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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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CONTRACTING ORGANIZATION: Medical University of South Carolina
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6. AUTHOR(S)
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Medical University of South Carolina
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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

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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** 132 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-MAY-2018 and 31-JULY-2018, 32 participants were screened and 9 were enrolled, 6 post assessment and 14 follow ups. During 01-AUG-2017 and 31-JUL-2018: 117 participants were screened, 42 were consented, and 38 were enrolled. This brings our total to date since the initiation of study procedures on 01-AUG-2014 to 119 enrolled. Additionally, 29 post assessments and 62 follow up assessments (i.e., 28 '3-month'; 34 '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.
- Recruitment activities that were implemented during Year 4 include:
  - Began a new referral stream with two clinicians who provide service to female Veterans at the Hinesville CBOC.
  - Posted new flyers to different areas of the Ralph H. Johnson VAMC and Savannah CBOCS.
  - Added new providers to the ongoing monthly newsletter list.
  - Met with the Veterans Mental Health Council to discuss study and recruitment with Veterans and community representatives.
  - Distributed flyers at Combat Veterans Motorcycle Association Island Hopping Campaign event.
  - Posted new community flyers around the Savannah/Beaufort area.
  - Screened 49 pages of patients flagged for MST by PTSD clinic at RHJ VAMC to potentially send out recruitment letters in subsequent quarters.
  - Met with a social worker who started two MST-related support groups at the RHJ VAMC to set up times where the study team could meet with the group to discuss potential participation.
  - Attended Women's Health event at local Vet Center and distributed flyers and resource materials, as well as study contact information.
  - Sent over 30 recruitment letters to patients flagged for MST by PTSD clinic at RHJ VAMC.
  - Assisted with Military Sexual Trauma resource fair at RHJ VAMC in April by handing out flyers and treatment resources to potential participants who came to study's information table.
  - Attended annual research day event at the Medical University of South Carolina and handed out

flyers and resources to visitors.
- Developed Memorial Day list of activities/discounts for Veterans with study information on the back.
- Assisted PTSD Clinical Team with annual Women's Day event in research area of RHJ VAMC.
- Attended evening women's group at the VA to discuss study and treatment options.
- Posted flyers around Charleston-area Vet center.
- Sent letters to patients screen in MUSC's medical records system and sent letters (with approval) via the EPIC system.

- ***What opportunities for training and professional development has the project provided?***
  Independent evaluators were trained on qualitative assessment measures and study therapists were trained on PE treatment. Additionally, in September 2016, study staff attended a specialized conference on participant recruitment and retention in Baltimore, MD. Further, staff have received on-going Prolonged Exposure (PE) training and consultation by Dr. Edna Foa and her team in conjuction 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. Manuscripts using existing data from the study are in progress.

- ***What do you plan to do during the next reporting period to accomplish the goals?***
  Recruitment will continue and study staff will maintain and strengthen relationships with referring providers at CBOCs due to the high volume of referrals that are received directly through other mental health and primary care providers. Study staff will expand further upon community resources by reaching out to leaders of women's groups and organizers of activities aimed for Veterans (and specifically female Veterans) to discuss possibilities of attending such events to provide education and contact information for the study. In order to gain interest from social media platforms, study staff will explore best methods of disseminating information via advertisements on Facebook to deliver study contact information to a wide range of people in the Charleston area who may not yet be affiliated with the VA, or who do not frequent the VA enough to see study flyers posted around the hospital/CBOCs. Furthermore, staff will continue adding primary referral contacts to the monthly newsletter to educate providers about the study and keep them informed of their options as they consider routes of referrals for their patients.

  Over the next year community referrals and participant follow up will be the primary focus as the VA and MUSC have implemented a new project to facilitate treatment for Veterans within South Carolina's rural community that are served by MUSC. Female Veterans who enroll in the VA through this system will be screened and offered the opportunity for treatment in this study if interest is indicated. Study staff will continue to utilize MUSC's "My Chart" records system to deliver recruitment letters directly to patients, and we will continue actively recruiting through MUSC's Research Match system.

4. IMPACT:

- ***What was the impact on the development of the principal discipline(s) of the project?***
  Data blinds are not yet broken for mid study analysis, 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?***
  As a direct result of earlier and current DoD funding of projects conducted in partnership with the VAMC in Charleston, this VA now offers more telemedicine and home based telemedicine for mental health services to Veterans than any other site in the country. Moreover, our procedures, refined and validated through research, have been so successful in terms of allocating effort where patients present, and in treating patients effectively so that they are able to complete mental health services, that we are now assisting other VAMC's both within and outside our VISN in meeting their two week wait service metrics.

5. CHANGES/PROBLEMS:

- ***Changes in approach and reasons for change***
  Recent recruitment efforts described above have improved the rate of recruitment and this trajectory in continuing. As a result, we have brought on additional recruitment volunteers so we can staff CBOC clinics more consistently. We will continue to foster relationships with potential referral sources both within and outside of the VA system. Also, per our extension request approved on 27-MAR-2018, we have increased the targeted enrollment to 132 from 100, in light of high attrition across both treatment conditions. This request was based on suggestions from the DSMC to maintain sufficient statistical power.

  This year participant enrollment has continued to exceeded our projections. Below is a chart of to-date enrollment (eligible and randomized), projected vs. actual.

Year / Quarter	Year 1 AUG 14 - JUL 15				Year 2 AUG 15 - JUL 16				Year 3 AUG 16 - JUL 17				Year 4 AUG 17 - JUL 18				Year 5 AUG 18 - JUL 19				Total as of Y4Q4
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
Enrollment Projected	-	5	7	9	8	8	9	8	7	9	8	9	6	7	8	8	8	8	0	0	116
Enrollment Actual	1	7	4	8	3	4	7	5	13	8	9	12	10	6	13	9					119
Over / (Under)	1	2	(3)	(1)	(5)	(4)	(2)	(3)	6	(1)	1	3	4	(1)	5	1					3

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

We are also continuing to preserve carryover funds for the additional time needed for recruitment and participant follow up.

- ***Actual or anticipated problems or delays and actions or plans to resolve them***
  No problems other than those addressed above

- ***Changes that had a significant impact on expenditures***
  We will have funds to carryover into year 5, which will be used for continued recruitment and follow-yp efforts.

- ***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***
  - DoD IPR presentations
  - Gilmore, A. K., Davis, M. T., Grubaugh, A., Resnick, H., Birks, A., Denier, C., Muzzy, W., Tuerk, P., & Acierno, R. (2016). "Do you expect me to receive PTSD care in a setting where most of the other patients remind me of the perpetrator?": Home-based telemedicine to address barriers to care unique to military sexual trauma and Veterans Affairs hospitals. *Contemporary Clinical Trials*, 48; 59-64. PMCID: PMC4926870.

- ***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:	*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 Scientist*
Nearest person month worked:	*6*
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:	*12*
Contribution to Project:	*Coordinates the day to day aspects of this project*

Name:	*Martina Radic*
Project Role:	*Research Assistant II*
Nearest person month worked:	*1 (currently on maternity leave)*
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*

Name:	*Stephanie Hamski*
Project Role:	*Research Assistant II*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment specialist*

Name:	*Cristina Lopez*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Tracey Rosenlieb*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Kimberly Veronee*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Nina Schneider*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Glenna Worsham*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Sally Murphy*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Michelle Pompei*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Linette Dubois*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Alyssa Johnson*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Rachel Harris*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Jonna Vaughn*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Jennifer Howell*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

Name:	*Savannah Guimaraes*
Project Role:	*Volunteer*
Nearest person month worked:	*2*
Contribution to Project:	*Recruitment efforts*

- ***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

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, 132 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 follow-up.

Pilot Data indicate MST survivors prefer PTSD Treatment via Home Based Televideo at a rate of 2:1.

Accomplishments this quarter:
Between 01-AUG-2017 and 31-JUL-2018, 117 participants were screened and 38 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 01-AUG-2014 to 119. Additionally, 29 post assessments and 62 follow up assessments (twenty-eight 3-month; thirty-four 6-month) have been completed during this

New recruitment activities this quarter:
• Assisted with Military Sexual Trauma resource fair at the RHJ VAMC in April by handing out flyers and treatment resources to Veterans.
• Sent over 30 recruitment letters to patients flagged for MST by the PTSD Clinic at the RHJ VAMC.
• Developed Memorial Day list of activities/discounts for Veterans with study information on the back and distributed in the community and around the hospital/CBOCs.
• Attended several women's groups at the RHJ VAMC and local Vet Center to discuss study.

Timeline and Cost

Activities / YEAR	1	2	3	4	5
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	NCE

Updated: (07-AUG-2018)

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 & 4 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
• YR 4 Actual Expenditure: **$469,842** (as of 31-JUL-2018)