Title	Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living With TBI-AD/ADRD
NCT Number	NCT05465109
Date	12.22.22

Consent Form

Title of Research Study: TBI-AD/ADRD Caregiver Support Intervention (TACSI)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Joseph E. Gaugler, PhD Investigator Departmental Affiliation: University of Minnesota, School of Public Health Phone Number: 612-626-2485 Email Address: gaug0015@umn.edu	Study Staff: Elizabeth Albers Affiliation: University of Minnesota, School of Public Health Phone Number: 612-454-0415 Email Address: alber304@umn.edu

The following consent form may be administered via telephone, mailed in hard copy (with verbal consent obtained via telephone), or signed electronically online.

If you choose to enroll in the study, a copy of this completed consent form will be sent to you. This study is being conducted by: Joseph Gaugler, PhD at the University of Minnesota School of Public Health. The contact information for Dr. Gaugler, as well as the study staff contact, is listed at the top of the consent form.

This research is supported by the Department of Defense.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you are caring for someone who has been diagnosed with TBI and dementia. This program offers support and education to caregivers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.

- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The TACSI research project is studying the effects of a support and education program for caregivers of individuals with a diagnosis of TBI and dementia. The study provides the caregiver with telephone or video-conferencing intervention sessions with a goal of providing knowledge and skills to help manage stress and reduce caregiver burden.

How long will the research last?

We expect that you will be in this research study for about 6 months.

What will I need to do to participate?

You will be asked to participate in multiple surveys, as well as possibly participate in a 6 session support and education program.

***More detailed information about the study procedures can be found under* "What happens if I say yes, I want to be in this research?"**

Is there any way that being in this study could be bad for me?

The conversations or the questions we ask you may be stressful. If at any point this becomes a concern to you, please let us know. Additionally, there is a risk of a security problem compromising the data you provide to us. Please note that we take multiple steps to protect your data. If you have any concerns about your health or well-being during the course of the study, please let the study team know and follow-up with your healthcare provider.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include knowledge and skills that may be useful in your caregiving role through the support and education provided in the TACSI program.

What happens if I do not want to be in this research?

You do not have to participate in this research. Instead of being in this research study, your choices may include: participating in educational programs or viewing other online resources, such as those provided by the Alzheimer's Association or the Brain Injury Association.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 95 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

The study procedures last about six months. If you agree to be in this study, we would ask you to do the following things:

- Review this consent form and agree to participate in the research study.
- If you agree to participate, we will ask you to complete an initial survey which will be sent online or by mail. The survey should take about 45 minutes to complete.
- The group you are assigned to will be decided by chance, like flipping a coin. Neither you nor the investigator will choose which group you are assigned to. You will have an equal chance of being assigned to either the intervention group (TACSI coaching and surveys) or the control group (surveys only). You will be told which group you are placed in after you have been randomized.
- Then, if assigned to the intervention group, you will begin the 6 TACSI sessions via telephone or video conference with a coach. Sessions generally occur weekly, but scheduling is individualized based on your needs. The sessions usually last between 1 hours each. Ad hoc sessions may occur, as needed.
- You will complete additional surveys 3 and 6 months following baseline completion. We expect the follow up surveys to take about 30 minutes.
- If you are a part of the TACSI intervention group, you may be asked to participate in a phone interview about your experience. This interview occurs following the study and the purpose of this interview is to get your feedback on the program. If you allow, this conversation would be recorded for data analysis.
- At the end of this form, you can provide consent for us to record your research-related interviews.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, contact the investigator so that the investigator can let the study team know of your decision.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your relationship with the University of Minnesota or academic standing as a student, or your present or future employment.

Will it cost me anything to participate in this research study?

There will be no cost to you for any of the study activities or procedures. If you choose to pursue health or caregiving resources presented throughout the study, you should inquire about any potential costs associated with participation.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring

compliance, as well as the Department of Defense, the study sponsor. Specifically, private health information may be disclosed to representatives of the Department of Defense. The project's Independent Safety Monitor (ISM) may also view data reported by the study team, but these reports will not identify you by name. We may publish the results of this research, however, we will keep your name and other identifying information confidential. A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Self-harm, intent to harm others, or current or ongoing child or vulnerable adult abuse or neglect.

Data Collected

Data collected as part of this study will be stored in Dr. Gaugler's research office in D351 Mayo Building at the University of Minnesota. All data collected online or entered will be stored on a secure Academic Health Center-Information Systems data server, as well as other secure platforms (such as Box, Qualtrics).

Your data will be maintained for approximately 2-3 years after the study is completed. At that time, we will remove all identifiable private information collected during this research. Your participant ID number, consent form, and contact information will be maintained (separate from your study data) for a minimum of 6 years in the event we need to contact you at a later date. De-identified study data may be kept indefinitely. If identifiers are removed from your identifiable private information collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of the University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done using your data.

Due to federal grant funding, a long-term data sharing and preservation plan will be used to store and make non-identifiable data publicly accessible beyond the life of the project. This plan will include depositing the data into Data Repositories, such as the Data Repository for the University of Minnesota (DRUM) or the Federal Interagency Traumatic Brain Injury Research (FITBIR).

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include deliberately jeopardizing the integrity of the study.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $100 for your time and effort. The compensation may be pro-rated. At the end of the study, participants can expect to receive $25 for completion of each of the following study activities: the initial baseline survey, the 3 month follow up survey, and the 6 month follow up survey. If you are a part of the TACSI treatment group, you may be selected to receive a final telephone interview, and would be offered an additional $25 for participation in the phone interview.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and birthdate. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Department of Defense employees and Active Service Members should check with their supervisor before

participating in this research or accepting payment for participation in this research. Active Service Members must follow command policies regarding participation in this research study, and cannot receive payment for participating in this research if on or off duty.

[Study staff to include appropriate signature block as needed].

Telephone Consent Signature Page

[Following reading the above consent form or participant reviewing the form in hard copy, staff document responses to the following questions]:

Do you have any questions about the study? [Staff to write notes about any questions answered]

Would you like to participate in the study?

_____Yes

_____No

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. *[Study staff to indicate participant's willingness to participate in these optional activities.]*

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio record my telephone interview to aid with data analysis. Unless all identifiers are removed, the investigator will not share these recordings with anyone outside of the immediate study (or transcription) team.
_____	_____	The research team may correspond with me using unencrypted email. Unencrypted email communication is not secure and can be intercepted. Note: The online survey system (Qualtrics) is secure.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Joseph E. Gaugler.

The following participant has provided verbal consent to participate in TACSI.

_____

Printed Name of Participant

_____ _____

Signature of Study Staff Obtaining Consent Date

_____

Printed Name of Study Staff Obtaining Consent

Participants will be sent a copy of this completed consent form to keep for their records.

Electronic Consent Signature Page:

Please contact study staff prior to signing this consent form if you have any questions related to the study.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio record my telephone interview to aid with data analysis. Unless all identifiers are removed, the investigator will not share these recordings with anyone outside of the immediate study (or transcription) team.
_____	_____	The research team may correspond with me using unencrypted email. Unencrypted email communication is not secure and can be intercepted. Note: The online survey system (Qualtrics) is secure.
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Joseph E. Gaugler.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant