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TITLE: Randomized Controlled Equivalence Trial Comparing Videoconference and Face-to-Face Delivery of Cognitive Processing Therapy for PTSD

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<b>14. ABSTRACT</b>  The proposed study seeks to address the problems that some veterans and service personnel have when trying to access appropriate health care for PTSD. One way to improve access to this care is to deliver the treatment over a video conferencing system (referred to as telemental health or TMH) so that personnel in geographically underserved areas can be treated by clinicians with specialized training. Specifically we will be comparing the efficacy of Cognitive Processing Therapy (CPT) when provided in traditional face-to-face (FTF) vs. via TMH. The study will compare these modalities of treatment among OEF/OIF veterans who have developed PTSD secondary to their military trauma. The treatment will directly help the veterans by providing education and skills-building to help them process their reactions to their traumas and decrease the experience of PTSD symptoms. This study has a unique component of having an accompanying website which allows the veterans in the TMH condition to complete their therapy assignments in a secure online environment.					
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### **INTRODUCTION**

The proposed study seeks to address the problems that some veterans and service personnel have when trying to access appropriate health care for PTSD. One way to improve access to this care is to deliver the treatment over a video conferencing system (referred to as telemental health or TMH) so that personnel in geographically underserved areas can be treated by clinicians with specialized training. Specifically we will be comparing the efficacy of Cognitive Processing Therapy (CPT) when provided in traditional face-to-face

### **BODY**

In the first 24 months of the study, we have been able to accomplish what we stated we would do in the 18 months in the Statement of Work. We have asked for and been granted a one-year no-cost extension so that we can meet the goals we set out for the study. As we reported in last year's annual report, We were greatly delayed by clearing all the regulatory bodies that needed to approve our study. Our funding runs through the University of Wisconsin (UW) and we are recruiting at two VA hospitals, therefore we had many interested parties from whom we needed to obtain approval. In addition, we had trouble getting approval for the study website due to privacy concerns. These concerns had to be reviewed locally, then with the VA regional counsel, and eventually were reviewed by VA Central Office counsel who concluded that the website did not pose a privacy threat since there was no identifying information on the website or stored by the website.

The Hines & Madison staff were trained in the SCID-I and CAPS interviews and after establishing initial reliability we have been checking ongoing reliability to ensure there is no "rater-drift". We created excel databases for entering data with a double entry system and hired work-study students to do ongoing data entry. We set up a system for subject payments and that has been working smoothly. We hired study coordinators for both sites and the PI, Co-PI, and research coordinators meet weekly to review study progress. Clinicians from both sites meet weekly with the PI and Co-PI for clinical supervision.

We have met the requirements for our ongoing IRB and VA R & D continuing reviews. We have had no adverse events. We are about to submit our two year continuing review to the UW IRB.

We have begun recruiting and currently have randomized 16 veterans – 8 to the TMH condition and 8 to the FTF condition. Of these 11 were randomized from Hines VA and one from the Madison VA. At Hines 59 patients have been screened. At Madison 15 have been screened. We are meeting with a variety of clinical teams at the Madison VA to increase enrollment.

One issue has been finding OEF/OIF vets who have the time to commit to coming to the study visits since after the baseline assessment, they need to come twice a week for 6 weeks. Since many of these Veterans have young families, work and go to school; coming in twice a week has been difficult. The PI is currently drafting a letter to other researchers who are doing clinical trials with OEF/OIF Veterans to determine ways we can improve our recruitment and retention.

### **Key Research Accomplishments**

Completion of study website and began recruiting of study participants. Presented a research poster on the study design and the study website at the Office of Mental Health Services conference "Implementing a Public Health Model for Meeting the Mental Health Needs of Veterans" in Baltimore, MD , July 26<sup>th</sup>-29<sup>th</sup>.

### **Reportable Outcomes**

There are no reportable outcomes at this time other than the completion of the website, our current recruitment, and the poster presentation mentioned above..

### **Conclusion**

In the first 24 months of the study, we have been able to accomplish what we stated we would do in 12 months in the Statement of Work due to the high number of regulatory boards involved in our study and privacy concerns regarding the study website which delayed our starting. We have begun recruiting and will be working on ways to increase our recruitment and retention. We have been granted a no-cost one year extension so that we can still meet our study goals.