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
Charleston, SC 29401

REPORT DATE: May 2018

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.			
1. REPORT DATE May 2018	**2. REPORT TYPE** Annual		**3. DATES COVERED** 22 April 2017 – 21 April 2018
4. TITLE AND SUBTITLE Evaluating the Feasibility of RESCUE: An Adjunctive HAI-Based Intervention for Veterans with PTSD			**5a. CONTRACT NUMBER** **5b. GRANT NUMBER** W81XWH-15-1-0087 **5c. PROGRAM ELEMENT NUMBER**
6. AUTHOR(S) Dr. Peter Tuerk, Dr. Anouk Grubaugh, Dr. Ursula Myers, and Ms. Kelsie H. Page E-Mail: tuerk@musc.edu, grubaugh@musc.edu, ursula.myers@va.gov, and kelly@chsri.org			**5d. PROJECT NUMBER** **5e. TASK NUMBER** **5f. WORK UNIT NUMBER**
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Charleston Research Institute (CRI), 109 Bee Street (151) Charleston, SC 29401			**8. PERFORMING ORGANIZATION**
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Material Command Fort Detrick, Maryland 21702-5012			**10. SPONSOR/MONITOR'S ACRONYM(S)** AMRMC **11. SPONSOR/MONITOR'S NUMBER(S)**
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			
13. SUPPLEMENTARY NOTES:			
14. ABSTRACT This report documents accomplishment of the following tasks: a) Completed case series, conducted qualitative interviews, and refined the protocol. Continued active recruitment of participants; currently on track with our projected recruitment targets. As of April 2018, 76 participants have been referred, 66 have been screened, 31 participants have consented, 5 are active in therapy, 10 completed and in follow up window, and 15 dropped out.			
15. SUBJECT TERMS psychotherapy; PTSD; veterans; prolonged exposure			
16. SECURITY CLASSIFICATION OF:		**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRMC
a. REPORT Unclassified	**b. ABSTRACT** Unclassified	**c. THIS PAGE** Unclassified	Unclassified	12	**19b. TELEPHONE NUMBER** (include area code)

Table of Contents

Page

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 compete 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:**

    - **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.

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

a) 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 2018, 76 participants have been referred, 66 have been screened, 31 participants have consented, 5 are actively in therapy,10 have completed and are in the follow up window, and 15 dropped out.

b) 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	66%
Submit annual IRB report for continuing review (local)	0-36	66%
Submit annual IRB report for continuing review and reports to HRPO as needed.	0-36	66%
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-knowledge gained in Specific Aim 1. Construct thematic interview protocol in line with established	0-6	100%
Major Task 2: Recruit combat veterans with PTSD for case series		
Utilize PTSD Clinical Team (PCT) developed referral stream for study recruitment	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, logistics,	6-10	100%
Major Task 5: Conduct post-treatment evaluations for case series participants		
Complete post-treatment standardized evaluations and clinical interviews.	8-10	100%
Complete post-treatment 60-minute thematic interviews/focus groups.	8-10	100%
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)/PE, or TAU/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 2nd Friday.	11-33	70%
Major Task 2: Facilitate robust study recruitment		
Utilize PTSD Clinical Team (PCT) referral stream for study recruitment	11-29	60%
Facilitate referral streams from Primary Care Mental Health Integration (PCMHI) team, Primary Care (PC), and the OEF/OIF Team for study recruitment.	11-29	60%
Facilitate referral streams from local Community-Based Outpatient Clinics (CBOCs) for study recruitment.	11-29	60%
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	60%
Major Task 3: Conduct RCT		
Conduct RCT treatment phase	11-31	60%
Supervise the assessment of all participants with weekly self-report measures	11-31	60%
Assess all participants at mid-treatment with standardized clinical interviews and quantitative measures.	11-31	60%
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	60%
Conduct qualitative thematic interviews regarding RESCUE components for all participants.	13-33	60%
Major Task 5: Ongoing Supervision of independent evaluators, study therapists, and study staff		
Supervision of study staff	6-34	40%
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	40%
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?**
  - Training is not a goal of the award, although Dr. Myers and Ms. Niepoth both completed a 15-hour Core Clinical Research Training Course.

- **How were the results disseminated to communities of interest?**
    - Nothing to report regarding results/protocol submitted to professional conference.
- **What do you plan to do during the next reporting period to accomplish the goals?**

1. Fine tune database and entry procedures as needed.
2. Cross reference of original source documents with entered data in 10% randomly selected cells, each 2nd Friday.
3. Continue utilizing PTSD Clinical Team (PCT) developed referral stream, in addition to facilitating referral steams from Primary Care Mental Health Integration (PCMHI) team, Primary Care (PC), OEF/OIF Team, and local Community-Based Outpatient Clinics (CBOCs).
4. Continue screening, obtaining consent, assessing, and enrolling participants.
5. Complete post-treatment standardized evaluations and structured clinical interviews.
6. Complete post-treatment 60-minute thematic interviews/focus groups.
7. Preparation and submission: Interim and process-related manuscripts, abstracts, and presentations.

