Meets 2018 Common Rule Requirements

Brooke Army Medical Center
CONSENT TO PARTICIPATE IN RESEARCH

Title: Utilizing Photobiomodulation Therapy for the Treatment of Lower Extremity Stress Fractures in a Military Training Setting

Principal Investigator: Dr. Nathan Parsons, DPT, DSc

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

The purpose of this research is to evaluate the effectiveness of photobiomodulation therapy (PBMT; low-level laser therapy) in the treatment of lower leg and/or foot stress fracture injuries, to improve function, decrease pain, promote healing, and resolve symptoms. You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study.

If you choose to enroll in this study, you will be in this study for about 4 months, or until Advanced Individual Training (AIT) graduation/dismissal, whichever comes first. While you are in the study, you will be asked to: complete questionnaires and functional testing evaluating your lower leg/foot function and pain, undergo diagnostic imaging, attend standard of care physical therapy, complete a home walk to run program, and maintain a daily activity log. You will be randomly assigned to one of two treatment groups, either:

(1) PT with PBMT, or
(2) PT with sham (placebo) PBMT.

This is a single-blind study, which means you will not know which group you are assigned to until you complete the study.

The PBMT device used in this study is the Omnilux Plus™ 830 nm. This is an FDA approved device being used in accordance with the approved labeling for pain management.

It is possible that you may benefit from this research by completing the standard of care physical therapy and walk to run program, and PBMT treatments may help your stress fracture healing process, pain, and function. You may receive therapeutic benefit if you are in the active PBMT

group. However, we cannot guarantee that you will directly benefit from your participation in this study.

The main risks from being in this study are the possible risks associated with PBMT, including discomfort from skin/tissue heating, and eye damage if you look directly into the light without appropriate eye protection (rare). Steps to minimize the risks are described later in this consent form.

If you are a biological female of child-bearing age and capacity, you will only be eligible to participate in this study and receive study treatment if you are not currently pregnant. If you become pregnant after enrolling in this study, please notify a study team member, and you will be formally withdrawn from study participation for your safety.

The alternative is to not participate in this study and receive the care you typically would to address your stress fracture injury.

Your decision will not affect your future care at Brooke Army Medical Center. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are a current AIT trainee at Fort Sam Houston that is seeking care for the treatment of a lower leg and/or foot stress fracture injury. The purpose of this research study is to learn about PBMT for the treatment of lower extremity stress fracture injuries. The duration of participation per visit is approximately one (1) hour.

There will be about 122 people taking part in the study at BAMC over a period of 2 years.

During the study, you will have an initial baseline study visit and up to three (3) in-person follow-up study visits at 3-weeks, 6-weeks, and 4-months. You will be asked to return to the clinic three (3) times per week for your treatment visits, over 6 consecutive weeks, or until return to duty or AIT graduation/dismissal, whichever comes first. Additionally, you will have weekly follow-up visits while you are receiving study treatment, that may occur either in person or be completed virtually.

At the end of this research study the clinical results, including research results, about you will be shared with you, at your request.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process." These tests may have been done or this information collected as a part of your regular medical care.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate in this research, you will be asked to complete the following study procedures after you sign the informed consent and Health Insurance Portability and Accountability (HIPAA) authorization forms:

Baseline Data Collection:

Formal Screening:
As part of formal screening procedures, all females of child-bearing age and capacity will be required to complete a urine hCG pregnancy test. If the test is positive, indicating pregnancy, you will be formally withdrawn from the study and unable to continue to receive study treatment.

Additionally, all participants' final eligibility status will be confirmed from diagnostic magnetic resonance imaging (MRI) indicating you have an inclusive stress fracture injury. MRI is a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of structures in the body. If an MRI has been completed within one month prior to your study enrollment, the previous images may be used. If diagnostic images are required, an MRI will be ordered by an authorized medical provider, and you will be asked to complete the imaging procedures prior to study randomization and treatment.

Demographics & Baseline Data Collection:
You will be asked complete 3 questionnaires to collect your contact information, demographics, and self-report measures of your medical history, lower leg and foot function, and pain.

