NCT Number: NCT06375421

Title: Pilot and Feasibility of MEMI for Chronic Traumatic Brain Injury

Document Date: 09/09/2024

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Emily Morrow, Ph.D., CCC-SLP **Revision Date: 06/09/2023**
Study Title: Development of Ecological Momentary Intervention for Memory in Chronic Traumatic Brain Injury
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

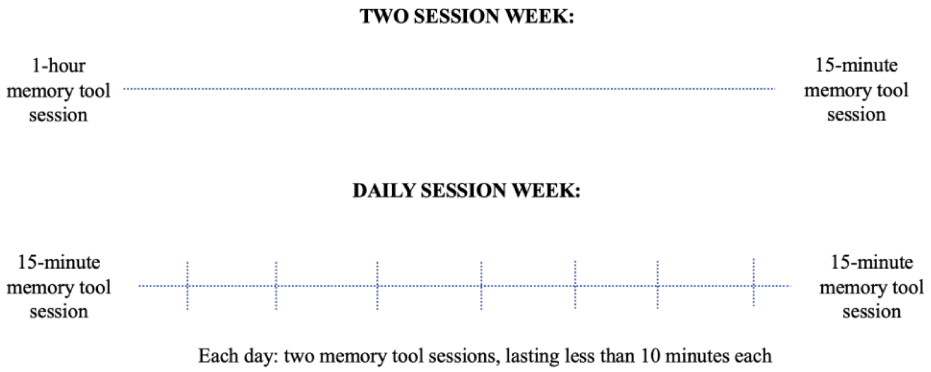
You are being asked to take part in this research study because you have a history of traumatic brain injury. The purpose of this study is to get feedback on a tool that is designed to track memory in everyday life. Your participation can help us learn how we can improve the tool so it can be helpful to others in the future.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Procedures to be followed and approximate duration of the study:

During this study, you will be asked to use the memory tool and tell us about your experience. Your participation will include:

- **Cell phone program:** Using the memory tool on your cell phone for two weeks. There are two different schedules for the two weeks of participation. During one of the weeks, your first memory tool session will last up to an hour, and then you will complete a 15-minute memory tool session at the end of the week. During the other week, the first memory tool session will be about 15 minutes long. After that, the memory tool will send you 2 text messages each day. You will click on a link in those messages to use the memory tool for 10 minutes or less. At the end of the week, you will complete one more 15-minute memory tool session.



The order of the two different weeks varies by participant, and we will tell you your schedule in advance if you choose to participate in the study.

- **Surveys and interview:** You will complete 3 sets of online surveys, each of which should last less than 30 minutes. You will complete one set today, one at the end of your first week of participation, and one at the end of your second week of participation.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study

With your permission, we will make an audio and/or videotape of your feedback on the memory tool.

I give you permission to make audio recordings and/or video recordings of me during this study.

[ ] Yes [ ] No

Expected costs:

If you do not have a cell phone plan with unlimited calls and/or text messaging, you may have to pay the cost of receiving/making calls and receiving/sending text messages to use the memory tool.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

- The time it takes to participate may be inconvenient for you.
- You may feel nervous or anxious about answering certain interview questions.
- You may receive a call/text at an inconvenient time of day.
- You may experience frustration or annoyance with text messages you receive or with technical problems in the messaging system.
- There is a risk of loss of confidentiality. The measures in place to protect your confidentiality are indicated in the "Confidentiality" section later in this document.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. We hope that your feedback will help us to develop better memory tools that will help people with traumatic brain injury in the future.

b) The benefits you might get from being in this study. We do not think you will get any direct benefit from being in this study.

Study Results: We plan to use your feedback to improve the memory tool. However, we do not plan to share the results of this study or other users' feedback with you.

Alternative treatments available: This is not a treatment study and will not affect your medical care, so no alternative treatments are available.

Compensation for participation:

Total possible compensation for this study is $70.00: Each week, you will receive $10.00 for your initial learning session and $10.00 for your final memory test. You will also receive $10 for each of the 3 sets of online surveys you complete. We will need your address to pay you for participating with a pre-paid debit card. It can take 4-6 weeks for your payment to arrive.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The Principal Investigator may withdraw your participation if we are unable to contact you for your study sessions or if, during the study, there is information to suggest that you may no longer qualify for the study. If you are withdrawn from the study, you will be told the reason why.

What happens if you choose to withdraw from study participation?

Your participation is completely voluntary. If you withdraw from the study, you will receive payment proportional to the amount of the study you complete. Withdrawing from the study will not affect your medical care. You can stop participating at any time by notifying Emily Morrow at emily.l.morrow@vanderbilt.edu, or Melissa Duff at 615-936-5057 or via email at melissa.c.duff@vanderbilt.edu.

Contact Information: If you should have any questions about this research study or possibly injury, please feel free to contact Emily Morrow at 615-208-4168 or my Faculty Advisor, Lindsay Mayberry, at 615-875-5821.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. To help protect your confidentiality, we will maintain all records in secure storage areas with access limited to researchers directly involved in this study. Any records removed from secure storage (e.g., for data analysis or publication) are identified only by a code number. Any records entered into a computer will be in password protected computer files. If we write a report or article about this study we will do so in such a way that you cannot be directly identified.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Melissa Duff, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Your non-identifiable data and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the further use of your data. Further use of your data may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your data may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title