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AWARD NUMBER: W81XWH-18-2-0070

TITLE: IMPLEMENTATION OF A BRIEF COGNITIVE REHABILITATION INTERVENTION TO ENHANCE EFFICIENCY OF SERVICE DELIVERY FOR SERVICE MEMBERS AND VETERANS WITH MTBI: CORE-SCORE

PRINCIPAL INVESTIGATOR: **Blessen Eapen, MD**

CONTRACTING ORGANIZATION: Foundation for Advancing Veterans' Health Research

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IMPLEMENTATION OF A BRIEF COGNITIVE REHABILITATION INTERVENTION TO ENHANCE EFFICIENCY OF SERVICE DELIVERY FOR SERVICE MEMBERS: CORE-SCORE

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6. AUTHOR(S)

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Lisa H. Lu, PhD; Co-Investigator
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Foundation for Advancing Veterans' Health Research

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This study's goal is to develop a streamlined treatment based on core key ingredients of an evidence-based cognitive rehabilitation treatment that will still improve cognitive functioning but is more feasible and acceptable to Service Members and Veterans with mild traumatic brain injury (mTBI). To accomplish this goal, we have developed a manualized treatment protocol based on the successful SCORE! treatment using a framework that identified active ingredients in rehabilitation. We have worked with the IRBs of both recruitment sites and are pursuing approval from one IRB of Record. Once approved, we plan to recruit 25 service members at BAMC and 25 veterans at the San Antonio VA to pilot whether this streamlined treatment is effective. We will collect data to determine feasibility and acceptability of this intervention for both patients and clinicians. If our study is successful, we will submit a follow-up grant to evaluate more fully the efficacy of this shorter version as delivered in in-person and telehealth modalities. Such an intervention would significantly increase the number of patients we could treat.

15. SUBJECT TERMS

blast injuries, clinical trial, cognitive rehabilitation, concussion, mild TBI, postconcussive syndrome, posttraumatic stress disorder, traumatic brain injury

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	15	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

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

Throughout the course of the wars in Iraq and Afghanistan, more than 250,000 service members sustained traumatic brain injuries, mostly characterized as mild traumatic brain injuries (mTBI) or concussions. Several studies have shown that cognitive rehabilitation can be effective for individuals with mTBI, including Service Members and Veterans with post concussive symptoms. While these treatments have great potential benefits, protocols studied to date are very time intensive, requiring up to 60 hours of treatment. These time demands make it impractical for many Service Members and Veterans, and place a time-burden on clinics providing the treatment. The current study proposes to identify the key ingredients of an evidence-based cognitive rehabilitation protocol to develop a streamlined version that is feasible and acceptable to Service Members and Veterans. To accomplish our goal, we will first spend six months analyzing manualized treatments from a successful cognitive rehabilitation intervention developed for Service Members using a framework developed to identify active ingredients in rehabilitation. Based on those results we will develop a manualized streamlined treatment protocol, which we will deliver to 25 Service Members and 25 Veterans over the following 18 months.

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

blast injuries, clinical trial, cognitive rehabilitation, concussion, mild TBI, postconcussive syndrome, posttraumatic stress disorder, traumatic brain injury

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?

Major Objectives to complete by the end of this study:

- **Objective #1:** To identify core ingredients and targets in SCORE and use these to develop a Core-SCORE protocol that can be delivered 3 hours per week X 3 weeks.
- **Objective #2:** To complete an implementation study of Core-SCORE with 50 Service Members and Veterans with mTBI.
- **Objective #3:** To collect preliminary effectiveness data for a future clinical trial comparing in-person Core-SCORE treatment to telehealth delivery.

What was accomplished under these goals?

Major Task 1: Develop Core-SCORE Manual – 100% COMPLETE as of 28-AUG-2019

- Train BAMC team (DC, MR, ML) in RTSS & Construct and implement RTSS application exercise – *completed 30-NOV-2018*
    - BAMC team trained in RTSS: Lyn Turkstra, research collaborator from McMaster University and expert in the Rehabilitation Treatment Specification System, attended project meetings with the BAMC clinical team from 30-NOV-2018 to 03-DEC-2018 for training and development of the RTSS-based Core-SCORE manual. *30-NOV-2018*
    - RTSS Application Exercise: RTSS exercise conducted during collaborative meetings to facilitate clinician understanding of the Rehabilitation Treatment Specification System as applied in a real-life setting. *03-DEC-2018*
- BAMC team specifies ingredients and targets in SCORE Arm 3 Manual – *completed 13-AUG-2019*
    - Completed during in-person meetings between BAMC team and Lyn Turkstra
- Naïve clinicians specify ingredients and targets in Core-SCORE application exercise -- *completed 28-AUG-2019*
    - Reviewed by 2 naïve Speech-Language Pathologists (one new to BAMC, one not) and 1 naïve Occupational Therapist (not new to BAMC)
- Create Core-SCORE manual – *final draft completed 28-AUG-2018*

Major Task 2: Prepare for Implementation of Core-SCORE – 42%, ONGOING

- Develop data forms that are compliant with FITBIR – *completed 13-MAY-2019*
    - Data points and elements finalized and outlined in detail for future compatibility with FITBIR once data collection starts.
- Finalize consent form & human subjects protocol – *in preparation for submission to IRB*
- Coordinate with Sites for IRB protocol submission – *ongoing; identified the University of Texas Health Science Center San Antonio (UTHSCSA) as the IRB of Record; submission expected by 30-NOV-2019.*
- Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO) – *pending IRB approval*
- Submit amendments, adverse events and protocol deviations as needed – *not yet initiated*
    - Not required until after protocol approval
- Coordinate with Sites for annual IRB report for continuing review – *not yet initiated*
    - Not required until after protocol approval

Major Task 3: Coordinate & Train Study Staff for Implementation Trial – 50%, ONGOING

- Coordinate with Sites for job descriptions design & Advertise and interview for project related staff – *completed 26-DEC-2018*
    - Job description submitted: Sent to the Henry M. Jackson Foundation to hire research staff *06-SEP-2018*
    - Project related staff hired: Caitlyn Nix, Research Assistant; hired 26-DEC-2018 following phone interview on 14-NOV-2018 and face-to-face interview 26-NOV-2018.

- Coordinate for space allocation for new staff: Office space in the Brain Injury Rehabilitation Service clinic assigned to Research Assistant – *completed 02-JAN-2019*
- Coordinate with Sites for training Psychometrist and Treating Clinicians & Train Psychometrist and Treating Clinicians at VA and BAMC – *in progress, BAMC study coordinator training completed on 11-OCT-2019.*
- Coordinate with sites for ongoing evaluation to maintain >95% treatment fidelity – *in progress, treatment fidelity tracking forms drafted 4-SEPT-2019*

Major Task 4: Participant Recruitment, Therapy, Participant Evaluation – 25%, ONGOING

- Coordinate with Sites for flow chart for all study steps: Data collection time points finalized. *13-MAY-2019*
- Begin subject recruitment – *not yet initiated, cannot begin before protocol approval*
- Participants complete treatment protocol (Baseline assessment + 3 weeks of treatment + 1 week follow-up) – *not yet initiated, cannot begin before protocol approval*
- Complete 3-month follow-up assessments (AIM-FIM-IAM, NSI, KBCI, PGIC) – *not yet initiated, cannot begin before protocol approval*

Major Task 5: Manual Evaluation and Dissemination **Not yet initiated.**

Major Task 6: Prepare Proposal for RCT: Core-SCORE In Person vs. via Telehealth **Not yet initiated.**

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

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

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

1. Obtain IRB approval across sites. Once IRB approval is obtained, further project goals can be initiated and completed (e.g. subject recruitment, treatment fidelity tracking, manual evaluation).

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

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.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

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

Following a pre-review of Core-SCORE in Q2, UTHSCSA IRB offices recommended completion of the study manual prior to official submission of Phase II. This resulted in a delay in being able to submit the study to either IRB. The BAMC IRB has communicated a willingness to defer to the UTHSCSA IRB as the IRB of Record. The VA site has worked with the UTHSCSA IRB to facilitate this change in plan, which would facilitate a decrease in time to enrollment at both sites. UTHSCSA has agreed to serve as the IRB of record, and submission of Phase II is anticipated by the end of November.

There have been changes to the study's proposed treatment protocol, and as a result the Science Officer has recommended that a modified Statement of Work be submitted for review. *Modified draft submitted 09-SEPT-2019.*

Changes that had a significant impact on expenditures

Nothing to Report.

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

Significant changes in use or care of human subjects

Nothing to report.

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.

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)**

Nothing to report.

- **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: Blessen Eapen, MD
Project Role: PI
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Leads study through various regulatory and hiring initiatives

Name: Amy Bowles, MD
Project Role: BAMC Site PI
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Lead the BAMC site in regulatory, hiring, and training of study personnel

Name: Lyn Turkstra, PhD
Project Role: McMasters Site PI
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Lead trainer on RTSS and coordination of manual development team

Name: Douglas Cooper, PhD
Project Role: Neuropsychologist
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Development of treatment manual and various regulatory tasks

Name: Carlos A. Jaramillo, MD, PhD
Project Role: Site PI, STVHCS
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Leads San Antonio PRC team on regulatory and study development processes

Name: Lisa Lu, PhD
Project Role: Neuropsychologist, BAMC
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Works with Dr. Bowles on site specific regulatory and development issues at BAMC

Name: Marina LeBlanc
Project Role: Occupational Therapist, BAMC
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Part of the manual development team

Name: Melissa Ray
Project Role: Speech-Language Pathologist, BAMC
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Part of the manual development team

Name: Glenn Curtiss, PhD
Project Role: Statistician, James Haley VAMC
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Developing study database and assisting in statistical analysis for regulatory bodies and FITBIR regulatory documents

Name: Caitlyn Nix
Project Role: Research Assistant, BAMC
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Works with Dr. Bowles and Dr. Lu on study development tasks

Name: Juan Carlos Aguilera
Project Role: Study Coordinator, STVHCS
Researcher Identifier:
Nearest person month worked: no change
Contribution to Project: Works with Dr. Eapen and Dr. Cooper on study development tasks

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

Nothing to report.

What other organizations were involved as partners?

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 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.