AWARD NUMBER: W81XWH-18-1-0081

TITLE: Peer Social Support During In Vivo Exposure for PTSD: A Program to Address Dropout from Prolonged Exposure

PRINCIPAL INVESTIGATOR: Wendy Muzzy, MRA, MLIS

CONTRACTING ORGANIZATION: Medical University of South Carolina, Charleston, SC

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PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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Peer Social Support During In Vivo Exposure for PTSD: A Program to Address Dropout from Prolonged Exposure

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5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

Medical University of South Carolina
179 Ashley Avenue
Charleston, SC 29425

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDR ESS(ES)
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This study seeks to address the problem of dropout from evidence-based treatment for PTSD. We will evaluate whether the opportunity to receive social support during in vivo exposure therapy assignments from Veterans who themselves have successfully competed PE (i.e., the therapeutic equivalent of an exposure therapy 'workout buddy') is effective in reversing dropout and improving PTSD outcomes. To achieve this objective, we will use a between group, randomized controlled repeated measures design comparing PE + Exposure Workout Buddy vs. PE + Peer General Support (i.e., the standard VA Peer Support program methods involving a peer who does NOT engage in any support during in vivo homework) to evaluate the 'PE + Exposure Workout Buddy' adjunctive therapy component in terms of its ability to increase likelihood that Veterans will (a) return to and complete treatment & (b) evince reduced PTSD symptomatology at post-treatment and 3- & 6-month follow-up. An exploratory objective is to determine whether the hypothesized differential advantage of the workout buddy program is more pronounced for Veterans who receive PE via telehealth vs. receiving PE in person, as data from previous studies indicate that this may be the case.

15. SUBJECT TERMS
PTSD

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)*

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1. INTRODUCTION:

Post-traumatic Stress Disorder (PTSD) is a significant problem for Veterans and Active Duty personnel. Although effective treatments for PTSD exist (e.g., Prolonged Exposure, PE; Cognitive Processing Therapy; CPT) and have, at great expense, been widely disseminated by VA and DoD, over of those 30% who start treatment subsequently drop out prior to completion. In our first preliminary study we addressed published survey data from Veterans indicating that dropout was related to logistical barriers such as travel time, cost, and stigma associated with care from mental health settings, and so overcame these barriers by delivering treatment via home-based telehealth. However, dropout remained virtually unchanged. Veterans in our study who dropped out of treatment, including that delivered via home based telehealth, were interviewed and a majority responded that they would (a) consider returning to treatment and (b) would be more likely to complete treatment if a peer who had themselves successfully completed treatment were available to help them with exposure homework. In keeping with this feedback, our second preliminary study examined the feasibility of using peers to (a) encourage Veterans who had dropped out of PE to return to treatment and (b) offer support during in vivo (real world) exposure therapy homework assignments (e.g., as they would during 'gym workouts'). Preliminary findings indicate that such an approach is feasible, and potentially effective, in that over 50% of dropouts from PE agreed to return to treatment and 30% of these actually did so immediately. We will evaluate whether the opportunity to receive social support during in vivo exposure therapy homework from Veterans who themselves have successfully competed PE (i.e., the therapeutic equivalent of an exposure therapy 'workout buddy') is effective in reversing dropout and improving PTSD outcomes; and, secondarily, to determine whether this program is particularly helpful for those receiving PE via telemedicine.

The major tasks of the SOW include: (1) **enroll** 100 Veteran participants with PTSD who previously dropped out or are at risk of dropping out of treatment and randomly **assign** to either PE + Peer General Support or PE + Exposure Workout Buddy; and (2) collect measures of PTSD and other psychopathology, attendance, and patient satisfaction at pre-treatment, post-treatment, and follow-up.

2. KEYWORDS:

PTSD; social support; exposure therapy; peer support

3. ACCOMPLISHMENTS:

➢ ***What were the major goals of the project?***

Objective 1: To determine relative differences in treatment dose obtained, measured in terms of the number of sessions completed upon return to treatment, in response to 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' in individuals who have previously dropped out of evidence based treatment for PTSD. Whether differences are amplified or diminished with respect to prior identified risk factors such as age, race, gender, substance use, or social support will also be determined.

Objective 2: To determine differential effectiveness, measured in terms of therapeutic gains over time on measures of PTSD symptomatology, of 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' with therapy dropouts in (i.e., 'treatment outcome'). Whether differences are amplified or diminished with respect to race, gender, age, substance use, or social support will also be determined.

