Title of Study: Cognitive-Communication Screening and Early Therapy for Adults with Concussion/Mild Traumatic Brain Injury

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Northern Arizona Healthcare
Institutional Review Board

NAH/NAU Collaborative Research
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

"Cognitive-Communication Screening and Early Therapy for Adults with Concussion/mild Traumatic Brain Injury"

Date: 9/01/16

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This Consent Form may contain words that you do not know. You should ask the study investigator(s) or the study staff to explain any words or information that are not clear.

BACKGROUND

You are being invited to participate in this research study because you recently received medical care at Flagstaff Medical Center for a concussion/mild traumatic brain injury (mTBI). This study looks at cognitive-communication abilities in adults following a concussion/mTBI. Cognitive-communication is the relationship between cognition, and its influence on verbal and nonverbal communication. Your participation is voluntary. This study is being conducted in Flagstaff and the surrounding communities, and approximately 300 research subjects will be enrolled.

This study is being funded by the National Institutes of Health and will be conducted by Emi Isaki, Ph.D., SLP; Viacheslav Fofanov, Ph.D.; and Cynthia D. Beckett, Ph.D., RNC-OB, LCCE. The individual chiefly responsible for this study is Dr. Isaki, who can be reached at (928) 523-7481.

Drs. Emi Isaki, Viacheslav Fofanov, and Cynthia Beckett will be compensated by the sponsor for their efforts and involvement. Flagstaff Medical Center and Northern Arizona University will receive some of this compensation for their part in the study.

If you decide to participate in this study, you will be asked to sign this consent form.

PURPOSE OF THE STUDY AND WHAT IS EXPERIMENTAL

The purpose of this study is to determine if selected cognitive and communication screening measures given at two weeks after a concussion/mild traumatic brain injury (mTBI) will identify any persistent symptoms at four weeks following injury. If the screening measures identify persistent cognitive-communication symptoms, another purpose of this study is to determine whether early cognitive-communication therapy will produce changes in functional outcomes (e.g., work, school, daily activities).

PROCEDURES

If you decide to take part in this study, this study will involve the following procedures:

1) Session one (1 hour) – Dr. Isaki or a research assistant will review the informed consent form with you, answer any of your questions, and if you would like to participate in the study, you will be asked to sign the informed consent form. Next, Dr. Isaki or a research assistant will ask you to complete a short worksheet requesting personal information (e.g., date of birth, age, gender, date of injury, ethnicity, address, years of education, occupation, phone number, and email address) and identification of symptoms related to concussion/mTBI, and then complete five short screening measures related to cognitive-communication. Finally, you will review an education sheet of symptoms and expectations for recovery following concussion/mTBI, and schedule an appointment for the second screening session.

2) Session two (1 hour) – Dr. Isaki or a research assistant will ask you to complete five short screening measures related to cognitive-communication. If the screening measures note any problems after the second session, Dr. Isaki or a research assistant will contact you to schedule therapy one time a week for one month. If you require therapy, you will be randomly assigned to one of two groups. Group one will receive therapy one month following injury, and Group two will receive therapy two months following injury. Random assignment means that you have an approximately equal chance of being assigned to different starting times for therapy. If you are identified as requiring cognitive-communication therapy, the services will be offered to you at no cost.

Typically, the standard of care for patients with concussion/mTBI is to receive cognitive-communication therapy much later in recovery (up to six months to a year following concussion/mTBI). This occurs only if patients report that they have problems to their physician

and then are referred for rehabilitation services. Some patients continue to have cognitive-communication problems, but they do not receive any services to address the problems. In the current study, both Groups one and two will be provided therapy early in recovery.

3) If you have been identified for cognitive-communication therapy, you will be asked to complete a functional outcome measure questionnaire prior to beginning your first therapy session and on the last day of therapy. Therapy will consist of: learning to use memory strategies, learning how to improve executive functions (e.g., initiation, insight, planning) and multi-tasking abilities, determining environmental changes, and identifying problematic cognitive-communication situations.

