

AWARD NUMBER: W81XWH-17-1-0690

TITLE: Building Resilience in Caregivers of Trauma Survivors

PRINCIPAL INVESTIGATOR: Deborah M. Little PhD

CONTRACTING ORGANIZATION: University of Texas Health Science Center Houston

REPORT DATE: OCTOBER 2021

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;  
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# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 0704-0188

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<b>1. REPORT DATE</b> OCTOBER 2021		<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 30SEPT2020 - 29SEPT2021	
<b>4. TITLE AND SUBTITLE</b>  Building Resilience in Caregivers of Trauma Survivors				<b>5a. CONTRACT NUMBER</b> W81XWH-17-1-0690	
				<b>5b. GRANT NUMBER</b>	
				<b>5c. PROGRAM ELEMENT NUMBER</b> AZ160075 USAMRAA	
Deborah M. Little PhD  E-Mail: Deborah.M.Little@uth.tmc.edu				<b>5d. PROJECT NUMBER</b>	
				<b>5e. TASK NUMBER</b>	
				<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  University of Texas Health Science Center Houston 7000 Fannin, UCT 1000 Houston Texas 77030-5400				<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012				<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b> CDMRP	
				<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited					
<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT</b>  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.					
<b>15. SUBJECT TERMS</b> Caregiver Stress					
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>  Unclassified	<b>18. NUMBER OF PAGES</b>  9	<b>19a. NAME OF RESPONSIBLE PERSON</b> USAMRDC
<b>a. REPORT</b>  Unclassified	<b>b. ABSTRACT</b>  Unclassified	<b>c. THIS PAGE</b>  Unclassified			<b>19b. TELEPHONE NUMBER</b> (include area code)

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## 1. INTRODUCTION:

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

## 3. ACCOMPLISHMENTS:

Please note, while major accomplishments remain the same, major aims and tasks as well as the timeline has changed significantly upon approval of a NCE to extend the project period to September 2022. Our Tasks and Aims have also become more specific in this process.

### o **What were the major goals of the project?**

There are four major goals of the project. These include:

1. completion of initial administration and human subject protections;
2. preparation for study data collection initiation involves recruitment of human subjects;
3. standardized assessments and manualized interventions;
4. recruitment and data collection, and caregiver and patient safety.

### o **What was accomplished under these goals?**

Prior to March 2020 we had completed all regulatory work, study manuals, procedures, and contracting. All human subjects research was suspended due to COVID. Given the uncertain and unpredictable course of the pandemic, degree of contagion, and hospital ICU status we have adapted the procedures to include both in person (when family members are allowed to visit loved ones in the ICU) and virtual methods.

A formal request for approval of these changes has been submitted to the Grants Officer and a NCE was approved, with a revised Statement of Work in November of 2021. To accomplish the revised SOW (which is included as an appendix), clinical work has been reduced to one site with a high trauma load, increased staffing at that home site, increased recruitment timeline, data quality goals, validation of the shortened problem solving protocol, and blinding (as all will be done at one site).

Based upon our SOW, we completed all human subjects approvals, creation and printing (a pdf of the two versions of the diary is attached), initial study staffing (one research assistant, one project coordinator, data manager (also database programmer), programming of all measures via redcap, validation of Doxy.me for informed consent, intervention, training of staff on assessment batteries at baseline, 3 months, and 6 months, patient assessment at 3 months and 6 months, training of staff on recruitment, identification and inclusion and exclusion criteria. We are also in the final stages of finalizing the shortened problem solving therapy arm. All existing staff have been credentialed at both UTHealth and Memorial Hermann Hospital with access to the electronic medical record.

- **What opportunities for training and professional development has the project provided?**

Although not expected, the development of the short term problem solving therapy is a novel approach mandated by telemedicine. Project staff have the opportunity to be part of the development of the materials and training manual. Once validated, our clinical staff will also be given the opportunity to attend training sessions by the CO-PI Dr. Dolan, Consultant Dr. Elliott (who helped establish the original PST protocols), and study psychologists Dr. Leslie Taylor and Dr. Sarah Jackson. Dr. Jackson has done similar development of longer protocols when time did not allow 12-14 week interventions during her military service. As such, this will provide an opportunity for training for interns, social workers, PHD level staff as well as study staff.

- **How were the results disseminated to communities of interest?**

Nothing to report as of yet

- **What do you plan to do during the next reporting period to accomplish the goals?**

In the first quarter of 2022 we expect to finalize the problem solving therapy intervention and well as the other two intervention conditions, finalized all study materials, hire our second round of second staff and most importantly begin study recruitment.

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?**

Nothing to report as of yet.

- **What was the impact on other disciplines?**

Nothing to report.