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

- Start-up activities and regulatory approvals have been submitted and obtained
    - IRB approval was obtained on 03-APR-2018
    - HRPO approval was obtained on 03-AUG-2018

- VA R&D approval was obtained on 07-JUN-2018

- Study personnel have been trained on the PE and peer protocols, as well as the televideo delivery protocols. Additionally, all study staff have also completed a certified program of instruction in the protection of human subjects in research (e.g., the University of Miami CITI course).
- Study assessment forms and data entry forms have been created. Staff have organized all case report forms (CRFs), regulatory binders, detail protocols, study procedures, and refined other study materials.
- Patient and therapist workbook materials have been finalized to be used during treatment sessions.
- Randomization procedures and all databases have been set up to ensure high quality data entry and data security throughout the course of the study.
- Screening and recruitment of potential peers and participants began 20-AUG-2018.
- Principal investigator and staff completed initial training sessions with peers. Resource materials were distributed.

Recruitment successes are as follows, first noting peers, then noting participants:

Between 15-MAR-2021 and 14-MAR-2022, 3 peers were screened and 3 were determined eligible, bringing our total enrolled peers to date since the initiation of study procedures on 15-MAR-2018 to 31; (19 of whom remain active).

Between 15-MAR-2021 and 14-MAR-2022, 74 participants were screened and 35 were enrolled, bringing our total enrolled participants to date since the initiation of study procedures to 108. Additionally, 24 post assessments and 47 follow-up (twenty-five 3-month and twenty-two 6-month) assessments were completed.

Below is a chart of to-date PEER enrollment.

Year / Quarter	Year 1 MAR 18 – FEB 19				Year 2 MAR 19 – FEB 20				Year 3 MAR 20 – FEB 21				Year 4 MAR 21 – FEB 22				Total as of Y4Q4
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Enrollment Actual	0	10	2	6	2	3	0	1	2	0	2	0	1	1	1	0	31
Active Peers	0	10	11	17	19	22	21	22	24	24	26	26	25	18	19	19	19

Below is a chart of to-date PARTICIPANT enrollment (eligible and randomized), projected vs. actual.

Year / Quarter	Year 1 MAR 18 – FEB 19				Year 2 MAR 19 – FEB 20				Year 3 MAR 20 – FEB 21				Year 4 MAR 21 – FEB 22				Total as of Y4Q4
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Enrollment Projected	0	0	10	11	10	11	10	11	10	11	12	12	8	0	0	0	116*
Enrollment Actual	0	0	7	3	5	9	9	14	2	8	10	6	14	8	7	6	108
Over / (Under)	0	0	(3)	(8)	(5)	(2)	(1)	3	(8)	(3)	(2)	(6)	6	8	7	6	(8)

**Overall recruitment is greater than predicted sample size to account for potential attrition or withdrawal immediately following consent but before any study treatments can be provided.*

Recruitment activities that were implemented since study initiation include:

Year 1

- Added new volunteer personnel to assist with study recruitment
- Discussed potential referral streams with providers from Post-Traumatic Stress Disorder Clinic Team (PCT) and primary care
- Identified providers in Charleston VA catchment area and Community Based Outpatient Clinics (CBOCs) to contact for referral collaboration
- Established procedures to identify potential participants who successfully completed Prolonged Exposure therapy to serve as peers
- Developed recruitment letter to send to list of potential participants once recruitment activities begin
- Added study information to research newsletter which is distributed monthly to healthcare providers at the Charleston VA and CBOCs
- Met with local wounded Veterans group to disseminate flyers
- Received IRB approval for new study flyer and updated assessment questionnaires
- Developed study brochure
- Expanded peer recruitment to local Savannah CBOC and enrolled first CBOC participants
- Posted new flyers at Ralph H. Johnson VAMC (RHJ VAMC) and Savannah CBOC
- Attended meeting with Veterans Enrichment Center (VEC) and PCT at RHJ VAMC to discuss referral of peers

