AWARD NUMBER: W81XWH-21-1-0726

TITLE: Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living with TBI-AD/ADRD

PRINCIPAL INVESTIGATOR: Joseph E. Gaugler

CONTRACTING ORGANIZATION: University of Minnesota Twin Cities, School of Public Health

REPORT DATE: OCTOBER 2022

TYPE OF REPORT: Annual Technical Report

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE
OCTOBER 2022

2. REPORT TYPE
ANNUAL

3. DATES COVERED
15SEPT2021 - 14SEPT2022

4. TITLE AND SUBTITLE
Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living with TBI-AD/ADRD

5a. CONTRACT NUMBER
W81XWH-21-1-0726

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Joseph E. Gaugler

E-Mail: gaug0015@umn.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Minnesota
200 Oak Street SE, Suite 450
Minneapolis, MN 55455-2070

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Annual Technical Report for study titled: "Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living with TBI-AD/ADRD.

15. SUBJECT TERMS
NONE LISTED

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	32	**19b. TELEPHONE NUMBER** *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION: *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The purpose of the proposed study is to design, refine, and test a telehealth, psychoeducational and psychosocial support intervention for family caregivers of persons with TBI-AD/ADRD based on our research team's experience adopting and evaluating evidence-based support interventions for dementia caregivers. Relying on an initial sample of 15 caregivers of persons with TBI-AD/ADRD, we aim to establish the feasibility, acceptability, and appropriateness of TACSI over a 3-month period (Phase I). We will use a pilot-randomized controlled trial design with 80 caregivers to evaluate the preliminary efficacy and successful implementation of a revised version of TACSI over a 6-month period (Phase II).

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Informal caregivers, Traumatic Brain Injury, Alzheimer's Disease and related dementias, informal caregivers, psychosocial, psychoeducational

3. ACCOMPLISHMENTS: *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Goal 1: To organize processes, set up study, train staff, and secure IRB approval (Months 1-6): 100% complete.
Goal 2: Recruit, enroll and administer the TACSI to 15 TBI-AD/ADRD caregivers (Months 2-8): ~50% complete.

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Goal 1: To organize processes, set up study, train staff, and secure IRB approval: 100% complete

1) Major Activities Completed
    a. PI to hold weekly meetings with UMN team and Co-Is
    b. PI to recruit and train Research Coordinator and Research Assistant
    c. PI and UMN team create/initiate data entry and management protocols, including manual of procedures
    d. PI and UMN team to create/submit study materials to IRB for approval
2) Specific objectives
    a. Train staff, set up study, and secure IRB approval
3) Significant results/key outcomes
    a. Staff was trained, study was set up, and IRB approvals were secured
4) Other achievements: NA

Goal 2: Recruit, enroll and administer the TACSI to 15 TBI-AD/ADRD caregivers.: ~50% complete

1) Major activities
    a. Co-I's from Mayo Clinic and VA inform potential participants of study and recruit 15 caregivers of persons with TBI-AD/ADRD
    b. PI and UMN team complete enrollment process and collect baseline data
    c. UMN TACSI interventionists administer intervention
2) Specific objectives
    a. Recruit and enroll 15 participants
    b. Collect baseline data
    c. Interventionist administers intervention
3) Significant results/key outcomes
    a. Currently have 8 participants enrolled in the study (as of 10/13/2022) – 53% of phase I target
    b. Have collected baseline data and started intervention with 7 participants (as of 10/13/2022)
4) Other achievements
    a. Successfully recruited participants from the Mayo Clinic and MVAHCS (a first for MVAHCS and UMN – see 'Section 4: Impact')

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

A. Interventionists attended 3 webinars on TBI through the Minnesota Brain Injury Association
    1. Brain Injury Basics: Caregiving
    2. Brain Injury Basics: Introduction to Brain Injury
    3. Brain Injury Basics: Adjustments to Brain Injury
B. Interventionists met with VA social worker to learn more about the VA's caregiver support programs for individuals with TBI.
C. Research Coordinator learned more about single IRB determinations/multi-site research through individual study and a University of Minnesota IRB-created webinar.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

To accomplish Goal 2 (Recruit, enroll and administer the TACSI to 15 TBI-AD/ADRD caregivers, currently ~50% complete per above), we plan on:

1) Recruiting and enrolling 7 additional participants
2) Collecting baseline data from the remaining participants and have the intervention administered to them as well
3) Complete 3-month data collection
4) Administer semi-structured interviews to all 15 participants