You will be asked to complete a brief hopping test and rate your pain. Additionally, you will be asked to complete a percussion test, in which a study team member will directly and indirectly palpate/tap your injury site, and you will rate your pain.

Before you leave the clinic, you will be given instructions to complete a walk to run exercise program and complete a daily activity log. This visit will take up to 1 hour. The MRI may take an additional 1 hour, when scheduled.

Randomization:
You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a 50% chance of being assigned to either of the groups. Participants that are assigned to the PBMT group will receive active treatment with PBMT 3 times each week, for up to 6 weeks, or until return to duty or study exit, whichever comes first.

You will have a one in two chance of being in the placebo group. A placebo is an inactive, harmless intervention, that looks like the active research study intervention, but contains no active treatment. In this study, the placebo is the sham PBMT, which is an inactive treatment that is intended to mimic the PBMT treatment. Participants that are assigned to the sham PBMT group will receive inactive treatment with sham PBMT 3 times each week, for up to 6 weeks, or until return to duty or study exit, whichever comes first.

This research study is a single blind study, which means that you will not know whether you are receiving the research study active treatment or a placebo, until after study completion at your final follow-up visit.

Study Treatment:
You will complete standard of care (SOC) physical therapy (PT), the walk to run program, and a daily activity log at home, until return to duty or study completion, whichever comes first.
You will also return to the clinic 3 times a week to receive your assigned study treatment, either PBMT or sham PBMT. This treatment schedule will occur every week, up to 6 weeks, until you are cleared for return to duty or until you exit the study at AIT graduation/dismissal, whichever comes first.

A trained member of the study team will apply the PBMT or sham PBMT. The PBMT device looks like a lamp and will be placed so the photons (small light particles) that come from it are at your lower leg and/or foot injury site. 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. Each treatment session will last approximately 10-16 minutes.

You will be asked to refrain from using perfumes or plant extracts (e.g., St. John's Wort) in the treatment area(s), as this can increase your skin photosensitivity.

Follow-Up Data Collection:

Weekly Follow-Up
Once a week, a study team member will follow-up with you to ensure you are completing the walk to run program and activity log. They will administer 1 brief pain questionnaire and assess for any adverse events. This follow-up visit can occur in-person or be completed virtually.

3-Week Follow-Up
You will be asked to return to the clinic to complete a brief pain and function questionnaire and complete the hopping and percussion tests.

6-Week Follow-Up
You will be asked to return to the clinic to complete a brief pain and function questionnaire, complete the hopping and percussion tests. Follow-up diagnostic MRI will be ordered by an authorized medical provider, and you will be asked to complete the appropriate imaging procedures.

4-Month Follow-Up
You will be asked to return to the clinic to complete a brief questionnaire assessing your pain, function, and return to duty status, complete the hopping and percussion tests. Follow-up diagnostic MRI will be ordered by an authorized medical provider, and you will be asked to complete the appropriate imaging procedures.

This follow-up data collection schedule will occur up to 4 months, or until you exit the study at AIT graduation/dismissal, whichever comes first, and your study participation will end. Once you complete your final study visit, as appropriate, you will be unblinded to the study group you were assigned to.

Medical Record Review:
When you exit the study, the study team will complete a chart review to collect information regarding the treatment you received during SOC PT and laboratory results that may have been completed as SOC at the time of your injury diagnosis. A study visit is not required on your behalf.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are minor risks associated with the study activities:

- Diagnostic Imaging:
  Possible risks include: experiencing anxiousness from being in a confined space, exposure to loud noises and heat that can cause harm if adequate protection isn't used. There are also additional risks associated with persons with certain metal or electronic devices in the body. Standard procedures for screening for these issues will occur to avoid harm or injury.
- Physical Therapy (PT):
  Possible risks include: worsening of pre-existing conditions, continued and/or increased pain that may limit activities, soreness, or falling and/or injury during physical therapy exercises and/or performance-based tests.
- Questionnaires:
  Some of the questions asked may make you uncomfortable. You can choose to skip or not answer any questions.
- Photobiomodulation Therapy (PBMT):
  Possible risks include: discomfort from skin/tissue heating, and a rare risk of damage to your eyes if you look directly into the light without appropriate eye protection.

