Joint Base Lewis McChord
CONSENT TO PARTICIPATE IN RESEARCH

Title: Assessing the Impact of Post-Exercise Photobiomodulation Application on Performance, Recovery, and Behavioral State in a Trained Special Operator Population

Principal Investigator: Bradley Cornell, DPT

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 effects of photobiomodulation therapy (PBMT; low-level laser therapy) on performance, recovery, and behavior in a tactical athlete special operator population. PBMT is a non-invasive (occurring outside of the body) procedure that involves applying certain forms of light to the body to enhance performance, stimulate healing, modulate recovery, and improve general wellness. You do not have to take part in this research. Participating in this research is your choice. You can also choose to stop participating at any time during the study.

If you choose to participate, you will be enrolled in this study for 3 weeks. While you are in the study and concurrently attending Tactical Human Optimization, Rapid Rehabilitation and Reconditioning (THOR3) coach-led training, you will be asked to complete the following-study related procedures: questionnaires, body composition/strength/performance testing, and wear an Oura Ring for the duration of the study. Please note, THOR3 training is independent of the study but is a requirement for study participation.

All study procedures will take place in the THOR3 Clinic. This study consists of an initial baseline visit, 2-3 PBMT treatment visits each week (based on your availability), and 3 weekly follow-up visits. The duration of participation per visit is 20-45 minutes for baseline and follow-up visits and 5-20 minutes for treatment visits.

You will be randomly assigned to 1 of 2 treatment groups, either:

(1) THOR3 training + PBMT, or
(2) THOR3 training + 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.

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The PBMT device used in this study is the LightForce® XLi therapy laser. This is an FDA approved device being used in accordance with the approved labeling.

It is possible that you may benefit from this research by experiencing improvement in performance and recovery. However, we cannot guarantee that you will directly benefit from your participation in this study.

The main risks associated with PBMT include discomfort from skin tissue heating and eye damage if appropriate eye protection is not worn. Steps to minimize risks are described later in this consent form.

The alternative is to not participate in this study.

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 an active-duty male, between the ages of 18-45 (inclusive), in 1st Special Forces Operations Group (SFG), and you are participating in THOR3 coach-led training. The purpose of this research study is to learn about the effects of PBMT on performance, recovery, and behavior in a trained special operator population. The duration of participation per visit is 20-45 minutes.

There will be about 116 people taking part in the study at Joint Base Lewis McChord (JBLM), over a period of 2 years.

During the study, you will have an initial baseline study visit and at least 2 (or, up to 3, if your schedule permits) PBMT treatment visits each week over 3 consecutive weeks. Additionally, you will have weekly follow-up visits while you are receiving study treatment, which may occur either in-person or be completed remotely.

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 provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process."

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

If you agree to participate in this study, you will be asked to complete the following procedures:

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Baseline Data Collection:
You will complete questionnaires to collect your contact information, demographics, and self-report medical history, military/work status, pain, and physical activity. A study team member will measure your height, weight, body composition, and quadriceps. Additionally, you will be asked to complete a counter-movement jump on a force plate (which measures force production) and lower body strength assessments.

You will be given an Oura Ring to wear daily for the duration of the study. You should only take it off when lifting weights and showering. The Oura Ring will continuously measure your blood oxygen levels, heart rate, and sleep quality. Additionally, you will be given a daily activity log and instructions for use. This baseline visit will take up to 45 minutes.

Randomization
You will be randomly assigned to 1 of 2 groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups.

Participants that are assigned to the PBMT group will receive active treatment with PBMT at least 2 (or, up to 3, if your schedule permits) times each week, for 3 weeks.

You will have a 1 in 2 (50%) 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 at least 2 (or, up to 3, if your schedule permits) times each week, for 3 weeks.

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 meet with the study team at least 2 (or, up to 3, if your schedule permits) times a week, for 3 weeks, to receive your assigned study treatment, either PBMT or sham PBMT.

A trained member of the study team will apply the PBMT or sham PBMT to your quadriceps. The PBMT device is a hand piece with a rolling glass massage ball that emits photons (small light particles). 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. Regardless of the treatment group you are randomized to, you will be asked to wear blackout glasses and headphones during your treatment. Each treatment session will last approximately 5-20 minutes.

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

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Follow-Up Data Collection:
Regardless of what study arm you are assigned to, you will be asked to wear an Oura Ring for the duration of the study, participate in THOR3 coach-led training, and maintain a daily activity log at home until study completion.

Weekly Follow-Up
Once a week, a study team member will follow-up with you to: collect your daily activity log and Oura Ring data, assess for any adverse events, measure your counter-movement jump on a force plate at before a THOR3 coach-led training session, and administer a delayed-onset muscle soreness questionnaire after your training. You will be provided with a THOR3 training program log to attest to the training that you completed each day of THOR3 training.

