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TITLE: Do You Really Expect Me to Get MST Care in a VA Where Everyone is Male? Innovative Delivery of Evidence-Based Psychotherapy to Women with Military Sexual Trauma

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Medical University of South Carolina
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this study is to determine whether a scientifically validated treatment for PTSD called Prolonged Exposure (PE) can be delivered effectively to Veterans with Military Sexual Trauma (MST) related PTSD using videoconferencing technology, which allows a therapist and patient, who are at great distance from one another, to communicate. We are interested in learning if this form of mental health service delivery is more acceptable than traditional face-to-face therapy at the VA, where many individuals who may resemble the perpetrator congregate. This study is being conducted at the Charleston VA Medical Center and affiliated satellite clinics (CBOCs), and will involve approximately 100 female participants.

15. SUBJECT TERMS
MST, PTSD, Telemedicine, Behavioral Activation, Prolonged Exposure, DOD/VHA research collaborations

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION:

Veterans who experience military sexual trauma (MST) are at heightened risk of developing psychiatric difficulties such as post-traumatic stress disorder (PTSD). Although the Veterans Health Administration (VHA) has identified MST positive Veterans as a high priority population, this group of Veterans may under-utilize evidence-based interventions for PTSD such as Prolonged Exposure (PE). Likely reasons for this under-utilization include unique barriers to care faced by MST survivors such as avoidance of VA medical facilities due to their potential to cue distressing memories and symptoms. The current study includes a randomized controlled study design comparing treatment engagement and clinical and quality of life outcomes between two groups: Veterans receiving PE for PTSD-related MST via home-based telehealth (PE-HBT) and Veterans receiving PE for PTSD-related MST via standard service delivery (PE-SD). The intervention component of the study is complemented by a qualitative component (i.e., patient interviews) designed to better understand Veterans' reactions, preferences, difficulties, and suggestions for the intervention, as well as to solicit feedback about this patient population's service needs and preferences more broadly. All Veterans enrolled in the study (i.e. Veterans in both groups) will benefit from receiving a well supported intervention for PTSD, Prolonged Exposure (PE), to address their MST-related symptoms. As such, all Veterans have the potential to experience significant symptom reduction related to their military sexual trauma post-intervention (i.e., within 12 weeks). However, women assigned to receive PE via home-based telehealth will have the particular advantage of being able to receive services from their home, thereby circumventing some of the traditional access to care barriers faced by this clinical population. It is anticipated that this advantage will result in increased session attendance and compliance, which in turn will result in better clinical and quality of life outcomes due to increased 'dosing' of the intervention. Thus, it is predicted that Veterans in PE-HBT will evidence better treatment engagement and more significant symptom improvement relative to Veterans in PE-SD. Treatment gains include a reduction of PTSD and other psychiatric symptoms such depression, as well as more global improvements in quality of life and social/occupational functioning. If, as anticipated, women in PE-HBT evidence improved outcomes relative to women in PE-SD, the current study findings can be used to establish an innovative service delivery model that will circumvent traditional barriers to care in an underserved, yet high risk patient population. Regardless of study outcomes, the proposed project stands to fill significant gaps in the literature with regard to how to optimally engage and retain MST positive Veterans in VA mental healthcare. Additionally however, there is only one PTSD treatment outcome study focused exclusively on female Veterans and no extant studies testing home-based telehealth for sexual assault victims. Thus, the proposed project also stands to make a significant contribution to mental health service delivery models for female Veterans and sexual assault victims more broadly.

The major tasks of the SOW include: (1) **enroll** 100 female Veteran participants with MST-related PTSD and randomly **assign** to either in person (IP) or home based treatment (HBT) for PTSD; and (2) collect measures of PTSD and other psychopathology, attendance, and patient satisfaction at pre-treatment, post-treatment, and follow-up.

Between 01-AUG-2014 and 31-JUL-2015, 107 participants were screened, 25 were consented and 20 were enrolled (randomized), bringing our total enrollment to date since the initiation of study procedures on 01-AUG-2014 to 20. Additionally, 6 post assessments and 3 follow up assessments (3 3-month; 0 6-month) have been completed during this period.

2. KEYWORDS:

Telehealth, primary care, telepsychiatry, telepsychology, rural health, access to care, patient attitudes, posttraumatic stress disorder (PTSD).

3. ACCOMPLISHMENTS:

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

- ***Objective 1***: To compare, at post-treatment and 3 & 6-month follow-ups, whether Prolonged Exposure delivered to Military Sexual Trauma Victims via home-based telehealth (PE-HBT) is superior in terms of PTSD outcomes to PE delivered via standard office based procedures (PE-SD)
- ***Objective 2***: To compare over a 6-month time-frame, whether PE-HBT is superior to PE-SD across critical process outcomes (e.g., session attendance, satisfaction, and treatment adherence) to determine if predicted superiority of PE-HBT is due to increased treatment attendance, reduced attrition, and increased treatment satisfaction.

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

- Start-up activities and regulatory approvals have been submitted and obtained
  - IRB approval was obtained on 02-JUN-2014
  - HRPO approval was obtained on 25-SEPT-2014
  - VA R&D approval was obtained on 04-SEPT-2014
- Study personnel have been trained on the PE protocol and 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).
- Telemental health protocols within existing infrastructure have been finalized and approved.
- Existing procedures have been refined to accommodate MST affected women.
- 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 to prepare for the recruitment phase.
- The randomization procedures and database have been set up, in collaboration with Dr. Knapp (Co-I), to ensure high quality data entry and data security throughout the course of the study.
- Screening and recruitment potential participants began 15-OCT-2014.