Year 2

- Staff hosted three hospital-wide recruitment events for PTSD Awareness Month to disseminate study information
- Met with individual PCT providers weekly to staff any patients who withdrew from treatment
- Added new research assistant to assist with study recruitment
- Met with director of PCT to discuss sending weekly emails to staff as reminders to send referrals of patients who dropped out of treatment
- Began organizing large research recruitment event to take place at the RHJ VAMC in August 2019
- Attended trauma symposium and Wounded Warriors Marathon to disseminate study information
- Met with mental health care providers at Trident and Savannah CBOCs
- Met with new PCT interns to discuss research options and offer information on referral process
- Attended orientation groups at Savannah CBOC
- Disseminated monthly newsletter to mental health and PCT staff
- PI and research assistant met with staff at Trauma Informed Care Training at local military base to discuss study
- Coordinated with PCT and Evidence Based Practice (EBP) team to join weekly staffing calls to identify treatment dropouts who may be amenable to research participation
- Staff set up meeting with telemental health director to discuss treatment dropouts
- Staff met with EBP Mental Health director to discuss study and set up weekly meetings
- Hosted local Veterans coffee talk
- Purchased "swag" with coordinator's main research line to give out at study recruitment events
- Presented to DoD staff at IPR meeting
- Hosted annual Veterans Research Day event at the RHJ VAMC; provided study flyers, presented research resources to veterans and clinical staff

- Set up recruitment tables at local fitness centers frequented by Veterans
- Contacted and set up meeting with Mental Health EBP team director
- Attended "Vet Fest" event to disseminate recruitment materials
- Scheduled information session with Director of Mental Health at local Active Duty base
- Discussed referrals to study with new clinic providers
- Met with other study teams at RHJ VAMC to discuss referring patients who have dropped out from their PTSD exposure treatment trials

Year 3

- Obtained approvals for consenting and completing study procedures virtually due to COVID-19
- Attended weekly PTSD clinic staffing meetings virtually to discuss patients who withdrew from treatment in mental health clinics
- Attended weekly EBP team meetings from the RHJ VAMC and CBOCs
- Discussed referrals to study with new clinic providers
- Distributed newsletter to providers highlighting study
- Disseminated study "cheat sheet" providers as easy referral resource
- Attended weekly mental health orientation group sessions virtually
- Placed new flyers around hospital as clinics began reopening
- Sent study information and opened up referrals to Trident CBOC
- Met with RHJVAMC social workers to discuss study and how to refer participants
- Set up meetings with providers at Trident CBOC for referrals; began receiving referrals from social workers
- Collaborated with other research teams to discuss study and referrals from patients who drop out of PTSD treatment

Year 4, Quarter 1

- Discussed study with active duty providers at Naval Weapons Station and Charleston Air Force Base which resulted in several referrals/patients enrolled
- Distributed bi-weekly newsletter to current and new staff in PCT clinic and other mental health clinics
- Attended Mental Health Orientation group at SAV CBOC
- Discussed study with other research teams who have had patients withdraw from exposure therapy
- Attended Mental Health Retreat at SAV CBOC to discuss study with new hire providers
- Attended new patient orientation to discuss research

Year 4, Quarter 2

- Continued collaborating with active duty providers at the Naval Weapons Station and Joint Base Charleston
- Attended Mental Health Orientation group at SAV CBOC
- Met individually with PCT providers to discuss patients that were treated via exposure therapy recently and may be interested in becoming peers
- Served as first line point-of-contact for participants who were referred to research by the PCT clinic
- Met with and accepted referrals from other study teams

Year 4, Quarter 3

- Continued collaborating with active duty providers at the Naval Weapons Station and Joint Base Charleston
- Attended PCT clinic and EBP meetings virtually
- Attended Mental Health Orientation group at SAV CBOC
- Met individually with PCT providers to discuss patients that were treated via exposure therapy recently and may be interested in becoming peers

- Served as first line point-of-contact for participants who were referred to research by the PCT clinic

Year 4, Quarter 4

- Put a final round of flyers out throughout RHJ VAMC hospital waiting areas
- Accepted more active duty referrals from Naval Weapons Station and Joint Base Charleston
- Attended Mental Health Orientation group at SAV CBOC
- Attended new patient orientation to discuss research
- Served as first line point-of-contact for participants who were referred to research by the PCT clinic

- ***What opportunities for training and professional development has the project provided?***
  Study therapists were trained on PE treatment with the addition of peers, independent evaluators were trained on assessment measures, and peers were trained on protocol procedures. Further, staff have received on-going Prolonged Exposure (PE) training and consultation by Dr. Edna Foa and her team in conjunction with another DOD award, The Efficacy of 90-Minute vs 60-Minute Sessions of Prolonged Exposure for PTSD: A Randomized Control Trial in Active Duty Military Personnel (PI: Edna Foa, PhD).

- ***How were the results disseminated to communities of interest?***
  DOD IPR will receive reports of study progress; interim results have been presented to VA in Charleston and Houston, as well as at grand rounds at affiliated universities.

