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TITLE: A Multisite, Randomized Clinical Trial of Virtual Reality and Prolonged Exposure Therapy for Active duty soldiers with PTSD

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**A Multisite, Randomized Clinical Trial of Virtual Reality and Prolonged Exposure Therapy for Active duty soldiers with PTSD**

**December 2013**

**Abstract**

This randomized, single blind study extends recruitment to an additional active duty site (Womack Army Medical Center at Ft Bragg) in support of a previously funded clinical trial to evaluate the efficacy of virtual reality exposure therapy (VRET) and prolonged exposure therapy (PE) with a waitlist (WL) group in the treatment of posttraumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. During the first year, the study team developed the infrastructure to implement the trial including personnel recruitment, hiring, and initial training, process development to identify, screen, and enroll participants, and research protocol development and approval by IRB’s. During the second year hiring of clinical staff and training of the study team was completed. Recruitment and enrollment commenced.

**Subject Terms**

exposure therapy, posttraumatic stress disorder, virtual reality, military, prolonged exposure
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INTRODUCTION:
This study extends recruitment to an additional active duty site (Womack Army Medical Center at Fort Bragg) in support of a previously funded randomized clinical trial to evaluate the comparative efficacy of virtual reality exposure therapy (VRET) and prolonged exposure therapy (PE) with a waitlist group (WL) for the treatment of active duty Soldiers with combat-related posttraumatic stress disorder (PTSD). We will test the general hypotheses that 10 sessions of VRET will successfully treat PTSD, therapeutically affect levels of physiological arousal, and significantly reduce perceptions of stigma toward seeking behavioral health services. Soldiers returning from deployments to Iraq or Afghanistan who are diagnosed with combat-related PTSD following administration of the Clinician-Administered PTSD Scale (CAPS) will be randomized to one of three groups: 1) PE, 2) VRET, or 3) WL. Soldiers will undergo clinical assessments at baseline and after 5 and 10 treatment sessions. Outcome measures will also be collected at 12 weeks and 6 months post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY:
During this reporting period the study team recruited, hired, credentialed and completed protocol training with a new clinical psychologist to replace the previously terminated treatment psychologist. Prior to termination of the treatment psychologist, the study team had received 46 referrals, consented 13 subjects and randomized 4 to study participation. Study activity and recruitment was halted while the new clinician completed protocol and treatment training. After training of the new psychologist was completed, the study re-launched recruitment in June of 2013 and recruitment has been strong. Since recruitment has recommenced, a total of 91 new referrals have been received, 41 subjects have consented to study participation and 15 subjects have been randomized. 13 subjects are currently active in the study; 4 of which are in the follow-up phase (awaiting 12 and 26 week assessment), 7 are currently receiving VR or PE treatment, 2 are in the waitlist condition. Two subjects have been dropped by the study team or deemed lost to follow-up. There is ongoing recording and review of 15% of sessions to ensure treatment fidelity.

Modifications:
No protocol modifications at this time.

Challenges:
As previously reported, recruitment of appropriate candidates for the 2 clinical psychologist positions during the first year of the study was a challenge (Phase I task 2; months 4-6: ‘hire project staff’). The challenges were likely due to the requirements of the military facility for credentialing, the limited availability of qualified candidates, and likely, the desirability of the geographic location of the duty location. During the second year, study enrollment was further delayed by the termination of the treating clinical psychologist. The hiring, credentialing and training of the new psychologist was completed during quarter 2 of year 3, and recruitment for the study was able to recommence during quarter 3. Although we are experiencing current success generating referrals to the study (91 referrals since June 2013), based on these delays to recruitment we anticipate a likely need for a 1-year no cost extension. This anticipated need has been discussed with the CDMRP Science Officer (Dr. Irvin) and he provided information on the process for requesting this extension. This information has been forwarded to the Geneva Foundation.
During quarter 3, the WAMC site clinical research coordinator relocated and resigned her position. The study team was able to relocate the part-time study project manager (previously located at MAMC) to WAMC and hire a part-time research assistant to fill the role of site CRC.

**KEY RESEARCH ACCOMPLISHMENTS:**

Administrative and logistical matters

a) Personnel.
   New treatment psychologist hired, recruited and trained on protocol and study treatments. Project manager relocated, research assistant hired and trained on protocol related activities.

b) Materials, supplies and consumables.
   1) Supplies and materials for study requirements continue to be coordinated in support of human subject enrollment.

c) Institutional Review Board.
   1) WAMC IRB deferred oversight to MAMC IRB for this multisite trial. Continuing review was conducted and approved by both sites June 2013 and August 2013. Required amendments, such as the addition of hired staff to the protocol, and additional continuing reviews will be submitted and addressed by the appropriate IRB.

**REPORTABLE OUTCOMES:**
None

**CONCLUSION:**
None

**REFERENCES:**
None

**APPENDICES:**
None

**SUPPORTING DATA:**
None