Many of the risks associated with participating, such as those related to diagnostic imaging and physical therapy are minor and no greater than receiving this care outside of the study.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

Safety of PBMT in pregnant women has not been established so the risks to pregnant women are unknown. It is not known whether PBMT can cause birth defects or other problems in an unborn child.

If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that PBMT might be harmful to an unborn child if you are pregnant. You will take a pregnancy test before you can participate in this study. You should not get pregnant while in this study. The only completely reliable methods of birth control are not having sex or surgical removal

of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

It is possible that you may benefit from this research by completing the SOC PT and walk to run program, and PBMT treatments may help your stress fracture healing process, pain, and function. You may receive therapeutic benefit if you are in the active PBMT treatment group. However, we cannot guarantee that you will directly benefit from your participation in this study.

By your participation in this study future patients with a similar condition may benefit from the knowledge gained and shared from this research project.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for stress fracture injury. Alternative treatments and/or procedures that may be available to you include: continuing your current course of treatment, standard pain management therapies, or no medical treatment at all. You should talk with your personal physician (if applicable) about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, for your participation, you will receive a $50 USD gift card following turning in your daily activity log at your 4-month follow-up visit or after returning to duty, whichever comes first.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Dr. Nathan Parsons, DPT, DSc,
Brooke Army Medical Center
Department of Rehabilitation Medicine
3551 Roger Brooke Dr
San Antonio, TX 78234
nathan.a.parsons.mil@health.mil
210-221-3700

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your de-identified research data.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. LOCATION OF THE RESEARCH:

Brooke Army Medical Center

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The research team will keep your research records. These records may be looked at by staff from the Brooke Army Medical Center research office, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits.

All paper research records will be stored in a locked cabinet inside of a locked room accessible only by authorized staff. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Your coded MRIs will be stored in Teleray, a secure, access controlled, and encrypted data platform. No identifiable information will be entered into REDCap or Teleray.

Once your coded data is entered in REDCap and Teleray, it will only be accessible by authorized study team members and oversight officials, the local BAMC research office, the IRB, authorized staff from USU, and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at USU, and is serving as the data coordinating center for this study. Representatives of MIRROR/USU will not have access to your identifiable information.

The Brooke Army Medical Center (BAMC) research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names, date of consent, date of birth, and DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that is only accessible to study personnel.

The BAMC research team will also maintain an intake form that collects your preferred contact information. This paper intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

The BAMC research team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed at study closure.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Those listed below will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law:

- The members of the research team
- The BAMC Human Research Protection Program (HRPP) Research Office
- The San-Antonio Institutional Review Board (IRB)
- The DoD Higher Level Review
- The United States Food and Drug Administration (FDA)

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. USE OF INFORMATION

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether we need to get additional permission from you.

If you consent to participate in this research study, your de-identified data, meaning that all of your personal identifiers have been removed, collected as part of this research may be kept for future research studies or given to others for future approved research studies without additional permission from you. If you would not like your de-identified data collected as part of this research to be kept for possible future research, you should not consent to participate in this research study.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

Your de-identified MRIs will be maintained within Teleray by the local BAMC research team indefinitely, or as long as it is practical to maintain, and while funding can be allotted for this service. These images may also be used in future research.

Any future research using your retained data will require a research protocol for the proposed study reviewed and approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants), an Exempt Determination Official (EDO), or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor, or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD

beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You will not have the option to decline receiving information about an incidental finding.

18. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.
You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email using the contact information provided in this document. If you decide to no longer participate in this research study, the researchers may keep and analyze data that was collection during your participation in this study. However, no additional data will be collected after the time of your withdrawal.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The Principal Investigator of this research study may terminate your participation in this research study at any time if they determine this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

20. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an

DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

21. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Nathan Parsons, DPT, DSc
Phone: 210-221-3700
Mailing Address: 3551 Roger Brooke Drive, Fort Sam Houston, Texas, 78234

BAMC Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Jennifer Sadler
Phone: 210-916-9425

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

San Antonio IRB Office, Brooke Army Medical Center
ATTN: MCHE-ZQ, Department of Quality and Safety
3551 Roger Brooke Drive
Fort Sam Houston, Texas 78234-4504
Phone: 210-916-2598

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date