4) Everyone who participates in this study will be contacted at six months and one year after the concussion/mTBI to ensure that symptoms of the injury have resolved. If symptoms related to concussion/mTBI have not resolved, referrals will be made to see a Northern Arizona Healthcare Research Consultant neurologist, your primary physician, or other healthcare professionals.

DATA COLLECTION

1) Cognitive Screenings & Questionnaires: For the first and second screening sessions, you will be asked to respond to questions on the concussion/mTBI questionnaire which will ask you for personal information and information related to symptoms related to the injury. Additionally, you will be asked to complete the five screening measures to obtain scores on these items. The screening measures evaluate memory, multi-tasking, executive functions (e.g., planning, initiation), and speed of processing. The responses on the concussion/mTBI questionnaire and scores on the screening items will be used for data. If you require cognitive-communication therapy, data will be collected for individual therapy sessions that will include performance on personalized therapy goals and the functional outcome questionnaire responses (given at week one and week four of therapy). Finally, your responses to a follow-up questionnaire related to concussion/mTBI will be obtained at six months and one year post-injury for data.

2) Audio/Video Recordings: All sessions will be audio and video recorded to ensure that your responses are scored and transcribed correctly, after which they will be destroyed (usually within one week of being recorded). Access to the audio and video recordings will be restricted to Dr. Isaki and the research assistants.

3) Phone Call Follow-up: At the six month and one year follow-up phone call, data will be collected from responses to a follow-up questionnaire related to concussion/mTBI symptoms.

RISKS AND DISCOMFORTS ASSOCIATED WITH THIS STUDY

There are some risks involved in this research study. Additionally, there is always the potential risk of uncommon or unknown side effects that could occur. You may experience all, some, or none of the side effects described below. If you have any unusual symptoms, you must report them immediately to your study investigator(s).

Potential risks to you can include: 1) Possible fatigue, anxiety, or fear associated with being asked to complete an unfamiliar battery of screening measures with unfamiliar individuals. 2) Possible feelings of anxiousness or sadness with any cognitive or communication deficits found following the initial or second screening session. 3) Possible feelings of anxiety when asked about personal information (e.g., age, date of birth, etc.) and concussion/mTBI symptoms. 4) Possible feelings of anger (due to the inability to improve on testing performance) or sadness if the second screening session identifies symptoms that require therapy. 5) Possible concerns about the security of how the screening and therapy information will be stored, and who has access to the information.

Dr. Isaki and her research assistants will do everything possible to ensure that you are comfortable during the screening sessions. All of the research assistants participating in this research study have received clinical training to work with adults with concussion/mTBI. The rooms used for therapy in the NAU Department of Communication Sciences and Disorders are quiet and conducive to clinical evaluations and therapy. You can decide to discontinue participation at any time.

For data security, Dr. Isaki has consulted with a Northern Arizona University Information (NAU) Technology (IT) specialist to ensure that the data will be stored on an encrypted, password protected database specifically dedicated for this research project. Access to the database will be given only to individuals involved in this research at NAU. No one outside of the NAU system will be allowed access to the data. The process to determine when the data were accessed can be monitored through the NAU system by reviewing who logged into the database at what specific time using the password. Personal information will be kept separate from the screening measure scores, questionnaire scores and responses, and therapy data (if applicable). Each subject will be provided a code for anonymity consisting of letters and numbers which will be used for data collection during screening and therapy (if needed).

In order to maintain confidentiality for audio, video, and paper data, all the audio and video data will be collected, transcribed, and erased within one week of collection. Dr. Isaki and the research assistants will have access to the database files so they can add new information when obtained. Dr. Fofanov, will have access to the files for statistical analyses. Paper data containing personal information will be kept separately from other paper data in different locked file cabinets in Dr. Isaki's locked office in the College of Health and Human Services, Department of Communication Sciences and Disorders (CSD), room 308, for three years following the study and then destroyed.