4. IMPACT: D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

This collaboration between the UMN and MVAHCS is significant. It is the first time that the MVACHS has actively recruited participants for a UMN-led study. We have documented the processes involved in making this sort of collaboration work and would like to create a guide for future use by our team and others.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

The following non-significant changes were UMN IRB-approved on 09/06/2022 due to involvement in screening procedures:

1. We added alternative methods for recruitment, specifically, individuals can contact us directly from clinicaltrials.gov or from studyfinder.umn.edu.
2. The eligibility criteria was altered slightly to be more inclusive. Specifically, some potential participants informed us during screening that they were unaware of their care recipient's diagnosis of either TBI or dementia. Since the participants recruited from the Mayo Clinic or MVACHS were drawn from ICD codes in care recipient's medical records, we were confident that the care recipient had been diagnosed with both TBI and dementia. Therefore, if a potential participant who was recruited from the Mayo Clinic or MVACHS, they do not have to confirm that the care recipient was diagnosed with both TBI and dementia. However, if they are recruited from another source, they would have to confirm a dual diagnosis of TBI and dementia during screening.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

There were delays after the study award date due to slow IRB approval processes and changes to how the IRBs were set up. First, we tried to have each site use their own IRB. However, since this was not allowed by the DoD, we then had to create new IRB applications where only the MVACHS and UMN were sIRBs (with Mayo as a p-site of the UMN). Even after this, the MVACHS IRB was more difficult to navigate than expected due to more extensive documentation.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

No significant changes were made. The only changes made to the protocol were as described above in "Changes in approach and reasons for change."

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a*

one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to Report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report.

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

1. Baseline data from 7 participants (as of 10/13/2022)
2. Contact Log [Interventionist data file]
3. Coaching notes [Interventionist data file]
4. TACSI Intervention

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of

compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:
Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*
Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name: *Joseph E. Gaugler*
Project Role: *Principal Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0003-4797-485X*
Nearest person month worked: *1.2*
Contribution to Project: *Dr. Gaugler has facilitated coordination between the UMN and Mayo Clinic and MVAHCS. He has also ensured study procedures are being followed, provided guidance as needed, and overall led the study.*
Funding Support: *N/A*

Name: *Sherry Chesak*
Project Role: *Co-Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0001-8126-4486*
Nearest person month worked: *0.3*
Contribution to Project: *Dr. Chesak has facilitated coordination between the UMN and Mayo Clinic and has ensured adequate recruitment at the Mayo Clinic.*
Funding Support: *N/A*

Name: *Edward Ratner*
Project Role: *Co-Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0002-2876-4008*
Nearest person month worked: *0.25*
Contribution to Project: *Dr. Ratner has facilitated coordination between the UMN and MVAHCS and has aided recruitment at the MVAHCS.*
Funding Support: *N/A*

Name: *Jacob Finn*
Project Role: *Co-Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0001-5333-4475*
Nearest person month worked: *0.25*
Contribution to Project: *Dr. Finn has facilitated coordination between the UMN and MVAHCS and has aided recruitment at the MVAHCS.*
Funding Support: *N/A*

Name: *Robyn Birkeland*
Project Role: *Interventionist*
Researcher Identifier (e.g. ORCID ID): *0000-0001-6093-046X*
Nearest person month worked: *1.9*
Contribution to Project: *Dr. Birkeland has aided in study start-up procedures, co-created the intervention, and delivered the intervention to participants.*
Funding Support: *N/A*

Name: *Katie Louwagie*
Project Role: *Project Specialist*
Researcher Identifier (e.g. ORCID ID): *0000-0002-4933-0145*
Nearest person month worked: *1.2*
Contribution to Project: *Dr. Louwagie has aided in study start-up procedures, reviewed the intervention, and aided in study coordination activities.*
Funding Support: *N/A*

Name: *Elizabeth Albers*
Project Role: *Study Coordinator*
Researcher Identifier (e.g. ORCID ID): *0000-0001-6244-406X*
Nearest person month worked: *3.1*
Contribution to Project: *Ms. Albers has aided in study start-up procedures, enrolled participants, and coordinated study activities.*
Funding Support: *N/A*

Name: *Hawking Yam*
Project Role: *Graduate Research Assistant*
Researcher Identifier (e.g. ORCID ID): *0000-0002-8286-9329*
Nearest person month worked: *0.5*
Contribution to Project: *Mr. Yam has aided in study coordination activities.*
Funding Support: *N/A*

Name: *Kathy Sheffield*
Project Role: *Research Coordinator*
Researcher Identifier (e.g. ORCID ID): *Unknown*
Nearest person month worked: *0.4*
Contribution to Project: *Ms. Sheffield has aided in recruitment at the Mayo Clinic.*
Funding Support: *N/A*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending

changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

See appendices regarding changes to the PI (Dr. Gaugler, Appendix A) and Co-I (Dr. Finn, Appendix B; Dr. Chesak, Appendix C) support since the start of the grant. Dr. Ratner reports there have not been changes in his support.

