

AWARD NUMBER: W81XWH-16-1-0527

TITLE: Improving Family Quality of Life through Training to Reduce Care-Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: David Geldmacher, MD

RECIPIENT: University of Alabama at Birmingham
Birmingham, AL 35294-0017

REPORT DATE: September 30, 2019

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for public release; distribution is unlimited.

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE		Form Approved OMB No. 0704-0188
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.		
1. REPORT DATE September 2019	2. REPORT TYPE Annual	3. DATES COVERED 1 Sep 2018 - 30 Aug 2019
4. TITLE AND SUBTITLE Improving Family Quality of Life through Training to Reduce Care-Resistant Behaviors by People with Alzheimer Dementia and Traumatic Brain Injury		5a. CONTRACT NUMBER
		5b. GRANT NUMBER W81XWH-16-1-0527
		5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S) David Geldmacher, MD David Geldmacher, MD E-Mail: dgeldmacher@uabmc.edu		5d. PROJECT NUMBER
		5e. TASK NUMBER
		5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Alabama at Birmingham 1720 7th Avenue South, Suite 620 Birmingham, AL 35233		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 REPORT NUMBER(S)
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited		
13. SUPPLEMENTARY NOTES		
14. ABSTRACT This project intends to determine whether distance-accessible real time caregiver coaching is associated with improved caregiver burden and quality of life among people providing care to individuals with behavioral and psychiatric symptoms of dementia or neuropsychiatric symptoms after traumatic brain injury. Development of caregiver training materials and intervention strategies occurred as planned and on schedule. Enrollment of participants began close to the original schedule and is ongoing. Potential barriers to recruitment, including the definition of "care resistant behavior" have been addressed and appear to have resolved a slow start to enrollment. Important qualitative observations about the intervention and participant responses have been derived by the intervention team and these are being considered for scholarly reporting and publication. An insufficient number of participants has completed the information for the research team to have collected quantitative data on caregiver burden and family quality of life for statistical analysis. This is consistent with our work plan and expectations for year 1. The project remains active and on schedule.		

15. SUBJECT TERMS Dementia – Traumatic Brain Injury – Caregiving – Caregiver Burden – Quality of Life					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	17	USAMRMC 19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	5
4. Impact.....	7
5. Changes/Problems.....	9
6. Products.....	10
7. Participants & Other Collaborating Organizations.....	13
8. Special Reporting Requirements.....	15
9. Appendices.....	15

1. INTRODUCTION

This research addresses whether theoretically-driven caregiver education and coaching in non-pharmacologic approaches to reduce care resistant behaviors as a trigger of behavioral and psychiatric symptoms of dementia (BPSD) and neuropsychiatric symptoms after Traumatic Brain Injury (NPTBI) will improve caregiver burden and improve quality of life (QOL) for patients and their families. This project will use the innovative approach of distance learning (DL) methods to **teach** caregivers of people with BPSD and NPTBI theoretically determined behavioral techniques and **coach** them on strategies to reduce those adverse behaviors. The combined qualitative, quantitative, and economic analyses will also provide pertinent information regarding the general acceptance, utility, reproducibility, and transferability of NeuroNS-Care to larger groups of family caregivers. These will help guide strategy for the near-certain implementation of synchronous and asynchronous caregiver training programs for both AD and TBI. The proposed study also has the potential to inform healthcare policy and practice for family caregivers of persons with dementia or recovering from TBI.

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

Dementia – Traumatic Brain Injury – Caregiving – Caregiver Burden – Quality of Life

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aims:

1. Translate a theoretically-driven intervention, demonstrated to be effective to reduce care resistant behaviors among nursing home resident with dementia to a distance-learning education, training, and coaching program for family caregivers of people with dementia or TBI.
2. Assess the efficacy of the intervention for reducing frequency or severity of CRB-triggered symptoms of agitation, aggression, and irritability.
3. Assess the efficacy of the intervention for improving quality of life of patients, caregivers, and families
4. Determine how patient and caregiver characteristics influence the effectiveness of the intervention
5. Evaluate how the intervention affects the health care costs of people with dementia or TBI.

Major Task 1: Adapt MOUTH techniques to NeuroNS-Care protocol	Target Month	
Subtask 1: Prepare Regulatory Documents and Research Protocol for Study		
Milestone Achieved: Local IRB approval at UAB	3	Completed 9/9/2016
<i>Milestone: HRPO approval</i>	4	Completed 12/20/2016
<i>Milestone : Educational materials completed and deployed to web site</i>	4	Completed 1/13/2017
<i>Milestone: Educational materials updated and maintained on web</i>	4-36	N/A

Major Task 2: Hire/Train/Maintain Staff for Clinical Trials	Timeline	
Subtask1: Hiring and Training of Study Staff		100 complete
<i>Milestone: Research staff trained</i>	4	100% complete
Subtask 2: Facilitate hiring, training, supervision and fidelity checks as needed for attrition	4-36	N/A
<i>Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials</i>	4-36	N/A
Major Task 3: Randomized Controlled Trial		
<i>Milestone: 1st participant consented, screened and enrolled</i>	5	Completed 3/15/2017
<i>Milestone: Report findings from overall studies</i>	36/post funding	Completed 9/30/2019
Major Task 4: Data Analysis		N/A
<i>Milestone: Report results from data analyses</i>	36	N/A

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.

- The study completed enrollment in February of 2019 with 44 caregiver/care-recipient dyads (68-AD participants and 20-TBI participants).
- The final 3 caregiver participants completed final (24-weeks) follow-up visits during the month of August 2019. All actively enrolled participants have completed the study.
- An abstract, “Feasibility of Online Synchronous Caregiver Dementia Coaching for Rejection-of-Care Behaviors” has been submitted to the Gerontological Society of America (GSA).

