Naval Hospital Camp Pendleton

CONSENT TO PARTICIPATE IN RESEARCH

Title: Treatment Optimization of Brain-Injured Warfighters: a Prescribed Sub-symptomatic Exercise Treatment (TOBI-SET)

Principal Investigator: Jason Bailie, Ph.D.

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 physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary and not command directed. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You have been asked to voluntarily participate in a research project entitled, "Treatment Optimization of Brain-Injured Warfighters: A Prescribed Sub-symptomatic Exercise Treatment (TOBI-SET)". This study is being done at the Intrepid Spirit Center at the Naval Hospital Camp Pendleton by researchers from the Traumatic Brain Injury Center of Excellence (TBICoE).

We are investigating the effects of a personalized physical exercise program on mild traumatic brain injury (mTBI) recovery. We are looking to see if an exercise program can impact your cognitive performance, physiological adaptation, locomotion, and military performance. We are conducting this study in order to evaluate two types of physical exercise techniques. We hope the results will contribute to efforts to improve treatments for mTBI patients including those experiencing persistent cognitive symptoms.

Involvement in this study will last for eight weeks. There will be an assessment the week prior to the exercise program, and the week following it. You will also be asked to attend a follow-up session at 3 months.

DoD
IRB NUMBER: NHCP.2022.0031
IRB APPROVAL DATE: 07/10/2023

The possible benefits to you as a research participant in this research study are that the program may reduce symptoms quicker, improve mental health, and increase physical fitness.

The chance of experiencing a risk or discomfort due to your taking part in this study is no greater than the "normal" risks of day-to-day life. However, it is possible that you may experience frustration, anxiety, headaches, general discomfort, skin irritation, fatigue, muscle soreness, and/or exhaustion due to the nature of the treatment.

Your alternative to taking part in this research is not to participate. Your decision will not affect your future care at *Naval Hospital Camp Pendleton or Intrepid Spirit 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.

NOTE: If you are providing consent as a legally authorized representative (LAR), "you" or "your" refers to the research participant.

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 military member with a history of mTBI and persistent post-concussive symptoms. The purpose of this research study is to learn about how a prescribed exercise program may be beneficial to those with persistent symptoms following a mTBI. The duration of participation per visit is 1 hour. You will have two 1-hour appointments at the ISC as well as three 1-hour exercise assignments at home each week.

There will be about 140 people taking part in the study at the Intrepid Spirit Center, Marine Corps Base Camp Pendleton, over a period of three years.

During the study, you will have two clinic visits per week for 8 weeks for treatment with study investigators. The total program will require 5 hours per week for 8 weeks. This study will take place in person at the Intrepid Spirit Center. Your appointments will occur every few days. In addition, you will come in for testing before and after the exercise program.

This study is looking at ways exercise may help with symptom relief following mild traumatic brain injury. Past research demonstrates that prescribed exercise is safe and effective in improving symptoms and returning patients to pre-injury activities following head injuries. However, this type of treatment is not well-studied in the military

population. This means that the exercise program in this study is considered experimental for the treatment of symptoms resulting from mTBI.

At the end of this research study, the clinical results, including research results about you will be shared with you. After you have finished participating in the study, you will be offered a feedback session with a study investigator to go over clinical data pertaining to neuropsychological testing results and/or improvement from the exercise treatment. Additionally, should you choose to share these results with your primary care manager (PCM), a study investigator will forward the relevant data to your PCM with the provision of a signed release form.

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 previously collected as a part of your regular medical care.

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

You will: receive 8 weeks of treatment with either group or individual sessions, with sessions lasting approximately 1 hour. During these sessions you will receive training and exercises that may help ameliorate symptoms you are experiencing. This study involves exercise training, neuropsychological, physiological, and physical assessments, and questionnaires.

In addition, you will complete testing during 3 different periods: before your program begins, after it ends, then again at 3 months post-training. These testing sessions will be administered by a researcher and will consist of: physical assessments, such as the combat fitness test; mental assessments such as paper-based and computerized activities; and physiological measures, such as blood flow, heart rate and balance tests. All of these assessments have been selected to help us understand your progress and to evaluate how much benefit you are receiving from the exercise program.

You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups. The group you are assigned to will determine which specific treatment program you will receive.

Participants in both groups will receive 8 weeks, 5 hours per week, for a total of 40 hours of a personalized exercise program. Participants will be trained in 2, one-hour sessions in the clinic and then will complete 3, one-hour sessions at home.