Please note that Dr. Lori Rhudy was included as a Co-I on the initial grant but moved to another organization and ended her involvement with the study prior to initial grant funding. Therefore, Dr. Rhudy's support is not included in this report.

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name: University of Minnesota
Location of Organization: Minneapolis, MN

Partner's contribution to the project

Facilities: Dr. Gaugler's secure suite in the Mayo Building includes his own office, three other connected office spaces, a meeting room, and a file area that house nine of his research team members. Dr. Gaugler's office suites are equipped with secure computers (including the necessary statistical software), multiple printers, web cameras, telephone access, and ample secure file space to conduct the proposed study. The computers have LAN access. Dr. Gaugler's suite is a private location to conduct research participant interviews when needed as well as collect and manage any related human subjects research data.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Appendix A - Changes to Dr. Gaugler Support

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

PHS 398 OTHER SUPPORT

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

Other Support – Project/Proposal

ACTIVE

*Title: Improving Outcomes for Families and Older Adults: Adult Day Service Plus Program

Major Goals: This translational research study will evaluate the effectiveness, cost benefit and implementation potential of a novel caregiver support program embedded in adult day services for older adults with complex conditions called ADS Plus. Using a practical trial design with cluster, re-randomization and mixed methodological techniques, we will involve 30 adult day services across the United States and 300 of their family caregivers and older adult clients.

*Status of Support: Active (No Cost Extension)

Project Number: R01 AG049692

Name of PD/PI: Gitlin, L. N.; Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 05/2016-4/23

* Total Award Amount (including Indirect Costs): $3,973,061

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.6

*Title: Geriatrics Workforce Enhancement Program

Major Goals: The goals of MN GWEP are to 1) educate and train Minnesota's primary care and geriatrics workforce to care for older adults in integrated geriatrics and primary care models, and 2) partner with community-based organizations across the state in rectifying gaps in the care of older adults and in promoting age-friendly primary healthcare and dementia friendly communities.

*Status of Support: Active

Project Number: U1QHP33076

Name of PD/PI: Pacala, J.

*Source of Support: HRSA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2019-6/24

* Total Award Amount (including Indirect Costs): $3,747,840

* Person Months (Calendar/Academic/Summer) per budget period.

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

Year (YYYY)	Person Months (##.##)
1. 2023	.75
2. 2024	.75

*Title: Microsimulation Modeling to Compare the Effectiveness and Cost-Effectiveness of Nondrug Interventions to Manage Clinical Symptoms in Racially/Ethnically Diverse Persons with Dementia

Major Goals: Using our cutting-edge and published ADRD microsimulation model, our proposed study will be the first to compare the effectiveness, cost-effectiveness, and affordability of nondrug ADRD interventions by race (African American, Asian, and White) and ethnicity (Hispanic) on outcomes of family time caregiving, days in a nursing home, costs to families/Medicaid/Medicare, and the person with ADRD's and their caregiver's quality-adjusted life-years.

*Status of Support: Active

Project Number: R01 AG060871

Name of PD/PI: Jutkowitz, E.

*Source of Support: NIA

*Primary Place of Performance: Brown University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2019-5/23

* Total Award Amount (including Indirect Costs): $1,672,905

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	1.2

*Title: NIA AD/ADRD Health Care Systems Research Collaboratory

Major Goals: There is an urgent need to improve care provided to patients with dementia (PWD) and their caregivers by health care systems (HCS). The knowledge, investigative experience, collaborations, and evidence generated by the proposed National Institute on Aging Alzheimer's disease (AD)/AD-related dementia (AD/ADRD) Collaboratory has the potential to transform the delivery, quality, and outcomes of care for Americans from all backgrounds suffering with AD/ADRD.

*Status of Support: Active

Project Number: U54AG063546

Name of PD/PI: Mor, V.; Mitchell, S.

