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TITLE: The Aging Brain ANSWERS Program

PRINCIPAL INVESTIGATOR: Nicole R. Fowler

CONTRACTING ORGANIZATION: The Trustees of Indiana University

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14. ABSTRACT

Veterans with Alzheimer's disease (AD) and Traumatic Brain Injury (TBI) receive the majority of their care in primary care (PC) settings, and require similar symptom management strategies and support from family caregivers. Family caregivers of individuals with AD and TBI are critical to the quality of life (QoL) of Veterans. The Aging Brain Care ANSWERS Program (ABC ANSWERS) will test if collaborative care and strength-based coping interventions for caregivers, can improve the QoL of Veterans with AD and TBI and their caregivers and reduce caregiver burden.

ABC ANSWERS is a 3-year randomized controlled trial that will enroll 200 dyads of Veterans with AD or TBI who receive their primary care from the Richard L. Roudebush VAMC in Indiana and one family caregiver of that Veteran. The dyads will either receive usual PC or the ABC ANSWERS program with PC. Patient and caregiver QoL and mental health states, caregiver burden, and dyadic strain will be collected at baseline and at 3, 6, and 12 months follow-up. The findings from this study will inform how to improve the delivery of high quality primary care to patients with AD and TBI by tailoring medical care to match the needs of Veterans and their caregivers.

15. SUBJECT TERMS

Alzheimer's disease; Traumatic Brain Injury; quality of life; caregiver burden; collaborative care; strength-based coping

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

ABC ANSWERS is a 3-year randomized controlled trial that originally planned to enroll 200 dyads of Veterans with Alzheimer’s disease or a related dementia (ADRD) or Traumatic Brain Injury (TBI) who receive their primary care from the Richard L. Roudebush VAMC in Indiana and one family caregiver of that Veteran. Following delays in recruitment due to Covid-19, a revised statement of work with an accompanying power calculation was submitted. The new goal is to recruit 124 dyads. The dyads will be randomized to either receive usual primary care (PC) or the ABC ANSWERS program with PC. Patient and caregiver quality of life (QoL) and mental health states, caregiver burden, and dyadic strain will be collected at baseline and at 3, 6, and 12 months follow-up. The findings from this study will inform how to improve the delivery of high-quality primary care to patients with ADRD and TBI by tailoring medical care to match the needs of Veterans and their caregivers.

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

Alzheimer’s disease and related dementias; Traumatic Brain Injury; quality of life; caregiver burden; collaborative care; strength-based coping

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.

SOW Task	Original Timeline (month)	Revised Timeline (month)	Site 1/4	Site 2	Site 3
Major Task 1: Project Infrastructure and Initiation					
Subtask 1.1: Revise ABC ANSWERS Protocol	1	Achieved	Fowler	Suelzer	Judge
Subtask 1.2: Train staff	1-2	Achieved	Fowler / Carnahan		Judge
Subtask 1.3: Obtain VAMC W.O.C. credentials for ABC ANSWERS Intervention Care Coordinators	1-3	Achieved		Suelzer	
Subtask 1.4: obtain local IRB Approval	3-4	Achieved	Fowler	Suelzer	
Subtask 1.5: obtain HRPO approval	5-7	Achieved	Fowler		
Subtask 1.6: build redcap tool	3	Achieved	Daggy		
Major Task 2: Recruitment					
Subtask 2.1: Meet and communicate with VAMC primary care providers about ABC ANSWERS	1-3	Achieved	Fowler	Suelzer	
Subtask 2.2: Obtain list of potentially eligible patients from the VHA CPRS system	7	Achieved	Fowler	Suelzer	
Subtask 2.3: Screen potential dyads for eligibility (actual	8-20	10-50	Fowler	Suelzer	

