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TITLE: Massed Cognitive Processing Therapy for Combat-related PTSD

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CONTRACTING ORGANIZATION: Boston VA Research Institute, Inc.
Boston, MA 02109

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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

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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
Milestone: Local IRB approval at FBCH, VABHS, UTHSCSA	*1/31/18*	*UTHSCSA: 5/8/18* *WRNMMC: 9/4/18* *VA Boston 1/24/19*
Milestone: HRPO approval for all protocols	*3/31/18*	*WRNMMC: 11/13/18* *UTHSCSA: 11/20/18* *VA Boston 1/25/19*
Major Task 2: Hiring and Training of Study Staff		
Milestone: Research staff trained *Milestone: Maintained trained therapists and evaluators throughout duration of the clinical trial*	*3/31/18* *6/30/21*	*2/1/19* *Ongoing*

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation		
Milestone: 1st participant consented, screened and enrolled *Milestone: Treatment completed* *Milestone: Assessments at all time points completed* *Milestone: Report findings comparing CPT treatment formats.* *Milestone: Report findings of predictors of treatment outcome.* *Milestone: Report findings of treatment tolerability.*	*4/30/18* *3/31/21* *6/30/21* *9/30/21* *9/30/21* *9/30/21*	*3/5/19*
Major Task 4: Data Analysis		
Milestone Achieved: Report results from data analyses	*9/30/21*	

What was accomplished under these goals?

Major Task 1: Prepare Research Protocol

- Coordinate with Sites for IRB protocol submission: WRNMMC approval was granted on 4 September 2018.
  --Amendment #1 to add an additional measure that was excluded from the initial approval was approved by WRNMMC IRB on 17 November 2018.
  --Amendment #2 requesting minor modifications and additions to the assessment measures was approved by WRNMMC IRB on 12 March 2019.
  --Amendment #3 adding Julian Burke as the research coordinator was approved by WRNMMC IRB on 11 April 2019.
  --Amendment #4 changing the site PI from Dr. Jennifer Weaver to Dr. Kris Morris was approved by WRNMMC IRB on 7 May 2019.
  --Amendment #5 adding Dr. Joy Mobley as an Associate Investigator was approved by WRNMMC IRB on 12 July 2019.
  --The continuing review was submitted to WRNMMC IRB on 9 July 2019 and granted on 9 August 2019.
- Coordinate with Sites for VA Boston IRB review: 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. Conditional approval was granted on 15 October 2018 pending review by the information security officer. Due to a backlog in the system for this review, the official approval memo and notice to proceed was granted by VA Boston IRB on 24 January 2019.
- Coordinate with Sites for UTHSCSA IRB review: The annual continuing review was approved by UTHSCSA IRB on 10 April 2019.
- 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. HRPO approval for the WRNMMC site was granted on 13 November 2018 and for the UTHSCSA site on 20 November 2018. HRPO approval for VA Boston was granted on 25 January 2019.
  ` --HRPO acknowledged receipt of the UTHSCSA continuing review on 7 May 2019.

--HRPO approved the protocol amendment changing the site-PI to Dr. Kris Morris on 28 May 2019.

--The WRNMMC continuing review approval was forwarded to HRPO on 30 Sept 2019.

- 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 2018, the approved agreement began routing for execution. The fully executed CRADA was received on 17 January 2019.

Major Task 2: Hiring and Training of Study Staff

- Advertise and interview for project related staff: Carey Schwartz, Ph.D. began work at FBCH as a study therapist on 1 October 2018 following completion of his postdoctoral fellowship.

--A new Research Coordinator, Julian Burke, MA, was hired in January 2019 to replace Rachel Nelson, MA. Mr. Burke has significant prior related experience and has been integral in establishing local procedures.

--Brittany Hall-Clark, Ph.D. was hired to serve as an intermittent independent evaluator in June 2019. Two master's level practicum students at FBCH were identified to serve as independent evaluators. Larissa Tate started in June and Amanda Lane started in July.

--Several applicants were interviewed for the posted Therapist position. Harry McCleary, Ph.D. was offered and accepted the position, beginning in August 2019.

- Provide initial training of therapists by expert CPT consultants: Dr. Schwartz had been previously trained in CPT prior to his start date of 1 October. Dr. McCleary had been previously trained prior to his start date of 1 August.