*Source of Support: NIA

*Primary Place of Performance: Brown University

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/2019-8/24

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

* Total Award Amount (including Indirect Costs): $53,400,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	1.13
2. 2024	1.13

*Title: Refining a Driving Cessation Management Intervention for Person with Dementia and their Family Caregivers: CarFreeMe REDUCED LEVEL OF EFFORT

Major Goals: This R21 will feature an international collaboration between the University of Minnesota and the University of Queensland to tailor and examine the feasibility of a novel adaption of CarFreeMe, a seven-module support program to help families and their cognitively impaired relatives navigate the driving cessation transition in joint fashion. If successful, the proposed R21 will position CarFreeMe for a subsequent randomized controlled evaluation and later as a flexible, much-needed evidence-based resource that healthcare systems and other providers could offer families during and after the driving cessation transition.

*Status of Support: Active

Project Number: R21 AG067537

Name of PD/PI: Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/2020-1/23

* Total Award Amount (including Indirect Costs): $418,083

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.12

*Title: The Public Health Center of Excellence in Dementia Caregiving NEW PREVIOUSLY PENDING

Major Goals: The Center will employ a systematic, public health strategy to implement CDC Road Map Actions to achieve the outcomes of increasing access to topic-specific tools and materials and increasing use of topic-specific best practices and proven strategies to best support unpaid caregivers of people living with Alzheimer's disease and related dementia.

*Status of Support: Active

Project Number: 1 NU58DP006910-01-00

Name of PD/PI: Gaugler, J. E.

*Source of Support: CDC

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/2020-8/2025

* Total Award Amount (including Indirect Costs): $2,500,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	2.4
2. 2023	2.4
3. 2024	2.4
4. 2025	2.4

*Title: Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives TBI/ADRD NEW

Major Goals: We plan to conduct a mixed methods, pilot randomized controlled evaluation of the TBI-AD/ADRD Caregiver Support Intervention (TACSI), an individual and family coaching intervention that takes place over six sessions with an experienced professional.

*Status of Support: Active

Project Number: W81XWH2110726

Name of PD/PI: Gaugler, J. E.

*Source of Support: DoD

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/2021-8/2023

* Total Award Amount (including Indirect Costs): $750,113

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2022	1.2
2. 2023	1.2

*Title: The PorchLight Project NEW

Major Goals: The proposed real-world efficacy trial (Stage III of the NIH Stage Model) features an established collaboration between Lutheran Social Service of Minnesota and the University of Minnesota to evaluate a novel adaption of a statewide volunteer program (the “Porchlight Project”) to assist people with AD/ADRD and their family caregivers better manage dementia at home. If successful, the Porchlight Project will offer a potentially efficient, wide-ranging service model for states and communities to implement for volunteers, persons with AD/ADRD, and family caregivers.

*Status of Support: Active

Project Number: R01 AG075890

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

Name of PD/PI: Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 4/2022-4/2027

* Total Award Amount (including Indirect Costs): $3,299,085

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	2.25
2. 2024	2.25
3. 2025	2.25
4. 2026	2.25
5. 2027	2.25

*Title: Emergency preparedness and support of caregivers of persons with dementia: The Disaster PrepWise study NEW

Major Goals: To test the impact of Disaster PrepWise intervention on caregiver outcomes (i.e., resilience, stress) and perceptions that may mediate the association between DPW and outcomes (caregiver self-efficacy, preparedness, social support); and evaluate implementation strategies to optimize dissemination.

*Status of Support: Funded

Project Number: R01 AG077436

Name of PD/PI: Ashida, S.

*Source of Support: NIA

*Primary Place of Performance: University of Iowa

Project/Proposal Start and End Date: (MM/YYYY) (if available): 4/2022-4/2027

* Total Award Amount (including Indirect Costs): $417,740

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.6
2. 2024	0.6
3. 2025	0.6
4. 2026	0.6
5. 2027	0.6

*Title: Definition and Caregiver Appraisal of Paradoxical Lucidity in Dementia NEW

Major Goals: Paradoxical lucidity is defined as spontaneous, relevant communication or

connectedness in a person who is assumed to have permanently lost cognitive capacity. This mixed-methods study will operationalize paradoxical lucidity (PL), assess prevalence and predictors of PL, and link PL to caregiver outcomes.

*Status of Support: Pending

Project Number: R33AG 69767

Name of PD/PI: Griffin, J.

*Source of Support: NIA

*Primary Place of Performance: Mayo Clinic

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/2022-8/2025

* Total Award Amount (including Indirect Costs): $153,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	0.45
2. 2024	0.45
3. 2025	0.45

*Title: Care Assistant for Family Caregivers of Persons with Dementia During Out of the Home Activities

Major Goals: Koronis Biomedical Technologies will develop a tracking solution that will give peace of mind to caregivers in both stationary and mobile scenarios, alerting the caregiver to wandering behavior and allowing them to quickly locate their loved one. It will consist of a monitoring system that features geo-fencing and wireless tether modes for both indoor and outdoor use. Efficacy of the proposed system will be assessed by family caregivers through a randomized clinical study, as well as through engineering evaluations.