No names, addresses, phone numbers, or birthdates will be used in any presentations or research papers.

BENEFITS ASSOCIATED WITH THIS STUDY

Although participation in this study offers some benefits, there are no guarantees that participation will result in better outcomes. Participation in this study could offer certain benefits. Those benefits could include: 1) You will have the direct benefit of being contacted for follow-up for one year after the concussion/mTBI to ensure that symptoms related to concussion/mTBI have resolved. 2) If needed, you will receive the benefit of having referrals made to neurologists, your primary care physician, or other healthcare professionals if symptoms do not resolve. Based on the risks which are thought to be minimal, the potential benefits to subjects and the overall knowledge obtained from this study appear to outweigh the risks.

Benefits to Society: The knowledge gained from this study could identify selected screening measures that would be administered quickly in hospital settings to allow healthcare workers to determine which patients with concussion/mTBI are susceptible to persistent cognitive symptoms. These patients can then receive more focused follow-up care if they are identified early in recovery. Additionally, knowledge about when to provide cognitive-communication rehabilitation and the effects of the therapies related to concussion/mTBI can change how services are delivered to this population of patients.

COSTS AND COMPENSATION ASSOCIATED WITH THIS STUDY

You will be paid $25.00 by check at the end of the first screening session, and $30.00 by check at the end of the second screening session. If you require cognitive-communication therapy, you will not be paid to participate in treatment. However, you will receive therapy free of charge. NAU parking fees will be paid for all screening and therapy sessions.

If you require further services from physicians or other healthcare professionals, the costs of those services, including medications, further testing, and hospital related charges will be billed to your insurance company or based on fee for service. You will not be compensated for costs outside of this research study.

Subjects will be responsible for their own transportation to and from NAU. These costs could include gas and bus fares.

PRIVACY & CONFIDENTIALITY

If you participate in this study, it will involve the use and disclosure of your information, including your ***name which is required for payment.*** Other personal information that will be collected will include: address, phone number, email address, birthdate, and date of concussion/mTBI which will be stored in Dr. Isaki's locked office in a locked file cabinet. You will be given a code for anonymity consisting of letters and numbers for identification throughout the study matched to your personal information. This information

will not be used for any publications or presentations. The information to be used and disclosed in papers and presentations include total number of subjects, and averages, total numbers, and/or group ranges for ***age, gender, ethnic origin, years of education, occupation, questionnaire results, cognitive-communication screening measure scores, and functional outcome scores.***

The following persons and classes of persons are authorized to use and/or disclose your information: The study investigator(s) identified elsewhere in this consent form as being responsible for this research, or as "Investigators," and support personnel who are assisting them in this research.

Your information may be disclosed to the following persons or classes of persons (recipients):

- The Northern Arizona Healthcare Institutional Review Board (IRB)
- Northern Arizona University Institutional Review Board (IRB)
- The National Institute on Deafness and Other Communication Disorders - NIH
- Office of Human Research Protections (OHRP)

It is possible that information which is disclosed to one or more of the above recipients will be re-disclosed and will no longer be protected by the terms of use and disclosure described in this consent form.

The purposes for which you would be authorizing the use and disclosure of your information, as a participant in this research project would be to promote the objectives of this research project as described elsewhere in this consent form, and to facilitate related monitoring, regulatory oversight, quality assurance activities, and payment activities.

There is no expiration date to your authorization for the use of disclosure of your information as described above. However, you may revoke your authorization at any time, and the revocation will be effective upon receipt. Please note that if you revoke your authorization, information that has already been obtained will continue to be used and disclosed as described above. Your revocation must be made in writing and addressed to the person noted below:

Principal Investigator's name	Emi Isaki, Ph.D., CCC-SLP
Principal Investigator's address	Northern Arizona University Department of CSD P.O. Box 15045 Flagstaff, AZ 86011-5045

By signing this consent form, you are authorizing the above uses and disclosures of your information as described above. If you do not sign this consent form, including this authorization, you will not be eligible to participate in this research project.

ALTERNATIVES

If you choose not to participate in the cognitive-communication therapy offered at NAU, alternative services are available from other speech-language pathology providers. You can go to your primary physician to determine if you are eligible for a referral to these services. However, you will not be provided with reimbursement for medical care other than what your insurance carrier may provide nor will you receive other compensation.

CONTACT PERSONS

Emi Isaki, Ph.D. or her research assistants have discussed this research study with you and you have been given the opportunity to ask questions which have been answered to your satisfaction. If you have any further questions regarding this study, you should call Dr. Isaki at (928) 523-7481.

An Institutional Review Board has been established at NORTHERN ARIZONA HEALTHCARE, composed of physicians, community representatives and members of the Hospital Administration. The purpose of this Board is to protect the interests of human research participants participating in research. The Board is an impartial third party not directly involved with the research. The Board invites any comments, questions or complaints which you may have regarding: 1) treatment; 2) response to this treatment; 3) patient's rights as an investigational research participant; and 4) research related injury. Comments may be addressed to:

Chair, Institutional Review Board – NORTHERN ARIZONA HEALTHCARE
c/o NAH IRB Office
1200 N. Beaver St, Flagstaff, AZ 86001
Telephone: (928) 773-2346 - 8:00 AM to 5:00 PM Monday through Friday.

VOLUNTARY PARTICIPATION

Participation in this study is strictly voluntary. You understand that you are free to withdraw your consent to participate in this treatment program at any time without prejudice to your subsequent care. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

You are free to seek care from a physician of your choice at any time. If you do not take part in or withdraw from the study, you will continue to receive care.

Your study investigator(s) may withdraw you from this study at any time he/she feels it is in your best interest. Your therapy will continue until your study investigator(s) and/or you decide to stop. This may include discontinuation without your consent. The study investigator(s) in charge of this protocol may remove you from the study without your consent based upon his/her medical judgment regarding your safety or due to your willful failure to follow the study schedule.

NEW INFORMATION

You will be informed of any significant new information pertaining to your safety. Any new important new information that develops during the course of this study, which may influence your willingness to continue participation in this study, will be told to you.

SIGNATURES

Research Participant's Printed Name:

_____

_____

Research Participant Signature (or legal representative) **Date**

By signing above, you acknowledge that you have read this Consent Form, you have been given the opportunity to ask questions and you understand what participation in this study will involve. You freely consent to participate, with the understanding that you may withdraw your consent by submitting your desire to withdraw in writing to the principal investigator at any time without penalty or loss of benefits to which you are otherwise entitled. You also acknowledge that you have received an appropriately executed copy of this informed consent and the Medical Research Subject Bill of Rights.

_____ _____

Witness Signature **Date**

_____

Investigator Name (Printed) (or person conducting informed consent)

_____ _____

Principle Investigator Signature **Date**

The above-signed hereby certifies that he/she has discussed the research project with the participant and has explained all of the information contained in the Consent Form to the participant, including any adverse reactions that may reasonably be expected to occur. The above-signed further certifies that the participant was encouraged to ask questions and that all questions were answered.

MEDICAL RESEARCH SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to participate in medical research.

As a research subject (participant), you have the following rights:

1. To be told the nature and purpose of the research.
2. To be told what will happen and whether any of the procedures, drugs or devices are different from what would be used in standard practice.
3. To be told about any significant risks, side effects or discomforts that can be reasonably expected from the research.
4. To be told of any expected benefits from participating in the research.
5. To be told the other available treatments that could be chosen instead, and how they may be better or worse than participating in the research.
6. To be allowed to ask any questions concerning the research both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate at all or to withdraw consent to participate at any time, without jeopardizing the right to receive present or future care.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether to agree to participate in the research.

Date: _____
Time: _____

Signature: _____ (patient)

Signature: _____ (parent/legal guardian)

If signed by other than patient, indicate relationship: _____

Witness: _____