n=652 with projected n = 1,000)					
Subtask 2.3: Consent eligible dyads (actual n=99 with projected n = 163)	8-20	11-50	Fowler	Suelzer	
Subtask 2.4: Recruit veterans with AD and caregiver dyads via telephone (projected 200 individuals total; n = 100 dyads)	8-20	11-50	Fowler	Suelzer	
Subtask 2.5: Recruit veterans with TBI and caregiver dyads via telephone (projected 100 individuals total, n=50 dyads)	8-20	11-50	Fowler	Suelzer	
Major Task 3: Deliver ABC ANSWERS Intervention to the respective dyads					
Subtask 3.1: Initial assessment phase; The ABC ANSWERS Research Nurse conducts a demographic and medical information interview, reviews medication lists and gathers and reviews any diagnostic testing and brain imaging results with the primary intention of identifying any reversible and co-morbid conditions, and conducts a brief cognitive assessment; biopsychosocial needs assessment of patient and informal caregiver, and medication reconciliation. This initially included a face-to-face visit in the home and was moved to all remote in spring 2020 due to Covid-19 (actual 47 dyads projected n=60 dyads)	8-20	11-56	Fowler / Carnahan	Suelzer	
Subtask 3.2: Collaborative strength-based care-plan development phase; This phase begins after the first home visit (now remote) and concludes with the second visit by the ABC ANSWERS care managers. At this phase the care managers and ABC ANSWERS medical director facilitate the creation of an individualized care plan with an emphasis on coordinating care with the Vet's primary care provider. (actual 47 dyads projected n=60 dyads)	9-21	11-56	Fowler / Carnahan	Suelzer	
Subtask 3.3: Follow-up phase	10-22	11-56	Fowler /	Suelzer	

It includes interaction with the Veteran or the CarePartner via face-to-face home or clinic visit, phone contact, fax or mail (was amended to be all remote on Spring 2020 due to Covid-19). Throughout the duration of the follow-up phase, the ABC ANSWERS team will continue to work with the Vet the CarePartner, and the Vet's primary care provider to monitor, implement, and adjust as necessary the individualized care plan. (actual 47 dyads projected n=60 dyads)			Carnahan		
Major Task 4: Data collection and submission					
Subtask 4.1: Conduct baseline assessments. All enrolled Vet's and all enrolled caregivers will complete a 30-45 mins assessment following enrollment and informed consent. This assessment includes 5-8 measures to assess quality of life, depression, anxiety, caregiver burden and other co-variables. (actual n= 92 dyads projected n = 124 dyads)	8-20	11-50	Fowler	Suelzer	
Subtask 4.2: All enrolled Vet's and all enrolled caregivers will complete a 30-45 mins follow-up assessments at 3, 6- and 12-months post-randomization. These assessments include 5-8 measures to assess quality of life, depression, anxiety, caregiver burden and other co-variables. (projected 248 individuals total; n = 124 dyads)	12-32	14-60	Fowler / Daggy	Suelzer	
Major Task 5: Data Analysis and Interpretation					
Subtask 5.1: Create single database for capturing recruit activities, enrollment data and tracking for contacting enrolled dyads throughout the study. Variables will include contact information for Vet's and caregivers, logs of contact to dyads, indication of refused, ineligible or enrolled.	22	Achieved	Fowler / Daggy		

Subtask 5.3: Create VA secure REDCap database for ABC ANSWERS intervention team to enter data collected during the initial assessment phase and care plan phase.	22	Achieved	Fowler / Daggy		
Subtask 5.3: Create VA secure REDCap database for capturing screening eligibility, randomization, baseline, 3, 6, and 12-month outcome assessment. This de-identified base will include the outcome measures that are collected at each time point and will be used for analysis.	13	Achieved	Fowler / Daggy		
Subtask 6: Conduct analyses and interpret results; Mixed effects models will be used with longitudinally collected QoL, depression and anxiety scores from Veterans and caregivers as the dependent variable, randomization group, time, and an interaction between group and time as the independent variables while adjusting for the stratification variables and baseline variables that are found to be different between the two groups. An unstructured variance-covariance matrix will be used in the mixed effects models to adjust for potential correlations among measures obtained from the same individual over time. A significant interaction between group and time would indicate differences in QoL changes over time between the ABC ANSWER and usual care groups. Linear contrasts will be used to compare the QoL scores at each follow-up time between the two groups. Absent of significant interaction, significant main group effects would suggest differences in QoL measures between the two groups across all follow-up times. Parameter estimation and	46-48	46-60	Fowler / Daggy		

<p>inference procedures for the mixed effects models are conducted using the maximum likelihood approach with robust parameter estimation and inference under many missing data mechanisms. We will also include additional covariates in the mixed effects models to determine whether specific family member characteristic (relationship to veterans, frequency or types of contact, other people living in the household, etc.) are associated with QoL changes over time.</p> <p>Additionally, for caregivers only, mixed effects model will be used with caregiver burden scores (OCBS) as the repeatedly measured outcome similarly to the approach described above.</p> <p>(projected 232 individuals total; n = 116 dyads)</p>					
Major Task 6: Communicate and Disseminate Results					
Subtask 6.1: Write abstracts and manuscripts	13-36	33-60			
Subtask 6.2: Write final DoD report	33-36	60			
Subtask 6.3: Present findings to DoD PRARP IPT	13-24	60			
Subtask 6.4: Present findings at meetings	24-36	60			

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.

