

AWARD NUMBER: W81XWH-15-1-0087

TITLE: Evaluating the Feasibility of RESCUE: An Adjunctive HAI-Based Intervention for Veterans with PTSD

PRINCIPAL INVESTIGATOR: Dr. Peter Tuerk

CONTRACTING ORGANIZATION: Charleston Research Institute (CRI), 109 Bee Street (151),
Charleston, SC 29401

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13. SUPPLEMENTARY NOTES:					
14. ABSTRACT This report documents accomplishment of the following tasks: 1. Obtained full MUSC IRB, VA R&D, and DoD HRPO approvals. 2. Conducted a 3-day PE therapy training with clinicians. 3. Independent evaluators completed 1-day Clinician Administered PTSD Scale (CAPS) training. 4. Continued animal shelter collaboration. 5. Completed case series, conducted qualitative interviews, and finalized study protocol. 6. Initiated recruitment through PCT and related clinics, and ongoing recruitment is on track with projected recruitment targets. 7. Submitted study abstract to conference.					
15. SUBJECT TERMS psychotherapy; PTSD; veterans; prolonged exposure					
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Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	7
5. Changes/Problems.....	7
6. Products.....	8
7. Participants & Other Collaborating Organizations.....	8
8. Special Reporting Requirements.....	11

1. **INTRODUCTION:** PTSD is a common mental health disorder among veterans. Currently, there are more veterans with PTSD who do not engage in or drop-out of treatment than there are veterans who complete treatment. Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE), is an adjunctive, Human Animal Interaction (HAI) intervention that will be developed for integration into Prolonged Exposure (PE) treatment. The goal of RESCUE is to increase emotional engagement and decrease emotional numbing, an important barrier to care, and thus improve functioning and EBT completion rates.
2. **KEYWORDS:** psychotherapy; PTSD; veterans; prolonged exposure
3. **ACCOMPLISHMENTS:**
 - o **What were the major goals of the project?**

Major Goal 1: Development of Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) provider manuals and patient handouts, Obtain approvals from oversight bodies. Major Goal 2: Conduct a case series wherein veterans (N=5) will be treated with the RESCUE/ PE protocol to work out any protocol/logistical difficulties and collect initial feasibility/accessibility. Major Goal 3: Test feasibility, acceptability, and initial efficacy of RESCUE/ PE in a pilot RCT conducted with veterans (N= 70) meeting Diagnostic and Statistical Manual Fifth Edition (DSM-V) criteria for PTSD randomly assigned to RESCUE/ PE or to TAU/ Prolonged Exposure (PE) followed by RESCUE.

- o **What was accomplished under these goals?.**
 - a) Obtained full IRB approval on 5/2/16 from the Medical University of South Carolina (MUSC)'s IRB (Pro53520), VA Research and Development (R&D) approval on 07/07/16, US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) on 9/7/16 (A-18529).
 - b) Conducted a 3-day PE therapy training with clinicians on study 9/14/16 – 9/16/16.
 - c) Independent evaluators completed 1-day Clinician Administered PTSD Scale (CAPS) training 10/31/16.
 - d) Began recruitment through PTSD clinical team; consented first participant 9/20/16. Completed case series, conducted qualitative interviews, and refined the protocol. Continued active recruitment of participants and we are currently on track with our projected recruitment targets. As of April 2017, 22 participants have been referred, 12 have been screened, 10 participants have consented, 5 are actively in therapy, 3 have completed and are in the follow up window, and 2 dropped out.
 - e) Study submitted to 51st Annual Convention of the Association for Behavioral and Cognitive Therapies entitled, "Using theory driven study design to examine the utility of adjunctive PTSD treatment with human-animal interaction: Methods of the RESCUE study"

See Chart for specific aims related to reporting period:

