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TITLE: Building Emotional Self-Awareness Teletherapy (BEST): A Tool to Optimize Psychological Health Outcomes for Persons with Traumatic Brain Injury

PRINCIPAL INVESTIGATOR: Dawn Neumann, PhD

CONTRACTING ORGANIZATION: Indiana University, Bloomington, IN

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

Indiana University
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Bloomington, IN 47405-7000

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

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U.S. Army Medical Research and Development Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Alexithymia is an emotional processing deficit that is present in approximately 60% of the traumatic brain injury (TBI) population, including those with mild TBI (mTBI). Alexithymia is characterized by poor emotional self-awareness and difficulty labeling, differentiating, and expressing emotions. Emotional self-awareness is fundamental to processing and regulating emotions, which is why individuals with alexithymia have problems with emotion dysregulation and are often afflicted with affective symptoms and psychological health (PH) problems. Studies in participants with TBI show that alexithymia is associated with poor emotion regulation, anxiety, aggression, depression, avoidant coping, suicidal ideation, somatization, caregiver burnout, and poor relationship and life quality. One study found that individuals with mTBI and high alexithymia had more post-concussion symptoms and higher anxiety and depression scores than participants with low alexithymia. To address this prevalent problem in the TBI population, we created an eight-session intervention to treat alexithymia-related deficits (e.g. reduced emotional awareness. **Objectives/ Hypothesis:** Objectives of this study are to explore the feasibility and early efficacy of our alexithymia intervention when delivered via teletherapy and in a sample of participants with mTBI, including military service members (SM). This intervention entitled, *Building Emotional Self-awareness Teletherapy (BEST)*, is expected to have good feasibility and acceptability in civilian and SM participants, and post-tests will show significant improvements in alexithymia, emotion regulation, resiliency, and affective symptoms.

15. SUBJECT TERMS

alexithymia, emotional labeling, emotion dysregulation, resilience, and affective symptoms

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	13	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.*

The study purpose is to explore the feasibility and early efficacy of our alexithymia intervention entitled, *Building Emotional Self-awareness Teletherapy (BEST)*, when delivered via teletherapy and in a sample of participants with mild Traumatic Brain Injury (mTBI), including military service members (SM). In this study, we will explore the following specific aims: (1) Explore acceptability of remote delivery of BEST in civilian and SM participants with mTBI (e.g., attrition; treatment satisfaction; global impression of change; adverse events); (2) Examine post-treatment changes in alexithymia, emotional labeling, emotion dysregulation, resilience, and affective symptoms (positive/ negative affect; anxiety; depression; anger; and posttraumatic stress) in participants with mTBI immediately (within 1 week) and 3-months after participating in BEST, compared to changes during a double pretest period; and (3) Explore phenotypes of responders and non-responders to BEST on alexithymia, emotional labeling, and emotion regulation measures in the entire sample and within the SM sub-group. The Aims will be accomplished with the following study design: Phase I proof of principle pilot study using a non-randomized, one-group pretest-posttest design with a double pretest and a 3-month follow-up in 40 participants with mild TBI (n=20 civilians and n=20 SM) who have alexithymia and emotion dysregulation. Study sites include 1) Indiana University School of Medicine (IUSM), which is responsible for enrollment, data collection, treatment delivery, and data analysis and 2) the National Intrepid Center of Excellence (NICoE), which is responsible for recruitment and referral of military individuals, ensuring we reach our 50% (n=20) of a military sample.

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

Alexithymia, psychological health, distress, emotion regulation, resilience, and affective symptoms

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.

Accomplishments by Major Tasks as Outline in the SOW *(abbreviations are included below this table)*		
	Timeline Months Goal	**Status**
Major Task 1: Prepare Regulatory Documents & Protocol Materials		
Milestone: Local IRB approval through State University and HRPO approval for all protocols	6	Achieved – Local IRB approval 8/16/2022, HRPO/OHRO approval 10/17/2022
Milestone: Treatment Manual and Manual of Procedures Finalized	6	Achieved
Milestone: Study successfully registered on ClinicalTrials.gov	6	Achieved – Published 11/18/2022
Major Task 2: Coordinate and Train Study Staff for BEST Clinical Trial		
Milestone: trained staff; and proficiency maintained	6-30 (started month 3)	Initial staff training achieved. Maintaining proficiency remains in progress.
Major Task 3: Participant Recruitment and Assessment and Delivery of Study Intervention		
Milestone: Meet quarterly enrollment expectations of 4-6 per quarter; 40 subjects enrolled and treated (50% service members; SM)	7-30 (started month 5)	Enrollment began sooner than anticipated and is ahead of schedule. Quarterly enrollment targets have been met to-date. We have exceeded these targets for enrollment of Civilians and have met targets for enrollment of SM
Milestone: 5% or less will have an adverse event deemed possibly or probably related to the study	7-33 (started month 5)	Began tracking in Month 5. Currently 0% Adverse Events
Milestone: 20% or less subject attrition	7-33 (started month 5)	Began tracking in Month 5. Currently 0% subject attrition to date
Major Task 4: Data Entry, Integrity, Compliance and Analyses		
Milestone: Monthly QC reports and resolution during data collection	7-33 (started month 6)	Started QC Reports in Month 6. Ongoing – Monthly QC reports were provided in April, May, and June, July, August, Sept 2023
Milestone: Two DSMB reports per year	Bi-annually	Achieved – DSMB Meeting 12/19/2022 and 6/5/2023