During Year 4 of the project, the primary focus has been on recruitment of dyads into the trial and adjusting to the changes required to complete the project during the Covid-19 pandemic. was to continue recruitment, data collection and delivering the intervention based on the re-evaluated timeline, budget and sample size (reflected in red in the Statement of Work above). Additionally, we initiated a Data Access Request (DART) to VA R&D to gather names of Veterans who may have become eligible for this project since the last data extraction in Winter 2020 right before COVID-19 and received that updated list in late July 2021.

PROTOCOL 1 of 1:

Protocol [HRPO Assigned Number]: A-20449.a (Site: Indiana University) , A-20449.b (Site: Richard L. Roudebush VA Medical Center)

Title: The Aging Brain Care (ABC) ANSWERS Program

Target required for clinical significance: 200 Veterans and 200 Caregivers of Veterans (400 individuals)

Target approved for clinical significance: 200 Veterans and 200 Caregivers of Veterans (400 individuals)

Total subjects as of 9/1/20: 79 dyads (158 individuals enrolled and 72 dyads (144) individuals randomized.

SUBMITTED TO AND APPROVED BY:

Indiana University IRB and Richard L. Roudebush VAMC Research and Development on 8/25/17. Approved by HRPO on 4/9/18

STATUS:

HRPO Protocol Number	Protocol PI Name	Organization	# Target	# Enrolled	# Completed	# Screened	# Recruited	# Ineligible	# Refused
A-20449.b	Fowler, Nicole	Richard L. Roudebush VAMC	400	158	44	509	158	187	243

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.

Nothing to report.

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.

During the next reporting period (which is a No Cost Extension period), the primary focus will continue to be screen dyads for eligibility, consent and recruitment eligible dyads. Additionally, we will continue implementation of protocol for dyads randomized to the intervention and control and collect outcomes data.

4. **IMPACT:** *Describe 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.*

Nothing to report.

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.

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.

No changes have been submitted to the IRB and the project is not required to submit for annual renewal.

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.

Like most human subjects protocols in 2020-2021, COVID-19 has impacted our ability to recruit and carry out the project. We have previously (in 2020) received approval to conduct remote recruitment, data collection and protocol implement and will continue that way for Y5 (the NCE).

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.

The supplemental funding that the project received in February 2021 will carry forward into the Y5 NCE

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

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

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).*

Carnahan, J.L., Judge, K.S., Daggy, J.K. *et al.* Supporting caregivers of veterans with Alzheimer’s disease and traumatic brain injury: study protocol for a randomized controlled trial. *Trials* 21, 340 (2020).
<https://doi.org/10.1186/s13063-020-4199-1>

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.

Nothing to report.

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: Nicole R. Fowler, PhD, MHSA
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-6465-0008
No change

Name: Kathie Judge, PhD
Project Role: Co-I
Researcher Identifier:
Nearest person month worked: 1
Contribution to Project: No Change

Name: Christopher Suelzer, MD
Project Role: Site PI
Researcher Identifier:
Nearest person month worked: 2
Contribution to the Project: No Change

Name: Krystal Lewis, RN
Project Role: Research Nurse
Researcher Identifier:
Nearest person month worked: 7.5
Contribution to the Project: No change

Name: Schonda Davis
Project Role: Interventionist
Researcher Identifier:
Nearest person month worked: 1
Contribution to the Project: No Change

Name: Melanie Scheive
Project Role: Research Assistant
Contribution to the Project: No Part time April 2020-July 2021

Name: Sneha Manoharan
Project Role: Research Specialist
Nearest person month worked: 0.2 calendar months
Contribution to Project: No change

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.

Nothing to report

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.*

Nothing to report.

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://ers.amedd.army.mil> for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) 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.*