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AWARD NUMBER: W81XWH-17-C-0022

TITLE: Interventions for Parent Caregivers of Injured Military/Veteran Personnel

PRINCIPAL INVESTIGATOR: Linda O. Nichols, PhD

CONTRACTING ORGANIZATION: VA Medical Center
Memphis, TN 38104

REPORT DATE: APR 2019

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

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4. TITLE AND SUBTITLE
Interventions for Parent Caregivers of Injured Military/Veteran Personnel

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5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

Memphis VA Medical Center
1030 Jefferson
Memphis, TN 38104

8. PERFORMING ORGANIZATION REPORT NUMBER

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

10. SPONSOR/MONITOR'S ACRONYM(S)

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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This randomized clinical trial of 160 parent caregivers of combat wounded adult children, half in each arm, will compare 6 30-minute online webinars to 6 one-hour individual sessions modeled on the REACH VA caregiver intervention, focusing on education, skills building and support over three months. Study aims are to Modify/refine REACH intervention and Caregiver materials for Parent Caregivers, Determine adherence to the intervention and barriers to adherence, Determine if Caregivers respond to individual and elearning interventions with improvements in depression, burden, anxiety, Caregiver frustrations, and management of Veteran problems, Determine Caregivers' subjective benefit from the two interventions (satisfaction, usefulness, suggested changes, topics, strategies missing or needing expansion, and relevance), and Determine appropriateness of eligibility criteria to identify Caregivers who experience subjective and objective benefit. Data are collected at baseline, 3, and 6 months.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	17	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This randomized clinical trial of 160 parent caregivers of combat wounded adult children, half in each arm, will compare 6 30-minute online webinars to 6 one-hour individual sessions modeled on REACH VA caregiver intervention, focusing on education, skills building and support over three months. Hypothesis is that caregivers in REACH will improve in depression, burden, anxiety, frustrations, and management of Veteran problems. Data collected at baseline, 3, and 6 months.

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

Parents, Adult Children, Caregivers, Military Personnel, Veterans, Multiple Trauma, Stress Disorders, Post-Traumatic

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

1. Prepare regulatory documents – target SEPT 17 – completed SEPT 17
2. Obtain study staff – target JUL 17 – completed OCT 17
3. Finalize protocol – target SEPT 17 – completed AUG 17
4. Recruit participants – target JUN 19 – 56% completed
5. Screen participants – target JUN 19 – 53% completed
6. Randomize – target JUN 19 – 79% completed
7. Deliver intervention – target SEPT 19 – 44% completed
8. Collect and enter data – target FEB 20 – 59% completed
9. Analyze data – target MAR 20 – 0% completed
10. Prepare and disseminate results – target MAR 20 – 0% completed

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 this year, 110 potential participants have been screened, 97 participants randomized, 97 participants had baseline interviews, and 82 participants had 3 month follow up interviews, and 71 participants had 6 month follow up interviews. All data so far have been entered.

Cumulative, 179 potential participants have been screened, 126 participants randomized, 126 participants had baseline interviews, and 88 participants had 3 month follow up interviews, and 71 participants had 6 month follow up interviews.

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

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.

During the next reporting period, we will continue to screen, enroll, randomize, deliver interventions, and collect and enter data.

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).

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 Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

Recruitment slowed down at the end of last calendar year (2018). We have identified additional avenues in the VA and have reached out to them to assist with recruitment. This has increased enrollment in the past month.

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 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

Because of changes in the Common Rule, we developed and submitted a new consent form, per our IRB's request. We will not be re-consenting previous participants. After local IRB approval, we will send the new consent to HRPO. After their approval, participants going forward will be consented using the new consent form. No information was changed in the consent form; information was just reorganized to fit the new format.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

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.*

- **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.

  www.memphis.va.gov/reachparent - information and recruitment website

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be 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. State whether an application is provisional or non-provisional and indicate the application number. 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;*
- *biospecimen 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.*

Six videos for the webinar arm were developed on post deployment challenges for parents; these are on the Sprout video warehouse site (https://sproutvideo.com/login) Topics are Overview/Safety, Problem Behaviors, Your Physical Health, Your Emotional Health, Social Support, and Red Flags/Review.

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: Linda Nichols
Project Role: PI
Person month: 1.8
Contribution: Overall direction and approval, writing and editing of materials

Name: Jennifer Martindale-Adams
Project Role: Co-P, Co-II
Person month: 2.4
Contribution: Staff supervision, writing and editing of materials

Name: Jeffrey Zuber
Project Role: Data analyst
Person month: 6.0
Contribution: Development of data collection materials and databases, data integrity

Name: Carolyn Clark
Project Role: Research specialist
Person month: 12
Contribution: Writing and editing MOP and Parent Caregiver Notebook, recruiting, screening, c enrolling, consenting, data collection

Name: Jessica Roxy Martin
Project Role: Interventionist/Program Coach
Person month: 6.0
Contribution: Recruiting, screening, enrolling, consenting, delivery of interventions

Name: John Chandler
Project Role: Research specialist
Person month: 12
Contribution: Recruiting, screening, enrolling, consenting, 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?
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: For collaborative awards, independent reports are required from BOTH the Initiating 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 CHART: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

RECRUITMENT AND RETENTION

CONSORT DIAGRAM

9. APPENDICES: N/A

Interventions for Parent Caregivers of Injured Military/Veteran Personnel

Log #:14029002
Contract #:W81XWH-17-C-0022

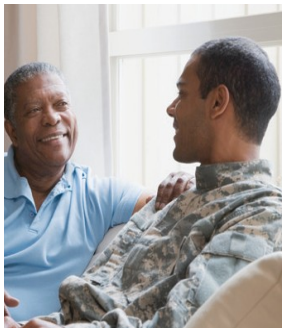
PI: Linda Nichols **Org:** Research, Inc/VA Memphis **Award Amount:** $1,258,621

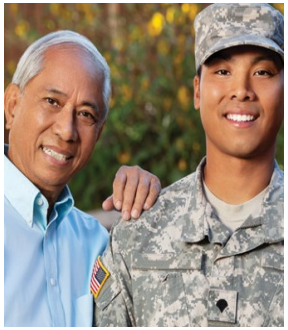
Study/Product Aim(s)

1. Modify/refine REACH intervention and Caregiver materials.
2. Determine adherence to the intervention and barriers.
3. Determine if Caregivers respond to individual and elearning interventions with improvements in depression, burden, anxiety, Caregiver frustrations, and management of Veteran problems.
4. Determine Caregivers' subjective benefit.
5. Determine appropriateness of eligibility criteria to identify Caregivers who experience subjective and objective benefit.

Approach

Randomized clinical trial of 160 parent caregivers of combat wounded adult children, half in each arm. Compare 6 30 minute online webinars to 6 one-hour individual session, focusing on education, skills building and support over three months. Data collected at baseline, 3, and 6 months.





Accomplishment: 126 participants enrolled, randomized, and begun interventions; 71 participants completed intervention

Timeline and Cost

Activities CY	17	18	19	20
Finalize materials, obtain approval, print materials				
Recruit subjects				
Administer interventions				
Collect, analyze, and process data				
Disseminate findings				
Estimated Budget ($K)	**$210**	**$419**	**$420**	**$210**

Updated: March 31, 2019

Goals/Milestones

CY17-18 Goals Completed

☑ Obtain regulatory approvals
☑ Hire/train staff
☑ Develop materials

CY18 Goal

☐ Recruit, enroll, and randomize

CY18-CY20 Goals

☐ Administer interventions
☐ Collect, analyze, process data
☐ Disseminate findings

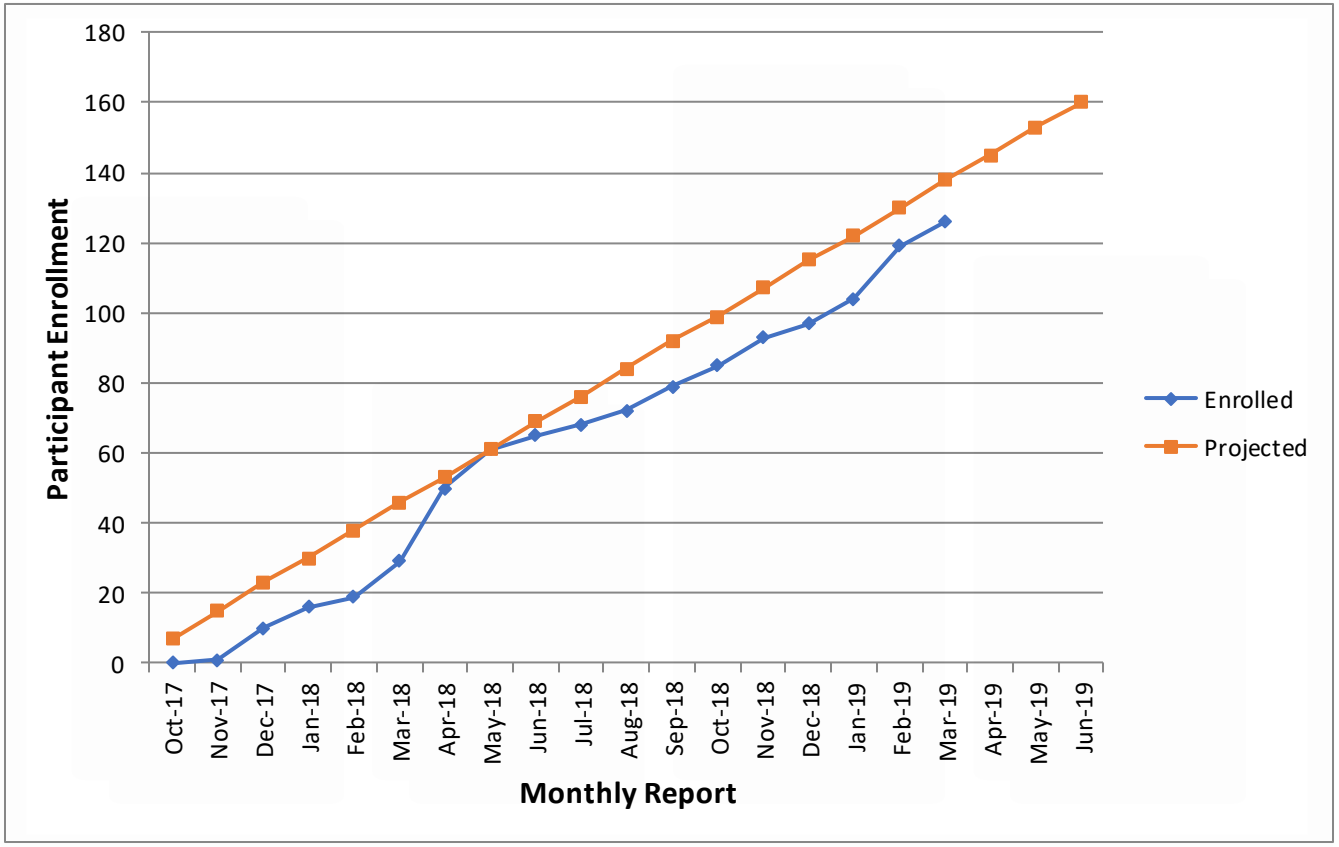
Comments/Challenges/Issues/Concerns

- Hiring concerns

Budget Expenditure to Date

Projected Expenditure: $828,209.40
Actual Expenditure: $491,712.33

Recruitment and Retention
W81XWH-17-C-0022



Percent of participants that complete study	**44.4%**

W81XWH-17-C-0022 CONSORT Diagram
4/1/17 – 3/31/19