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TITLE: The Aging Brain ANSWERS Program

PRINCIPAL INVESTIGATOR: Fowler, Nicole R.

CONTRACTING ORGANIZATION: The Trustees of Indiana University
Indianapolis, IN

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The Aging Brain ANSWERS Program

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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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13. SUPPLEMENTARY NOTES

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 enrolled 118 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

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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1. INTRODUCTION:

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 final number of enrolled dyads is 118. The dyads are 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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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 (n=746)	8-20	Achieved	Fowler	Suelzer	
Subtask 2.3: Consent eligible	8-20	Achieved	Fowler	Suelzer	

dyads (n=118)					
Subtask 2.4: Recruit veterans with AD and caregiver dyads via telephone (n = 84 dyads)	8-20	Achieved	Fowler	Suelzer	
Subtask 2.5: Recruit veterans with TBI and caregiver dyads via telephone (n=34 dyads	8-20	Achieved	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. (n=55 dyads)	8-20	Achieved	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. (n=55 dyads)	9-21	Achieved	Fowler / Carnahan	Suelzer	
Subtask 3.3: Follow-up phase 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,	10-22	Achieved	Fowler / Carnahan	Suelzer	

implement, and adjust as necessary the individualized care plan. (n=55 dyads)					
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-variates. (n = 110 dyads)	8-20	Achieved	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-variates. (n = 110 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	46-48	46-60	Fowler /		

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 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.			Daggy		

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. (220 individuals total; n = 110 dyads)					
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			

During Year 5 of the project, the primary focus has been on completing recruitment of dyads into the trial and adjusting to the changes required to complete the project during the Covid-19 pandemic. In Year 5 we completed recruitment and completed the delivery of the intervention and continued outcome data collection. Final recruitment numbers are reflected in red in the Statement of Work above as are the completed outcome data as of 8/31/22).

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 8/31/22: 118 dyads (236 individuals enrolled and 118 dyads (110 dyads 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	236	138	746	118	248	380

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period (which is a No Cost Extension period), the primary focus will be to complete data collection and analyses.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

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

Like most human subjects protocols in 2020-2021, COVID-19 impacted our ability to recruit and carry out the project as protocol. We have previously (in 2020) received approval to complete the project by conducting remote recruitment, data collection and protocol implementation. For year 5 we completed recruitment and the intervention. Data collection will continue during the NCE and until 3.31.22.

Changes that had a significant impact on expenditures

Funds for this project ended on 8/31/22 and all were expensed.

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

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:

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

Journal publications.

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.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

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

Nothing to report.

- **Technologies or techniques**

Nothing to report.

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

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

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: Ended June 15, 2022

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?

Nothing to report

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES: