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Award Number: W81XWH-08-2-0130

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

PRINCIPAL INVESTIGATOR: Tracey L. Smith, Ph.D.

CONTRACTING ORGANIZATION: University of Wisconsin
Madison, WI 53706-1490

REPORT DATE: June 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

X Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
30/06/09	Annual	1June 2008 – 31 May 2009

4. TITLE AND SUBTITLE
Randomized Controlled Equivalence Trial Comparing Videoconference and Face-to-Face Delivery of Cognitive Processing Therapy for PTSD"

5a. CONTRACT NUMBER
W81XWH-08-2-0130

5b. GRANT NUMBER
PT075415; New Investigator Award

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Tracey L. Smith, Ph.D

Tracey.Smith2@va.gov

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Wisconsin
750 University Avenue
4th Floor Peterson Bldg
Madison, WI 53706-1490

8. PERFORMING ORGANIZATION REPORT NUMBER
USA MED RESEARCH AND MATERIEL COM
FORT DETRICK MD 21702-5012

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Ft. Detrick, MD 21702

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

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.

15. SUBJECT TERMS
PTSD; Cognitive Processing Therapy; Video-conferencing; psychotherapy; telemental health

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			Tracey L. Smith
U	U	U	UU	4	**19b. TELEPHONE NUMBER** *(include area code)*

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INTRODUCTION

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BODY

In the first 12 months of the study, we have been able to accomplish what we stated we would do in 6 months in the Statement of Work. Because we are a two site study and have to run our funding through the University of Wisconsin (UW) we had more interested parties from whom we needed to obtain approval. We had the UW IRB, the Madison VA R & D Committee, the Hines VA IRB and the Hines VA R & D, as well as HRPO. We have completed 95% of the regulatory review process and obtained approval from the various involved agencies for use of human subjects. We are currently waiting for the UW IRB to complete an expedited review of the changes (expected approval) to the consent form necessitated by the receipt of the Certificate of Confidentiality (COC) and the addition of new personnel (a study coordinator and new study therapists). Then we will route these changes through the Madison VA R & D, the Hines VA R & D and the DOD HRPO office. We hope to begin recruiting subjects the first week in September.

We have completed the design and testing of the study website and are awaiting the final changes (based on that testing) by the programmers. The website will be completed and ready for use by August 14. Test website is currently posted here (http://ptsstest.sundialsc.com/PTSSUserSecurity/UserLogin.aspx) before being moved to a secure server.

The Hines & Madison Staff have been trained in the SCID-I and CAPS and are completing their ratings for establishing initial inter-rater reliability. We have collected and copied all the required assessment instruments. We have created the excel databases for entering data with a double entry system. We have purchased the equipment to video and convert the video to DVD for adherence ratings. The statistician has created the randomization schedules. We have set up the systems needed for tracking patients and their progress through the study. We are in the process of setting up a system for subject payments.

We recently hired a research coordinator for the Madison site; we decided to wait until we were close to recruitment to conserve funds. We have discussed applying for a one year no-cost extension so that we will be able to meet our recruitment goals and to that end have been careful in our spending. Staff is ready to begin the study as soon as we get approval from each regulatory board.

The Madison VA R & D meets August 20th. We expect to have UW IRB approval before then (based on their pre-review). The Hines VA said they can do an expedited review. Then we will send all this to HRPO.

KEY RESEARCH ACCOMPLISHMENTS
Since we have not begun recruiting subjects, we have no research accomplishments.

REPORTABLE OUTCOMES
There are no reportable outcomes at this time other than the completion of the website.

CONCLUSION
In the first 12 months of the study, we have been able to accomplish what we stated we would do in 6 months in the Statement of Work due to the high number of regulatory boards involved in our study. We will be able to begin subject recruitment in early September and have done all the necessary pre-recruitment work in order to have a successful well-run study.

REFERENCES
None to report

APPENDICES
None