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| **AWARD NUMBER:** | W81XWH-17-1-0574 |
| **TITLE:** | The Aging Brain ANSWERS Program |
| **PRINCIPAL INVESTIGATOR:** | Fowler, Nicole R. |
| **CONTRACTING ORGANIZATION:** | The Trustees of Indiana University<br>Indianapolis, IN 46202 |
| **REPORT DATE:** | **Sept 2018** |
| **TYPE OF REPORT:** | Annual |
| **PREPARED FOR:** | U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012 |
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| **1. REPORT DATE**<br>Sept 2018 | **2. REPORT TYPE**<br>Annual | **3. DATES COVERED**<br>1 Sept 2017- 31 Aug 2018 |
| **4. TITLE AND SUBTITLE**<br><br>The Aging Brain ANSWERS Program | | **5a. CONTRACT NUMBER**<br><br>**5b. GRANT NUMBER**<br>W81XWH-17-1-0574<br>**5c. PROGRAM ELEMENT NUMBER** |
| **6. AUTHOR(S)**<br><br>Nicole R. Fowler, PhD, MHSA<br><br>**E-Mail:** fowlern@iupui.edu | | **5d. PROJECT NUMBER**<br><br>**5e. TASK NUMBER**<br><br>**5f. WORK UNIT NUMBER** |
| **7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**<br><br>**The Trustees of Indiana University**<br>980 Indiana Ave.<br>Room 2232<br>Indianapolis, IN 46202-5130 | | **8. PERFORMING ORGANIZATION REPORT** |
| **9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**<br><br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012 | | **10. SPONSOR/MONITOR'S ACRONYM(S)**<br><br>**11. SPONSOR/MONITOR'S NUMBER(S)** |
| **12. DISTRIBUTION / AVAILABILITY STATEMENT**<br><br>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 |
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| **a. REPORT** | **b. ABSTRACT** | **c. THIS PAGE** | | | **19b. TELEPHONE NUMBER** |
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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 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.

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

Alzheimer's disease; 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.*

**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
**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: 6/28/18 and is ongoing

**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.*

During Year 1 of the project, the research team completed all regulatory aspects of the award prior to initiating recruitment. That included submission of applications and receiving approval from both the Indiana University IRB and the Richard L. Roudebush Indianapolis VA Research and Development board. Additionally we worked with our HRPO PO to submit all required documentation for approval. The study was also registered on clinical trials.gov. Regarding project operations we successfully outlined the roles and responsibilities of all team members, held multiple training sessions for both the ABC ANSWERS intervention team and for the research staff conducting blinded outcome assessments. We developed several standard operating procedures for conducting the study and created the database to capture recruitment data and outcomes data. Additionally, we tested and finalized the database and created the scoring document for the study statistician. Also, in the beginning of Y1, all study materials for subjects who will be in the intervention and the control arms of the study. In Q3, the Research Nurse on the project retired from Indiana University and a search was initiated for her replacement.

In preparation for recruitment, we met with all Indianapolis VAMC Primary Care clinics to provide information about ABC ANSWERS. These meetings were a success in that the clinics were excited and engaged about the project.

In April of 2018 (Q3), we received HRPO approval. Screening and recruitment started in May 2018.

In Q4 we successfully hired and orientated the new study Research Nurse and amended all documentation to reflect this new hire.

At the end of Y1, recruitment is the main activity. Given the number of Veterans with cognitive impairment who are seen at the VA Older Adult Mental Health Clinic, we have added that site to recruit Veterans with dementia who are also receiving primary care from the VA. We also expanded the team by adding effort from an experienced part- time evening Research Assistant, to help with reaching dyads outside normal business hours, and a VA Pharmacist liaison to our intervention team.

Also in Q4, we received our annual renewal approval by both the University and the VA on 8/6/18 and 8/29/18 respectively. All documentation for the renewal has been sent to HRPO.