Milestone: Hypotheses tested and results interpreted. Knowledge gained regarding feasibility and acceptability (including satisfaction), preliminary effectiveness of intervention (including effect sizes and standard deviations); and phenotypes of responders versus non-responders in Civilians and SMs with mTBI	34-36	Not planned to start for ~ 22 months.
Major Task 5: Report, Disseminate and Translate Study Findings		
Milestone: Manualized treatment for alexithymia	6-30	A treatment manual has been completed for this study. The treatment has been presented at 2 conferences and the current manual has been shared with 28 clinicians who requested it to-date. We will determine based on feedback and findings from this study if any improvements should be made to the final manualized treatment manual.
Milestone: Educational materials for people with TBI who have alexithymia and emotion dysregulation and service providers who treat these individuals	34-36	Not planned to start for ~ 22 months.
Milestone: Next phase translation plan	34-36	Not planned to start for ~ 22 months.

Abbreviations List: BEST= Building Emotional Self-awareness Teletherapy; CAC=Community Advisory Council; cRA=clinical Research Assistant; CBPR=Community Based Participatory Research; CRADAs= Cooperative Research and Development Agreements; CTA= Clinical Trial Agreements; DSA= Data Sharing Agreements; DoD=Department of Defense; DSMB=Data Safety Monitoring Board; HRPO= Human Research Protection Office; IRB= Institutional Review Board; IUSM=Indiana University School of Medicine; LEC=Lived Experience Consultant; MOA=Memoranda of Agreement; MOU=Memoranda of Understanding; MTA= Material Transfer Agreements; mTBI=mild Traumatic Brain Injury; NICoE=National Intrepid Center of Excellence; QC=Quality Control; Qrtly=Quarterly; RA=Research Assistant; SM=Service Member; SD=Standard Deviation; TRIP=Translating Research Into Practice; USAMRDC= United States Army Medical Research & Development Command

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.

Specific objectives: For the past year our main objectives were to set-up all necessary contracts; get single site IRB approval and OHRO approval; hire and train staff; create manual of procedures and treatment manual; and enroll 12 participants (6 civilian and 6 SM), and complete major activities outlined below for this quarter. All of these objectives have been met within the anticipated timeline.

Major activities: Monthly team meetings have continued; data quality reports conducted; DSMB meetings have been held; and met with Lived Experience Consultant as planned. Annual IRB renewed, was submitted to and approved by OHRO.

Developments: Though we are meeting our targeted SM enrollment at this time point, we would like to increase the pace of SM enrollment to be more balanced with Civilian enrollment. We are under our ambitious target of over-enrolling 25% Black and Hispanic/Latinx participants (16%). We would also like to continue to identify more eligible service members, and more Black and Hispanic/Latinx participants. To-date, we currently have 1 Black and 2 Hispanic participants enrolled (out of 19 subjects). Some potential ideas to meet these ambitious goals continue to be explored. Of note We are exceeding our enrollment goal for women (Actual enrollment of female participants is 58% vs goal: 35%).

Achievements: We began recruitment 2 months earlier than planned for civilians and we have exceeded our goal of enrolling 12 participants by September 30, 2023. We are currently exceeding our enrollment goals, with 19 participants enrolled to-date (13 civilians and 6 SM). No withdrawals or adverse events. Drs. Neumann and Pickett presented a poster related to this study at MHSRS. Dr. Neumann was Co-I on a DoD grant submitted this Summer that aims to begin clinical implementation efforts of the BEST intervention at select Intrepid Spirit Centers. Dr. Pickett was a consultant on that submission.

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.

In terms of training and professional development,

- 4 clinical research assistants have been trained on the contents and delivery of the intervention.
- All staff have been provided with training materials to better understand military culture.
- The Research Coordinator has participated in a workshop on recruitment of underrepresented individuals.

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.