- ***What do you plan to do during the next reporting period to accomplish the goals?***
  We received a no-cost extension and plan to end recruitment in the next quarter as the goal of the extension is to treat existing patients and complete all timepoints of follow up. We will continue to accept referrals from local and active duty providers and present at PCT staff meetings until the final date of recruitment (04/01/22). The main focus of the next quarter is completing treatment for active and newly enrolled participants and gathering as much follow up data as possible. We will begin preliminary analyses and finalize the database as patients complete study procedures.

4. IMPACT:

- ***What was the impact on the development of the principal discipline(s) of the project?***
  Though too early to report at this time, the clinical outcomes may be significant. Over 30% of those who access treatment for PTSD drop out prematurely. Previous studies indicated that Veterans, who were surveyed after dropping out of PE, stated that they would be more likely to complete treatment if they had a peer who had already completed treatment and were available to help them with exposure homework. A subsequent pilot study was implemented and the feasibility of the program, measured in terms of successful peer recruitment, training, and patient coordination with peer/therapist for in vivo exposure meetings, and patient willingness to return treatment (52%) appears to be strongly supported.

- ***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***
  No changes

- ***Actual or anticipated problems or delays and actions or plans to resolve them***
  No changes

- ***Changes that had a significant impact on expenditures***
  No changes

- ***Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents***
  No changes

- ***Significant changes in use or care of human subjects***
  No changes

- ***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***
  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:	*Wendy Muzzy*
Project Role:	*Principal Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Responsible for conceptual and practical resolution of scientific questions and data analytic decisions that inevitably present themselves during the course of a RCT*

Name:	*Ronald Acierno*
Project Role:	*Co-Principal Investigator*
Nearest person month worked:	*2*
Contribution to Project:	*Responsible for all scientific, technical, and financial aspects of the project*

Name:	*Rebecca Knapp*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Serves as statistician*

Name:	*Melba Hernandez*
Project Role:	*Co-Investigator*
Nearest person month worked:	*2*
Contribution to Project:	*Provides expertise in the area of completing exposure activities with a peer, treatment fidelity, and clinical supervision*

Name:	*Daniel Gros*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Provides guidance in the interpretation, analysis, and publication of data*

Name:	*Anna Birks*
Project Role:	*Clinical Coordinator*
Nearest person month worked:	*1*
Contribution to Project:	*Provides overall assessment supervision, including overseeing assessment measure procedures, and assists with clinic referral flow*

Name:	*Stephanie Hart*
Project Role:	*Research Assistant II*
Nearest person month worked:	*12*
Contribution to Project:	*Coordinates the day-to-day aspects of this project*

Name:	*Tracey Rosenlieb*
Project Role:	*Human Services Coordinator II*
Nearest person month worked:	*3*

Contribution to Project:	*Conducts all interviews/assessments as detailed in the protocol; serves as a study clinician*

Name:	*A. Raquel Vining*
Project Role:	*Research Assistant II*
Nearest person month worked:	*1*
Contribution to Project:	*Serves as documentation coordinator*

Name:	*Michelle Pompei*
Project Role:	*Research Assistant II*
Project Role:	*9*
Contribution to Project:	*Serves as a participant recruiter*

Name:	*Linette Dubois*
Project Role:	*Research Assistant I*
Project Role:	*9*
Contribution to Project:	*Serves as a participant recruiter*

Name:	*Stephanie Hamski*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Tatiana Davidson*
Project Role:	*Volunteer*
Contribution to Project:	*Research Monitor*

Name:	*Kimberly (Veronee) Blitch*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Nina Schneider*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Sally Murphy*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Jonna Vaughn*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Bethany Wangelin*
Project Role:	*Volunteer*
Contribution to Project:	*Assists with recruitment efforts/VA liaison*

- ***Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?***
  No changes to report

- ***What other organizations were involved as partners?***
  Organization Name: Lowcountry Center for Veterans Research
  Location of Organization: 22 Westedge Steet Suite 410, Charleston, SC 29403

  Organization Name: The University of Texas Health Science Center at Houston
  Location of Organization: 7000 Fannin, UCT 1006 Houston, TX 77030-5401

  Partners' contribution to the project *(identify one or more)*
  Collaboration

8. SPECIAL REPORTING REQUIREMENTS:

- **COLLABORATIVE AWARDS:**
  N/A

- **QUAD CHARTS:**
  Attached

9. APPENDICES:
N/A

Peer Social Support During In Vivo Exposure for PTSD: A Program to Address Dropout from Prolonged Exposure