The co-Investigators have started a draft protocol manuscript for the project with a planned submission to a journal in, Y2.

**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.

**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.

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

During the next reporting period, the primary focus will be screening and recruitment and implementation of protocol for dyads randomized to the intervention and control.

***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.*

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.

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:*

Nothing to report.

**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.*

Nothing to report.

**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**

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).*

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.*

We created a recruitment database in excel and an 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?**

*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
*Nearest person month worked: 2 calendar months*
*Contribution to Project:* Dr. Fowler has led the development of The Aging Brain Care (ABC) ANSWERS Program study protocol, materials, databases, and study team trainings. She has liaised with other local staff pertaining to patient identification. Dr. Fowler has facilitated all necessary regulatory approvals and led discussions surrounding communication strategies with collaborating VA providers who may have eligible patients. She has also lead the team in the creation of the standard operating procedures (SOPs) for screening, recruitment, enrollment and documentation.

*Name:* Kathie Judge, PhD
*Project Role:* Co- Investigator
*Researcher Identifier:*
*Nearest person month worked: 1 Summer month*
*Contribution to Project:* Dr. Judge has refined the ABC ANSWERS intervention materials and education materials. She has conducted training sessions for the intervention staff and participated in the creation of the recruitment dashboard.

*Name:* Laurie Plue, MA
*Project Role:* Project Coordinator
*Researcher Identifier:*
*Nearest person month worked: 2 calendar months*
*Contribution to Project:* Ms. Plue has facilitated regulatory aspects including, IRB, VA R&D and HRPO submission. She has participated in all training sessions and assisted in the development of study materials and internal SOPs. She has assisted in the development of the study the Access database and (prospective) recruitment materials. She supervises the research staff.

*Name:* Christopher Suelzer, MD
*Project Role*: Site PI
*Researcher Identifier:*
*Nearest person month worked: 0 calendar month (100% VA)*
*Contribution to the Project*: Dr. Suelzer has led the creation of the communications plan for collaborating VA providers, given input on the protocol development and outlined the template that the intervention staff will use to chart and communicate in the VA EMR. He has provided expertise in the local electronic medical record system from a physician point of view and assisted with the R&D submission.

*Name*: Ashley Schwartzkopf, MSW
*Project Role:* Intervention Social Worker
*Researcher Identifier:*
*Nearest person month worked: 4 calendar months*
*Contribution to the Project*: Ms. Schwartzkopf has participated in training for the ABC ANSWERS intervention. She has collaborated with Dr. Judge on refining the ANSWERS intervention. She has collaborated with other local social workers to gain experience with the delivery of the various aspects of the collaborative care portion of the intervention. Additionally, she serves the primary point person for the dyads randomized to the intervention.

*Name*: Sandra Beech, MPH
*Project Role:* Research Assistant
*Researcher Identifier:*
*Nearest person month worked: 6 calendar months*
*Contribution to the Project*: Ms. Beech has contributed to the refinement of the outcome assessments, the outcomes database, the data dictionary, and patient recruitment materials. She is the main project recruiter and will conduct follow-up assessments.

*Name*: Nicki Coleman, RN
*Project Role:* Research Nurse
*Researcher Identifier:*
*Nearest person month worked: 3 calendar month*
*Contribution to the Project*: Ms. Coleman serves as the project research nurse. Her start date was 6/4/18. In this role she works with the project social worker and Dr. Wang to deliver the intervention protocol to dyads randomized to the intervention.

*Name*: Gloria Nicholas, RN
*Project Role:* Research Nurse
*Researcher Identifier:*
*Nearest person month worked: 3 calendar month*
*Contribution to the Project*: Ms. Nicholas participated in development of the education materials for subjects and in the training for the ABC ANSWERS intervention. She has collaborated with other local research nurses to gain experience with the delivery of the various aspects of the collaborative care portion of the intervention. Her last day on the project was 3/31/18.

**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.*