

AWARD NUMBER: W81XWH-17-1-0574

TITLE: The Aging Brain ANSWERS Program

PRINCIPAL INVESTIGATOR: Fowler, Nicole R.

CONTRACTING ORGANIZATION: The Trustees of Indiana University
Indianapolis, IN

REPORT DATE: September 2020

TYPE OF REPORT: Annual Report

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

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REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188		
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1. REPORT DATE September 2020		2. REPORT TYPE Annual		3. DATES COVERED 01Sep2019- 31Aug2020	
4. TITLE AND SUBTITLE The Aging Brain ANSWERS Program			5a. CONTRACT NUMBER		
			5b. GRANT NUMBER W81XWH-17-1-0574		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S) Nicole R. Fowler, PhD, MHSA E-Mail: fowlern@iupui.edu			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Trustees of Indiana University 980 Indiana Ave. Room 2232 Indianapolis, IN 46202-5130			8. PERFORMING ORGANIZATION REPORT		
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)		
			11. SPONSOR/MONITOR'S NUMBER(S)		
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
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 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					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER

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1. INTRODUCTION:

ABC ANSWERS is a 3-year randomized controlled trial that plans 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. 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:

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?

Major Task 1: Project Start-Up (As defined by the SOW)

1a. Finalized ABC ANSWERS Protocol Manual (Month 6)

Actual Completion Date: 2/28/18

1b. Obtained VAMC W.O.C. Dr. Fowler (PI) (Month 6)

Actual Completion Date: 2/21/18

1c. Worked with HRPO PO (P. Shank) on application for approval. Submitted amendment to local IRB and site IRBs based on HRPO feedback. (Months 1-6)

Actual Completion Date: Original IU IRB approved 9/1/17 and VA R&D approved 9/28/17. Cleveland State original IRB approval 12/8/17. Amendments submitted to IU and VA R&D 2/27/18 and Cleveland State 2/23/18.

1d. Meet with VAMC Indianapolis primary care providers about ABC ANSWERS (Months 1-6)

Actual Completion Date: 2/21/18

1e. FITBIR Reporting Orientation

Actual Completion Date: 2/5/18

1f. Test query code for identifying a list of potentially eligible Veteran-caregiver dyads (Months 4-5)

Actual Completion Date: 1/31/18

1g. Obtained HRPO Approval (Months 1-9)

Actual Completion Date: 4/09/18

1h. Build RedCap Survey Tool (Months 7-9)

Actual Completion Date: 5/18/18

1i. Hire new study RN (Months 9-10)

Actual Completion Date: 6/4/18

1j. Trained new RN

Actual Completion Date: 6/29/18

1k. Hired and trained new research coordinator, research assistant and interventionist.

Actual Completion Date: 2/28/19

1l. Hired and trained additional, new research assistant

Actual Completion Date: 8/31/19

Major Task 2: Recruitment (As defined by the SOW)

2a. Meet / communicate with VAMC primary care providers about ABC ANSWERS (Months 1-3)

Actual Completion date: 3/31/18

2b. Obtain list of potentially eligible patients from the VHA CPRS system (Upon HRPO Approval)

Actual Completion date: 4/30/18

2c. Screen and consent eligible dyads (Months 10-ongoing)

Started 5/16/18 and is ongoing

2d. Recruit dyads of Veterans and caregivers (months 8-20)

