Neurofeedback Impact on Chronic Headache, Sleep and Attention Disorders Experienced by Veterans with Mild Traumatic Brain Injury

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Department of Veterans Affairs
VA Pacific Islands Health Care System
Spark M. Matsunaga Medical Center
Honolulu, Hawaii

VA RESEARCH CONSENT FORM

Version Date: September 27, 2019

Subject Name: _____ **Date:** _____

Title of Study: Neurofeedback Impact on Chronic Headache, Sleep and Attention Disorders Experienced by Veterans with mild Traumatic Brain Injury

Principal Investigator: Dr. Judy Carlson, EdD, APRN, BCN **VAMC:** Honolulu

Study Sponsor: *Department of Veterans Affairs Clinical Science Research and Development (CSR&D) Services Merit Review Award Program*

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study will evaluate neurofeedback (NFB) training as a low risk, non-invasive, effective treatment for our Veterans diagnosed with mild traumatic brain injury (mTBI) and experiencing chronic post-concussive symptoms. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn if NFB will reduce chronic headaches and enhance sleep, attention and quality of life in Veterans with mTBI.

WHAT DO I NEED TO TAKE PART IN THE STUDY?

To participate in this study, the following must be met:

- OEF, OIF, OND Veteran who received a mTBI while in theatre and diagnosed with a mTBI
- Male and non-pregnant female ages 18 to 65, inclusive
- Have chronic headaches, insomnia, and attention difficulties
- Able to read and write English
- Able to comprehend what they read
- Able to follow directions
- Able to come to VA Pacific Islands Honolulu (Tripler Campus) 3-5x/week for 8-10 weeks
- Access to telephone
- Reside on the Island of Oahu or able to stay on Oahu for 8-10 Weeks

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

NFB is like other biofeedback processes in which information about a person's specific body functioning is made known to the person through a special computer program, which can help that person make the specific body function work better through training.

We will randomly place Veterans who agree to participate into one of two groups, (an intervention or a control group). You will have an equal chance of being in either group. Those placed in the control, will also receive NFB after completion of the control group activities.

Veterans who are placed in the intervention or delayed intervention group will receive NFB up to 5 times a week, but usually 3 times a week for a total of 20 sessions. Each session is an hour long.

Both the intervention and control group will participate in four assessment sessions (lasting up to 2 ½ hours each) that involve completing questionnaires and a 20-minute attention evaluation.

The assessment sessions will occur at the beginning of the study, at 4-6 weeks, at 8-10 weeks, and 2-months later. You will receive $25 for taking the baseline assessment; $50 each for 4-6 week and 8-10 week assessments, and $100 for the 2-month follow-up assessment. A participant will receive $27 for gas, time and valet parking for each intervention and assessment session.

Participation in this research will last about 4 months for those in the intervention and 8 months for those in the delayed intervention group. Remember, all participants will receive the neurofeedback treatment by the end of the study.

WHAT ARE KEY REASONS I MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

A person who participates in this study may experience a reduction in his or her chronic head aches, and an enhancement of sleep, attention and quality of life. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS I MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There may be a worsening of symptoms until the individualized training plan for a person can be identified. During an NFB session, brief moments of dizziness while sitting, muscle tension, or tingling may be experienced. For a complete description of risks, refer to the Detailed Consent.

DO I HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF I HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

You may contact Dr. Judy Carlson or a member of her research team during the day or after hours at (808) 433-6677 if you have questions, concerns, complaints or wish to provide input about the research study or in the event of illness or injury that you believe to be related to the research study. If Dr. Judy Carlson or a member of her research team cannot be reached or if you wish to talk to someone other than Dr. Judy Carlson or a member of her research team, you may contact the Institutional Review Board by calling the VAPIHCS Research and Development Office at (808) 433-7785 (if you are in Oahu). If you are outside Oahu, you may call 1-800-214-1306, press 1 and ask to be transferred to extension 7785. If you have any questions about your rights as a research participant, you may contact the VAPIHCS Office of Regional Counsel at (808) 433-0136.

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn whether neurofeedback (NFB) will help our Veterans who continue to have problems related to the concussion (also called mild traumatic brain injury or mTBI) they received while at war. Some of these problems that are related to a concussion are headaches, trouble thinking, and difficulty with sleep and negative feelings about their life that can last for many years after their injury.

HOW LONG WILL I BE IN THE STUDY?

The entire research study is expected to take approximately 5 years. We plan to enroll 72 Veterans. Your individual participation in the project will take 4 months if you are in the intervention group and 8 months if in the control/delayed intervention group.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you decide to take part in this study, this is what will happen:
1) You will receive neurofeedback if you select the envelope that would place you in the intervention group. If you select the envelope that places you in the control group, you will not receive neurofeedback until after you complete the control group activities. As a member of the control group you would be required to complete the initial assessment and come in at 4 weeks after enrolled in the study, at 8 weeks and 2 months later for assessment sessions. While in the control group, you will also receive brief (15 minute or less) calls once a week from one of the Investigators to touch base with you and discuss a relevant health topic relating to your current chronic post-concussive symptoms. In either case, you will continue with your usual care and treatments as prescribed or needed.

2) Dr. Judy Carlson, EdD, APRN and Co-Investigator will be overseeing the study. They, along with any other member of the research team, will be responsible for explaining to you about the study and its potential risks and benefits of the treatment as well as obtaining consent from you to take part in the study.

3) Dr. Judy Carlson, EdD, APRN, an Advance Practice Registered Nurse (APRN) and Board Certified in Neurofeedback (BCN), will be one of the NFB Specialists who will be providing the NFB treatment. Dr. Carlson has over 20 years' experience providing this treatment. The other NFB specialists are part of the investigative team and are licensed healthcare professionals who have been fully trained to offer NFB.

4) A research coordinator and research assistant will be helping with the study. They will be contacting you about the study, making appointments and appointment reminders, assessment visits and any other research related details. Research staff will reach out via telephone or mailing or electronically (e.g., e-mail or VA secure messaging) based on your preference(s). Copies of the written communication will be saved and kept with research records.

5) The research will be done within space designated for VA research on the VA or Tripler campus.

6) Each neurofeedback session will take 1 hour in length and you will come in up to 5 times a week, but usually three times a week for 8-10 weeks to receive a total of 20 sessions.

a. While you are comfortably sitting, the neurofeedback training system (which resembles a very high-tech computer game) will be connected to you by thin sensors (that look like thin tubing) with little cup ends that are placed against your scalp using an easily removable paste-like substance.

b. The neurofeedback system can pick up the brain waves from the sensors and will interpret your brain waves and the special computer game will respond to your brain wave patterns. In general, a person's brain waves can change based on how they feel. For instance, if a person is very stressed, brain patterns are very fast. Or if a person is very sleepy, the brain wave patterns are very slow. When a person is focused, calm, and alert, their brain wave patterns will move at a steady, moderate rate.

c. While training on a neurofeedback system, when you become focused, calm, and alert, the computer will recognize this and let you know by automatically displaying on the computer screen the positive progression of the game you are playing, such as the plane moving forward or a flower opening.

d. The brain really likes to be in this pattern and when it is, people feel good. As a result, any issues experienced by a person may decrease by the completion of the entire program.

e. Each person's brain has a particular setting on the neurofeedback equipment it prefers, and it may take a few sessions before the NFB Specialist identifies that particular setting. When that setting is identified, certain symptoms, for example, insomnia, may get better. Until the NFB Specialist finds that particular setting, it may be possible that some symptoms may feel a little worse. This is not bad news, since it informs the NFB Specialist more about a person's brain and the particular setting that a brain prefers can be found more quickly. The NFB Specialist can always find that preferred setting with the individual's help by letting the NFB Specialist know how they are feeling. If any discomfort occurs, it is very short-term, not usually more than a minor discomfort, e.g. muscle tension, headache, and easily fixed.

f. As with other types of training, it takes multiple times doing the neurofeedback training before it becomes a usual part of life and that is the reason for the 20 sessions.