Specific Aim 1: Development of Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) provider manuals and patient handouts, Obtain approvals from oversight bodies.	Timeline / Months	Percentage Complete
Major Task 1: Knowledge elicitation from consulting experts and key stakeholders.		
Consult experts in combat-related PTSD, Empirically Based Treatment (EBT), behaviorism, and therapeutic Human Animal Interaction (HAI)	0-2	100%
Engage key stakeholders as a means of identifying potential treatment barriers and to facilitate study recruitment later.	0-2	100%
Established/continue working relationship with local SPCA facility staff.	0-36	100%
Major Task 2: Finalize treatment and control protocols		
Review of protocols/treatment materials by consulting experts in combat-related PTSD treatment and Human Animal Interaction (HAI) /animal behaviorism for theoretical soundness, usability, and quality.	0-3	100%
Major Task 3: Obtain IRB approval		
Develop eligibility criteria, exclusion criteria, and screening protocol	0-3	100%
Develop consent form and human subjects protocol	0-3	100%
Prepare and submit protocol to Charleston VAMC R&D and MUSC IRB	0-4	100%
Submit IRB protocol to DOD/HRPO	0-4	100%
Obtain IRB, R&D, and HRPO approvals to move forward	0-6	100%
Submit amendments, adverse events and protocol deviations as needed	0-36	33%
Submit annual IRB report for continuing review (local)	0-36	33%
Submit annual IRB report for continuing review and reports to HRPO as needed.	0-36	33%
Major Task 4: Recruit & train IEs and study therapists		
Recruit, facilitate hiring, and train study independent evaluators (IEs)	0-6	100%
Facilitate and coordinate training and PE certification, supervision, and fidelity checks as needed for project therapists.	0-6	100%
Specific Aim 2: A case series wherein veterans (N=5) will be treated with Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) and Prolonged Exposure (PE) to work out any protocol/logistical difficulties and collect initial feasibility/accessibility data.	Timeline / Months	
Major Task 1: Finalize Thematic Interview Measures/Focus group procedures Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) case series		
Synthesize thematic interview based on scientific- and key stakeholder-	0-6	100%
Major Task 2: Recruit combat veterans with PTSD for case series		
Utilize PTSD Clinical Team (PCT) developed referral stream for study	6 - 8	100%
Major Task 3: Conduct pre-treatment evaluations for case series		
Screen, obtain consent, assess, and enroll participants	6 - 8	100%
Major Task 4: Conduct RESCUE/PE treatment with case series participants		
Conduct and complete case series for additional refinements in design,	6-10	100%
Major Task 5: Conduct post-treatment evaluations for case series participants		
Complete post-treatment standardized evaluations and clinical interviews.	8-10	40%
Complete post-treatment 60-minute thematic interviews/focus groups.	8-10	40%

Major Task 6: Data review and Refinement of protocol and materials		
Consulting experts review randomly selected sessions	8 - 11	100%
Review and analysis of thematic interview outcomes	8 - 11	100%
Review and analysis of quantitative case report measures	8 - 11	100%
Protocol refinement as indicated	11	100%
Specific Aim 3: Feasibility, acceptability, and initial efficacy testing of Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) in a pilot RCT conducted with combat veterans (N= 50) meeting Diagnostic and Statistical Manual Fifth Edition (DSM-V) criteria for PTSD randomly assigned to RESCUE/Prolonged Exposure (PE) or to TAU/ Prolonged Exposure (PE) followed by RESCUE.		
Major Task 1: Develop RCT database and data integrity monitoring		
Use SPSS to develop a database for all measures, data will be entered in a “Tall” format to facilitate longitudinal mixed modeling with export to HLM7 software, and graphical interface with export to JMP software; and will be transformed into a traditional “Long” format to facilitate univariate and descriptive analyses native to SPSS and JMP, with well developed protocols to protect integrity.	6 - 8	100%
Pilot and revamp data base and entry procedures based on case series data entry	6 - 8	100%
Cross reference of original source documents with entered data in 10% randomly selected cells, each 2 nd Friday.	11-33	5%
Major Task 2: Facilitate robust study recruitment		
Utilize PTSD Clinical Team (PCT) referral stream for study recruitment	11-29	15%
Facilitate referral streams from Primary Care Mental Health Integration (PCMHI) team, Primary Care (PC), and the OEF/OIF Team for study recruitment.	11-29	15%
Facilitate referral streams from local Community-Based Outpatient Clinics (CBOCs) for study recruitment.	11-29	15%
Major Task 2: Conduct pre-treatment evaluations; randomize veterans to Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE)/PE, or TAU/PE followed by RESCUE.		
Assess all participants with screening measures, pre-treatment standardized clinical interviews, and self-report clinical measures; randomize into groups	11-29	15%
Major Task 3: Conduct RCT		
Conduct RCT treatment phase	11-31	15%
Supervise the assessment of all participants with weekly self-report measures	11-31	15%
Assess all participants at mid-treatment with standardized clinical interviews and quantitative measures.	11-31	15%
Major Task 4: Conduct post-treatment and follow-up evaluations for pilot RCT participants		
Assess all participants at post treatment and 3 month follow-up points with standardized clinical interviews and self-report measures	13-33	15%
Conduct qualitative thematic interviews regarding RESCUE components for all participants.	13-33	15%

Major Task 5: Ongoing Supervision of independent evaluators, study therapists, and study staff		
Supervision of study staff	6-34	20%
Major Task 6: Data Cleaning & Analysis		
Final data cleaning and cross referencing checks	33-34	0%
Lock the data for analysis & format files for export	33-34	0%
Conduct primary and secondary analyses for Specific Aim 3	34-36	0%
Major Task 7: Prepare and submit: study dissemination products, publications, and treatment manual for distribution.		
Preparation and submission: Interim and process-related manuscripts, abstracts, and presentations.	6-36	20%
Preparation and submission: Primary and secondary outcome manuscripts, abstracts, and presentations.	35-36	0%

