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TITLE: Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the Treatment of Soldiers with PTSD

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic 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 hiring and training, process development to identify, screen, and enroll participants, completion of study-related VR Iraq scenarios, and research protocol development. Recruitment of soldiers for study participation continued during this reporting period. By the end of this reporting period, 145 referrals for treatment had been received, 84 subjects consented to study participation and 45 met all of the inclusion and none of the exclusion criteria and were randomized to treatment. There are few current challenges. New physiological assessment equipment is currently being acquired due to artifact levels found in preliminary analyses. Although enrollment is slightly behind schedule, the study is generally expected to proceed according to established timelines.

15. SUBJECT TERMS
PTSD, virtual reality exposure therapy (VRET), prolonged exposure therapy (PE)

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INTRODUCTION.

This randomized, single blind study is evaluating the efficacy of virtual reality exposure therapy (VRET) by comparing it to prolonged exposure therapy (PE) and a waitlist (WL) group in the treatment of post-traumatic stress disorder (PTSD) in active duty (AD) Soldiers with combat-related trauma. The study 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 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 and 26 weeks post-treatment. Physiological arousal, patient satisfaction with treatment, and stigma toward seeking behavioral health services will also be explored.

BODY.

With initial IRB study approval in May 2009, the study team has continued recruitment, enrollment and follow-up of study participants throughout the year. Advertising campaigns have been identified and implemented for web-based content, posters, flyers and newspaper ads. The clinical psychology team participates in continual evaluations of treatment fidelity and inter-rater reliability. The research assistant continues to be trained in a variety of administrative and computer skills required for successful study conduct. During the past year the study team has recruited, hired and trained a psychologist working in the role of psychologist/project director.

Recruitment of soldiers for study participation began May 2009. By the end of this reporting period, 145 referrals for treatment had been received, 84 subjects consented to study participation and 45 met all of the inclusion and none of the exclusion criteria and were randomized to treatment. 10 subjects randomized to 'waitlist' completed their study participation through post-assessment visit, 13 subject randomized to either treatment group had completed 10 sessions of treatment and are in the follow-up phase. 4 subjects randomized to treatment completed their 26-week follow-up and are done with study participation.

Ongoing recording and review of sessions has been implemented in order to ensure treatment fidelity of 15% of treatment sessions.

<u>Modification</u>

August 2009 revisions were made to the protocol to update the recruitment strategy by adding posters, flyers and print advertisement in local newspapers. The IRB approved these changes, as well as the use of a weblink with video for providers and potential participants.

September 2009 the IRB added a HIPPA addendum to the consent process and a request for modification of additional information regarding the videotaping of subjects described in the consent was approved.

October 2009 the IRB approved a modification request to add the psychologist/project director and remove an AI who had left the department. In December 2009 a request for

modification of the study was approved to increase the recruited number of subjects to 300 and to add Service Members who had deployed in support of OEF. The increase in numbers allowed for a 50% screen fail rate not included in the original calculation and reflective of the screen fail rate. Recruitment posters, flyers and advertisement text were amended to reflect the addition of OEF deployed soldiers. The consent form was also modified to reflect OEF inclusion. All subjects currently enrolled in the study were re-consented.

Study modification of the protocol was approved February 2010 updating the advertising campaign to reflect the inclusion of Operation Enduring Freedom (OEF) deployment history to web-based recruitment text and video. Addition of an additional Associate Investigator was also granted.

Received P000003 (dated 24 February 2010) from USAMRAA approving the revised statement of work to permit the study team to provide treatment to participants that were randomized to the waitlist group and have completed the waitlist time period, and also to provide treatment to those volunteers who have screen failed due to the inclusion/exclusion criteria but who exhibit post-traumatic stress disorder symptoms and would benefit from the protocol treatment. A request for study modification of the protocol was not approved by the Madigan Army Medical Center (MAMC) IRB because it was not research related activity and they do not have authorization to approve or disapprove the treatment.

Challenges

A decrease in active participant recruitment occurred due to staffing shortage while hiring and training the psychologist/project director and the loss of a previously trained investigator.

The NEXUS-10 equipment used for physiological data collection is likely going to be replaced due to preliminary data showing heavy artifact and data collection interference, likely due to the use of Bluetooth connection in our facility. Other biofeedback systems are being investigated for possible use on this trial.

KEY RESEARCH ACCOMPLISHMENTS.

Administrative and logistical matters.

a). Personnel.

1) Recruitment, hiring and training of a psychologist to support the study at 100% in the psychologist/project director role

2) Training of the clinical psychologist in PE and VRET therapy.

b) Materials, supplies and consumables.

1) Supplies and materials for study requirements continue to be coordinated in anticipation of human subject enrollment.

c) Institutional Review Board.

1) An annual review of the study by the MAMC IRB was approved for continuation of study conduct in December 2009.

REPORTABLE OUTCOMES.

None

CONCLUSION.

None

REFERENCES.

None

APPENDICIES.
None