-- Drs. Morris, Carey, and Schwartz conducted a pilot of the MCPT intervention using clinical cases in November 2018.

-- Drs. Carey and Schwartz continued to treat clinical cases under close supervision prior to study enrollment. Dr. McCleary continues to treat clinical cases under close supervision prior to being cleared to treat study participants. Therapists continue to receive weekly ongoing supervision from Drs. Wachen, Morris, and Galovski.

- 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. Katherine Buchholz, the Assessment Supervisor.

-- Two masters-level clinicians (Ally Carry and Fernanda DeOliveria) completed training and certification by Dr. Buchholz but left the study in July 2019 at the end of their training year. Three additional master's level assessors (Larissa Tate, Amanda Lane, and Christiana Shao) joined the study in summer 2019. Dr. Hall-Clark and Larissa Tate have completed the training and certification process for the CAPS with Dr. Buchholz and are currently conducting assessments of study cases. Drs. Morris, Carey, and Schwartz also completed training and certification by Dr. Buchholz for the conduct of baseline CAPS assessments as needed. Training for the other assessors is ongoing.

- Coordinate with Sites for training and supervising Therapists and Independent Evaluators throughout study:

-- Drs. Carey and Schwartz began treating study cases in March 2019. The therapists continue to receive weekly ongoing supervision from Drs. Wachen, Morris, and Galovski.

--Independent evaluators have ongoing weekly telephone consultation with Dr. Buchholz.

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation

- Coordinate with Sites for all study steps, data collection and database requirements:
  --The REDCap database for the study has been developed. All survey instruments have been built within the database. It was tested for production prior to data entry. Data entry is ongoing.
  --Site PIs and study Co-Investigators participate in weekly teleconferences to discuss details of study implementation. Topics include logistics of study procedures, regulatory submissions, space and resources, training and supervision, hiring, database development, and data security.
  --Dr. Wachen and Dr. Dondanville traveled to FBCH for a site visit on 15-16 May 2019 to meet with study staff and oversee study processes.
  --Dr. Wachen attended a site visit at FBCH on 26 Sept 2019 to meet with study staff and oversee study processes.
- Begin subject recruitment and treatment:
  --Recruitment began in February 2019 after receiving full HRPO approval. The first participant was screened on 11 February 2019. The first consent and baseline assessment occurred on 5 March 2019. Recruitment has been ongoing, with a steady stream of referrals since recruitment began. Referrals are generated primarily through the Adult Behavioral Health Clinic, although outreach efforts to the satellite clinic have generated additional referrals. As of 30 September 2019, 68 potential participants were screened, 50 were consented and completed baseline assessments, and 44 were eligible and randomized to treatment. The first five cohorts of the MCPT condition have been completed; the sixth cohort is scheduled to begin on 4 November 2019. As of 30 September 2019, 5 additional participants were pending consent and 24 participants had completed treatment.
- Complete assessments at baseline, one month, and 4 months posttreatment:
  --As of September 30, 2019, 50 baseline assessments have been completed, resulting in 44 participants eligible for study participation. Follow-up assessments are ongoing for enrolled participants. As of 30 Sept, 11 Week-5 assessments and 11 Week-10 assessments, and 3 Week-17 assessments have been completed.

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

- The Research Coordinator, 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 25-28):

Major Task 1: Prepare Research Protocol

- Coordinate with Sites for IRB protocol submission: Maintain all regulatory approvals at all study sites and submit amendments as needed.

Major Task 2: Hiring and Training of Study Staff

- Provide initial training of therapists by expert CPT consultants: Dr. McCleary will continue treating clinical training cases prior to treating study participants. All therapists will continue to receive ongoing weekly supervision from Drs. Wachen, Morris, and Galovski.
- 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: Data collection and data entry will continue.
- Begin subject recruitment: Recruitment of participants will continue.
- Begin treatment of consented participants in standard and massed CPT conditions: Randomized consented participants will continue to receive treatment through the study.
- Complete assessments at baseline, one month, and 4 months posttreatment: 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, WRNMMC, and VA Boston took longer than anticipated. Project staff were expeditious in responding to stipulations in order to move the process forward as quickly as possible. HRPO approval was granted on 25 January 2019. Recruitment began immediately after approval. These regulatory delays resulted in a delay in beginning recruitment. However, current recruitment rates are higher than initially proposed. We anticipate that by continuing active recruitment, expanding recruitment to additional sites if needed, and condensing the frequency of the cohorts, the resulting delay to the recruitment timeline will be minimized.