*Status of Support: Pending

Project Number: R44 AG058336

Name of PD/PI: Anderson, S. M.

*Source of Support: NIA

*Primary Place of Performance: Koronis Biomedical Technologies Corporation

Project/Proposal Start and End Date: (MM/YYYY) (if available): 4/2023-4/2024

* Total Award Amount (including Indirect Costs): $180,081

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
2. 2023	.45
3. 2024	.45

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

PENDING

*Title: Academic Leadership Career Award

Major Goals: Although considerable investment in dementia care science has occurred, questions continue as to whether the existing evidence base is sufficient to warrant widespread dissemination and implementation of innovations to improve the health and well-being for people living with dementia and their caregivers. My short-term career objective and the focus of this K07 is to implement graduate curricula, extensive mentoring, and robust support to enhance pre- and post-doctoral training in the science of dementia care interventions (the Advanced Behavioral Intervention Design in Dementia Care program). The long-term objective that will result from the proposed K07 is the creation, leadership, and maintenance of infrastructure at the University of Minnesota that serves as a national resource for advanced methodology in dementia care intervention science.

*Status of Support: Pending

Project Number: 1 K07 AG076616-01A1

Name of PD/PI: Joseph E. Gaugler

*Source of Support: NIA/NIH

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 12/01/2022 – 11/30/2027

* Total Award Amount (including Indirect Costs): $685,800

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	3.3
2. 2024	3.2
3. 2025	3.2
4. 2026	3.1
5. 2027	3.0

*Title: Home Alone: Developing a Home-Based Intervention for People with Cognitive Impairment Who Live Alone

Major Goals: There is a lack of viable intervention strategies to alleviate the potential health risks of living alone with cognitive impairment (CI). This proposed R21 will develop and test the feasibility, acceptability, and usefulness of a homebased, seven module intervention ("Home Alone") to assist persons successfully navigate the challenges of living independently. If successful, the proposed R21 will position Home Alone for a subsequent randomized controlled evaluation and later as a flexible, much needed evidence based resource that is scalable for healthcare systems and other dementia support providers.

*Status of Support: Pending

Project Number: 1 R21 AG080744-01

Name of PD/PI: Joseph E. Gaugler

*Source of Support: NIA/NIH

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 12/01/2022 – 11/30/2024

* Total Award Amount (including Indirect Costs): $439,087

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2023	1.2
2. 2024	1.2

*Title: Aging Trajectories in Colorectal Cancer Survivors and their effect on cancer caregivers

Major Goals: The major goal of this project is to evaluate the role of accelerated aging on health outcomes in colorectal cancer survivors and their caregivers.

*Status of Support: Pending

Project Number: TBA

Name of PD/PI: Bharat Thyagarajan

*Source of Support: NIA/NIH

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/01/2023 – 06/30/2028

* Total Award Amount (including Indirect Costs): $3,895,047

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2024	0.24
2. 2025	0.6
3. 2026	0.6
4. 2027	0.6
5. 2028	0.6

COMPLETED

*Title: The Residential Care Transition Module

Major Goals: The Residential Care Transition Module (RCTM) provides 6 formal sessions of consultation over a 4-month period to those family caregivers who have admitted a cognitively impaired relative to a residential long-term care setting. This mixed method, randomized controlled trial will determine whether and how the RCTM decreases family caregivers' emotional and psychological distress and placement-related strain over a 12-month period.

*Status of Support: Completed

Project Number: R01 AG048931

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

Name of PD/PI: Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 06/2016-6/22

* Total Award Amount (including Indirect Costs): $3,046,049

*Title: The Residential Care Transition Module

Major Goals: This supplement examines adaptation to the COVID-19 pandemic among caregivers of persons with Alzheimer's Disease/Alzheimer's Disease-related dementia (AD/ADRD) in residential long-term care (RLTC).

*Status of Support: Completed

Project Number: 3 R01 AG048931

Name of PD/PI: Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 07/2020-6/22

* Total Award Amount (including Indirect Costs): $262,510

*Title: Care to Plan: Preliminary Efficacy of a Tailored Resource for Family Members of Persons with Dementia

Major Goals: The proposed study will refine and conduct a preliminary efficacy evaluation of Care to Plan. Care to Plan is an online care planning tool that provides a succinct and clear overview of various types of dementia caregiver interventions, administers a brief validated assessment of risk, and generates individualized recommendations for dementia caregivers as well as resources that link users to a selected recommendation.