As part of the study, you will be completing questionnaires and asked to keep track of your exercise in a diary. In order to monitor physical activity in the clinic and at home, you will be provided with a wearable exercise sensor. You will have the option of downloading an app on your phone so that you can monitor your own activity as detected by this wearable device.

As part of this research, it is important for us to understand how our treatments effect your "real life". Most of the time, studies like ours just rely on laboratory tests and they may not tell us if the treatment really improves your ability to do our job. To better address this, we would like to contact your direct supervisor so that they can answer some questions, in the form of a survey, about your performance duty. Potential risks may include, but are not limited to, your participation in research may be disclosed. If you would like to participate in this part of the study, we will collect your supervisor's contact information from you. Your supervisor will fill out a survey and will NOT have access to any of your study data. If you do NOT want to participate in this part of the study, you can opt out of the survey, and it will not impact the rest of your involvement in this research

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

If you choose to take part in this study, there is a risk of:

- Frustration and anxiety over training progress and assessment performance
- Headache from the mental exertion of training and assessments (particularly if you are headache prone)
- Anxiety, claustrophobia, fatigue, nausea, dizziness, skin rash and/or irritation from sensors on wearable devices during the collection of physiological measures
- Fatigue, exhaustion, and muscle soreness during exercise training and assessments
- Your participation in this research study may be disclosed to direct supervisor.

Your participation in the job performance survey may impact your military career
The chance of experiencing a risk or discomfort due to your taking part in this study is no greater than the “normal” risks of day-to-day life. If you are injured during your study participation, you will not be compensated for your injuries by this research study. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

There may be risks to you and your career if we contact your supervisor and ask them to fill out the job performance survey. You have the option to opt out of participating in this survey.

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.

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 that the program may reduce symptoms quicker, improve mental health, and increase physical fitness. 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. If you choose not to participate it will not affect your current treatment plan or future care. You will still receive standard treatment, which may include techniques that are part of this study.

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

No, you will not receive any compensation for participating in this study. We will provide you with a certificate at the end of your participation to demonstrate our appreciation for your time.

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):

Jason Bailie, Ph.D.
Intrepid Spirit Center
Phone: (760) 719-4201
Mailing Address: 2016 San Jacinto Road
Camp Pendleton, CA 92058

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

USA MED RESEARCH ACQ ACTIVITY
820 CHANDLER ST
FORT DETRICK MD 21702-5014

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:

This study is being funded through a research grant awarded by the Congressionally Directed Medical Research Program (CDMRP) Office, US Army Medical Research Acquisition Activity.

13. LOCATION OF THE RESEARCH:

Intrepid Spirit Center, Naval Hospital Camp Pendleton
2016 San Jacinto Road
Camp Pendleton, CA 92058

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

No Financial Interests 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: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from the Naval Hospital Camp Pendleton, the Traumatic Brain Injury Center of Excellence, 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:

- Giving subjects ID numbers
- Keeping personally identifiable information (PII) physically and electronically separate from subject data. All electronic data will be housed in password-protected databases, and physical files will be located in a locked file cabinet in a researcher's office.
- Having study personnel trained on management of data containing PII and protected health information (PHI).
- Removing all links with your identity from the data before they are shared. Only coded data, which does not include anything that might directly identify you, will be shared with the general scientific community for research purposes.
- Not obtaining or storing identifying information, including PII, IP address and geo-location, on online survey forms
- Only allowing approved study team members to access survey platform servers and removing all data from online servers at the completion of the study

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

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.

Your information may be shared with any of the following:

- The sponsor of the study
- the Federal Interagency Traumatic Brain Injury Research (FITBIR)
- Representatives of the DoD
- State and Federal agencies which have authority over the research
- This hospital or clinic
- Accrediting agencies, such as Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Clinical staff who may not be involved in the study directly but who may become involved in your care
- Traumatic Brain Injury Center of Excellence (TBICoE)
- General Dynamics Information Technology (GDIT)
- Defense Health Agency (DHA)

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 coded.