7) After your consenting and initial assessment visit, you will come in for three more assessment sessions (at 4-6 weeks, at 8-10 weeks, and at a 2-month follow-up) that will take approximately two and a half hours. During the assessment sessions you will complete 12 questionnaires and take a 20-minute evaluation of attention. You are free to skip any questions that you would prefer not to answer.

8) A research assistant or research coordinator will be overseeing the assessment sessions.

9) Your responsibilities in participating in this study:

- If in the intervention group, you will receive neurofeedback 1-hour sessions up to 5 times but usually 3 times a week for 8-10 weeks.
- Both groups (intervention and control) will come in for two-and-a-half-hour assessment sessions initially, at midpoint (at about 4-6 weeks) at the end of the study (at about 8-10 weeks) and 2 months later to answer 12 questionnaires and take a 20-minute evaluation of attention. You will need to bring a list of your current medications to each assessment session in addition to any additional or change in treatments you may be receiving.
- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

There is minimal risk to those Veterans who receive neurofeedback. Because this intervention is a personal biofeedback process, whereby you will be training yourself based on your own brainwave responses, no serious adverse event is anticipated or expected. Some reported brief side effects include: anxiety, a tightness in muscles, stomach discomfort, or mental cloudiness which had gone away within minutes. The NFB Specialist will be checking with you during the session to determine how you are feeling. If you are experiencing any discomfort during the session, the NFB Specialist will intervene to adjust the program, so you will feel more comfortable. Most people feel relaxed and calm during and after NFB training.

As mentioned earlier, each person's brain has a particular setting on the equipment that it prefers, and until the NFB Specialist finds that particular setting, it may be possible that some symptoms may feel a little worse when the individual goes home or the next day. This can be considered good news since it informs the NFB Specialist more about a person's brain and the particular setting that a brain prefers can be found more quickly. The NFB Specialist can always find that setting especially with the individual's help by letting the NFB Specialist know how they are feeling. In very little time, an NFB Specialist can find that setting, and any symptoms the individual was experiencing before the study may begin to get better. If any discomfort occurs at all, it is very short-term, not usually more than a minor discomfort, and easily adjusted.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

There are some limited risks related to completing questionnaires. Some people become uncomfortable at being asked questions about their stress or psychological well being. If, for any reason, you wish not to answer specific questions, or you wish to terminate the session, you will be able to do so.

To reduce any possible risk to pregnant women and the possible hormonal influence on headaches experienced and sleep patterns, pregnant women (or women who are planning to become pregnant in the next five months) will be excluded from participating in this study.

You will be asked during the consenting process to complete a Suicide Risk Assessment form. If a positive screen is obtained, you will not enroll in the study. Immediate assistance will be provided based on your preference and/or need. The Veterans Crisis Line offers free and confidential

assistance 24 hours a day. Call 988 or 1-800-273-TALK(8255) and press 1. If appropriate, you may enroll in the study at a later date.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?
We cannot promise that you will get any benefits from taking part in this research study. However, possible benefits may include a decrease in the number and severity of headaches, enhanced sleep, and attention ability and an overall perception of enhanced quality of life. In addition, the participant may experience enhanced emotions. Indirect benefits include the knowledge that the participant has contributed to the body of knowledge relating to the effectiveness of NFB. There may be no direct benefit to volunteers.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?
Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- All information will be kept in locked filing cabinets and on computers protected with passwords. Only the investigators, research coordinator and research assistant will have access to your data. The statistician will have access to your data that has been de-identified for the purposes of inputting data into a statistical program and analyzing the data. Only the project staff will have access to your name and IDs. This information will be kept in a locked secure filing cabinet. The investigators, research coordinator and research assistant will have your name and contact information.
- Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.
- Identifiers will be removed from private information and after that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you should you agree to that on this consent form.
- Your participation in this study will be noted in your health record, however no other information related to it will become part of your official medical record.