W81XWH-18-1-0081 / BA160297

PI: Wendy A. Muzzy, MRA, MLIS **Org:** Medical University of South Carolina **Award Amount:** $2,112,716

Study/Product Aim(s)

Objective 1: To determine relative differences in treatment dose obtained, measured in terms of the number of sessions completed upon return to treatment, in response to 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' in individuals who have previously dropped out of evidence-based treatment for PTSD. Whether differences are amplified or diminished with respect to prior identified risk factors such as age, race, gender, substance use, or social support will also be determined.

Objective 2: To determine differential effectiveness, measured in terms of therapeutic gains over time on measures of PTSD symptomatology, of 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' with therapy dropouts in (i.e., 'treatment outcome'). Whether differences are amplified or diminished with respect to race, gender, age, substance use, or social support will also be determined.

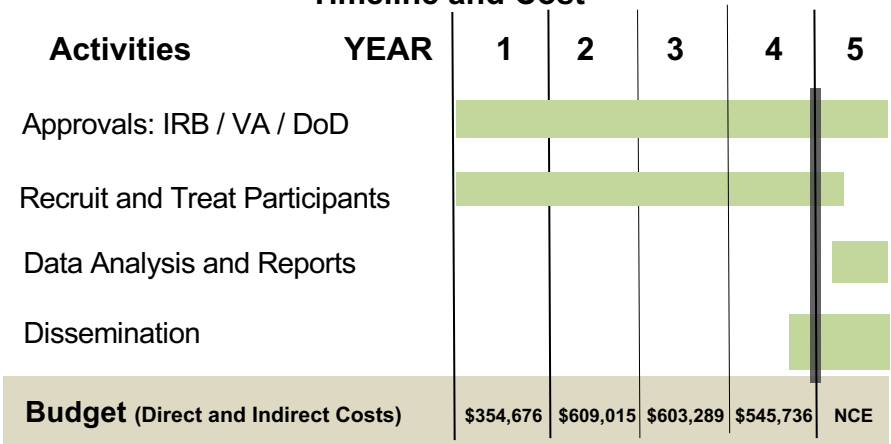
Approach

Using a between group, randomized controlled repeated measures design comparing PE + Exposure Workout Buddy vs. PE + Peer General Support (i.e., the standard VA Peer Support program methods involving a peer who does NOT engage in any support during in vivo homework) to evaluate the 'PE + Exposure Workout Buddy' adjunctive therapy component in terms of its ability to increase likelihood that Veterans will (a) return to and complete treatment & (b) evince reduced PTSD symptomatology at post-treatment and 3- & 6-month follow-up.

Accomplishments this year:

- Three peers were eligible and enrolled, bring our total enrolled peers to date to 31, 19 of which are active.
- Thirty-five participants were enrolled, bringing our total enrolled participants to through year four to 108. Recruitment and enrollment continued this year despite many challenges posed by the ongoing COVID-19 pandemic.
- Attended weekly PTSD clinic staffing meetings virtually to discuss patients who withdrew from treatment in mental health clinics
- Attended weekly EBP team meetings from the RHJ VAMC and CBOCs
- Distributed newsletter to providers highlighting study
- Served as first line point-of-contact for participants who were referred to research by the PCT clinic
- Attended Mental Health Orientation group at SAV CBOC
- Collaborated with other research teams to discuss study and referrals from patients who drop out of PTSD treatment
- Continued collaborating with active-duty providers at the Naval Weapons Station and Joint Base Charleston
- Attended Mental Health Retreat at SAV CBOC to discuss study with new hire providers
- Attended new patient orientation to discuss research

Timeline and Cost



Updated: 12-APR-2022

Goals/Milestones

YR1 Goal – Institutional Human Subject Approvals Submitted
☒ IRB, VA Research, DoD HRPO approvals obtained

YR2 Goals – Recruitment, Reports
☒ Establish recruitment protocols and procedures
☒ Recruit and consent participants

YR3 & YR4 Goal – Recruitment, Reports
☒ Continue to recruit and consent participants

YR5 Goal – Complete Recruitment, Analyze Data, Submit Publications
☐ Submit final report and presentations to DoD

Comments/Challenges/Issues/Concerns
- None at this time

Budget Expenditure to Date
- Actual Expenditure: $1,479,193 (as of 3/14/2022)