3-Week Follow-Up
You will be asked to meet with a study team member to complete a counter-movement jump on a force plate, and lower body strength assessments before a THOR3 coach-led training session, and follow-up questionnaire after your training. You will turn in your Oura Ring and activity log and you will be unblinded to your study treatment. This visit will take up to 25 minutes.

Your participation in this study will end after the completion of the 3-week follow-up visit.

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

If you choose to take part in this study, there are risks associated with the study procedures.

The risks associated with PBMT are minimal. PBMT is used by a variety of healthcare practitioners for painful clinical conditions. Mild discomfort may be experienced during the treatment. The treatment should not feel "hot," but you should notify the study team member if you feel any uncomfortable warming. Individuals with neuropathies or difficulty distinguishing changes in skin temperature are at higher risk. Potential research-related risks include damage to eye structures, headaches post-procedure, uncomfortable skin heating or erythema/redness, which are both very rare.

The risks associated with the counter-movement jump and strength testing are minimal risks that may be experienced in everyday life, including loss of balance, fall, discomfort, or injury.

Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information researchers have stored about you.

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?

The possible benefits to you as a research participant in this research study are improved recovery and performance. However, there is no guarantee that you will benefit from being in this research.

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

Your alternative is not to participate in this research.

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

Yes, for your participation, you may receive up to $150 in the form of a gift card. The opportunities to receive payment will occur when you turn in your completed activity log at the following intervals:

- 1-week follow-up visit - $50
- 2-week follow-up visit - $50
- 3-week follow-up visit - $50

Greenphire will act as an agent of The Geneva Foundation to manage the payments for your participation. You will be issued a Greenphire ClinCard card which is a visa debit card that your funds are loaded onto. When a study visit is completed, funds will be approved and loaded onto your card. The funds will be available within approximately 2-5 business days and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost, the site can replace it for you-once at no cost. The card will expire within 3 years of distribution.

Payment received as compensation for participation in research is considered taxable income. If your payments exceed $600 in any one calendar year, The Geneva Foundation will file a 1099 (Miscellaneous Income) form. The Geneva Foundation will need to collect certain information about you, on a W-9 including: name, address, date of birth and Social Security Number. All information is stored in a secure fashion.

If you are active duty or a federal employee, you must be on leave or off-duty at the time that you complete your activity log in order to be eligible to receive compensation.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study. You will not be held responsible for lost or damaged Oura Rings.

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

Bradley H. Cornell, DPT
1st SFG(A) GRP PT
9655 Madigan ByPass
JBLM, WA 98433
253-477-2130
Bradley.H.Cornell.mil@socom.mil

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 (DoD) may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:
Research funding is provided from the DoD Defense Health Agency (DHA) through USU.

13. LOCATION OF THE RESEARCH:
1st SFG, THOR3, JBLM

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 United States Army Special Operations Command (USASOC) Human Research Protections Program (HRPP), 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 by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The research team will maintain a confidential electronic master list that matches your unique coded study number with your personally identifiable information. The master list will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access.

- All coded paper research records will be stored in a locked cabinet inside of a locked room accessible only by authorized staff. The 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.

- 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 USU in Bethesda, MD. No identifiable information will be entered into REDCap. Once your coded data is entered in REDCap, it will only be accessible by authorized study team members and oversight officials, the USASOC HRPP, the IRB, and authorized staff from USU and MIRROR. MIRROR is serving as the data

coordinating center for this study. Representatives of MIRROR/USU will not have access to the study master list.

- Your signed consent form will be securely stored for 6 years following study closure; your coded research forms for 5 years following study closure; and, the master 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 above 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.

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 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.

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 MIRROR at the time that your data is entered into REDCap, and will be stored at 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. In addition to MIRROR maintaining your de-identified data, USASOC will also retain a copy for future use.

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 Exemption 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 CSC/CSU surgeon, 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.

Because information regarding your health may be required to be reported to appropriate medical or command authorities, you will not have the option to opt out of receiving the results of incidental findings from this research.

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?

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 study, the researchers may keep and analyze data that was collected during your participation. However, no additional data will be collected after the time of your withdrawal.

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.

If you withdraw from the study, you will be asked to return any study materials including the Oura Ring. A study team member will contact you to coordinate returning the study devices.

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 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.

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: Bradley H. Cornell, DPT
Phone: 253-477-2130
Mailing Address: 9655 Madigan ByPass, JBLM, WA 98433

USASOC Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Director (HPD)/HRPP POC: Brenda Hanson, PhD
Phone: 910-432-4261

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:

Uniformed Services University (USU) Human Research Protection Program (HRPP)
4301 Jones Bridge Road, Bethesda, MD 20814
IRB1@usuhs.edu
301-295-3303

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.

Please initial the sentences that reflect your choices, and then sign below:

_____ I *do NOT* authorize the storage of my contact information for the purpose of being contacted for participation in future research studies.

_____ I *do* authorize the storage of my contact information for the purpose of being contacted for participation in future research studies.

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

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