A Pragmatic Functional Rehabilitation Intervention for Mild Traumatic Brain Injury in Service Members (SMs): The Active Rehab Study

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants
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Title of Study: A Pragmatic Functional Rehabilitation Intervention for Mild Traumatic Brain Injury in Service Members (SMs): The Active Rehab Study

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CONCISE SUMMARY
You are being asked to participate in this research study because you are in the military and have suffered a mild traumatic brain injury (mTBI). The purpose of this study is to understand outcomes following mTBI under current practices and how different activities may help concussion recovery. Your decision to participate is completely voluntary. As part of the study you may be asked to complete questionnaires about yourself and your medical history. You will also complete clinical assessments of balance/coordination, thinking/memory, functional performance, and heart-rate/blood pressure at initial enrollment, around 2-weeks after enrollment, when you are symptom free from your mTBI and when you return to duty. You may be asked to complete various types of progressive activities, based on your symptoms. There is a potential you may benefit from the various activities in the progressive return, study exercises and/or study assessments. You may withdraw from the study at any time without penalty. Once you complete the return-to-duty assessment, your participation in the study is complete. Your medical records may be reviewed to obtain key information about your mTBI characteristics and recovery as well as injuries occurring after your return to duty. The risk to the study includes an increase in symptoms during assessments or activity and breach of confidentiality. The research team will make all efforts to reduce these risks including monitoring of symptoms and medical referral as needed and conducting assessments in private spaces as well as using unique identifiers to separate your personal information from study data to keep your information confidential.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Your decision will not affect your current or future care. 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.

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.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time. You may also wish to talk to others (for example, your friends, family, or your personal doctor) about your potential participation in this research study

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

What is the purpose of this study?
The purpose of this research study is to better understand outcomes across different types of post-injury return to activity strategies after concussion both under current practices and with an earlier introduction of symptom-directed activity. The study goal is to use this understanding to better define optimal treatment pathways following concussion in military personnel. You may experience an increase in your symptoms as part of study activities. The study team will help you monitor these and help connect you with your healthcare provider for any concerns.

You are being asked to be in the study because you are in the military and you have suffered a mTBI/concussion.

What is the 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 study team can confirm if you qualify for the study. This is the "screening process." The information to be provided may have been part of your regular care.

Study personnel will administer a study inclusion/exclusion screening checklist once you consent to study participation. Screening will also include confirmation of the diagnosis and severity criteria via medical record review or through the provider.

If you do not meet defined inclusion/exclusion criteria, you will not be asked to complete any additional study procedures and will be informed immediately by study personnel of your exclusion in study participation. Due to the nature of the inclusion and exclusion criteria, you will not be rescreened once determined you do not meet all inclusion and exclusion criteria.

Are there any reasons you should not be in this study?
You should not be in this study if:

- You are not current active duty personnel assigned to USASOC or the 82nd Airborne Division
- If your initial provider diagnosis of concussion/mTBI was more than 2 weeks after your injury
- If you are not able to report to clinic/provider at Fort Bragg for recruitment within 2 weeks of concussion/mTBI injury date
- This is your third concussion/mTBI in the past 12 months
- Your concussion/mTBI symptoms clear at rest and exertion within 48 hours of your injury
- You have a Moderate-Severe TBI
- You have had polytrauma (multiple other injuries at the same time as your concussion) or other injuries preventing completion of the initial study assessments within the initial 2-week window
- You do not consent to the study

How many people will take part in this study?
Approximately 142 active duty personnel at Fort Bragg will take part in this study.

How long will your part in this study last?
Following recruitment and screening, your involvement in the study will last from your time of enrollment until you complete a post full return to duty assessment. At the end of this research study the clinical results, including research results about you, will not be shared with you.

What will happen if you take part in the study?
You will be asked to complete a screening questionnaire. You may be asked to complete surveys on: general demographics including combat exposure, concussion history, medications, and medical history.

You may also be asked to completed measures of the following at initial intake, 2-weeks after your enrollment, when your symptoms are better, and when you return to duty (as appropriate at

each timepoint). During the study you will have approximately 4 visits with a member of the study staff at Fort Bragg. Each visit will last approximately 1-2 hours.

- Military performance: exertional and functional exams *(7 mins)*
- Physiological function: heart-rate and vital signs measures (*20 mins)*
- Clinical recovery: cognition, mental status, coordination, dual-tasking *(45 mins)*
- Visual-Vestibular screening *(10 mins)*
- Psychological health: symptoms, quality of life, psychological symptoms, impressions of care, life satisfaction *(25 mins)*

As part of the study, you may also be asked to:

- Track your activities and your symptoms during your time in the study and may be asked to wear an activity tracker
- Complete twice weekly follow-ups on symptoms and activity levels/progression
- Take part in progressive return to activity exercises (per normal progression or with early activities), directed by your medical providers and study personnel 3-4 times per week until you have been cleared to return to duty

You may also receive study reminders via text, email, or phone for the symptom/activity tracking and to remind you of study-related visits and activities.

Additionally, if you consent to take part in this study, researchers will also collect information from your medical records related to your traumatic brain injury. These records may include your medical records and the results of X-rays, CT or MRI scans, eye examinations, other injuries in the year after you injury, return duty and profile information, and provider examinations to determine characteristics and recovery trajectory following injury.