*Status of Support: Completed

Project Number: R21 AG060419

Name of PD/PI: Gaugler, J. E.

*Source of Support: NIA

*Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 08/2019-5/22

* Total Award Amount (including Indirect Costs): $1,672,905

Name of Individual: Joseph E. Gaugler
Commons ID: joe.gaugler

* Title: Utilizing Senior Companions to Enhance Dementia Care Services and Supports R61

Major Goals: The proposed R61-R33 project will feature a collaboration between Lutheran Social Service of Minnesota and the University of Minnesota to evaluate a novel adaption of the volunteer Senior Companion Program (SCP) to: a) assist families better manage ADRD at home; b) identify and facilitate the use of LTSS; and c) improve engagement with primary care providers throughout the state of Minnesota. If successful, the SCP-Dementia will offer a potentially efficient, wide-ranging service model for states and communities to implement for persons with ADRD and their caregiving families.

*Status of Support: Completed

Project Number: AG061903

Name of PI: Gaugler

Source of Support: NIH/NIA

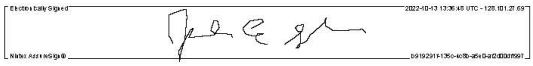
Primary Place of Performance: University of Minnesota

Project/Proposal Start and End Date: (MM/YYYY) (if available): 09/01/18-08/31/20

* Total Award Amount (including Indirect Costs): $227,248

***Overlap** (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: 

Date: 10/13/2022

Appendix B – Changes to Dr. Finn Support

1. From the initial other support page, "Improving Footwear Options for Veterans with Amputations" and "Improving Communication about Sexual Health for Persons Undergoing Acute Neurorehabilitation for TBI" have ended.
2. From the initial other support page, "Improved Understanding of Medical and Psychological Needs (I-MAP) in Veterans and Service Members with Chronic TBI" has been extended to 9/30/2026, with the same effort level for the remaining years of the grant.
3. The following grants were added as support:

Title: Characterization, Evaluation, and Implementation of Innovative TBI Intensive Evaluation and Treatment Programs (IETP)

Major Goals: Characterize and evaluate VA TBI residential individualized education and treatment programs (IETP) using qualitative and quantitative methods.

Project Number:

Name of PD/PI: Haun, J.; Nakase-Richardson, R.; Pugh, M.J.

Source of Support: Department of Veterans Affairs Quality Enhancement

Research Initiative Primary Place of Performance: Minneapolis VA Health

Care System

Project Start and End Date: 10/01/2021 – 09/30/2024

Total Award Amount (including Indirect

Costs): Person Months per

budget period: 0.3 calendar months

Title: Leveraging Nationwide Research Infrastructure to Enrich Brain Health after TBI: the ENRICH Brain Health Study

Major Goals: We propose 5 unified projects to investigate the clinical manifestations and biological underpinnings of long-term cognitive and psychological health challenges after TBI in Service Members, Veterans, and the American public.

Project Number: Project Number is Pending (Application Number: TP210516)

Name of PD/PI:

Dams-O'Connor, K.

Source of Support:

Department of

Defense

Primary Place of Performance: Minneapolis VA Health Care System / Icahn School of Medicine at Mount Sinai

Project Start and End Date: 09/30/2022 - 09/29/2026

Total Award Amount (including Indirect

Costs): Person Months per

budget period: 0.12 calendar months

Title: Impact of Improving Footwear Options for Women Veterans with Amputations

Major Goals: We are examining the psychosocial impact of a developed prosthesis system for women veterans with lower limb amputations that facilitates greater footwear options.

Project

Number:

Pending

Name of

PD/PI:

Hansen,

A.

Source of Support: Department of Veterans Affairs Office of Research &

Development Primary Place of Performance: Minneapolis VA Health

Care System

Project Start and End Date:

1/1/2023-12/31/2025 Total

Award Amount:

Person Months per budget period: 0.6 calendar months

Appendix C – Changes to Dr. Chesak Support

PREVIOUS-CURRENT-PENDING SUPPORT FOR DOD

CHESAK, SHERRY

PREVIOUS/COMPLETED (completed within the last 5 years**)**

Grant Title/Main PI's Last Name/Grant Number:	Feasibility of a Wearable Health Monitor to Measure Stress in Family Caregivers Chesak
Effort (Calendar Months):	4 Months/Year
Funding Agency:	Mayo Clinic Center for Clinical and Translational Science Small Grant
Grants Officer Name & the Address of Funding Agency:	Mayo Clinic Center for Clinical and Translational Science 200 First Street SW Rochester, MN 55905
Project Dates:	04/01/2019-12/31/2019
Funding Amount:	
Project Goals:	To assess the feasibility and acceptability of the use of a wearable health monitor (Health Tag) for measuring stress among family caregivers (FCGs) of palliative care patients.
Specific Aims:	1) Determine if participants are adherent to wearing the Health Tag over the course of two weeks. 2) Identify if participants find the Health Tag and associated smart device application to be acceptable for use.
Overlap:	None