- **What was the impact on technology transfer?**

Nothing to report.

- **What was the impact on society beyond science and technology?**

Nothing to report as of yet.

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**

COVID-19 has significantly impacted the research in multiple ways. First, human subjects research was suspended at all three sites. Second, visitors were not allowed in the hospital (we were recruiting family members out of the ICU). This is still the status at the parent institution and is variable at the other two sites. However, with the promise of a vaccine, we expect some degree of reopening to visitor status although this is likely to differ based upon time, hospital capacity, and study site. As such, we have proposed to shift the research from in-person to virtual to allow the research to continue. We propose to maintain the virtual design for the intervention conditions regardless of hospital status. We have also proposed to offer a hybrid option of in person or virtual consent and retain virtual assessments. We have proposed these changes as hospital policies have continued to shift over time and this is the only way to move the research forward. We have just recently (November 2022) obtained approval for a revised SOW and NCE.

These changes include all of the requests outlined above including moving from three to a single study site for consolidation of effort, training, oversight, and consistency of assessments. Study randomization will occur at Baylor University who will mail out subject materials and manage the blinding of study subjects. The timeline has been adjusted as well. As the number 1 trauma center in the country, our primary study site has sufficient patient flow to meet study requirements in the revised time line.

- **Actual or anticipated problems or delays and actions or plans to resolve them**

COVID-19 has significantly impacted initiation of research. A proposal to shift to a hybrid virtual study design has been proposed to the Science Officer, Program Officer, and has been approved as part of a revised SOW and approved NCE.

- **Changes that had a significant impact on expenditures**

Funding has only been used at the parent site to support research staff for alterations in study design and study material creation. Upon approval of the science officer, we will request alterations in the budget in parallel with obtaining revised human subjects approval at each institution and with HRPO.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Not Applicable however minor revisions related to the changes in SOW will require minor revisions.

- **Significant changes in use or care of human subjects**

COVID-19 has mandated a shift from in person to virtual human subjects interactions. Our institutions have now approved use of virtual consents. To confirm competency to provide informed consent, we now propose to assess competency in all subjects. We have also added two additional PhD level psychologists and have adapted Doxy.me as the platform for the intervention. Doing this will allow us to provide clinical coverage in the case that any one of our potential caregivers indicates suicidal ideation at any point of the center. Doxy allows study staff to notify one of our licensed PHDs who can then join the Doxy session without ever letting the potential subject out of contact. Management of risk will follow human subjects protocols.

- **Significant changes in use or care of vertebrate animals.**

Not Applicable.

- **Significant changes in use of biohazards and/or select agents**

Not Applicable.

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**

Not Applicable.

- **Journal publications.**

Nothing to report.

- **Books or other non-periodical, one-time publications.**

Nothing to report.

- **Other publications, conference papers, and presentations.**

Nothing to report.

- **Website(s) or other Internet site(s)**

A website has been created to provide study information. Once revised human subjects approvals and approval from the science officer on changes to the design of the study are obtained we will go live.

- **Technologies or techniques**

Nothing to report.

**Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

In addition to the below named persons, please note that conference calls between site PIs occur 2x per week.

Name:	<i>Deborah Little</i>
Project Role:	<i>PI</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3
Contribution to Project:	<i>Redesign in response to COVID, creation of study materials, procedure guides, re-budgeting, hiring, training, overall management.</i>
Funding Support:	

Name:	<i>Claire Carson* (will be moving on with replacement identified)</i>
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12 (1FTE on Project)
Contribution to Project:	<i>Literature reviews, study materials, testing of virtual delivery methods.</i>

Funding Support:	
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Name:	<i>Michelle Nguyen</i>
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12 (1FTE on Project)
Contribution to Project:	<i>Literature reviews, study materials, testing of virtual delivery methods.</i>
Funding Support:	

Name:	<i>Leslie Taylor PhD</i>
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.6 PM (5% on Project; will become 20% on Jan 1)
Contribution to Project:	<i>Development of PST intervention, oversight and validation of training, consent</i>
Funding Support:	

Name:	<i>Hande Christensen</i>
Project Role:	Data Management/Programmer
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1PM
Contribution to Project:	<i>RedCap Programing, Data Integrity Protocol</i>
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

The PI has received additional funding from CDMRP (GW200069) and has also had funding from CDMRP end. (GW130063)

- **What other organizations were involved as partners?**

Baylor Scott and White is no longer involved in the project.

Baylor University and Houston Methodist remaining involve as partners.

## 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://ebrap.org> for each unique award.*
- **QUAD CHARTS:** The quad chart is included.

## 9. APPENDICES: Quad Chart, Study Diaries