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. Therapists and assessors have now been hired and training is ongoing. Current expenditures are now more in line with the proposed project budget.

6. PRODUCTS

- Nothing to report at this time.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

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

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

Name:	*Julian Burke, MA*
Project Role:	*Research Coordinator*
Nearest person month worked:	9
Contribution to Project:	*Coordination of IRB submission, Recruitment, Participant tracking, daily study operations*

Name:	*Allison Cole, B.S.*
Project Role:	*Research Assistant*
Nearest person month worked:	*12*
Contribution to Project:	*Coordination of IRB submission, Database development, study preparation*

Name:	*Nicole Carey, Psy.D.*
Project Role:	*Study Therapist*
Nearest person month worked:	12

Contribution to Project:	*Study therapist, baseline assessor*

Name:	*Carey Schwartz, Psy.D.*
Project Role:	*Study Therapist*
Nearest person month worked:	12
Contribution to Project:	*Study therapist, baseline assessor*

Name:	*Harry McCleary, Ph.D.*
Project Role:	*Study Therapist*
Nearest person month worked:	1
Contribution to Project:	*Study therapist, assessor*

Name:	*Tara Galovski, Ph.D.*
Project Role:	*Co-Investigator*
Nearest person month worked:	1.8
Contribution to Project:	*Protocol development, training and supervision*

Name:	*Katy Dondanville, Psy.D.*
Project Role:	*Co-Investigator*
Nearest person month worked:	1
Contribution to Project:	*Protocol development, expert consultation*

Name:	*Katherine Buchholz, Ph.D.*
Project Role:	Assessment supervisor
Nearest person month worked:	1.2
Contribution to Project:	*Training and supervision of evaluators*

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

Quad Chart

Massed Cognitive Processing Therapy for Combat-related PTSD

BA160492

W81XWH-17-2-0067

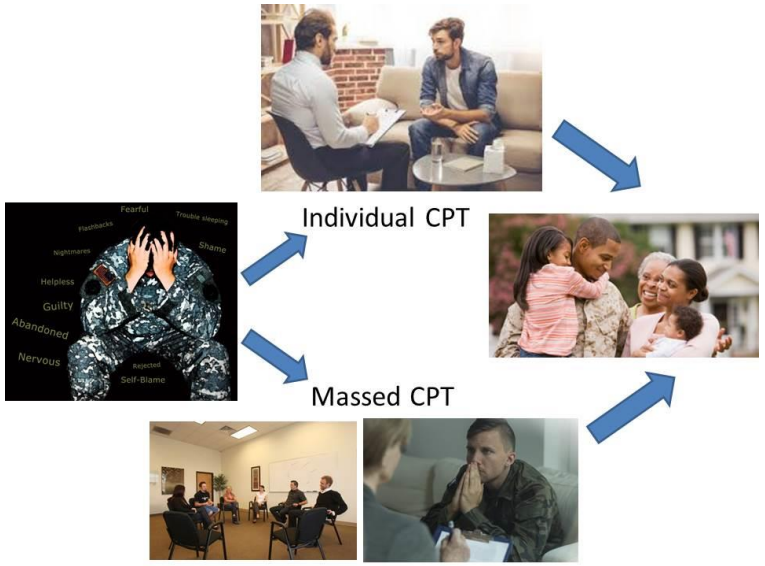
PI: Jennifer Wachen, Ph.D. **Org:** Boston VA Research Institute, Inc. **Award Amount:** $3,282,395

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				
Hire/Train personnel				
Recruitment/Treatment				
Data Collection				
Data Analysis/Write-up				
Estimated Budget ($K)	**782**	**903**	**941**	**656**

Updated: 30 September 2019

Proposed Timeline Actual Timeline

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

- IRB approvals took longer than expected.
- Therapists and assessors hired and trained.
- Recruitment, assessment, and treatment has begun.

Budget Expenditure to Date

Projected Expenditure: See Timeline and Cost Table

Actual Expenditure: $ 648,183