- Dissemination of related information (on alexithymia) to Professionals (clinicians and researchers). The below presentations resulted in dissemination of treatment manual and materials to 28 clinicians globally.
    - **Neumann, D.** Alexithymia and Emotion Dysregulation. (Invited Workshop). 46th Australian Society for the Study of Brain Impairment (ASSBI) Annual Brain Impairment Conference, Darwin, Australia, May 4, 2023.
    - **Neumann, D.** Emotional and Behavioral Dyscontrol after Brain Injury: Examining Social Cognition Culprits via the James Gross "Process Model of Emotion Regulation" . (Invited Keynote). 46th Australian Society for the Study of Brain Impairment (ASSBI) Annual Brain Impairment Conference, Darwin, Australia, May 6, 2023.
    - **Neumann, D.** Treatment approaches to address emotional dysregulation after brain injury (Invited Presentation). Social Cognition from Diagnostics to Treatment: A Case Study Driven Symposium, Zwolle, Netherlands, June 8, 2023 (organized University Medical Center of Groningen).
    - **Neumann, D.** Two frequently overlooked social cognition deficits after brain injury: What are they, why are they so important, and how can you help? (Invited Presentation). Betto Deelman Award Ceremony honoring recipient, Dr. Anne Buunk , Groningen, Netherlands, June 9, 2023.
    - **Neumann, D.,** Hammond, F., Sevigny, M., Finn, J., Klyce, D., Sander, A., Bushnik, T., Ketchum, J., Chung, J., and Bogner, J. Advancing Knowledge on Alexithymia in Civilians and Veterans with Traumatic Brain Injury: A Traumatic Brain Injury Model Systems Study. 14thWorld Congress on Brain Injury, Dublin, Ireland, March 31, 2023.
    - **Neumann, D.** Hammond, F., Finn, J, Sander, A, Chung, J, Kylce, D., Bushnik, T, Bogner. J, Sevigny, M, Ketchum, J, Parrott, D. Pickett, T., and French, F. Examining Alexithymia as a Predictor of Psychological Health and as a Treatment Target for Improving Outcomes in Veterans, Service Members, and Civilians with Traumatic Brain Injury. MHSRS 2023, Kissimmee, Florida.
    - Neumann, D., Pickett, T. Clinical Trial Opportunity for Emotion Dysregulation after mTBI. National Intrepid Center of Excellence, Presentation at Clinician Huddle, August 10, 2023

- Dissemination to consumers with lived experiences
    - Neumann, D. Alexithymia Clinical Trials for Emotion Dysregulation after TBI. RHI NBIC Lunch and Learn, February 1, 2023.
    - **Neumann, D**. Alexithymia and Brain Injury. Building Brain Awareness Seminar Series. February 2, 2023 (virtual).
    - Neumann, D. Don't Know How you Feel After Brain Injury?: Outcomes and Opportunities. Speech, Language, Hearing Bloomington Brain Injury Support Group, March 6, 2023 (Virtual).
    - Neumann, D. Don't Know How you Feel After Brain Injury?: Outcomes and Opportunities. Indianapolis Brain Injury Support Group, March 6, 2023.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

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

- Continue recruitment and enrollment of participants
- Continue data collection
- Continue monthly reports and quality integrity checks
- Continue staff meetings
- Hold 2 DSMB meetings (one already scheduled for December 2023)
- Attend MHSRS 2024.

4. **IMPACT:** D*escribe 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).

Dissemination efforts to-date have resulted in dissemination of treatment manual and materials to 28 clinicians globally.

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

What was the impact on technology transfer?
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.*

1. Worked with CreateAbility, a software development company and partner, to develop an electronic App called TREAT App Emotional Awareness, which houses some training exercises that are utilized as part of our intervention. Available in Apple and GooglePlay This was overseen by Indiana University's Innovation Commercialization Office. *Note: The TREAT App is not necessary for the intervention, it is just one possible mode of delivery. The exercises in the App are available within our existing treatment materials, delivered with PowerPoint.*
2. Submitted a grant application (as Co-I) to Toyota Wayward fund to modify content for adolescents with mild TBI and to create an electronic app.

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

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.

Nothing to report.

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.

Nothing to Report

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.

Nothing to Report

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

Significant changes in use or care of vertebrate animals

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

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, 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.*

- **Neumann, D.** Alexithymia and Emotion Dysregulation. (Invited Workshop). 46th Australian Society for the Study of Brain Impairment (ASSBI) Annual Brain Impairment Conference, Darwin, Australia, May 4, 2023.
- **Neumann, D.** Emotional and Behavioral Dyscontrol aftrr Brain Injury: Examining Social Cognition Culprits via the James Gross "Process Model of Emotion Regulation" . (Invited Keynote). 46th Australian Society for the Study of Brain Impairment (ASSBI) Annual Brain Impairment Conference, Darwin, Australia, May 6, 2023.
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- Neumann, D., Pickett, T. Clinical Trial Opportunity for Emotion Dysregulation after mTBI. National Intrepid Center of Excellence, Presentation at Clinician Huddle, August 10, 2023

- **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.

- ClinicalTrials.gov: https://classic.clinicaltrials.gov/ct2/show/NCT05623046
- IU Press Release: Indiana University School of Medicine. (2023, February 7). *IU School of Medicine Researchers awarded Department of Defense Grant to improve treatment for mild traumatic brain injury*. https://medicine.iu.edu/news/2023/02/traumatic-brain-injury-department-defense-grant

- **Technologies or techniques**

  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Indirectly related to research activities that took place before this grant:
Worked with CreateAbility, a software development company and partner, to develop an electronic App called TREAT App Emotional Awareness, which houses some training exercises that are utilized as part of our intervention. Available in Apple and GooglePlay This was overseen by Indiana University's Innovation Commercialization Office. *Note: The TREAT App is not necessary for the intervention, it is just one possible mode of delivery. The exercises in the App are available within our existing treatment materials, delivered with PowerPoint.*

- **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.

None to report

-

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.*

BEST treatment manual and powerpoint slides of treatment content and exercises

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".

Name:	Dawn Neumann, PhD
Project Role:	Principal Investigator
Nearest person month worked:	3 calendar months per year
Contribution to Project:	Led study planning, directed and provided oversight of major activities in preparing the study for launch
Name:	Treven Pickett, PhD
Project Role:	Co-Investigator, Site Principal Investigator for NICoE
Nearest person month worked:	.6 calendar months per year
Contribution to Project:	Contributes to study decisions and study oversight
Name:	Flora Hammond, MD
Project Role:	Co-Investigator
Nearest person month worked:	.24 calendar months per year
Contribution to Project:	Contributes to study decisions and study oversight
Name:	Jie Ren, PhD
Project Role:	Co-Investigator, Biostatistician
Nearest person month worked:	.6 calendar months per year
Contribution to Project:	Oversight of database development. Will supervises data quality, DSMB reports, and will oversee statistical analyses, reports and write-up.
Name:	Sruthi Bhamidipalli
Project Role:	Staff Biostatistician
Nearest person month worked:	.6 calendar months per year
Contribution to Project:	Guidance and oversight of database development. Will assist with data quality reports, DSMB reports, and will conduct statistical analyses.
Name:	Amanda Melton
Project Role:	Study Coordinator
Nearest person month worked:	3.6 calendar months per year
Contribution to Project:	Oversees IRB approval and compliance, provides supervision to Research Assistants and Clinical Research Assistants, delivers remote intervention.
Name:	Stephanie Crockett
Project Role:	Research Assistant
Nearest person month worked:	2.4 calendar months per year
Contribution to Project:	Consenting participants, scheduling study visits, and data collection.
Name:	Sarvesh Ganesh Ragade (employment started August 2023)
Project Role:	Data Manager
Nearest person month worked:	.18 calendar months per year
Contribution to Project:	Develops and maintains database. Will provide data quality reports and help prepare DSMB reports.
Name:	Jimmy Mendez (employment ended June 2023)
Project Role:	Data Manager
Nearest person month worked:	1.64 calendar months per year
Contribution to Project:	Develops and maintains database. Will provide data quality reports and help prepare DSMB reports.
Name:	Raven Hill
Project Role:	Clinical Research Assistant
Nearest person month worked:	.58 calendar months per year
Contribution to Project:	Delivers remote intervention

Name:	Chiara Racioppi
Project Role:	Research Assistant
Nearest person month worked:	6 calendar months per year
Contribution to Project:	Military recruitment

Name:	David Guise
Project Role:	Data Manager
Nearest person month worked:	.53 calendar months per year
Contribution to Project:	Assists with database development and maintenance.

Name:	Jena Robinson (employment ended 5/19/2023)
Project Role:	Research Assistant
Nearest person month worked:	.84 calendar months per year
Contribution to Project:	Recruitment, consenting participants, scheduling study visits, and data collection.

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.

Organization Name: National Intrepid Center of Excellence (NICoE)
Location of Organization: Bethesda, MD
Partner's contribution to project: Collaboration

Organization Name: The Henry M. Jackson Foundation for the Foundation for the Advancement of Military Medicine
Location of Organization: Bethesda, MD
Partner's contribution to project: Grants and Contracts services; Project Staff (CR)

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://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

See Quad Chart in 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.*
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