

AWARD NUMBER: W81XWH-17-2-0067

TITLE: Massed Cognitive Processing Therapy for Combat-Related PTSD

PRINCIPAL INVESTIGATOR: Jennifer Wachen, Ph.D.

CONTRACTING ORGANIZATION: Boston VA Research Institute, Inc. (BVARI)
Boston, MA 02130

REPORT DATE: October 2018

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE October 2018			2. REPORT TYPE Annual			3. DATES COVERED 30 Sep 2017 - 29 Sep 2018			
4. TITLE AND SUBTITLE Massed Cognitive Processing Therapy for Combat-Related PTSD						5a. CONTRACT NUMBER			
						5b. GRANT NUMBER W81XWH-17-2-0067			
						5c. PROGRAM ELEMENT NUMBER			
6. AUTHOR(S) Jennifer Wachen, Ph.D. E-Mail: Jennifer.wachen@va.gov						5d. PROJECT NUMBER			
						5e. TASK NUMBER			
						5f. WORK UNIT NUMBER			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Boston VA Research Institute, Inc. (BVARI) 5 Post Office Square Boston, MA02130						8. PERFORMING ORGANIZATION REPORT NUMBER			
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012						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 Cognitive Processing Therapy (CPT) is identified as one of the most effective treatments for posttraumatic stress disorder (PTSD) in a wide range of trauma populations. This study will test the efficacy of massed intensive outpatient CPT compared to standard CPT delivery. A sample of 140 active duty service members will be assigned randomly to receive either Massed CPT (MCPT) or standard CPT. MCPT will be delivered in an intensive outpatient setting (12 sessions in 5 days) composed of both group and individual sessions. By contrast, standard delivery of CPT consists of 12 sessions over 6 weeks and involves only individual sessions. Participants will be assessed before and after treatment, and several times up to four months after treatment completion to determine if MCPT is as efficacious as standard CPT and to examine predictors of treatment response in each condition.									
15. SUBJECT TERMS Posttraumatic stress disorder, cognitive processing therapy, intensive outpatient therapy, combat trauma									
16. SECURITY CLASSIFICATION OF:						17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON	
a. REPORT	b. ABSTRACT	c. THIS PAGE	USAMRMC						
U	U	U	UU		11	19b. TELEPHONE NUMBER (include area code)			

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	7
5. Changes/Problems.....	8
6. Products, Inventions, Patent Applications, and/or Licenses.....	8
7. Participants & Other Collaborating Organizations.....	8
8. Special Reporting Requirements.....	10
9. Appendices.....	NA

1. INTRODUCTION: Cognitive Processing Therapy (CPT) is identified as one of the most effective treatments for posttraumatic stress disorder (PTSD) in a wide range of trauma populations, with a higher effect size than any other evidence-based treatments for PTSD. However, CPT has been shown to be somewhat less effective in active duty and veteran populations when compared to civilian trauma victims. One reason may be that service members have difficulty committing to a six-week course of therapy due to the demanding nature of active duty military operations schedules. In addition, limited availability of clinical providers may reduce access to care. One way to address these barriers may be to administer CPT in an intensive, 5-day format. This format may increase rates of treatment completion and produce faster symptom improvement than the standard administration of CPT. This study will test the efficacy of massed intensive outpatient CPT compared to standard CPT delivery. A sample of 140 active duty service members will be assigned randomly to receive either Massed CPT (MCPT) or standard CPT. MCPT will be delivered in an intensive outpatient setting (12 sessions in 5 days) composed of both group and individual sessions. By contrast, standard delivery of CPT consists of 12 sessions over 6 weeks and involves only individual sessions. Participants will be assessed before and after treatment, and several times up to four months after treatment completion to determine if MCPT is as efficacious as standard CPT and to examine predictors of treatment response in each condition.

2. KEYWORDS: combat-related posttraumatic stress disorder, active duty military personnel, service members, behavioral health interventions, cognitive processing therapy, intensive outpatient treatment

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The specific aims of the study are: (1) To evaluate the efficacy of massed CPT in a sample of active duty military; (2) To examine predictors of treatment outcome; (3) Exploratory- Evaluate the tolerability of massed versus standard administration of CPT

Major Task 1: Prepare Research Protocol	Target Date	Completion Date
<i>Milestone: Local IRB approval at FBCH, VABHS, UTHSCSA</i>	1/31/18	10/15/18
<i>Milestone: HRPO approval for all protocols</i>	3/31/18	Pending
Major Task 2: Hiring and Training of Study Staff		
<i>Milestone: Research staff trained</i>	3/31/18	Ongoing
<i>Milestone: Maintained trained therapists and evaluators throughout duration of the clinical trial</i>	6/30/21	
Major Task 3: Participant Recruitment, Therapy, Participant Evaluation		
<i>Milestone: 1st participant consented, screened and enrolled</i>	4/30/18	
<i>Milestone: Treatment completed</i>	3/31/21	
<i>Milestone: Assessments at all time points completed</i>	6/30/21	
<i>Milestone: Report findings comparing CPT treatment formats.</i>	9/30/21	
<i>Milestone: Report findings of predictors of treatment outcome.</i>	9/30/21	

<i>Milestone: Report findings of treatment tolerability.</i>	<i>9/30/21</i>	
Major Task 4: Data Analysis		
<i>Milestone Achieved: Report results from data analyses</i>	<i>9/30/21</i>	

What was accomplished under these goals?

Major Task 1: Prepare Research Protocol

- Refine eligibility criteria, exclusion criteria, screening protocol: The study team has finalized the eligibility criteria, exclusion criteria, and screening protocol for the study.
- Refine assessment battery: The study team has finalized the assessment battery to be used for data collection for the study.
- Finalize consent form & human subjects protocol: The study team has drafted and finalized the consent form, HIPAA form, and human subjects protocol as required by the Walter Reed National Military Medical Center (WRNMMC) IRB, which will provide oversight of research activities at Fort Belvoir Community Hospital (FBCH).
- Coordinate with Sites for IRB protocol submission: Dr. Wachen worked closely with research staff at FBCH to determine the requirements for submission to the WRNMMC IRB. Study personnel at FBCH (Drs. Jennifer Weaver and Kris Morris) obtained access to the WRNMMC eIRB system. As recommended by the WRNMMC IRB, consultation was sought with the statistical expert, MHS data expert, and Communications department at FBCH. The initial EIRB protocol was submitted to FBCH on 16 Feb 2018. Drs. Wachen, Morris, and Weaver responded to several rounds of stipulations and received FBCH approval on 2 April 2018. The protocol was forwarded to WRNMMC IRB for review on 2 April 2018. The study protocol was discussed at the WRNMMC IRB meeting on 10 May 2018. Drs. Weaver, Wachen, and Morris participated in the meeting via telephone to respond to questions raised by the committee. On 18 May 2018 the study team received notification from the WRNMMC IRB that the submission was deferred pending response to a number of stipulations and recommendations. The required modifications were submitted to the WRNMMC IRB on 4 June 2018. The revised protocol was discussed at the WRNMMC IRB meeting on 29 June 2018. The submission was deferred once again due to minor additional questions from the committee. The study team responded to the requested stipulations on 19 July 2018 and provided additional requested information on 26 July 2018. The study protocol was discussed at the WRNMMC IRB meeting on 10 August 2018. Drs. Weaver, Wachen, and Morris participated in the meeting via telephone to respond to questions raised by the committee. Conditional approval was granted on 14 August 2018 with a request for minor changes to the protocol and consent form. The requested changes were submitted on 22 August 2018. The WRNMMC approval memo was sent on 4 September 2018.
- Coordinate with Sites for VA Boston IRB review: Initial administrative approval from the VA Boston Research & Development (R&D) committee was received on 28 March 2018. The VA Boston Initial IRB materials were submitted on 17 September 2018 upon receipt of approval from WRNMMC. The protocol was reviewed by the VA Boston IRB on 24 September 2018. The initial approval was deferred due to some minor stipulations. Revisions to the application were submitted on 5 October 2018. The protocol was reviewed on 15 October 2018, after the date of this report. Conditional approval has been granted pending review by several subcommittees.
- Coordinate with Sites for UTHSCSA IRB review: The IRB protocol was submitted to the UTHSCSA IRB on 19 April 2018. The protocol was approved by Expedited Review on 8 May 2018.

- Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO): Materials for the WRNMMC portion of the study were submitted for HRPO approval on 24 September 2018. Materials for VA Boston and UTHSCSA were submitted on 26 October 2018 after the date of this report.
- Formation of a CRADA with FBCH: A CRADA was submitted to FBCH/WRNMMC DRP on 7 March 2018. Once the IRB protocol was reviewed, the CRADA moved forward to the Agreement Review Committee (ARC) at WRNMMC for review. On 03 October, the approved agreement began routing for execution and is expected to be fully executed by 31 October. In addition, the Data Sharing Agreement Application was submitted and approved on 24 July.

Major Task 2: Hiring and Training of Study Staff

- Advertise and interview for project related staff: BVARI received nearly 100 applications in response to the job posting for a Research Assistant. Of those, 12 were screened and 6 were invited for in-person interviews. One candidate (Richard Vandiver) was selected for the position. He brought experience as a Veteran of the Air Force and a bachelor's degree in neuropsychology, with a strong research background. He began work in February 2018, but left in August 2018 when he learned that he was admitted to a clinical psychology doctoral program. Several candidates were interviewed to replace him. Allison Cole was identified and began work in August 2018.

A number of applications were received for the Research Coordinator position at the FBCH study site. Several candidates were interviewed. Rachel Nelson was selected began work in April 2018.

A number of candidates for the therapist positions were identified and interviewed, and 3 therapists were hired in May 2018. Corrie Avila, LCSW, and Nicole Carey, Psy.D. began work at FBCH in June 2018. Carey Schwartz, Ph.D. will begin work at FBCH on 1 October 2018 following completion of his postdoctoral fellowship. He has completed the credentialing process and is on target for this start date. Drs. Wachen and Morris identified four master's level clinicians engaged in training at FBCH who are interested in serving as independent evaluators on the project on a part-time basis. Dr. Katherine Buchholz has been identified as the Assessment Supervisor and will provide ongoing consultation during the study.

- Provide initial training of therapists by expert CPT consultants: Dr. Wachen traveled to FBCH on 17-18 July 2018 to conduct training in CPT for the study therapists. Study therapists are conducting treatment with clinical training cases under the supervision of Dr. Morris and consultation of Dr. Wachen. Dr. Schwartz has been previously trained in CPT prior to his start date of 1 October.
- Train and certify Independent Evaluators for study assessments: The independent evaluators have completed the online CAPS training course offered through the National Center for PTSD to become qualified to serve as independent assessors on the study. They are conducting assessments on training cases and meeting for weekly supervision with Dr. Buchholz.

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation

- Coordinate with Sites for all study steps, data collection and database requirements: Study staff have identified a data collection tool (Research Electronic Data Capture-REDCap) to be used for the study. Study staff consulted with staff at Geneva who have extensive experience with the REDCap system and received instruction on the use of the database. The database has been developed will be finalized prior to the initiation of data collection.
- Dr. Wachen attended a site visit at FBCH on 7-8 March 2018. Activities included facility tours, introduction to key personnel, meetings with FBCH research staff, and meeting with potential clinical collaborators to discuss study logistics. Another site visit is scheduled for October 2018.

- Site PIs and study Co-Investigators participate in weekly teleconferences to discuss details of study implementation. Topics include logistics of study procedures, hiring, and data security.
- Development of the REDCap database will continue prior to recruitment and data collection.

What opportunities for training and professional development has the project provided?

- The Research Coordinator and Research Assistant, Rachel Nelson and Allison Cole, received training in the REDCap database from Elissa Thomas, the REDCap expert at Geneva.
- The study therapists received training in Cognitive Processing Therapy from Dr. Wachen and are receiving ongoing consultation and supervision from Drs. Wachen and Morris.
- All study therapists and independent evaluators completed the online NCPTSD CAPS training. They are completing training cases and receiving weekly supervision from Dr. Buchholz.

How were the results disseminated to communities of interest?

- Nothing to report at this time.

What do you plan to do during the next reporting period to accomplish the goals?

Tasks for next reporting period (months 13-15):

Major Task 1: Prepare Research Protocol

- Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO): Materials were submitted for HRPO approval on 24 September and 26 October 2018. Study staff will respond to requests for information in a timely manner to expedite approval.

Major Task 2: Hiring and Training of Study Staff

- Provide initial training of therapists by expert CPT consultants: Therapists will continue treating clinical training cases prior to enrolling and treating study participants upon HRPO approval.
- Train and certify Independent Evaluators for study assessments: Independent Evaluators will continue to assess training cases and receive expert consultation through the Assessment Supervisor at VA Boston.

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation

- Coordinate with Sites for all study steps, data collection and database requirements: The REDCap database to be used in the study for participant tracking and data collection is nearly complete and will be finalized prior to participant recruitment and evaluation.
- Begin subject recruitment: Recruitment strategies have been identified. Upon receipt of HRPO approval, recruitment of participants will begin.
- Begin treatment of consented participants in standard and massed CPT conditions: Upon receipt of HRPO approval, randomized consented participants will receive treatment through the study.
- Complete assessments at baseline, one month, and 4 months posttreatment: Upon receipt of HRPO approval, randomized consented participants will complete assessments at all major timepoints.

4. IMPACT:

- Nothing to report at this time.

5. CHANGES/PROBLEMS

Actual or anticipated problems or delays and actions or plans to resolve them

- The process of obtaining local IRB approval through FBCH and WRNMMC took longer than anticipated due to FBCH research staff absences and local delays in signing off on approvals. The protocol was submitted to the WRNMMC IRB, but approval was delayed by a number of stipulations requested by the IRB committee and the resulting requirement of multiple full board reviews. Project staff were expeditious in responding to stipulations in order to move the process forward as quickly as possible. WRNMMC approval was granted on 4 September 2018. The IRB application to VA Boston was submitted shortly after receipt of WRNMMC approval. To expedite the HRPO approval, we began submission for the process immediately upon receipt of WRNMMC approval so that WRNMMC activities may begin following HRPO approval for that site. Submission of local IRB materials to HRPO occurred after the reporting period of this report. Dr. Wachen is in close communication with HRPO staff to provide any required information in order to expedite approval as quickly as possible and begin study recruitment.

Changes that had a significant impact on expenditures

- We delayed the hire of study therapists and assessors until closer to the time of anticipated recruitment in order to conserve study funds. These funds may be used to hire additional therapists or extend the study timeline if needed to meet recruitment goals in the future. Therapists have now been hired and training is ongoing. As part of the training process, therapists are treating clinical patients outside the scope of the research study so that training will be complete when HRPO approval is received and recruitment is ready to begin. Assessors have been identified and are completing training so that they may assess study participants upon receipt of HRPO approval.

6. PRODUCTS

- Nothing to report at this time.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name:	<i>Jennifer Wachen, Ph.D.</i>
Project Role:	<i>Principal Investigator</i>
Nearest person month worked:	<i>4</i>
Contribution to Project:	<i>Protocol development, Coordination of IRB submission, Hiring, Training</i>

Name:	<i>Richard Vandiver</i>
Project Role:	<i>Research Assistant</i>
Nearest person month worked:	<i>7</i>

Contribution to Project:	<i>Protocol development, Coordination of IRB submission, Study preparation</i>
--------------------------	--

Name:	<i>Kris Morris Ph.D.</i>
Project Role:	<i>Co- Investigator</i>
Nearest person month worked:	<i>4.8</i>
Contribution to Project:	<i>Protocol development, Coordination of IRB submission, Hiring, Training</i>

Name:	<i>Jennifer Weaver, MD</i>
Project Role:	<i>Site-Principal Investigator</i>
Nearest person month worked:	<i>1.2</i>
Contribution to Project:	<i>Protocol development, Coordination of IRB submission</i>

Name:	<i>Rachel Nelson, MA</i>
Project Role:	<i>Research Coordinator</i>
Nearest person month worked:	<i>5</i>
Contribution to Project:	<i>Protocol development, Assistance with IRB submission, Study preparation</i>

Name:	<i>Allison Cole</i>
Project Role:	<i>Research Assistant</i>
Nearest person month worked:	<i>1</i>
Contribution to Project:	<i>Coordination of IRB submission, Database development, study preparation</i>

Name:	<i>Nicole Carey, Psy.D.</i>
Project Role:	<i>Study Therapist</i>
Nearest person month worked:	<i>2</i>

Contribution to Project:	<i>Training in therapy</i>
--------------------------	----------------------------

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

- Nothing to report

What other organizations were involved as partners?

Organization Name: Geneva Foundation
Location of Organization: Tacoma, WA
Collaboration: Hiring of personnel at Fort Belvoir site

8. SPECIAL REPORTING REQUIREMENTS:

See Quad Chart attached.

9. APPENDICES

None

Massed Cognitive Processing Therapy for Combat-related PTSD

BA160492

W81XWH-17-2-0067



PI: Jennifer Wachen, Ph.D.

Org: Boston VA Research Institute, Inc.

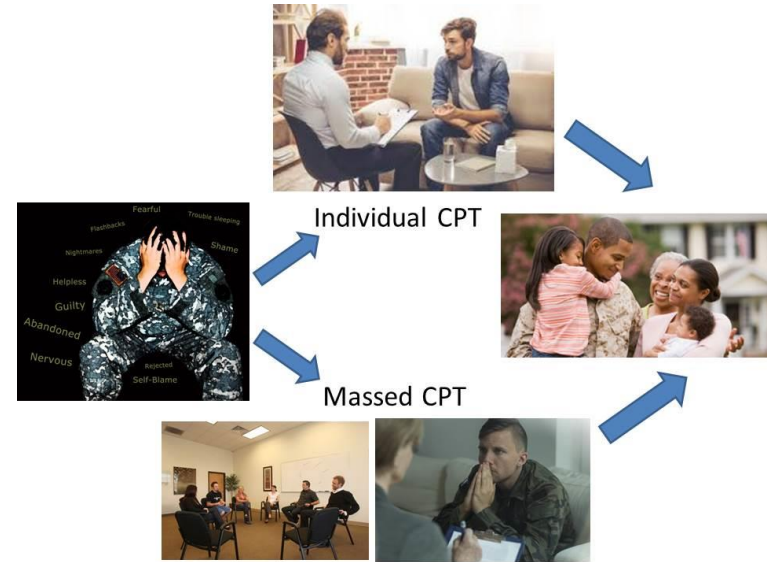
Award Amount: \$3,282,395.00

Study/Product Aim(s)

- To examine the effectiveness of a massed version of Cognitive Processing Therapy (MCPT) for treatment of PTSD in Active Duty military.
- To examine predictors of symptom reduction in each condition.
- (Exploratory): To evaluate the tolerability of massed versus standard administration of CPT.

Approach

- Randomized controlled trial conducted with active duty service members at Fort Belvoir Community Hospital.
- Participants will be randomized to received MCPT in a 5-day intensive outpatient format or standard CPT 2x/week for 6 weeks.
- Outcomes of interest include PTSD, depression, social functioning, aggression, and physical health.
- Exploratory outcomes of non-specific factors including perceptions of burden (in terms of time and effort), rapport, and therapeutic alliance will also be examined.



Timeline and Cost

Activities	CY	18	19	20	21
Obtain & maintain IRB approvals		Proposed Timeline			
Hire/Train personnel		Proposed Timeline			
Recruitment/Treatment		Proposed Timeline			
Data Collection		Proposed Timeline			
Data Analysis/Write-up					Actual Timeline
Estimated Budget (\$K)		782	903	941	656

Goals/Milestones

CY18 Goals – Develop protocol and obtain approvals

- Finalize assessment measures and create study protocol
- Obtain approvals from regulatory agencies (IRB)- *Ongoing*
- Hire and train study staff- *Ongoing*

CY18-21 Goals – Perform intervention and data collection

- Recruit participants and conduct treatment
- Collect treatment and follow-up data

CY21 Goal – Interpret Results

- Analyze data and report results.

Comments/Challenges/Issues/Concerns

- Protocol submitted to Walter Reed IRB.
- Therapists will be hired following IRB submission

Budget Expenditure to Date

Projected Expenditure: See Timeline and Cost Table

Actual Expenditure: \$189,406

Updated: 29 September 2018

Proposed Timeline (Green bar) Actual Timeline (Purple bar)