- ***What opportunities for training and professional development has the project provided?***
  Independent evaluators were trained on qualitative assessment measures. Additionally, study therapists were trained on PE treatment.

- ***How were the results disseminated to communities of interest?***
  DoD IPR #1 and (in September) #2 will receive reports of study progress

- ***What do you plan to do during the next reporting period to accomplish the goals?***
  Recruitment will continue, recruitment sources and relationships will be expanded (we have recently started actively recruiting directly from CBOC satellite clinics, rather than passively waiting for CBOC referrals, as was required in the past.

4. IMPACT:

- ***What was the impact on the development of the principal discipline(s) of the project?***
  Too early to report at this time, however, the telemedicine research work funded (this and past projects) by the Department of Defense in Charleston through the Medical University of South Carolina and the Charleston Research Institute has resulted in the fact that Charleston, despite its average size, is the leading VAMC in the country with respect to overall number of telemental health service.

- ***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***
  Per previous quarterly reports, the sub award with CRI did not start until February 2015; therefore we are planning to carryover a significant amount of funds into year two.

- ***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, other than DoD IPR presentations.

- ***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:	*4*
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:	*Peter Tuerk*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Provides expertise in the area of conducting exposure therapy delivered via telemental health technology, exposure therapy for PTSD in Veteran's homes, treatment fidelity, and clinical supervision.*

Name:	*Anouk Grubaugh*
Project Role:	*Co-Investigator*
Nearest person month worked:	*3*
Contribution to Project:	*Experienced in the collection, interpretation, analysis, and publication of qualitative data.*

Name:	*Heidi Resnick*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Experienced both in the treatment of sexual assault, as well as in using technology to deliver evidence-based treatment.*

Name:	*Carol Denier*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Facilitates referrals from patients that have screened positive for MST and PTSD.*

Name:	*Anna Birks*
Project Role:	*Clinical Coordinator*
Nearest person month worked:	*2*
Contribution to Project:	*Provides clinical supervision, including overseeing assessment measure procedures, and assists with clinic referral flow.*

Name:	*Wendy Muzzy*
Project Role:	*Research Coordinator*
Nearest person month worked:	*3*
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 Zeigler*
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:	*6*
Contribution to Project:	*Conducts all interviews/assessments as detailed in the protocol*

Name:	*A. Raquel Vining*
Project Role:	*Research Assistant I*
Nearest person month worked:	*2*
Contribution to Project:	*Documentation coordinator*

- ***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: 176-A Ashley Avenue
  Charleston, SC 29403

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

Do You Really Expect Me to get MST Care in a VA Where Everyone is Male? Innovative Delivery of Evidence Based Psychotherapy to Women with Military Sexual Trauma

W81XWH-14-1-0264 / PT130434

PI: Ronald Acierno, PhD **Org:** Medical University of South Carolina **Award Amount:** $2,064,315

Study/Product Aim(s)

•Objective 1: To compare, at post, 3 and 6-month follow-up, whether PE-HBT is superior to PE PE-SD across critical clinical and quality of life outcomes (i.e., PTSD, depression, quality of life) due to increased PE 'dosing' that results from improved session attendance and reduced attrition.

•Objective 2: To compare at post-intervention whether PE-HBT is superior to PE-SD across critical process outcomes (e.g., session attendance, satisfaction, and treatment adherence).

Approach

Using a randomized, between groups, repeated measures design, 100 female Veterans with MST-related PTSD will be recruited from the Charleston VA medical center catchment area during the study time frame. Veterans will be randomized 1:1 to one of two conditions: PE via home-based telehealth (PE-HBT) or PE via standard service delivery (PE-SD). The active intervention phase is 12 weeks. Participants randomized to PE-HBT will receive 12 weekly sessions of PE via in-home video-conferencing technology, and participants randomized to PE-SD will receive 12 sessions of PE via standard in-person care delivery. All participants will be assessed at baseline, post-treatment, and at three and 6 months followup.

Accomplishments this Year:

- Between 01-AUG-2014 and 31-JUL-2015, 107 participants were screened, 25 were consented and 20 were enrolled (randomized), bringing our total enrollment to date since the initiation of study procedures on 01-AUG-2014 to 20. Additionally, 6 post assessments and 3 follow up assessments (3 3-month; 0 6-month) have been completed during this period. The research team has engaged in several recruitment activities this year. Our biggest recruitment successes thus far have come from distributing fliers throughout the hospital and Trident/Goose Creek Community-Based Outpatient Clinics (CBOCs), so the research team continually re-stocks these areas with fliers on a weekly basis.

Pilot Data indicate MST survivors prefer PTSD Treatment via Home Based Televideo at a rate of 2:1. AK Summit Televideo software has been approved for VA computers.

Timeline and Cost

Activities CY	14	15	16	17
Approvals: IRB / VA / DoD				
Recruit and Treat Participants				
Data Analysis and Reports				
Dissemination				
Budget (Direct and Indirect Costs)	**$459,071**	**$537,799**	**$553,331**	**$514,114**

Updated: (10-AUG-2015)

Goals/Milestones

CY14 Goal – Institutional Human Subject Approvals Submitted
☑ IRB, VA Research, DoD HRPO approvals obtained

CY15 Goals – Recruitment, Reports
☑ Establish recruitment protocols and procedures
☑ Recruit and consent participants

CY16 Goal – Recruitment, Reports
☐ Continue to recruit and consent participants

CY17 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: **$368,130** (as of 31-JUL-2015)