CURRENT/ACTIVE

Grant Title/Main PI's Last Name/Grant Number:	Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living with TBI-AD/ADRD Chesak W81XWH2110726	
Effort (Calendar Months):	Year (YYYY)	Person Months (##.##)
	1. 2021	00.30 calendar
	2. 2022	00.30 calendar
	3. 2023	00.30 calendar
Funding Agency:	Department of Defense	
Grants Officer Name & the	Nicholas Heroux U.S. Army Medical Research and Development Command 810 Schreider St	

Address of Funding Agency:	Frederick, Maryland 21702-5012
Project Dates:	09/15/2021-09/14/2024
Funding Amount:	
Project Goals:	To design, refine, and test a telehealth, psychoeducational and psychosocial support intervention for family caregivers of persons with TBI-AD/ADRD
Specific Aims:	1) Develop and implement TBI-AD/ADRD Caregiver Support Intervention (TACSI) for 15 family members of persons with a dual diagnosis of TBI & AD/ADRD to assess the feasibility, acceptability, and appropriateness of TACSI over a 3-month period (Phase I). 2) . Use a pilot-randomized controlled trial design with 80 caregivers to evaluate the preliminary efficacy and successful implementation of a revised version of TACSI over a 6-month period (Phase II).
Overlap:	None

Grant Title/Main PI's Last Name/Grant Number:	SCH: Wearable Augmented Prediction of Burnout in Nurses: A Synergy of Engineering, Bioethics, Nursing and Wellness Sciences Athreya R01NR 20362-1
Effort (Calendar Months):	1.2 calendar months
Funding Agency:	National Institutes of Health
Grants Officer Name & the Address of Funding Agency:	Christopher Bough National Institute of Nursing Research 9000 Rockville Pike Bethesda, Maryland 20892
Project Dates:	04/11/2022-01/31/2026
Funding Amount:	
Project Goals:	To develop a technology to predict burnout in RNs by combining workplace, psychological, and physiological factors, and exploring the barriers to adopting such a technology.
Specific Aims:	1) Create a unique, open-access, de-identified dataset that transforms the science of burnout. 2) Develop an analytical framework combining probabilistic graphical models (PGMs) and multitask learning (MTL). 3) Explore barriers (bioethics and administrative) to adopting burnout prediction technologies.
Overlap:	None

PENDING

Grant Title/Main PI's Last	A Cluster-Randomized Trial of a Workplace Resilience Intervention for Child Care Providers' Mental Health & Well-Being

Name/Grant Number:	Chesak, Sherry FP00116148-A1
Effort (Calendar Months):	Year (YYYY) / Person Months (##.##) 1. 2023 — 02.40 calendar 2. 2024 — 01.80 calendar 3. 2025 — 01.80 calendar 4. 2026 — 01.80 calendar 5. 2027 — 02.40 calendar
Funding Agency:	National Institutes of Health
Grants Officer Name & the Address of Funding Agency:	National Center for Complimentary and Integrative Health 9000 Rockville Pike Bethesda, Maryland 20892
Project Dates:	09/01/2022-08/31/2027
Funding Amount:	
Project Goals:	To examine the efficacy, reach/representativeness, and long-term maintenance of a Stress Management and Reslience Training program for childcare providers
Specific Aims:	1) Improve the mental health and well-being of a high-need, diverse, and under-studied population – childcare workers. 2) Address gaps in previous resilience interventions.
Overlap:	None

