Full Title: Remediating narrative discourse impairments in Veterans with TBI: Initial treatment development

ClinicalTrials.gov Title: Narrative Discourse Treatment Development

ClinicalTrials.gov ID: NCT05008419

Principal Investigator: Karen Lê

IRB Approval Date: 02/15/24

Subject Name: _____ Date: _____

Title of Study: Remediating narrative discourse impairments in veterans with TBI: Initial treatment development

Principal Investigator: Karen Lê, PhD Version Date: 02/05/24 Study Phase: 2

RESEARCH SUMMARY

You are invited to take part in a research study because you have communication difficulty following a traumatic brain injury (TBI). This study is sponsored and funded by the VA Rehabilitation Research and Development Service. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This initial summary is to give you key information to help you decide whether to participate. Detailed information follows this brief summary. Ask the research team questions. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how to help Veterans with communication difficulty following TBI improve their ability to tell stories and share their stories in conversations. Your active participation in this research will last about 4-6 months.

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

You may want to volunteer for this study because it will help us to learn more about how to help Veterans with TBI improve their ability to communicate. The study will not interfere with usual treatment services. Although you might not benefit directly, information from this study may lead to knowledge that may help others. For a complete description of benefits, refer to the Research Details.

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

You may choose not to participate in this study because you may find answering questions about yourself uncomfortable, because you do not have access to equipment and technology to participate in telehealth sessions, because you do not wish to participate in telehealth sessions, because you do not wish to be audio/video-recorded and/or because you can obtain treatment for your communication difficulty without going through study procedures. For a complete description of risks, refer to the Research Details.

DO YOU 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.

Subject Name: _____ Date: _____

Title of Study: Remediating narrative discourse impairments in veterans with TBI: Initial treatment development

Principal Investigator: Karen Lê, PhD Version Date: 02/05/24 Study Phase: 2

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

The primary purpose of this study is to develop a treatment for communication problems that occur after TBI and to learn how to best deliver communication treatment to Veterans with TBI by obtaining feedback from the Veterans themselves. People with TBI frequently have trouble communicating when they have to speak more than a single sentence at time, such as telling stories and having conversations. These communication problems can cause challenges in aspects of functioning, such as securing and keeping steady work and maintaining social relationships. By conducting this research study, we hope to learn how to help Veterans with communication difficulty following TBI improve their ability to tell stories and share their stories in conversations.

HOW LONG WILL YOU BE IN THE STUDY?

This research study is expected to take approximately 5 years and is divided into 2 phases. Your individual active participation in the project will be for Phase 2 only and take approximately 4-6 months. This will include active involvement in the initial screening, baseline and post-treatment testing, communication treatment 2 times a week over 8 weeks, and a feedback session. Phase 2 involves participation in the communication treatment, 3 test sessions and a feedback session where we will collect input from Veterans about the treatment and test sessions. We will use information from Phase 2, to refine the treatment in preparation for a larger treatment trial in the future. If you agree to be in this study, you will be participating in Phase 2 only. We hope to have approximately 40 Veterans complete Phase 2. Veterans will be split into 2 groups, a control group and a treatment group.

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

You will be randomly selected to either receive the communication treatment or continue with your usual care. This selection process is by chance and similar to flipping a coin. If you are assigned to the communication treatment, will ask you to participate in all study procedures. If you are assigned to "no treatment" control group, you will only participate in screening and testing. This will allow us to compare results of those who receive treatment and those that do not.

Screening: We will schedule an initial meeting with you to learn more about your medical history by asking you questions in a structured interview. We will also examine your medical record to confirm eligibility for the study. We will ask that you complete some questionnaires that ask about your history of TBI, your difficulties and functioning after TBI, your communication ability, your psychiatric history and your substance use history. You are free to skip any questions that you do not want to answer. We will also administer screenings to ensure that you have ability to follow directions, adequate language and hearing ability and ability to

remember directions in order to participate in the study. The interview, questionnaires, and screenings will occur in a private office. It will take about 1 hour to complete these procedures.

Testing: . There will be 3 test sessions: baseline testing, post-treatment testing, and 1-month follow-up testing. After the initial meeting, we can administer the baseline test session or schedule you to return for the baseline test session. There will be a second test session after you complete the treatment, and the last test session will be about 1 month after you complete treatment. We will administer tests of communication and cognition (thinking skills). We will also administer surveys where you will be asked to rate your functioning related to your communication, general life activities, mental health, pain, and headache. Each test session will be about 2.5 hours long. There will be some flexibility to split the test session into multiple sessions and to complete the surveys and some tests over the phone or virtually.

