AWARD NUMBER: W81XWH-18-2-0070

TITLE: **Implementation of a Brief Cognitive Rehabilitation Intervention to Enhance Efficiency of Service Delivery for Service**

PRINCIPAL INVESTIGATOR: **Blessen Eapen, MD**

CONTRACTING ORGANIZATION: FOUNDATION FOR ADVANCING VETERANS' HEALTH 7400 MERTON MINTER BLVD

SAN ANTONIO TX 78229-4404

REPORT DATE: October 2020

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command

Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2020	Annual	30SEPT2019 - 29SEPT2020

4. TITLE AND SUBTITLE

Implementation of a Brief Cognitive Rehabilitation Intervention to Enhance Efficiency of Service Delivery for Service

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-2-0070

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Amy O. Bowles, MD; Co-Principal Investigator
Lisa H. Lu, PhD; Co-Investigator
Caitlyn Nix; Research Assistant

E-Mail: amy.o.bowles.civ@mail.mil; lisa.h.lu.ctr@mail.mil; caitlyn.a.nix.ctr@mail.mil

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

FOUNDATION FOR ADVANCING VETERANS' HEALTH
7400 MERTON MINTER BLVD
SAN ANTONIO TX 78229-4404

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)
USAMRMC

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

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 50 veterans at the San Antonio VA to pilot whether this streamlined treatment is effective. The study outcome will be a treatment protocol (Core-SCORE) that can be delivered efficiently and effectively in person or via telehealth, to minimize functional limitations after mTBI. We will collect data to determine feasibility and acceptability of this intervention for both patients and clinicians. 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, telehealth

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	10	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:**

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, and that can be delivered efficiently and effectively in person or via telehealth.

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 50 Veterans over the following 18 months. We will determine feasibility and acceptability of this intervention and collect preliminary efficacy data.

2. **KEYWORDS:**

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

3. **ACCOMPLISHMENTS:**
   - **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 25 Service Members and 50 Veterans with mTBI.

- **Objective #3:** To collect effectiveness data for comparing in-person Core-SCORE treatment to telehealth delivery. Access to services can be a major barrier for Service Members and Veterans. Adding a telehealth delivery of the treatment manual is critical to increase access to care to Service Members and Veterans, as well as potential translation to civilian populations.

- **What was accomplished under these goals?**

Major Task 1: Develop Core-SCORE Manual – 100% COMPLETE as of 28-AUG-2019
Major Task 2: Prepare for Implementation of Core-SCORE – 50%, ONGOING

- Develop data forms that are compliant with FITBIR – completed last reporting period, **13-MAY-2019**
- Finalize consent form & human subjects protocol – IRB documents drafted **4-MAR-2020**
- Coordinate with Sites for IRB protocol submission – in progress
    - IRB protocol documents reviewed by all sites and prepared for submission following stabilization of COVID-19 crisis. **4-MAR-2020.**
    - IRB protocol documents revised to add in a telehealth version of the intervention alongside the in-person version for the veteran population **5-JUN-2020.**
    - Feedback from team regarding revised protocol documents given to study coordinator **16-JUN-2020.**
    - Submission anticipated **01-NOV-2020.**
- Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO) – in progress
    - Submission template filled out and documents currently being compiled. Waiting for IRB approval to have complete document set for submission to HRPO.
- 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 – 67%, ONGOING

- Coordinate with sites for job description design – completed last reporting period
- Advertise and interview for project related staff; Coordinate for space allocation for new staff –
    - WOC Status (without compensation appointment) attained for BAMC RA to facilitate research coordination on the VA side before a dedicated RA and Psychometrist for that site were hired, enabling more efficient training upon their arrival. **25-JUN-2020**
    - Staff Hired for VA site: Kim Forcier, Study Psychometrist – **11-AUG-2020**, and Daisy Rodriguez, Research Area Specialist – **1-SEP-2020**
- Coordinate with Sites for training Psychometrist and Treating Clinicians & Train Psychometrist and Treating Clinicians at VA and BAMC
    - Training for treating clinicians scheduled for 26 and 27-MAR-2020, canceled due to COVID-19 situation. Will be rescheduled. Tentatively: **2- and 3-NOV-2020**
- Coordinate with sites for ongoing evaluation to maintain >95% treatment fidelity
    - Treatment fidelity tracking forms drafted as of **4-SEP-2019**, and are undergoing edits as the IRB protocol is finalized.

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 in the previous reporting period.
  - Procedure SOP for study staff in progress - to be completed by **31-OCT-2020.**

- Begin subject recruitment – not yet initiated, cannot begin before protocol approval

- Participants complete treatment protocol (Baseline assessment + 3 weeks of treatment + 1 week, 4 week, and 12 week follow-ups) – 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?**

Goals for the upcoming quarter:

- Complete training of study clinicians and research staff
- Complete SOP manual for research staff
- Obtain IRB approval across sites via the University of Texas Health Science Center San Antonio (UTHSCSA) IRB
- Submit protocol to DoD HRPO for approval
- Begin participant recruitment

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**

     - Following the COVID-19 crisis in the U.S., the plan going forward is to amend the statement of work and protocol to integrate a telehealth-based version of this intervention for the veteran population alongside the in-person version. A white paper explaining the situation and proposed solution was submitted to the Science Officer. **21-MAY-2020**
     - Approval received from CDMRP for increased sample size and telehealth addition. **30-JUL-2020**

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

     - We anticipate delays in task completion and IRB approval because of COVID-19-related travel restrictions and social distancing. IRB officials in particular may not be available or have the same turnaround times for review as they usually would.
     - The COVID-19 crisis is likely to change accessibility for outpatient visits. To account for this a telehealth arm has been added to the study, which will be integrated into veteran population recruitment along with the in-person version.

   - **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:**
   - **Publications, conference papers, and presentations**
     - **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: McMaster University 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: Co-PI, Neuropsychologist, STVHCS
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

Name: Kim Forcier
Project Role: Study Psychometrist, STVHCS
Research Identifier:
Nearest person month worked: 2 months
Contribution to Project: Will administer psychometric tests to study participants at the VA site

Name: Daisy Rodriguez
Project Role: Research Area Specialist, STVHCS
Research Identifier:
Nearest person month worked: 1 month
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?**

Douglas Cooper, PhD (Co-Principal Investigator at STVHCS) is now employed by the Foundation for Advancing Veterans' Health Research rather than the Defense and Veterans Brain Injury Center. Duties and office location have not changed.

- **What other organizations were involved as partners?**
  - **Organization Name:**
  - **Location of Organization:**
  - **Partner's contribution to the projec**t
    - **Financial support;**
    - **In-kind support**
    - **Facilities**
    - **Collaboration**
    - **Personnel exchanges**
    - **Other.**

Nothing to report.

8. **SPECIAL REPORTING REQUIREMENTS**
   - **COLLABORATIVE AWARDS:**
   - **QUAD CHARTS:** Attached.
9. **APPENDICES:**