- **What opportunities for training and professional development has the project provided?**
 - The postdoctoral coordinator completed Clinician Administered PTSD Scale for DSM-5 (CAPS-5) training. Further, Dr. Myers, who was already trained in Prolonged Exposure (PE), assisted with PE training conducted in the fall. Dr. Myers participates in weekly PE video consultation with members of the PCT clinical team, along with clinical study supervision with Dr. Lozano.
- **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?**

Continue to conduct the RCT, including:

- a. Facilitating robust study recruitment,
- b. Conducting pre-treatment evaluations; randomizing Veterans to Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE)/PE, or TAU/PE followed by RESCUE,
- c. Supervising the assessment of all participants with weekly self-report measures,
- d. Assessing all participants at mid-treatment with standardized clinical interviews, and quantitative measures,
- e. Conducting qualitative thematic interviews regarding RESCUE components for all participants, and
- f. Ongoing Supervision of independent evaluators, study therapists, and study staff.

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**
 - Nothing to report.

- **What was the impact on other disciplines?**
 - Nothing to report.
- **What was the impact on technology transfer?**
 - Nothing to report.
- **What was the impact on society beyond science and technology?**
 - Nothing to report.

5. CHANGES/PROBLEMS:

- **Changes in approach and reasons for change**
 - Nothing to report.
- **Actual or anticipated problems or delays and actions or plans to resolve them**

Nothing to report.

- **Changes that had a significant impact on expenditures**

36% of the annual budget has been spent for this reporting period. Importantly, the half-time independent evaluator and full-time postdoctoral study coordinator started mid-way through the first year, as we awaited HRPO/IRB approval (to safeguard protected staff time during the study recruitment phase). In the next reporting period we plan to increase the therapist effort with the increased number of participants. Accordingly, we deem the financial health of the study to be sound.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
 - Nothing to report.
- **Significant changes in use or care of human subjects**
 - Not applicable.
- **Significant changes in use or care of vertebrate animals.**
 - Not applicable.
- **Significant changes in use of biohazards and/or select agents**
 - Not applicable.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Study submitted to 51st Annual Convention of the Association for Behavioral and Cognitive Therapies in November 2017 in San Diego, CA entitled, "Using theory driven study design to

examine the utility of adjunctive PTSD treatment with human-animal interaction: Methods of the RESCUE study.”

- **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**
 - Not applicable.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Dr. Peter Tuerk
Project Role:	PI
Nearest person month worked:	3
Contribution to Project:	Consulted with experts in combat-related PTSD, Empirically Based Treatment (EBT), behaviorism, and therapeutic Human Animal Interaction (HAI). Obtained MUSC IRB, VA R&D, and DoD HRPO approvals. Recruited, facilitated hiring, and trained study coordinator, and independent evaluators (IEs). Facilitated and coordinated training and PE certification, supervision, and fidelity checks as needed for project therapists. Prepared interim and process-related manuscripts, abstracts, and presentations.

Name:	Dr. Ronald Acierno
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	0000-0001-8799-8210
Nearest person month worked:	1
Contribution to Project:	Provided consultation on MUSC IRB, VA R&D and DoD HRPO submissions. Assisted with protocol refinement.

Name:	Dr. Donald L. Myrick
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Provided consultation on MUSC IRB, VA R&D and DoD HRPO submissions. Assisted with protocol refinement.

Name:	Dr. Bethany Wangelin
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Continued reviewing protocols/treatment materials. Facilitated referral streams from PTSD Clinical Team (PCT), Primary Care Mental Health Integration (PCMHI) team, Primary Care (PC), the OEF/OIF Team, and Community-Based Outpatient Clinics (CBOCs) for study recruitment.

Name:	Dr. Kristy Center
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Continued engaging key stakeholders (e.g., veteran support groups, animal rescue groups) as a means of identifying potential treatment barriers and to facilitate study recruitment. Established working relationship with local shelter facility staff.

Name:	Dr. Brian Lozano
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Reviewed protocols/treatment materials. Provided clinical supervision to PE therapists.

Name:	Dr. Anouk Grubaugh
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Consulted with experts in combat-related PTSD, Empirically Based Treatment (EBT), behaviorism, and therapeutic Human Animal Interaction (HAI). Synthesized thematic interview based on scientific- and key stakeholder-knowledge gained. Began conducting interviews with participants.

Name:	Dr. Ursula Myers
Project Role:	Postdoctoral Study Coordinator
Nearest person month worked:	12
Contribution to Project:	Developed and submitted consent form and human subjects protocol, and submitted to (1) MUSC IRB, (2) VA R&D, and (3) DoD HRPO committees. Obtained study approvals from all review boards. Recruited, screened, obtained consent, assessed, and enrolled participants with PTSD from different referral streams. Used SPSS to develop a database for all measures.