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.

1. Qualitative Data derived from the coaching sessions will be used in support of doctoral training in Nursing for Matthew Cooper, MSN, CRNP under the mentorship of co-investigator Jablonski

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.

Nothing to Report

- 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).

An abstract titled, “Feasibility of Online Synchronous Caregiver Dementia Coaching for Rejection-of-Care Behaviors” describing methods use by intervention coaches for online coaching of dementia caregivers has been submitted to GSA. This will includes detailed example of synchronous online coaching as an innovative method for management and reduction of care resistant behavior.

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.*

Throughout the follow-up visits, participants (especially the AD caregivers), have continues to verbalize the impact that the coaching sessions had on their ability to cope with changes in the behaviors of their care-recipient. The strategies learned during the coaching sessions has help to improve their relationship with the care-recipient as well. This continued feedback is highly suggestive that online/tele-coaching has the potential to improve the lives of those caring for persons with Alzheimer's disease.

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.

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 or care of vertebrate animals

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*

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	David Geldmacher, MD (no change)
Name	Rita Jablonski-Jaudon, PhD (no change)
Name	Vicki Winstead (no change)
Name	Felicia Underwood (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

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to 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.*

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

9. APPENDICES: N/A

Improving Family Quality of Life through training to reduce care-resistant behaviors by people with Alzheimer Disease and Traumatic Brain Injury

AZ150084

W81XWH-16-1-0527

PI: Dr. David Geldmacher

Org: University of Alabama at Birmingham Award Amount: \$734,955

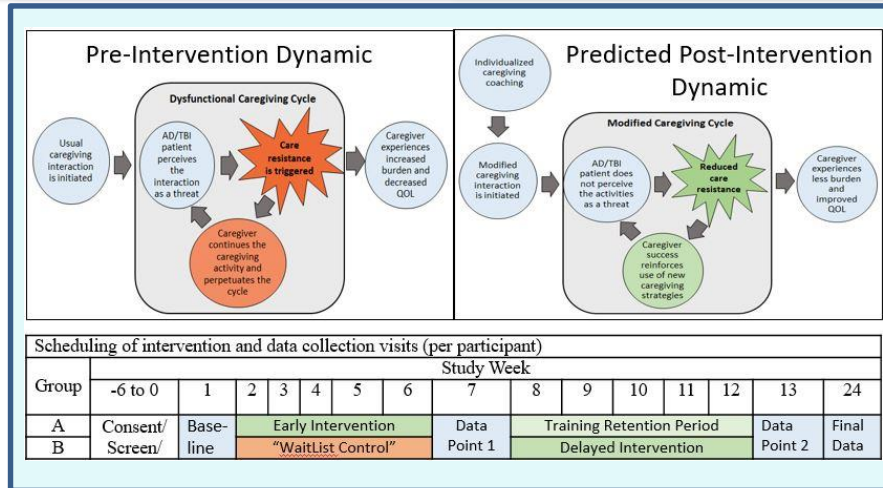


Study/Product Aim(s)

- Translate a theoretically-driven intervention, demonstrated to be effective to reduce care resistant behaviors among nursing home resident with dementia to a distance-learning education, training, and coaching program for family caregivers of people with dementia or TBI.
- Assess the efficacy of the intervention for reducing frequency or severity of CRB-triggered symptoms of agitation, aggression, and irritability.
- Assess the efficacy of the intervention for improving quality of life of patients, caregivers, and families
- Determine how patient and caregiver characteristics influence the effectiveness of the intervention

Approach

- The MOUTH intervention for reducing care resistant behavior was translated to a distant-learning coaching approach for individual caregivers of persons diagnosed with Alzheimer's and TBI.
- Family caregivers will be randomized to immediate intervention or a 6 week delayed intervention to participate in the 6-week coaching intervention. Each coaching intervention will be one hour and include strategies to reduce the severity of CRB



Accomplishment: A strategy of "entering the care-recipients reality" to affirm the care recipients' emotions is a gentler strategy and helpful in reducing the occurrence of a dysfunctional caregiving cycle.

Timeline and Cost

Activities	CY	17	18	19	20
Adapt MOUTH techniques to NeuroNS-CARE protocol					
Hire, train and maintain staff for clinical trials					
Randomized Controlled Trial					
Data Analysis, Abstracts and Publications					
Estimated Budget		\$62,983.45	\$225,460.57	\$288,339.67	\$158,171.31

Goals/Milestones CY17 Goal – Recruitment, enrollment, active intervention, data collection and entry

- ✓ Participant screenings from 2 sites UAB Memory Disorders Clinic and UAB Spain Rehabilitation

CY18 Goal – Recruitment, enrollment, active intervention, data collection and entry

- ✓ Add additional recruitment sites added; UAB Geriatric Clinics and Alabama Head injury Foundation

CY19 Goal – Last subject-last assessment; data verification /cleaning; Preliminary data analysis

- ✓ Publish qualitative report on process and content for online coaching for family caregivers
- ✓ Complete all caregiver coaching sessions
- ✓ Complete follow-up testing with 44 informal caregivers

CY20 Goal – Completion of data analysis, preparation of abstracts, publications and final study report

Comments/Challenges/Issues/Concerns

- If timelines change, comment here.
- If off by more than one quarter in spending, comment here.

Budget Expenditure to Date

Projected Expenditure: 734,955.00

Actual Expenditure: 576,783.69

Updated: September 23, 2019