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

REPORT DATE:  September 2018

TYPE OF REPORT:  Annual

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

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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.
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

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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.

<table>
<thead>
<tr>
<th>Major Task 1: Adapt MOUTH techniques to NeuroNS-Care protocol</th>
<th>Target Month</th>
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<tr>
<td>Subtask 1: Prepare Regulatory Documents and Research Protocol for Study</td>
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<tr>
<td><strong>Milestone Achieved: Local IRB approval at UAB</strong></td>
<td>3</td>
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<td>4</td>
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<tr>
<td><strong>Milestone: Educational materials completed and deployed to web site</strong></td>
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<tr>
<td><strong>Milestone: Educational materials updated and maintained on web</strong></td>
<td>4-36</td>
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<tr>
<th>Major Task 2: Hire/Train/Maintain Staff for Clinical Trials</th>
<th>Timeline</th>
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<tbody>
<tr>
<td>Subtask 1: Hiring and Training of Study Staff</td>
<td>100 complete</td>
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<tr>
<td><strong>Milestone: Research staff trained</strong></td>
<td>4</td>
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<tr>
<td>Subtask 2: Facilitate hiring, training, supervision and fidelity checks as needed for attrition</td>
<td>4-36</td>
</tr>
<tr>
<td><strong>Milestone Achieved: Maintained trained and available Independent Evaluators throughout duration of both clinical trials</strong></td>
<td>4-36</td>
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<th>Major Task 3: Randomized Controlled Trial</th>
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<tr>
<td><strong>Milestone: 1st participant consented, screened and enrolled</strong></td>
<td>5</td>
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<tr>
<td><strong>Milestone: Report findings from overall studies</strong></td>
<td>36/post funding</td>
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<th>Major Task 4: Data Analysis</th>
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<tr>
<td><strong>Milestone: Report results from data analyses</strong></td>
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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
During this reporting period, 26 dyads (19-AD and 7-TBI), have completed the 6 weekly coaching sessions. We currently have 5 dyads (4- AD and 1-TBI) active in coaching sessions. During the summer months, June – July, we experienced a reduction in enrollment but have since seen a peak in interest and referrals as we enter into the fall season.

Additionally, we received IRB approval for a revision to the inclusion criteria to allow enrollment of subjects (per the clinician’s judgment) with visual and physical disabilities and subjects with more severe cognitive deficits due to advanced stages of Alzheimer’s disease. To account for subjects enrolled with more severe cognitive deficits, an informant questionnaire on cognitive decline has been added as an alternative to direct assessment of cognition.

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. Preliminary findings from coaching sessions that are useful to the practice of physicians, psychologists, registered nurses and advanced practice nurses in caring for people with dementia (PWD) and their families were accepted for presentation on September 25, 2018 at the UAB Behavioral Neurology monthly conference.
2. 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.

Preliminary results will be disseminated to the local academic nursing community as a poster titled “Merging Practice with Research: Birth and Maturation of NeuroNSCare.” at the “Faculty Practice Poster Fair: Celebrating the Impact of Nursing Practice” conference held at the UAB School of Nursing on November 8, 2018 as a poster.

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.

| 1.  | We plan to continue our recruitment efforts. We will continue to request referrals from all sources on a regular basis. Pending IRB approval, we plan to include an additional recruitment site for Traumatic Brain Injury participants. Regular coaching sessions will continue with Drs. Jablonski and Winstead. |
| 2.  | Coaching sessions are continuously being refined based on caregiver feedback to ensure continued participation. |
| 3.  | Quantitative data analysis will commence after last patient/last visit occurs in the next reporting period. |

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).
Important qualitative observations about the intervention and participant responses have been derived by the intervention team. These will be presented at the UAB School of Nursing Faculty Practice Poster Fair on November 8, 2018. Sharing our observations in this venue should trigger useful conversations that may help shape future similar interventions for dementia, TBI, and other illness states with high caregiver burden.

A manuscript describing the methods used by the intervention coaches is in preparation. It has been invited for submission to a special issue of the journal *Healthcare* subtitled, “Care of People Living with Dementia.” This will include specific examples of interactions between coaches and participants. We hope to present innovative ways enabling caregivers to successfully apply the strategies and knowledge to their specific situation.

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.

Feedback from caregiver participants indicates that online coaching is an effective means of providing caregiver support, knowledge, and reinforcement of strategies. This suggests that broad implementation of caregiver coaching through methods like app-based teleconsulting, such as Teladoc (www.teledoc.com) should be cost-effective and viable in the future. The findings from this currently funded study could readily serve as the basis for the design of future of personalized coaching.

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 coaching sessions, participants (especially the AD caregivers), have repeatedly verbalized how much the coaching sessions have improved their relationships with their care-recipients. The overall interactions suggest that telecoaching has the potential to be cost effective and improve the lives of those caring for persons with Alzheimer’s disease and Traumatic Brain Injury.

These findings also indicate a likely role for further research on group-based, rather than individual coaching, and on-demand personalized access to caregiver coaching outside traditional fee-for-service payment models which are not configured to support such services. This has significant implications for larger health-management systems that do not depend on fee-for-service models like DoD and the VA.

### 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:

<table>
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<th>Changes in approach and reasons for change</th>
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<td>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.</td>
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<th>Actual or anticipated problems or delays and actions or plans to resolve them</th>
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<td>Describe problems or delays encountered during the reporting period and actions or plans to resolve them.</td>
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Original issue: Follow-up visits require both caregiver and person with AD/TBI to travel to the original study site(s) in Birmingham, AL. To reduce caregiver burden, we received approval for an amendment to the protocol and consent forms to the local IRB to allow follow-up visits to be done online or by phone if preferred.

An additional amendment was submitted that allowed caregivers in the delayed intervention to access AD and TBI resources immediately after randomization rather than delaying access out six weeks. This was also approved by the local IRB.

Enrollment continues to lag behind projections, especially for the TBI group. We have sought an expanded recruitment base for both AD and TBI, but unfamiliarity with the methods and the perceived time commitment for participants remains a limiting factor in participant interest. While this is a problem, it also has provided important information on future directions for telecoaching research and care delivery.

**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.*

Significant salary increases for the PI and other faculty investigators have accelerated spending well beyond what was anticipated. Cost-sharing with UAB to maintain effort dedicated to the project while conserving resources is under discussion.

**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

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.
• **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

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”.

Nothing to Report
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.)

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<thead>
<tr>
<th>Name</th>
<th>David Geldmacher, MD (no change)</th>
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<tr>
<td>Name</td>
<td>Rita Jablonski-Jaudon, PhD (no change)</td>
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<tr>
<td>Name</td>
<td>Vicki Winstead (no change)</td>
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<tr>
<td>Name</td>
<td>Felicia Underwood</td>
</tr>
<tr>
<td>Project Role</td>
<td>Program Manager</td>
</tr>
<tr>
<td>Research Identifier</td>
<td>orcid.org/0000-0003-3784-5763</td>
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<td>Nearest person month worked</td>
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<tr>
<td>Contribution to Project:</td>
<td>Felicia Underwood contributed to recruitment and participant follow-up. She worked with grant personnel in resources site improvement and in providing access to participants. She completes initial screenings and baseline testing for referred participants. She will succeed Dr. Winstead in the program manager role</td>
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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.

Dr. Geldmacher has been appointed site PI of the ADNI-3 study (U19AG024904); M. Weiner; PI. NIH/UCSD/University of Southern California. Assigned effort is 1 calendar months.

Dr. Geldmacher has relinquished Site PI responsibilities for NIA U19AG010483 and Alzheimer’s Association/USC clinical trials contract CTALEARN012.

Effort committed to this project has been reduced from 2.40 to 2.04 calendar months annually.

Dr. Winstead has relinquished her position as program manager but continues in her coaching role.

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.
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.