Enrolled first dyad: 7/28/18 and is ongoing

**What was accomplished under these goals?
(Continued) ACCOMPLISHMENTS:**

Major Task 3: Deliver ABC ANSWERS Intervention (to intervention group)
 3a. Initial assessment phase
 Started 7/28/18 and is ongoing
 3b. Collaborative, strength-based care-plan development phase
 Started 8/01/18 and is ongoing
 3c. Follow-Up phase
 Started 12/01/18 and is ongoing
Major Task 4: Data collection and submission
 4a. Conduct baseline assessments
 Started 6/28/18 and is ongoing
 4b. Follow-up survey assessments
 Started 12/01/18 and is ongoing
 4c. Applied for FITBIR submission account and had orientation with FITBIR contact
 4d. Created new Access database for recruitment tracking
 Actual Completion Date: 7/1/19
Major Task 5 (unplanned from proposal): Amended study protocol and procedures to adjust for remote -only study due to Covid-19
 5a. Revised protocol to ensure that all enrollment and consent procedures, intervention and data collection could be done via phone.(April 2020)
 5b. Submitted amendment to IU IRB and notified HRPO (April 2020)
 5c. Submitted remote access for study staff to be approved to access VA systems remotely. (April 2020)
 5d. Continue study as a remote-only study with no in person contact with participants. (April 2020-ongping)

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.

During Year 3 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. In spring / summer 2019 the project experienced some staff turnover which slowed recruitment activities while staff were being replaced, credentialed and trained and this occurred while the entire project was transitioning to all remote. In Q3 Year 3 the project required an amendment to adjust for the all remote requirement of the Indianapolis VA. At the end of Y3, recruitment continues to be the main activity and some decisions will need to be made about if the original recruitment goals can be met or if it needs to be revised. In Q4 of Y3, we received a no cost extension from the DOD to extend the project to 8/31/21.

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

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.

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, 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.

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

In spring 2020 the project submitted an amended protocol to the IU IRB, the VA R&D Committee and the HRPO to approve changes that will allow the project to continue all remote. Those main change includes allowing verbal consent and authorization for enrolled participants.

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

In spring 2020 Emily Fortier and Michael Stiles transitioned from the ABC ANSWERS project to other projects at Indiana University. New staff were hired, trained and credential at the Indianapolis VA to work on this project, but, it caused a delay.

Changes that had a significant impact on expenditures

Staff turnover in Y2 has delayed recruitment activities. All positions have been filled as of 8/1/20.

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

We now have IRB permission to conduct verbal consent during this time to all remote research at the Indianapolis VA.

Significant changes in use or care of vertebrate animals

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**

We replaced our Excel recruitment database with an Access database that allows for easier reporting. Additionally, we enhanced our outcomes database using the VA version of RedCap. Both databases are located on the VA service, behind the VA firewall.

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- Investigator
No Change

Name: Christopher Suelzer, MD
Project Role: Site PI
No Change

Name: Nicki Coleman, RN
Project Role: Research Nurse
Retired 2/28/20

Name: Emily Fortier
Project Role: Project Coordinator
Nearest person month worked: 3.5 calendar months
Ended the on 4/15/20

Name: Schonda Davis
Project Role: Interventionist
Nearest person month worked: 3.5
No Change

Name: Raven Kraft
Project Role: Research Assistant
Nearest person month worked: 1 calendar month. Part time February 1 2019-present
Contribution to the Project: Assists with recruitment.
Ended 3/31/20

Name: Michael Stiles
Project Role: Research Assistant
Ended 3/31/20

Name: Krystal Lewis, RN
Project Role: Research Nurse
Contribution to Project: Ms. Lewis started on the project 2/1/20 to assume the role of research nurse with the intervention in preparation for the retirement of Ricki Coleman.

Name: Melanie Scheive
Project Role: Research Assistant
Nearest person month worked: 0.2 calendar month. Part time April 2020-present
Contribution to the Project: Assists with recruitment and outcome assessments. Assists the Project Coordinator with reporting and regulatory issues.

Name: Sneha Manoharan
Project Role: Research Specialist
Nearest person month worked: 0.2 calendar months
Contribution to Project: Ms. Manoharan started in the project 4/1/20. Once she was fully credentialed at the VA, in this reporting period she has supervises Ms. Scheive and assists the PI materials for weekly project meetings, including, but not limited to, recruitment reports and materials. She also assists with recruitment and data collection.

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: