Landstuhl Regional Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Effectiveness of Photobiomodulation Compared to Usual Care for Plantar Fasciitis

Overall Principal Investigator: Ann Ketz, PhD

Funding Source(s)/Sponsor: TriService Nursing Research Program

INTRODUCTION

You are being asked to participate in a research study conducted at the Landstuhl Regional Medical Center (LRMC) by Ann Ketz. You are being asked to participate in this research because you are experiencing foot and/or heel pain from plantar fasciitis.

Your participation in this research is voluntary. It is important that you read what is written below, and ask questions about anything you do not understand. You may want to talk with your family, friends, or others to help you decide if you want to be part of this study. When you feel that your questions have been answered, you will be asked if you agree to be part of the research or not. If you agree, you will be asked to sign this consent form. You will be given a copy of this form to keep.

WHY IS THIS RESEARCH BEING DONE?

This research is to determine if treatment with photobiomodulation (PBM) therapy, or low level laser therapy, 1. is a doable and acceptable form of treatment compared to stretching and ice at home, 2. improves foot function and decreases pain, and 3. Improves foot function and decreases pain more effectively at different doses. Even though PBM has been used for a variety of pain conditions in many different settings, we do not know how well it works for the pain of plantar fasciitis, or what the best dose is for treating plantar fasciitis. If the results of this study show that PBM is more helpful or faster than stretching at home for treating pain from plantar fasciitis, the study team will be able to plan other studies comparing PBM to more invasive treatments, like injections or surgery.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following things after you sign the consent and Health Insurance Portability and Accountability (HIPAA) forms:

Day 1, Today – Complete a total of 3 questionnaires to include your demographic information, measures of your foot and ankle ability, and level of pain. A member of the study team will also measure your foot size, around your calf, and the flexibility of your ankles.

You will also be given instructions on how to do the daily exercises that are part of the study, and how to complete the daily pain diary. We will also ask for good contact information (email and phone) so that we can contact you for follow up questionnaires. This visit will take up to one (1) hour.

Randomization: You will be randomly assigned to one of three groups to either receive usual care (stretching exercises and ice at home) or usual care PLUS either a high or low dose group for the PBM treatment. Randomization is a process like flipping a coin and means you will have an equal chance of being in each group.

_____(initial) Days 2-21 USUAL CARE GROUP – Complete your exercises and ice at home and complete your daily pain diary.

_____(initial) Days 2-21 USUAL CARE PLUS PBM GROUPS – Complete your exercises at home and complete your daily pain diary. You will also come to the CNSCI office three times a week for a PBM

treatment session. A trained member of the study team will apply the PBM treatment. The device is a plastic handle with a glass massage ball at the end where light comes out. The trained study team member will roll the massage ball on the bottom of your foot and back of your calf. If you feel uncomfortable at any time, the treatment can be stopped. Both you and the trained study team member will wear special eye protection (goggles) during the entire treatment. This will last approximately 10 minutes.

Day 21 ALL GROUPS – Return to our office to complete 2 questionnaires (measures of your foot and ankle ability, and level of pain) and turn in your pain diary. A member of the study team will also measure how the flexibility of your ankles.

Day 22-41 ALL GROUPS - Complete your exercises and ice at home and complete your daily pain diary.

Day 42 ALL GROUPS - Return to our office to complete 2 questionnaires (measures of your foot and ankle ability, and level of pain) and turn in your pain diary. A member of the study team will also measure how the flexibility of your ankles. We will also make sure we have good contact information (email) so that we can contact you for follow up questionnaires.

This visit may take up to 1 hour.

Month 3 and 6 – You will receive 2 questionnaires electronically in your email to complete and send back to the study team. It is important that you complete these questionnaires so that we know how the treatment worked for you after a longer period of time.

After the 6 month follow up, if you are in the usual care group and would like to receive PBM treatment, you may request PBM treatment from a trained provider on the study team – no data will be collected for the purposes of the study.

A total of 114 study participants are expected to be enrolled in the study here at LRMC.

If we learn new information during the study that could affect your decision to remain in this study, we will tell you this information. For example, if we learn about new side effects of the treatment, we will tell you about these side effects. The results of the research will be provided to you if you so desire

WHAT ARE THE POTENTIAL RISKS AND DISCOMFORTS FROM BEING IN THIS RESEARCH?

The risks associated with PBM treatment are minimal.

DISCOMFORT: Some mild discomfort may be experienced during the treatment. The treatment should not be “hot”; please tell the study team member if you feel any uncomfortable warming. If the sensation is not communicated there is a risk of burning the skin.

Eye protection: Protective eyewear will be provided. It is important to keep these goggles on at all times during the treatment in order to protect your eyes from accidental laser exposure. Closing one’s eyes does not protect them from risk as the laser is designed to penetrate tissue.

As is the case with any medical treatment there may be risks associated with this treatment that are currently unforeseeable. No serious adverse events have been reported using this treatment. Safety of PBM treatment in pregnant women has not been established so the risks to pregnant women are unknown.

If you have a nerve problem or difficulty feeling changes in your skin temperature, you should not participate in this study as you may be at higher risk for burns.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

The possible benefits of your participation in this study are: the stretching and ice at home and PBM treatment might help your heel/foot pain and improve function; these improvements might happen

faster if you are in one of the PBM groups. Information learned from your participation in this study may help others with plantar fasciitis in the future.

WHAT ALTERNATIVE OPTIONS TO PARTICIPATION ARE AVAILABLE TO ME?

