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TITLE: Building Resilience in Caregivers of Trauma Survivors

PRINCIPAL INVESTIGATOR: Deborah M. Little PhD

CONTRACTING ORGANIZATION: University of Texas Health Science Center Houston

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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

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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:**
   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.

   - **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.

   - **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). Since the last annual reporting period we finalized a novel, 4 session problem solving therapy protocol appropriate for caregivers of trauma patients, hired and trained a project coordinator, two research assistants, a part time social worker, and a second half time project coordinator. The social worker and second half time coordinator have been added recently due to increased recruitment. We also finalized all programming of the patient screening, caregiver screening, consent processes, and caregiver and patient data collection redcap workflows. Due to the pending expiration of funds, we requested and were approved to change from a cost reimbursement to an advance pay contract

allowing us to continue data collection until August of 2023. A final extension without funds, given our productively at that point in time, was approved to extend our period of performance until August 2024.

As history, we finally began data collection in March of 2022 and have continued to adjust our recruitment strategies as we have learned more about our population. Initially, our recruitment was exceptionally slow and as of late has increased to 3-4 per week. What we have learned is that having first phone contact by a social worker is more successful than other study staff and have added a social worker to our team for that reason. The number of "not interested" responses has been cut in half since the time she joined our team. The other major development is that our success at recruitment has increased as a function of how much time study staff spend in the ICU to increase our first contact in person contacts. We have recruited an additional half-time staff member to cover the weekend in the ICU and remaining study staff are now covering the remaining days of the week..

At present, we have screened 1012 patient records (patient injury inclusion criteria and identification of potential inclusion), approached 149 potential caregivers who were interested and began the consent process, 147 potential caregivers who completed the consent process; 135 who completed the baseline assessment (we lost a number of potential caregivers due to rapid discharge); 106 who have completed the 1 month assessment and 57 who have met our primary outcome at 3 months. The 106 at 1 month and 57 at 3 months both have 30 pending their 1ist 1 month assessment and 42 their 3 month assessment. As a comparison, the annual report last year reported 250 patients screened. This represents a 4-fold increase in productivity.

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 opportuning to attend training sessions by the CO-PI Dr. Dolan, Consultant Dr. Elliott (who helped established the original PST protocols), and study psychologists Dr. Leslie Taylor and Dr. Sarah Jackson. Dr. Jackson has done similar develop 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. This is a double blinded study.

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

  We plan to spend the next reporting period collecting data and recruiting patients.

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**

     In the last year, our recruitment has increased 4-fold and is on track. We have exceptional staffing and no changes have been made. We continue to push forward both in person at the hospital and virtually.

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

     I have one employee going out on FMLA. In expectation of this I have negotiated time from a MD who has tremendous clinical trial experience to spend 50% time on this project. The department is supporting this time. While this will not fully cover a full FTE, it will offset some of the loss. I, as PI, will take over in the in-hospital duties with increased effort (without increased cost), to cover the remaining effort lost while she is on FMLA.

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

     Due to the additional no cost extension, the PI reduced salary to maintain sufficient support to continue the remaining effort of all other study staff. This was included in the NCE and approved.

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

     None.

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

     None.

   - **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. This is a double blinded study.

     - **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 and community resources for caregivers and their family members. https://med.uth.edu/psychiatry/caregiver

- **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?**

Name:	*Deborah Little*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	https://orcid.org/0000-0003-4498-4649
Nearest person month worked:	2.4 PM
Contribution to Project:	*Oversight, regulatory, patient recruitment, hiring, training, overall management.*
Funding Support:	

Name:	*Leslie Taylor PhD*
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	.6
Contribution to Project:	*Development of PST intervention, oversight and validation of training, consent*
Funding Support:	

Name:	*Sarah Jackson PhD*

Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2.4 PM
Contribution to Project:	*Supervision of Intervention, Recruitment*
Funding Support:	

Name:	Hande Christensen
Project Role:	Data Analyst
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3.6 PM
Contribution to Project:	*RedCap programming, quality assurance of data collection, database management*
Funding Support:	