Name:	Bridgette Niepoth, M.S.
Project Role:	Research assistant II
Nearest person month worked:	6
Contribution to Project:	Recruited, screened, obtained consent, assessed, and enrolled participants with PTSD from different referral streams. Assisted with data entry in SPSS.

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
 - Not applicable.
- **What other organizations were involved as partners?**
 - Not applicable.

7. SPECIAL REPORTING REQUIREMENTS

- **COLLABORATIVE AWARDS:**
 - Not applicable.
- **QUAD CHARTS:** Attached.

8. APPENDICES: Not applicable.

Evaluating the Feasibility of RESCUE: An Adjunctive HAI-Based Intervention for Veterans with PTSD

Log Number: 13046027

Award Number: W81XWH-15-1-0087



PI: Peter W. Tuerk, Ph.D.

Org: Charleston Research Institute

Award Amount: \$709,517

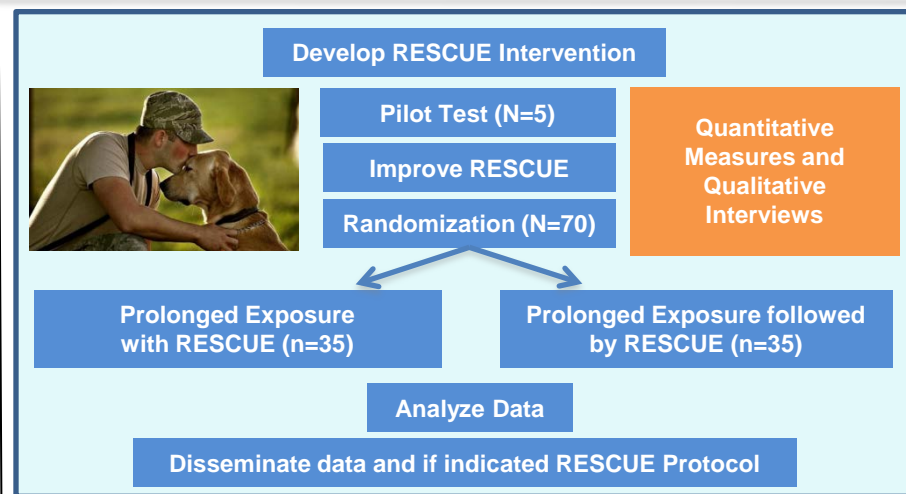
Study/Product Aim(s)

- To develop and pilot test feasibility, acceptability, and efficacy of RESCUE, an adjunct scalable human animal interaction (HAI) intervention involving shelter dogs for use with disseminated Empirically Based Treatments (EBT) for posttraumatic stress disorder (PTSD) to increase treatment engagement and completion.

Approach

The project is organized into 3 sequential phases/aims:

- (1) Development of treatment protocols;
- (2) A case series wherein 5 Veterans will be treated with Prolonged Exposure (PE) therapy in tandem with the experimental RESCUE component to work out protocol/logistical difficulties and collect initial feasibility and accessibility data; and
- (3) A randomized controlled trial using a crossover design with 50 Veterans (recruit 70) with PTSD randomized to PE simultaneously with RESCUE or PE followed by RESCUE. Outcomes will include standard PTSD assessments and qualitative interviews.



Year 1 Accomplishments: Recruited study staff, initiated development of RESCUE protocol, created study materials, submitted to Internal Review Board (IRB), initiated outreach to partner and stakeholder organizations. Actively recruiting and enrolling participants in project, averaging one consent per week; Completed pilot case series on first 5 participants; Developed SPSS database for all measures, and began to enter data from case series participants.

Timeline and Cost

Activities	CY	16	17	18
Develop treatment				
Pilot test treatment and revamp				
Conduct RCT				
Analyze data				
Disseminate findings & study knowledge				
Estimated Budget \$709.5K		\$238,595	\$242,434	\$228,487

Updated: 05/11/17

Goals/Milestones

CY16 Goals – Treatment development & test pilot

- ☒ Develop treatment protocols
- ☒ Develop thematic interviews
- ☒ Conduct outreach to partner and stakeholder organizations
- ☒ Complete pilot case series
- ☒ Revamp protocol as indicated by data

CY17 Goals – Randomized controlled trial of treatment (N=70)

- ☐ Recruit and consent 52 participants
- ☐ Complete treatment and assessments

CY18 Goal – Complete trial, analyze data, disseminate findings

- ☐ Recruit and consent 18 participants
- ☐ Complete treatment and assessments
- ☐ Analyze data
- ☐ Disseminate findings.

Comments/Challenges/Issues/Concerns: None

Budget Expenditures to Date: \$178,596.48