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**

    During an annual consent audit by the IRB, we discovered that eight participants were consenting in a manner that was not clearly identified in the approved protocol. As soon as we discovered this, we re-consented these participants and submitted an amendment (now approved) that clearly explains this process for participants which participate in therapy via telehealth.

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

    To date, our recruitment has been on/close to our target rate. However, we are seeing higher study dropout rates that we had previously expected during the project submission (rate close to 50%, original predicted rate of 30%). We believe that our current dropout rate is reflecting current trends in dropout seen in more recent PTSD studies and as well as non-study patients seen through the PTSD clinic. As such, we are anticipating the need to recruit more than our original intended number in order to accommodate a higher dropout rate. We are currently projecting the need for a 3-month no-cost extension in order to recruit additional participants, and have the needed budget to accommodate this extension.

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

60% of the annual budget has been spent for this reporting period. We have had one staff member (Dr. Center) leave the Ralph H. Johnson VAMC for a different job, and another staff member (Dr. Myers) transition to a staff clinician on the PTSD clinical team (remaining as a Co-I on this study). We have hired additional staff members to assist with this transition (Drs. Keller and Denier), and do not believe there will be any issue maintaining recruitment and study coordination at this time. However, we may have a surplus until the hiring process is complete for the new staff members/changing salary roles. 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. Proactive budgeting projections indicate that all study funds will be used.

- **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 presented 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. Left position at Ralph H. Johnson VAMC and is no longer on the project.

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. Continued conducting interviews with participants. Is taking over project as PI.

Name:	Dr. Ursula Myers
Project Role:	Co-I
Nearest person month worked:	3
Contribution to Project:	Maintained 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. Moved from fulltime coordinator to Co-I on project.

Name:	Bridgette Niepoth, M.S.
Project Role:	Coordinator
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.

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

Name:	Dr. Stephanie Keller
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Took over Dr. Center's role engaging key stakeholders (e.g., veteran support groups, animal rescue groups) as a means of identifying potential treatment barriers and to facilitate study recruitment.

- **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 for outgoing PI, incoming PI submitted Other Support as part of approval process.
- **What other organizations were involved as partners?**
  - The Medical University of South Carolina has a subcontract on this award to cover salary for some on the study team. Additionally, we refer participants to the following animal shelters: Pet Helpers, Summerville, Goose Creek SPCA, Beaufort SPCA, Hinesville SPCA, Waccamaw Animal Rescue, and North Myrtle Beach SPCA. In order to protect the anonymity of participating veterans ongoing relationships with the shelters are informal and require no formal information or material exchange.

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.

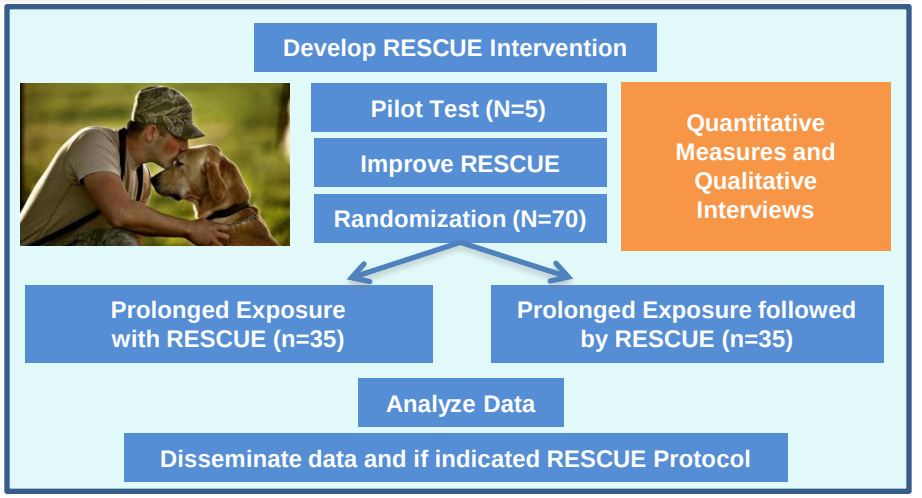
Approach

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.



Accomplishments: Completed case series, conducted qualitative interviews, and refined the protocol. Continued active recruitment of participants; currently on track with our projected recruitment targets. 76 participants have been referred, 66 have been screened, 31 participants have consented, 5 are active in therapy, 10 completed and in follow up window, and 15 dropped out.

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:05/16/18

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: 426,752.96