16. AUTHORIZATION TO USE OR DISCLOSE (RELEASE) HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY:

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

A. What health information will be used or disclosed about you?

For this research study, we will collect information about your overall health, any side effects that you may experience, and how the exercise sessions are affecting your post-concussive symptoms. In addition, we will review your medical records and gather information pertaining to your medical history, including information about medical encounters, mental health diagnosis, medications, comorbidities cognitive assessments, concussion diagnosis and history, neuroendocrine tests, and imaging records. Research staff will also collect information related to your demographics (age, sex, race/ethnicity, education, and marital status) and military information (MOS, rank, branch of service, unit, and number of deployments), . The Personal Identifiable Information (PII) we collect will include the following: full name, email address, phone number, age, date of birth, place of birth, months and dates of major life events, medical record numbers, and military rank. PII will be stored separately from your study data and will be utilized only for creating study IDs. We will also ask you to complete various evaluations including taking part in neurocognitive assessments, physiological assessments, and self-report measures but this data will be collected separate from your medical record.

B. Who will be authorized to use or disclose (release) your health information?

Military Treatment Facilities (MTF) who have treated you in relation to your head injury, or subsequent symptoms resulting from a head or neck injury, will be permitted to use or disclose your health information in the research study. The members of the research team will also have access to your health information in order to confirm if you qualify to participate in this study, to

monitor your progress, and to analyze the research data. Additionally, your PHI may be made available to oversight groups such as the DoD and the IRB.

C. Who may receive your health information?

- The sponsor of the study, or its agents, such as data repositories
- Representatives of the DoD
- State and Federal agencies which have authority over the research
- This hospital or clinic
- Accrediting agencies, such as Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Clinical staff who may not be involved in the study directly but who may become involved in your care
- Traumatic Brain Injury Center of Excellence (TBICoE)
- General Dynamics Information Technology (GDIT)
- Defense Health Agency (DHA)
- Federal Interagency Traumatic Brain Injury Research (FITBIR)

D. What if you decide not to sign this Authorization?

You do not have to sign this form, but if you do not, you will not be able to participate in this research study.

The Military Health System **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this form.

E. Is your health information requested for <u>future</u> research studies?

Yes, your health information *<u>is</u>* requested for future research studies however, if you choose to withdraw from the study, your data will be disposed of properly.

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.

- If you want to revoke your Authorization, you must write to:

Principal Investigator: Jason Bailie, PhD
Phone: (760) 719-4201
Mailing Address: 2016 San Jacinto Road
Camp Pendleton, CA 92058

H. Does this Authorization expire?

Yes, it will expire on September 2026, which is the anticipated end date of this study.

I. What else may you want to consider?

- No publication or public presentation about the research described
- above will reveal your identity without another signed Authorization from
- you.
- If information that does or can identify you is removed from your
- health information, the remaining de-identified information will no longer
- be subject to this Authorization and may be used or disclosed for other
- purposes.
- In the event your health information is disclosed to an organization
- that is not covered by HIPAA (such as information requested for future use
- in other research studies), the privacy of your health information cannot be
- guaranteed.
- Once your information has been disclosed outside DHA, it may no
- longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

17. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. Coded information we collect during this study will be shared with the Federal Interagency Traumatic Brain Injury Research **(**FITBIR) System, which will allow others in the scientific community to view and analyze the data we collect. All links with your identity will be removed from the data before they are shared. Only de- identified data which do not include anything that might directly identify you will be shared with FITBIR users and the general scientific community for research purposes. You have several options with regard to this request. You may also choose either to not allow any further use of your data or give consent now for the use of your coded data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) 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.

18. 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 care provider 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 a choice to opt out of receiving results.
Due to the nature of the study and involvement of your supervisor, the findings may impact your military career.

19. VOLUNTARY PARTICIPATION

The decision to participate in this research study is completely voluntary. 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.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the point of contact for this study, Dr. Jason Bailie, PhD (Principal Investigator) at (760) 719-4202. If you decide to no longer participate in this research study, the researcher will remove your data that was part of this research study.

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 he determines 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.

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: Jason Bailie, PhD
Phone: (760) 719-4201
Mailing Address: 2016 San Jacinto Road
Camp Pendleton, CA 92058

Naval Hospital Camp Pendleton 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: Juliet Jimenez
Phone: (760)719-3663

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:

Phone: (619) 532-9927

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

Please initial next to one of the following choices to indicate whether we may use your data for future research:

_____ I give permission for my coded data to be used in future research

_____ I DO NOT give permission for my coded data to be used in future research

You may be eligible to participate in other studies as well. If you are interested in finding out about other research, please initial below:

_____ I consent to being contacted by phone or email for possible participation in future studies.

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