If you choose to not participate in this study, you can continuing with the current course of treatment (prescribed or over-the-counter methods), standard pain management therapies, wearing night splints, wearing shoe inserts, consultation for injections or surgery, or no medical treatment at all.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will not be paid directly to take part in this research study. If you qualify to participate in the study and complete the study, you will receive travel reimbursement for up to $75. This covers travel solely for the purpose of the study and does not include travel that is made to commute to work at LRMC or for other scheduled appointments at LRMC. When you turn in the final sleep diary on Day 42, you will receive an AAFES gift card (or Visa gift card only if you do not have AAFES privileges) as reimbursement towards gas used for travel to the study visits. The amount reimbursed will be based on the standard $0.56 per mileage and will not exceed $75 total.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

If at any time you believe you have suffered an injury or illness as a result of participating in this research, please contact Ann Ketz at the main office phone, 314-590-4059/06371-9464-4059, Bldg 3842, Apt L, Landstuhl Regional Medical Center.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty in the military, dependent), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?

The principal investigator will keep records of your participation in the research. To protect your privacy, any of your research-related records will be labeled or "coded" with an assigned research participant number that will not include your name or social security number. Study team members will keep the link between your participant number and your research records in a locked file cabinet and password-protected study computer/file at the nursing research office. The principal investigator and co-investigators listed above are the only personnel who will be able to match your research participant number with any of your personal identifying information.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data

Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:

- U.S. Army Medical Research & Materiel Command Institutional Review Board
- U.S. Army Human Research Protections Office and other DOD offices charged with oversight of human research
- The Uniformed Services University of the Health Sciences, Bethesda, MD
- U.S. Food & Drug Administration (FDA)
- The Europe Regional Medical Command

Complete confidentiality cannot be promised for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

Your participation in this research is voluntary. You may decline to participate now or stop taking part in this research at any time without any penalty or loss of any benefits. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your entitlement for medical care or your future relationships with LRMC.

In addition, you have the option to request your research data be removed from the study by a **written** request to the Ann Ketz, CMR 1282, APO AE 09180.

WHAT COULD END MY INVOLVEMENT IN THE RESEARCH?

The investigator or study sponsor may withdraw you from participating in this research if circumstances arise which warrant doing so. The investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the investigator that remaining in the study might be dangerous or harmful to you.

WHAT IF ANY NEW INFORMATION IS FOUND OUT?

During the course of the research, the investigators will tell you of any new findings that might cause you to change your mind about continuing in the study. If new information is provided to you, the investigators will obtain your consent to continue participating in this study.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?

If you have questions about the research at any time, you should contact the study coordinator at Cell +49 (0) 174-375-6086, DSN (314) 590-5641, or Civilian +49 (0) 6371-9464-5641

If you have questions regarding your rights as a research participant, you may contact the LRMC Human Protections Administrator at DSN (314) 590-4934, , or by email at brenda.s.hanson2.civ@mail.mil; or the HQ USAMRMC IRB Office at 301-619-6240, DSN (312) 343-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil.

A description of this clinical trial will be available on *www.clinicaltrials.gov*, as required by US 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.

I agree to be contacted in the future about other research studies related to or as a follow-up to this study.

_____Yes _____No (Initial your choice)

For the purposes of study reminders & follow up related to safety, please provide an email & telephone number. This information will remain confidential and be used solely for the purposes of the study.
Email:_____Telephone:_____

SIGNATURE OF RESEARCH PARTICIPANT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

My signature certifies that the participant signed this consent form in my presence as his/her voluntary act and deed.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Authorization for the Use and Disclosure of Your Health Information

The Health Insurance Portability & Accountability Act of 1996 (also known as HIPAA) establishes privacy standards to protect your health information. This law requires the researchers to obtain your permission (by signing this form) before they obtain, use or disclose (share) your protected health information for research purposes in the study "Effectiveness of Photobiomodulation Compared to Usual Care for Plantar Fasciitis."

By signing this form, you are authorizing Landstuhl Regional Medical Center (LRMC), including the overall Principal Investigator, Ann Ketz, PhD, and other members of the research staff, to use and share your health information for the following purposes: for discussion and dissemination of data collected, and as otherwise needed for the research study. This health information includes demographic data (age, rank, race), medical conditions (foot function and pain).

Your health information may be shared with the Uniformed Services University of the Health Sciences, Bethesda, MD, the sponsor of this research; the Headquarters, US Army Medical Research and Materiel Command Institutional Review Board that reviews this research to make sure that it is ethical; the Army Human Research Protections Office; and state and federal government agencies, including, but not limited to, the Food and Drug Administration (FDA), the Department of Health and Human Services, and the Department of Defense. Health information that has been shared may be re-disclosed by the recipient of the information; these other organizations may then share your health information with others without your permission.

You do not have to sign this Authorization. If you decide not to sign, it will not affect your treatment or your eligibility for benefits, however you will not be able to participate in the research study.

There is no expiration date for this authorization and you may be contacted in the future regarding studies related to or as a follow-up to this study

You have the right to revoke this authorization. To take back your permission, you must send your **written** request to Ann Ketz, CMR 402 Box 1282, APO AE 09180 to inform her of your decision. If you take back your permission, the researchers may only use and share the protected health information already collected for this research study. If you take back your permission, you will not be allowed to continue to participate in the study.

LRMC will not share your health information with you during the course of the research study. You may request copies of records containing your health information after the research is completed.

You will receive a signed copy of this form.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date