Some of the tasks will involve you talking about topics that will be provided to you or giving a spoken response. We will audio/video-record these sessions in order to analyze your communication and thinking skills.

To better understand your communication ability, we will ask that you identify a significant other (e.g., spouse/partner, family member, friend) with whom you interact on a regular basis and ask that individual to complete the same survey you will complete about your communication. We will ask them to complete the survey at about the same times you complete it (baseline testing, post-treatment, and 1-month follow-up). We will only contact this individual if you give us permission to do so and provide their name and contact information to us. We will verify their relationship with you, but we will not collect any other information from this individual. If you do not wish to identify a significant other, you can still participate in the study.

Treatment: After the initial meeting, we will schedule you for the treatment phase of the study. The communication treatment will occur in individual, hour long sessions twice a week over about 2 to 3 months, for a total of about 14 to 18 one-hour sessions. The aim of the treatment is to provide 2 sessions each week, but we allow for some amount of flexibility to accommodate issues, such as missed appointments and holidays and “catch up” appointments. Because of this flexibility, your participation could last up to 6 months. You can select your preferred treatment format, either telehealth or in-person appointments. While we encourage you to keep the same treatment format for the duration of treatment, there will be flexibility to accommodate a change in format if requested. We will deliver telehealth sessions using a VA-approved telehealth platform. We will send a link to each telehealth session to your e-mail account prior to each telehealth appointment. The in-person treatment sessions will occur in a private office. Research staff will conduct the telehealth session in a private office and will ask you to confirm that you are in a private space at the beginning of each session.

The communication treatment will involve education about stories, including what a story is, the parts of a story, and what makes a good story. The treatment will focus on two main aspects of good stories: content and organization. Training of story content will involve helping you to tell stories that are complete and not missing important information and teaching you to provide information in stories that helps you get your main points across to your communication

partners. Training of story organization will involve helping you to tell stories that are well-organized and make sense in how the story unfolds as you tell it.

We will present materials to help you tell stories, such as picture scenes, story cards, and video clips. We will also ask you to tell stories that draw upon your life activities and experiences, such as stories that would want share with communication partners, like your friends, family members or colleagues. To support your learning and growth of good storytelling skills, we will provide you with prompts and guidance in reflecting on your stories and ask you to complete weekly homework assignments.

We will audio/video-record treatment sessions in order to transcribe and analyze the stories you tell. Only members of the study team will have access to the videos. We will not disclose the videos outside of VA. Because we use the videos to understand changes in your communication in treatment, you cannot take part in the study if you refuse recording.

Feedback: At the end of your last treatment session or within about 2 weeks after your last treatment session, we will request your feedback about the treatment. We will ask you to participate in an exit interview and complete questionnaires on your satisfaction with the treatment and test sessions and how you felt about the content of the treatment. Some items will involve providing a rating and other items will involve a verbal response, such as what you thought was the most or least helpful aspect of the treatment you received. The feedback session should take about 30 to 45 minutes for the interview and about 15 minutes for the questionnaires.

WHAT IS EXPECTED OF YOU IF YOU TAKE PART IN THIS STUDY?

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.

Complete your treatment assignments as instructed.

Ask questions as you think of them.

Report any new symptoms or other changes in your health that you experience.

If you want to participate in another research study, please let us know. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

DISCOMFORTS MIGHT YOU HAVE IF YOU TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. There are no foreseeable risks except those involving a loss of privacy and confidentiality. There are no known physical risks to any of the interviews, screenings, questionnaires, tests, or treatment materials.

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.

Risks of the usual care you receive are not risks of this study. Usual care refers to the care you have been receiving from your treatment team for your TBI and other health conditions you may have. 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.

Some people become uncomfortable when asked questions about their medical history, history of TBI, psychiatric history, substance use, or their day to day functioning. You might find the questions and surveys boring or tiring. If, for any reason, you wish not to answer specific questions or you wish to terminate a research session, you will be able to do so.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. The information we get from this study may help others. If participants find the communication treatment acceptable and useful and provide feedback about the treatment, we will use that information to improve the treatment. If the treatment helps people with TBI communicate better, the treatment may become recommended for people with communication problems after TBI.

WHAT OTHER CHOICES DO YOU HAVE IF YOU DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices, such as standard cognitive-communication and language therapy through the VA Speech Pathology service. You may discuss these options with your treatment team or doctor

HOW WILL YOUR 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:

- Paper documents are locked in filing cabinets in locked offices.
- Information collected electronically will be done so on computers protected with passwords and stored on the secure VA network and/or on VA-approved external storage devices that are kept in locked cabinets in locked research offices.
- Only authorized persons will have access to the information gathered in this study.
- Only a code number will identify your research records. The code number will not be based on any information that can identify you (for example, social security number, initials, birthdate, etc.)

- The master list linking names to code numbers will be kept separately from the research data.

There are times when we might have to show your records to other people. For example, our local Research and Development Committee, the Government Accountability Office (GAO), the Office for Human Research Protections (OHRP), Office of Research Oversight (ORO), or other study monitors who may look at or copy portions of records that identify you.

As part of the assessments, we will ask you questions about psychiatric symptoms. If, in the course of our study procedures, we have reason to be concerned for your safety or feel that you may be a threat to the safety of others, we will inform your VA clinician who may wish that you be evaluated in the Psychiatric Emergency Room at VA Connecticut Healthcare System. Your clinician or the psychiatrist on duty might decide to hospitalize you, even if you do not wish to be hospitalized. If we are unable to contact your clinician and have concerns about your safety, we may escort you to the psychiatric emergency room, where you will be evaluated, and a decision may be made to hospitalize you. In a telehealth session, if we have reason to be concerned for your safety or feel that you may be a threat to the safety of others, we will stay with you in the session and call your VA clinician or the Veterans Crisis Line and connect you with a clinician. If an emergency arises, we will call 911 and provide your location and stay with you in the session until help arrives.

Storage and Future Use of Data or Specimens:
Your research data will be stored by the study Principal Investigator, Karen Lê, at VACHS indefinitely, with access restricted to authorized research personnel. Identifiers might be removed from the identifiable private information that is collected. 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 or your legally authorized representative.

We will not collect any specimens or tissue in this study.

Medical Record
We will include information about your study participation in your medical record. These notes may be read by others involved in your medical care. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records apply to your VA record.

Clinical Trial
A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT ARE THE COSTS TO YOU IF YOU 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.

IS THERE PAYMENT TO YOU IF YOU TAKE PART IN THIS STUDY?

Payment is included in this study to compensate you for your time and inconvenience. All participants will be paid for their participation as follows:

- Screening: $25
- 3 Assessment batteries : $50 each ($150 total)
- 14 to 18 communication treatment sessions: $10 each ($140 to $180 total)
- Weekly homework returned assignments: $5 each ($40 to $50 total)
- Feedback session exit interview: $10
- Feedback session questionnaires: $10

Maximum total payment is $425.

Payment will be made according to current VA procedures. Participants may choose to have a check mailed to the address they provide or they may choose electronic fund transfer (EFT) if they provide required banking information. Study payments are subject to withholding for outstanding federal debts (i.e. defaulted student loans, interstate child support, back taxes, etc.) without notification. Due to limitations in the Financial Management System, payments made to participants through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Your social security number will be used for this purpose. An alternative payment option is via a voucher to be used at the VA Canteen store or cafeteria.

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study subject with study procedures. Emergency and ongoing medical treatment will be provided as needed. There are no plans to provide compensation for disability or other losses occurring over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:
Dr. Karen Lê at 860-840-7604 or
Dr. Joanna Fiszdon at 203-932-5711 x 1-2231

and

AFTER HOURS:
Psychiatric Emergency Room at 203-932-5711 x1-4471

WHO ELSE MAY YOU CONTACT IF YOU HAVE QUESTIONS?

If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Chairman of the Human Studies Subcommittee at 203-932-5711 x1-3350.
If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input you may call Dr. Karen Lê at 860-840-7604 or Dr. Joanna Fiszdon at 203-932-5711 x 1-2231.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary and refusal to take part in this study, or withdrawing from the study, will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part in this study at any time without any penalty or loss of benefits. If you withdraw from the study you can still receive the same standard of care that you otherwise would have received. Data already collected prior to your withdrawal will still be used but no further information will be collected.

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

Your participation in this study may be terminated or suspended if you are hospitalized, or if your clinician feels that your participation in this study is interfering with your care or is making your symptoms worse. If, in the opinion of the principal investigators, a participant is no longer appropriate for the study, his or her participation may be discontinued without regard to the participant's wishes.

WILL YOU BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If any new findings are developed during the course of the research which may affect your willingness to continue in the research, you will be contacted and provided with the information.

RE-CONTACT

We may wish to re-contact you to invite you to participate in future research projects of this type.

Initial here: _____ I agree to be contacted for future research projects of this type.

Subject Name: _____ Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the research team has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study You also confirm that you have read this consent document, or it has been read to you. You will receive a copy of this consent document after you sign it.

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

_____ Person Obtaining Consent	_____ Person Obtaining: Signature	_____ Date