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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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13. SUPPLEMENTARY NOTES

14. 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.

15. 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 completed hiring, credentialing and protocol training of the clinical psychologists in assessor and treating clinician roles. Initial recruitment for this study began in July 2012. During this reporting period 46 referrals for treatment were received. 13 subjects consented to study participation and 4 of those met all of the inclusion and none of the exclusion criteria and were randomized to treatment. Of the 2 subjects randomized to the waitlist condition, 1 has completed study participation through the post-assessment and 1 withdrew consent. Of the 2 subjects randomized to either active treatment group, 1 was dropped by the study team due to termination of the treating psychologist and the other withdrew consent prior to completing the treatment phase. No subjects are currently in the active phase of this study. Ongoing recording and review of 15% sessions has been implemented in order to ensure treatment fidelity of treatment sessions.

Modifications: No protocol modifications at this time

Challenges:

As previously reported, during the first year recruitment of appropriate candidates for the 2 clinical psychologist positions was a challenge (Phase I task 2; months 4-6: 'hire project staff') 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.

In addition to psychologist recruitment, hiring and credentialing delays study enrollment has been further delayed by the termination of the treating clinical psychologist. At the end of this reporting period potential

candidates were being interviewed for this position with the goal of starting study enrollment again during quarter 1 of year 3.

KEY RESEARCH ACCOMPLISHMENTS:

Administrative and logistical matters

a) Personnel.

Local site PI, Medical Monitor were trained on protocol requirements. Grant-funded staff, local site research coordinator, treating clinician and assessing clinican were hired and trained on protocol related activities.1) Both clinical psychologists were hired and credentialed.

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 2012. 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