- While this study is being conducted, the research team will have access to your research related health records.
- While this study is being conducted, you will not have access to your research related health records.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?
You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE ANY PAYMENT?
Each of the four assessment sessions will take approximately 2.5 hours of time and each participant will receive a $25 gift card for the baseline assessment, a $50 gift card for the 4-6 week assessment and the 8-10 week assessment and a $100 gift card for the 2-month follow-up assessment session. In addition, participants in the intervention group will receive a $27 gift card for gas, time, and parking each time they complete an NFB and assessment session. Each subject in the intervention group will complete 20, one hour, sessions over an 8-10-week period; receiving up to 5 but usually 3 NFB sessions weekly. Subjects in the post control intervention group, will receive payment of a $27 gift card for gas, time, and parking for the 20 NFB and assessment sessions and a $50 gift card for the midpoint assessment and end of treatment assessment and a $100 gift card for the 2-month follow-up assessment session.

Research staff will have the gift cards available for each participant. The participant will need to acknowledge that they received the gift card. Written acknowledgment methods will be used.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). This study is a minimal risk study and no injury is anticipated, however, that does not alter the rights and welfare of the participants.

DO I HAVE TO TAKE PART IN THE STUDY?
Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which the participant is otherwise entitled.

The participant may withdraw and still receive the same standard of care that he or she would otherwise have received.

For data already collected prior to the participant's withdrawal, the investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Participants may be terminated from the study without their concurrence for health and safety reasons. Also, participants who become non-compliant with study procedures may be terminated from the study. For example, participants who miss more than two neurofeedback sessions and who do not reschedule the sessions they have missed will be dropped from the research protocol and they will be notified by mail about their termination from the study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Any new significant findings developed during the research that may affect the participant's willingness to continue participation will be shared with the participant.

IF ONE OF THE INVESTIGATORS IS YOUR TREATING PROVIDER

As previously indicated, participation in this study is totally voluntary and will not impact the medical treatment you receive at the VA. Thus, if one of the investigators is your treating provider, he or she will remain as your provider and you should expect to receive the same quality of care even if you decide against participating in this study. If you decide to participate in this study, you should understand that the role of the treating provider is that of investigator. Thus, his or her duty is to conduct an objective study and to ensure the safety of each participant within the context and time frame of the study. It is important that you are aware that this role is distinct from any role he or she has as your treating provider.

FUTURE USE OF DATA AND RE-CONTACT

The de-identified study data from the assessment forms could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you if you agree on this consent form. The Privacy Officer and Information Security officer will certify the database is de-identified.

In addition, your contact information will be kept for future possible relevant studies if you agree on this consent form. This information will be stored in a secure, VA password protected computer file. Only the investigators on this present study will have access to the information. If a new study has as part of its plan to determine the long-term effects of NFB, you will be contacted to see if you would like to participate in this new study. The new study would need to be approved by the Institutional Review Board, which reviews all new studies. All study information and contact information will be kept in a secure VA password protected computer file. Participants can rescind their consent about their study

information and contact information for future study use at any time upon communication with the primary investigator.

If participants agreed to have their de-identified data kept for future use, but later rescind this consent, these data cannot be removed since they are de-identified and no linkages are possible.

Please place your initials in the box next to the statement to which you agree.

☐ **I agree to have my de-identified assessment data available for future use in other studies by the investigators of this study.**

☐ **I agree to have my de-identified assessment data distributed to other investigators for future use in other studies.**

☐ **I agree to having my contact information saved in a secure password protected file on a VA server by the investigators of this study for possible follow-up studies relating to the long term effects of neurofeedback.**

☐ **I agree to participate in this current study.**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ (Print Name), a member of the research team, has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I also confirm that I have read this consent, or it has been read to me. I confirm I have indicated my preference for the future use of my de-identified data or contact information by my placement of my initials next to each statement to which I agreed. I will receive a copy of this consent after I sign it. A copy of this signed consent will also be put in my medical record.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date