Grant Title/Main PI's Last Name/Grant Number:	Accelerated Resolution Therapy for Early Maladaptive Grief: A Clinical Trial Chesak FP00116828-A1
Effort (Calendar Months):	Year (YYYY) / Person Months (##.##) 1. 2023 — 01.80 calendar 2. 2024 — 01.80 calendar 3. 2025 — 01.80 calendar 4. 2026 — 01.80 calendar 5. 2027 — 01.80 calendar
Funding Agency:	National Institutes of Health
Grants Officer Name & the Address of Funding Agency:	National Institute on Aging 9000 Rockville Pike Bethesda, Maryland 20892
Project Dates:	09/01/2022-08/31/2027
Funding Amount:	
Project Goals:	To test the effects of ART on pre-loss grief and complicated grief among older adult FCGs, when compared to with a usual care group, matched for time and attention.
Specific Aims:	1) Test the efficacy of ART compared with an attention control condition on pre-loss grief and complicated grief among older adult FCGs. 2) Examine personal, social, and psychological factors associated

	with ART treatment response (defined as post ART scores < 175 on the Marwit-Meuser Caregiver Grief Inventory and < 26 on the Inventory of Complicated Grief post-bereavement). 3) Examine changes in cognitive appraisal and integration of loss over time using mixed methods.
Overlap:	None

Appendix D – Annual Quad Chart

Designing and Evaluating a Comprehensive Support Program for Families Caring for Relatives Living with TBI-AD/ADRD

AZ200106
W81XWH-21-1-0726

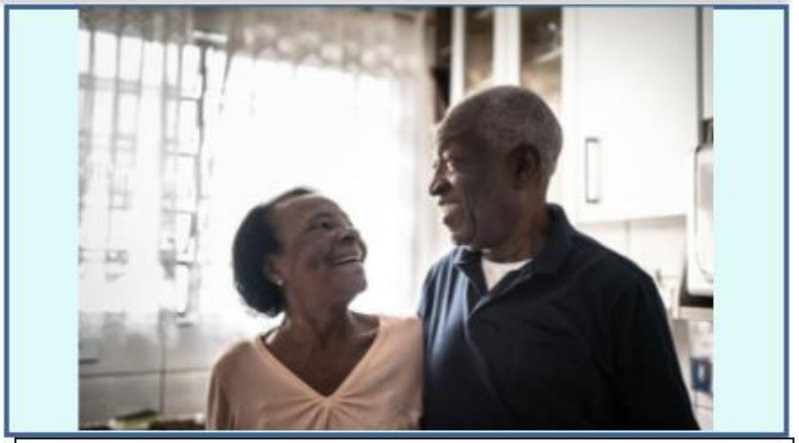
PI: Joseph E. Gaugler **Org:** University of Minnesota **Award Amount:** $750,113.00

Study/Product Aim(s)

- Evaluate TACSI (TBI-AD/ADRD Caregiver Support Intervention) for feasibility, acceptability, and utility with 15 family caregivers of persons with TBI-AD/ADRD in Phase I.
- Assess whether our recruitment, screening, randomization, treatment fidelity, and retention processes are appropriate for 80 family caregivers of persons with TBI-AD/ADRD
- Evaluate TACSI for feasibility, acceptability, and utility among 40 family caregivers of persons with TBI-AD/ADRD who received the intervention in Phase II.

Approach

The proposed project will utilize a two-phase, mixed methods, pilot randomized controlled trial (RCT) design in collaboration with the Mayo Clinic and the Minneapolis Veterans Affairs Healthcare System. In Phase I, we will enroll 15 TBI-AD/ADRD caregivers to receive TACSI. In Phase II, we will enroll 80 TBI-AD/ADRD caregivers and randomly assign them to receive usual care control or TACSI treatment.



Accomplishment: Initiated Project

Timeline and Cost

Activities CY	21	22	23	24
Initiate Phase 1, Recruit/Enroll				
Administer TACSI, Analyze Data & Refine TACSI				
Initiate Phase 2, Recruit/Enroll				
Administer TACSI, Analyze Data & Dissemination				
Estimated Budget ($750K)	**$47K**	**$263K**	**$251K**	**$189K**

Updated: 10/14/2022

Goals/Milestones

CY21 Goal – Initiate Phase 1
☒ Begin project management/study setup, seek approvals
CY22 Goals – Recruit and Enroll, Administer TACSI, Analyze Data and Refine TACSI
☒ Recruit and Enroll 15 participants
☒ Administer TACSI
☐ Analyze data and refine TACSI
CY23 Goal – Initiate Phase 2 and Recruit/Enroll
☐ Initiate Phase 2, and recruit and enroll 80 participants
CY24 Goal – Administer TACSI, Analyze Data and Dissemination
☐ Administer TACSI
☐ Analyze data and disseminate findings

Comments/Challenges/Issues/Concerns

- Still seeking approval from VA IRB and HRPO which is delaying start
- Under budget since CVRE is not approved and Mayo has not invoiced subs yet and staff hours are reduced until recruitment begins

Budget Expenditure to Date: Projected Expenditure: $245,696
Actual Expenditure: $154,387