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: Ronald Acierno, PhD

CONTRACTING ORGANIZATION: Medical University of South Carolina

Charleston, SC 29425

REPORT DATE: APR-2019

TYPE OF REPORT: ANNUAL

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
APR-2019	Annual	15-MAR-2018 – 14-MAR-2019

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

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-1-0081

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Dr. Ronald Acierno

E-Mail: acierno@musc.edu

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 ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

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

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

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			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	UU		USAMRMC

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

Page

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:

Between 15-MAR-2018 and 14-MAR-2019, 19 peers were screened and 18 were determined eligible, bringing our total enrolled peers to date since the initiation of study procedures on 15-MAR-2018 to 18, 17 of which remain active.

Between 15-MAR-2018 and 14-MAR-2019, 20 participants were screened and 10 were enrolled, bringing our total enrolled participants to date since the initiation of study procedures to 10. Additionally, 2 post assessments have been completed. There were no 3- or 6-month follow up assessments due during this period.

Below is a chart of to-date PEER enrollment.

Year / Quarter	Year 1 2018-2019				Year 2 2019-2020				Year 3 2020-2021				Year 4 2021-2022				Total as of Y1Q4
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Enrollment Actual	0	10	2	6	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	18
Active Peers	0	10	11	17	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	

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

Year / Quarter	Year 1 2018-2019				Year 2 2019-2020				Year 3 2020-2021				Year 4 2021-2022				Total as of Y1Q4
	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	-	-	-	21*
Enrollment Actual	0	0	7	3	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	10
Over / (Under)	0	0	(3)	(8)	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	Future	(11)

**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 during year 1 include:

- 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 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 RHJ VAMC 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 and Savannah CBOC.
- Attended meeting with Veterans Enrichment Center (VEC) and PTSD Clinic Team (PCT) at Charleston VAMC to discuss referral of peers.

➢ ***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.

➢ ***What do you plan to do during the next reporting period to accomplish the goals?***
Recruitment will continue; we will focus heavily on distributing information to local providers both at the Charleston VAMC and CBOCs in order to garner more direct referrals. We will be present at staffing meetings for PTSD Clinical Team (PCT) to recruit patients who dropped out of treatment with providers. We will continue to post flyers around the Charleston VAMC and CBOCs, as well send recruitment letters.

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 problems

- ***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:	*Ronald Acierno*
Project Role:	*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:	*Experienced in the collection, interpretation, analysis, and publication of data*

Name:	*Carol Denier*
Project Role:	*Co-Investigator*
Nearest person month worked:	*0.34*
Contribution to Project:	*Facilitates referrals from patients that have screened positive for PTSD from PTSD Clinic Team (PCT)*

Name:	*Anna Birks*
Project Role:	*Clinical Coordinator*
Nearest person month worked:	*0.53*
Contribution to Project:	*Provides overall assessment supervision, including overseeing assessment measure procedures, and assists with clinic referral flow*

Name:	*Wendy Muzzy*
Project Role:	*Research Scientist*
Nearest person month worked:	*Funding pending*
Contribution to Project:	*Assists in conceptual and practical resolution of scientific questions and data analytic decisions that inevitably present themselves during the course of a RCT*

Name:	*Stephanie Hart*
Project Role:	*Research Assistant II*
Nearest person month worked:	*6*
Contribution to Project:	*Coordinates the day to day aspects of this project*

Name:	*Martina Radic*
Project Role:	*Research Assistant II*
Nearest person month worked:	*(currently on maternity leave)*
Contribution to Project:	*Conducts all interviews/assessments as detailed in the protocol*

Name:	*A. Raquel Vining*
Project Role:	*Research Assistant II*
Nearest person month worked:	*Funding pending*
Contribution to Project:	*Documentation coordinator*

Name:	*Stephanie Hamski*
Project Role:	*Research Assistant II*
Nearest person month worked:	*Funding pending*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

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

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*

Name:	*Kimberly Veronee*
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:	*Glenna Worsham*
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:	*Michelle Pompei*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a participant recruiter*

Name:	*Linette Dubois*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a participant recruiter*

Name:	*Rachel Harris*
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:	*Jennifer Howell*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a study clinician and participant recruiter*

Name:	*Bethany Wangelin*
Project Role:	*Volunteer*
Contribution to Project:	*Recruitment efforts/VA liaison*

Name:	*Jazmine Hasty*
Project Role:	*Volunteer*
Contribution to Project:	*Recruitment efforts and data entry*

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

Name:	*Gabrielle Frook*
Project Role:	*Volunteer*
Contribution to Project:	*Serves as a participant recruiter*

- ***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: Charleston Research Institute
  Location of Organization: 109 Bee Street (151), Charleston, SC 29401

  Partner's 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: Ronald Acierno, PhD **Org:** Medical University of South Carolina **Award Amount:** $2,112,716

Study/Product Aim(s)

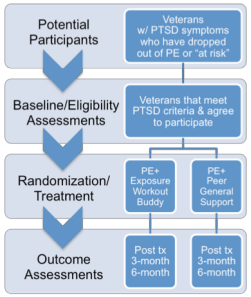
Objective 1: To determine relative differences in treatment dose obtained, measured in terms of the number of sessions completed upon return to treatment, in response to 'PE + Exposure Workout Buddy' vs. 'PE + Peer General Support' in individuals who have previously dropped out of evidence based treatment 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.

Logic Model and Study Design



Accomplishments this year:

-Between 15-MAR-2018 and 14-MAR-2019, 19 peers were screened and 18 were determined eligible, bringing our total enrolled peers to date since the initiation of study procedures on 15-MAR-2018 to 18, 17 of which remain active.
-Between 15-MAR-2018 and 14-MAR-2019, 20 participants were screened and 10 were enrolled, bringing our total enrolled participants to date since the initiation of study procedures to 10. Additionally, 2 post assessments have been completed. There were no 3- or 6-month follow up assessments due during this period.
-Principal investigator and staff met with primary care team at local CBOC to discuss study and set up system to refer.
-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 CBOCs to contact for referral collaboration.
-Established procedures to identify participants who successfully completed Prolonged Exposure therapy to serve as peers.
-Developed recruitment letter.
-Added study information to research newsletter which is distributed monthly to healthcare providers at the RHJ VAMC and CBOCs.
-Met with local wounded Veterans group to disseminate flyers.
-Received IRB approval for new study flyer and updated assessment questionnaires.
-Expanded peer recruitment to local Savannah CBOC and enrolled first CBOC participants.
-Posted new flyers at Ralph H. Johnson VAMC and Savannah CBOC.
-Attended meeting with Veterans Enrichment Center (VEC) and PTSD Clinic Team (PCT) at Charleston VAMC to discuss referral of peers.

Timeline and Cost

Activities YEAR	1	2	3	4
Approvals: IRB / VA / DoD				
Recruit and Treat Participants				
Data Analysis and Reports				
Dissemination				
Budget (Direct and Indirect Costs)	$463,509	$558,143	$572,048	$519,016

Updated: (10-APR-2019)

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 Goal – Recruitment, Reports
☐ Continue to recruit and consent participants

YR4 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: $ **96,928** (as of 03/14/2019)