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before. During and after the study, the researchers will send information about your behavior and in some cases your child's genetic information to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. You may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you individually about specific studies. You may decide now or later that you do not want to share your information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you

would like more information about FITBIR, this is available on-line at http://fitbir.nih.gov.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There is a potential you may benefit from the various activities in the progressive return, study exercises and/or study assessments. However, there is no guarantee that you will benefit from being in this research.

What are the possible risks or discomforts involved from being in this study?
Your risk of experiencing discomfort or issues as a result of the assessments is minimal. However, when participating in the progressive return to activity or additional study exercises, you may experience increases in symptoms or other unknown discomforts (10—25%) as often occurs within any type of progressive activity/rehabilitation. You should report these to the researchers and/or medical professionals at the clinic. Your medical care provider can help decide if you need to change your activity level or type. In addition, should you feel you need to stop, you may do so at any time. The research staff and medical professionals will help you get follow-up care if needed.

There is a rare risk of emotional distress associated with completing the validated psychosocial scales. Any question may be skipped. In very rare instances, responses related to self-harm may be immediately communicated to your medical provider if they exceed threshold triggers.

Additionally, there is always a small risk of confidentiality breach we will make every effort to keep information confidential through unique identifiers, privacy during data collection, and storage of data on secure systems. There may be uncommon or previously unknown risks. You should report any problems to the research team and your medical provider.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive treatment. You should reach out to the medical providers for additional treatment options. There may be other research studies involving experimental treatments that could be helpful to your condition. You should talk with your medical provider about other options.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Recruitment will occur away from others. All study consent processes and assessments will be conducted in a private environment. Phone follow-ups and conversations will occur with only study personnel. Only the Fort Bragg based study employees will access medical records under the supervision of study investigators with access to medical records.

All electronic data will be collected and stored on password-protected and secure servers and computers. Some paper documents will be required, and these will be stored in a locked file cabinet in a locked office of study site personnel. During the study, your contact information will be securely stored at each clinical site for internal use during the study.

No identifiable data about you will be shared outside the research team or the data center. Participants will not be identified in any report or publication about this study. The researchers 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. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, an independent external research monitor, research sponsors, or government agencies, including the study sponsor, the Department of Defense, for purposes such as quality control or safety. As such, the Department of Defense may access research records as a part of its human subjects protection oversight activities in accordance with DoD Instruction 3216.02. All data will be stored within secure servers at UNC-CH or on DoD cleared computers/drives. Identifiers will not be linked to study data. A copy of any linked data will be stored electronically, separate from the other study-related data. A copy of this consent form will be available to your primary unit provider as needed. This will allow people caring for you to know what tests or activities you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study. 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

Additionally, all public dissemination of study data [e.g. manuscripts and scientific abstracts] will undergo Public Affairs, Intelligence and Security reviews as applicable.

Your records related to this research study may only be shared 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 online at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The committee responsible for protecting research participants, called the Institutional Review Board (IRB), may also look at your records as part of their duties. These duties include making sure that the research participants are protected.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What happens if the researchers see an incidental finding?
There is a possibility that while reviewing your study assessment information, the researchers may see an abnormality that they did not expect to see in this study. This is what is called an "incidental finding."

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

The researchers will also give information about this incidental finding to your primary doctor or 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.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be

responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you are injured because you took part in this research study and you are a DoD healthcare beneficiary, 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 think you have been injured from taking part in this study, call the Principal Investigator or study contacts at the phone number and/or email provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal. The study team will attempt to follow-up with you for any remaining safety concerns and to complete the end of study form. There are no known consequences of your withdrawal from the study.

You will no longer be eligible for research-related treatment. Contact your personal doctor to discuss medical treatment for your condition.

Please note that taking back your consent to take part in this research does not take back your HIPAA Authorization to use or reveal your protected health information. To take back your authorization, please send a letter to the Principal Investigator as discussed in the HIPAA form.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
There are no known cost to you, other than your time for the study. All research activities will be conducted by the study team and covered by the study.

Who is sponsoring this study?
The Department of Defense is sponsoring this study.

This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What is the location of the research?
This research study will take place at USASOC facilities, the Intrepid Spirit Center and the Robinson Health Clinic.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

Womack Army Medical Center (WAMC) Human Research Protection Program (HRPP) Office
The Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator: Caryn L. Duchesneau
Phone: (301) 639-0374
Email: caryn.l.duchesneau.civ@mail.mil

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Future use of information and/or specimens

Please initial the sentences that reflect your choices:

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

_____I *do not* give permission to use my health information for future research studies.

_____I give permission to use my health information for future research studies.

_____I *do not* authorize the storage of data collected as a part of this study for future use in research studies.

_____I authorize the storage of data collected as a part of this study for future use in research studies.

With regard to future research studies done on stored data that has a link to my personal identity.

_____I *do not* wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that study investigators may use any appropriate identifier to locate me in the future.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Your signature below indicates that:

- You authorize the Military Health System to use and reveal your health information for the research purposes stated above
- You have read (or someone has read to you) the information in this consent form.
- You agree that you 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 you. You have been provided with the opportunity to ask questions
- You voluntarily consent to take part in this research study.

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

_____ _____

Signature of Research Subject Date

_____

Print Name of Research Subject

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent