

AWARD NUMBER: W81XWH-17-1-0690

TITLE: Building Resilience in Caregivers of Trauma Survivors

PRINCIPAL INVESTIGATOR: Deborah M Little PhD

CONTRACTING ORGANIZATION: Baylor College of Medicine
Houston Texas 77030-3411

REPORT DATE: Oct 2019

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution 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 Oct 2019		2. REPORT TYPE Annual		3. DATES COVERED 09/30/2018 - 09/29/2019	
4. TITLE AND SUBTITLE Building Resilience in Caregivers of Trauma Survivors				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER W81XWH-17-1-0690	
6. AUTHOR(S) Deborah M Little PhD E-Mail: Deborah.M.Little@uth.tmc.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Baylor College of Medicine One Baylor Plaza Houston Texas 77030				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development 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 Post-9/11 US Armed Forces have faced extended combat in support of Operations Iraqi Freedom, Enduring Freedom, New Dawn, Inherent Resolve and Freedom's Sentinel. These combat operations have led to hundreds of thousands of injured troops some of whom require informal caregivers upon their return home which places the caregiver at risk for longer term costs to their mental and physical health. The purpose of the research is to quantify the impact of trauma on informal caregivers, to determine if common methods to provide support to caregivers are effective in this younger cohort when delivered within days of the trauma, and to determine which factors influence successful outcomes of common interventions. A total of 200 potential caregivers, with a loved one who was admitted to a Level I trauma center, will be recruited. Following baseline assessments, the potential caregiver will be randomized to a control group (support as usual), a traditional problem solving therapy group, or a ICU diary with structured problem solving cues group.					
15. SUBJECT TERMS Caregiver Stress					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	5
5. Changes/Problems	6
6. Products	8
7. Participants & Other Collaborating Organizations	10
8. Special Reporting Requirements	12
9. Appendices	13

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

Post-9/11 US Armed Forces have faced extended combat in support of Operations Iraqi Freedom, Enduring Freedom, New Dawn, Inherent Resolve and Freedom's Sentinel. These combat operations have led to hundreds of thousands of injured troops some of whom require informal caregivers upon their return home which places the caregiver at risk for longer term costs to their mental and physical health. The purpose of the research is to quantify the impact of trauma on informal caregivers, to determine if common methods to provide support to caregivers are effective in this younger cohort when delivered within days of the trauma, and to determine which factors influence successful outcomes of common interventions. A total of 200 potential caregivers, with a loved one who was admitted to a Level I trauma center, will be recruited. Following baseline assessments, the potential caregiver will be randomized to a control group (support as usual), a traditional problem solving therapy group, or a ICU diary with structured problem solving cues group.

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

Caregiver, post traumatic stress, secondary stress, veteran, brain injury, depression, problem solving therapy

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.

Please note that the project is pending transfer and only activities that are required prior to the execution of transfer have been initiated.

Major Goal 1: Administration and Human Subject Protections (Months 1-6)	Completion 66%
Minor Goal 1A: Prepare Study Manual and Diary (Months 4-6)	Completion 50%
Minor Goal 1B: Staffing (Months 4-6)	Completion 0%
Milestone 1A: Local IRB/IACUC Approval (Month 3)	Completion 100%
Milestone 1B: HRPO/ACURO Approval (Month 6)	Completion 33%
Major Goal 2: Study Manual Creation and Printing (Month 6)	Completion 15%
Minor Goal 2A: Procedures Manual (Month 6)	Completion 50%
Minor Goal 2B: Training on Procedure Manual and Intervention (Months 6-7)	Completion 0%
Major Goal 3: Recruitment and Data Collection of 200 Participants (Month 9-36)	Completion 0%
Major Goal 4: Data Analysis and Manuscript Preparation (Months 9-36)	Completion 0%
Minor Goal 4A: Quality Assurance (Months 9-36)	Completion 0%
Minor Goal 4B: Baseline Manuscript (Month 24)	Completion 0%
Minor Goal 4C: Intervention Manuscript (Month 36)	Completion 0%
Minor Goal 4D: Factors that Influence Outcome Manuscript (Month 36)	Completion 0%

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.

Accomplishments under the award thus far include institutional human subjects approvals for all three sites. HRPO approval for one site has been obtained and is pending at the remaining two sites.

We have also designed the ICU diaries and once spending under the grant is allowed can be sent to the printer.

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. Data collection has not yet been initiated.

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. Data collection has not yet been initiated.

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

We expect to have HRPO approval, complete the multi-site training and initiate data collection at all 3 sites.

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. Data collection has not yet been initiated.

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. Data collection has not yet been initiated.

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. Data collection has not yet been initiated.

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. Data collection has not yet been initiated.

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.

None

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.

There have been a number of problems that have limited progress to date. The most significant is that the original parent site had a policy that does not allow any spending under the award until HRPO approval is obtained. That has negatively affected the development and validation of the training manual, creation of study materials, hiring, and training. All activities that were included under the SOW to occur concurrent with pending HRPO approval.

We have also had one member of the team change institutions and the award is now pending transfer which we have been informed should be completed in the near future. Given this, we have conducted interviews and identified candidates for the first two data collection sites.

Finally, the HRPO reviewer identified for the project is no longer employed at HRPO. We have finally (Jan 2020) received the outstanding reviews and are submitted changes to the protocol for institutional approval at present.

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.

There have been no expenditures on the grant due to the above reference institutional policy on spending prior to HRPO approval.

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.

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.

tract, 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".

<i>Name:</i>	<i>Deborah Little</i>
<i>Project Role:</i>	<i>PI</i>
<i>Nearest person month worked:</i>	<i>2</i>

<i>Contribution to Project:</i>	<i>Dr. Little has maintained primary responsibility for obtaining IRB approval at each site and for submission to HRPO. Dr. Little has also created the ICU diary and has completed 20% of the study manual. Please note, as funding cannot be used due to institutional regulations surrounding HRPO Approval, no salary has been charged to the grant.</i>
---------------------------------	--

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 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.*

Building Resilience in Caregivers of Trauma Survivors

AZ160075 Peer Reviewed Alzheimer's Research Program Quality of Life Research Award
W81XWH-17-1-0690



PI: Deborah M. Little PhD

Org: Baylor College of Medicine

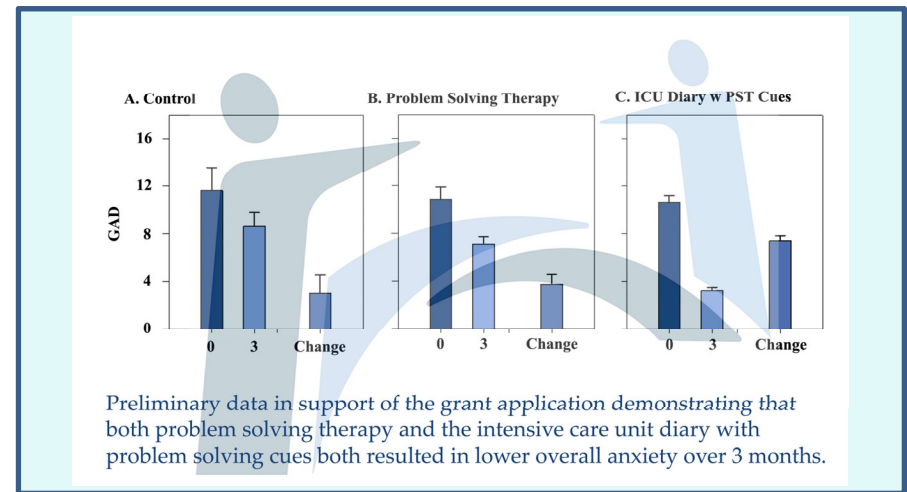
Award Amount: \$1,887,757

Study/Product Aim(s)

- Examine how baseline characteristics are associated with caregiver depression, anxiety, and substance use;
- Evaluate the effectiveness of traditional psychotherapy using problem solving therapy to reduce depression, anxiety, and substance use;
- Evaluate the effectiveness of providing an ICU diary and instruction on that diary to reduce depression, anxiety, and substance use in caregivers at 3 and 6 months following a critical injury to a loved one.

Approach

A total of 300 potential caregivers will be identified based upon severity of injury to a loved one admitted to one of 3 Level I trauma centers. The potential caregiver will complete baseline assessments within 72 hours of critical injury to a loved one and then randomized to (i) care/support as usual, (ii) psychotherapy with a focus on problem solving therapy or (iii) ICU diary with cues to identify challenges. Outcomes and factors that influence outcomes will be assessed at 3 and 6 months post injury.



Accomplishment: The research is pending HRPO Approval. Data collection has not begun.

Timeline and Cost

Activities	CY	17	18	19	20
Regulatory Approvals/Training		█	█		
Recruitment				█	█
Preliminary Analyses				█	
Analysis and Manuscripts					█
Estimated Budget (\$K)		\$0	\$622	\$628	\$638

Updated: 11.30.18

Goals/Milestones (Example)

CY18 Goal – Regulatory

- ✓ Institutional Approvals
- ☐ HRPO Approvals

CY18 Goals – Cross Site Training, Initiation of Data Collection

- ☐ Training on all study assessments, interventions in Dallas
- ☐ Initiation of Data Collection

CY19 Goal – Data Collection and Recruitment

CY20 Goal – Data Collection and Analyses

Comments/Challenges/Issues/Concerns

- We are awaiting HRPO approval to initiate data collection
- Institutional regulations do not allow spending prior to HRPO approval

Budget Expenditure to Date

- Projected Expenditure: \$621,604
- Actual Expenditure: \$0 (no funds spent to date)