days you do the exercises. All patients will participate in the following as part of the standard evaluation of foot pain or as part of the standard of care for plantar fasciitis -

- Weight-bearing x-rays of the foot
- NSAIDS
- Heel cup
- Home exercises
- Physical Therapist 2x/week for 6 weeks
- Clinic visit at 3 months

Additionally, you will be asked to go to the Human Movement Biomechanics Lab at the University of Arizona to receive an investigational treatment. Half of the participants in this study will receive ITU and the other half will receive fake-ITU. You will not be able to choose or to know which ITU you will receive, and neither will any of the researchers on the study because this could influence the results of the study. You will be randomly assigned to receive either ITU or fake-ITU. You will need to remain in this group the entire time of the study and agree not to participate in any other treatments for plantar fasciitis. In addition to this investigational treatment using ITU, we will collect information about the fascia on the bottom of your foot using ultrasound. You will be asked to come to the lab at least, but probably no more than 5 times. While in the lab you will be asked to do at least the following-

1. Provide the number of times you went to the physical therapist
2. Provide the number of times you did each exercise (exercise log)
3. Lie on an exam table with your feet hanging over the end for at least 20 min during the treatment and/or ultrasound exam
4. Answer online questionnaires if not completed before coming to the lab.

Finally, we will collect information from your medical record including your medical history and any physical exam findings.

4. How long will I be in the study?

If you take part in the study, your participation will last for 6 months. Standard of care treatment and lab visits (including online questionnaires) will occur every other week for 6 weeks, followed by an additional visit and questionnaire at 3 months, and a final online questionnaire at 6 months. You will receive a reminder call/email at 6 months requesting that you complete the online questionnaire.

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

Exposure to ITU may produce short-term sensations which may cause mild discomfort and the skin to be red for up to a few hours following the exposure.

If you take part in this research, you will be exposed to a number of x-rays that may be part of the regular care for your condition and research purposes. A possible health problem seen with radiation exposure is the development of a cancer later in life. These estimates are very uncertain, and the known risks are very small. However, if you have concerns about the overall radiation exposure, you should discuss them with your physician.

7. What benefits can I expect from being in the study?

You may not receive any benefits from being in this study. However, the possibility exists that those participants receiving the ITU treatment may experience a more rapid relief of their symptoms or more complete healing.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study, their agents or study monitors
- The University of Arizona Health Network (UAHN)

The University of Arizona Health Network (UAHN) uses an electronic medical record system called EPIC. This study will utilize EPIC to track your participation in the study. If you do not have a UAHN medical record one will be created for you. Therefore, people involved with your future care and insurance may become aware of your participation in this study and of any information added to your medical record as a result of your participation in this study.

Study information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your research records are kept separate from the medical record and available to research staff working on this study.

10. What are the costs of taking part in this study?

No costs are associated with participating in this study.

11. Will I be paid for taking part in this study?

You will receive no compensation for participating in this study.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Daniel Latt at (520) 626-4024.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://orcr.arizona.edu/hspp.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Daniel Latt at (520) 626-4024.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	**Signature of subject**
	Date and time AM/PM
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**Date and time** AM/PM

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent
	AM/PM
	Date and time