Name:	*Michelle Nguyen*
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12 PM
Contribution to Project:	*Literature reviews, study materials, testing of virtual delivery methods, subject recruitment, management of study calendar, subject consenting/testing.*
Funding Support:	

Name:	*Jada Malveaux*
Project Role:	Research Assistant II
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12PM

Contribution to Project:	*Subject Recruitment, Consenting, Delivery of Interventions*
Funding Support:	

Name:	*Emily Crusius*
Project Role:	Research Assistant I
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12PM
Contribution to Project:	*Subject Recruitment, Consenting, Assessments*
Funding Support:	

Name:	*DeShantra Moore LCSW-S*
Project Role:	Senior Social Worker
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3PM
Contribution to Project:	*Subject Recruitment*
Funding Support:	

Name:	*Erica Fuller*
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	6 PM
Contribution to Project:	*Subject Recruitment out of the ICU*
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?**

  Yes, there have changes in active other support since the grant was awarded. Current other support is listed below. Current support for 2022 is 10.27PM. Current support for 2023 is 9.12PM. There is no current pending support.

  *Title: Building Resilience in Caregivers Trauma Survivors
  Project Number: W81XWH-17-1-0690
  Name of PD/PI: Little, Deborah M.
  *Source of Support: DOD/USAMRAA
  *Primary Place of Performance: UT Health, Houston
  Project/Proposal Start and End Date: 03/2018 – 08/2024 (NCE)

* Total Award Amount (including Indirect Costs):
* Person Months (Calendar/Academic/Summer) per budget period.
Year Person Months
1. 2023-2024 2.4 calendar

*Title: Defining And Characterizing GWI Pathobiology Using Longitudinal Brain Imaging Biomarkers Of White Matter Integrity And Hemodynamic Response
Project Number: W81XWH-19-1-0767
Name of PD/PI: Sullivan, Kimberly
*Source of Support: DOD/AMRAA
*Primary Place of Performance: UT Health, Houston
Project/Proposal Start and End Date: 09/2019 – 09/2022
*Total Award Amount (including Indirect Costs):
*Person Months (Calendar/Academic/Summer) per budget period.
Year Person Months
1. 2022 1 calendar

*Title: Expanding the Characterization and Application of Clinical MRI Markers in Gulf War Illness
*Major Goals: To characterize brain health and/or injury in Gulf War Veterans who meet the case definition for Gulf War Illness.
Project Number: W81XWH-21-1-0963
Name of PD/PI: Little, Deborah M.
*Source of Support: DOD/USAMRAA
*Primary Place of Performance: UT Health, Houston
Project/Proposal Start and End Date: 09/2021 – 09/2023
*Total Award Amount:
*Person Months (Calendar/Academic/Summer) per budget period.
Year Person Months
1. 2022 2.52 calendar
2. 2023 2.64 calendar

*Title: ALTO-100-001, An Open-Label of Alto-100 in adults with major depressive disorder and/or posttraumatic stress disorder
Project Number: W81XWH-14-1-0622
Name of PD/PI: Little, Deborah M.
*Source of Support: Alto Neuroscience
*Primary Place of Performance: UT Health, Houston
Project/Proposal Start and End Date: 05/2022 – 05/2023
*Total Award Amount:
*Person Months (Calendar/Academic/Summer) per budget period.
Year Person Months
1. 2023 0.24 calendar

*Title: ARPA Funding SB 8, Section 8, TCHATT – UT Health's Trauma and Resilience Center, Child Services Expansion
Project Number: None
Name of PD/PI: Taylor, Leslie
*Source of Support: ARPA/UT System
*Primary Place of Performance: UT Health, Houston
Project/Proposal Start and End Date: 01/2022 – 12/2023
*Total Award Amount:
*Person Months (Calendar/Academic/Summer) per budget period.

Year Person Months
1. 2023-4 0.9 calendar

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

  Baylor University and Houston Methodist remaining involve as partners.

8. **SPECIAL REPORTING REQUIREMENTS**
   - **QUAD CHARTS:** The quad chart is included.
9. **APPENDICES:** Quad Chart