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TITLE: Massed Cognitive Processing Therapy for Combat-related PTSD

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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.					
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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
<i>Milestone: Local IRB approval at FBCH, VABHS, UTHSCSA</i>	1/31/18	UTHSCSA: 5/8/18 WRNMMC: 9/4/18 VA Boston 1/24/19
<i>Milestone: HRPO approval for all protocols</i>	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		
<i>Milestone: Research staff trained</i>	3/31/18	2/1/19
<i>Milestone: Maintained trained therapists and evaluators throughout duration of the clinical trial</i>	6/30/21	Ongoing

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation		
<i>Milestone: 1st participant consented, screened and enrolled</i>	4/30/18	3/5/19
<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>	9/30/21	
Major Task 4: Data Analysis		
<i>Milestone Achieved: Report results from data analyses</i>	9/30/21	

What was accomplished under these goals?

Major Task 1: Prepare Research Protocol

- Coordinate with Sites for IRB protocol submission:
 - Amendment #6 adding Dr. Ronnie Zeussman, the research monitor to EIRB; adding additional recruitment sites including the Warrior Transition Unit, Quantico, the Pentagon, Vigilant Torch Association, Andrews Airforce Base, Walter Reed, and Fort Meade; and correcting typos on the PCL and PHQ daily assessment measures was approved by WRNMMC IRB on 9 December 2019.
 - Amendment #7, changing the phone number on the recruitment flyer and adding an additional assessment (URICA-T, measuring readiness to change) was approved by WRNMMC IRB on 30 January 2020.
 - Amendment #8, requesting that assessments be completed remotely via telehealth and REDCap online surveys due to the COVID-19 outbreak, was submitted to WRNMMC IRB on 25 March 2020 and approved on 24 April 2020. Following USAMRAA and WRNMMC guidance, in order to minimize disruption to the research and patient care, this modification was implemented prior to approval and was reported to WRNMMC and HRPO.
 - Amendment #9, requesting that treatment of ongoing cases be completed remotely via telehealth due to the COVID-19 outbreak, was submitted to WRNMMC IRB on 1 May 2020. Following USAMRAA and WRNMMC guidance, in order to minimize disruption to the research and patient care, this modification was implemented prior to approval and was reported to WRNMMC and HRPO. WRNMMC IRB approval was granted on 29 May 2020 and was reported to HRPO.
 - Amendment #10, documenting the change in subcontractor from the Geneva Foundation to the Henry M. Jackson Foundation was submitted to WRNMMC on 18 May 2020 and approved on 1 June 2020.
 - Amendment #11, requesting to administer the consent process to new participants via telehealth and adding the Coronavirus Health Impact survey to the assessment packet was submitted to WRNMMC on 19 June 2020 and approved on 8 July 2020.
 - The continuing review was submitted to WRNMMC IRB in July 2020 and approval was granted on 20 August 2020.

- Coordinate with Sites for VA Boston IRB review: --The annual continuing review was approved by VA Boston IRB on 7 October 2019. The IRB determined that the study meets criteria for Expedited Category 4 under the 2018 Common Rule and that continuing review is no longer required. A brief status check-in is required two years from the approval date.
- Coordinate with Sites for UTHSCSA IRB review: The annual continuing review was approved by UTHSCSA IRB on 10 April 2019. The IRB deemed the study exempt from future continuing review.
- Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO): The WRMNNC continuing review documents were submitted to HRPO on 30 September 2019. The HRPO approval memo was received 10 January 2020.
 - The VA Boston continuing review documents were submitted to HRPO on 8 November 2019. HRPO approval of the continuing review was received on 12 November 2019.
 - On 9 April 2020, HRPO was notified about suspending enrollment to new participants due to COVID and about the WRNMMC modification requesting that enrolled participants will receive therapy and follow-up assessments by telehealth via Skype, telephone, and online REDCap survey. HRPO acknowledged receipt on 13 April 2020 with no further action required.
 - On 3 June 2020, HRPO was notified about the WRNMMC approvals of the study to be conducted via telehealth and of the administrative transfer of the subcontract from the Geneva Foundation to the Henry M. Jackson foundation.

Major Task 2: Hiring and Training of Study Staff

- Provide initial training of therapists by expert CPT consultants: Drs. Carey, Schwartz, and McCleary are fully trained to deliver treatment to study participants.
- Train and certify Independent Evaluators for study assessments: Two advanced graduate student assessors (Murphy Danahy and Sonya Kang) joined the study in July 2020. They completed training and certification under the direction of the expert CAPS assessor and are currently conducting assessments of study cases.
- Coordinate with Sites for training and supervising Therapists and Independent Evaluators throughout study:
 - Therapists continue to receive weekly ongoing supervision from Drs. Wachen, Morris, and Galovski.
 - Independent evaluators have ongoing weekly telephone consultation with the assessment team.

Major Task 3: Participant Recruitment, Therapy, Participant Evaluation

- Coordinate with Sites for all study steps, data collection and database requirements:
 - Data entry is ongoing through the REDCap database. Data entry is currently up to date for all completed baseline and follow-up assessments.
 - Site PIs and study Co-Investigators participate in weekly teleconferences to discuss details of study implementation. Topics include logistics of study procedures, adverse events, regulatory submissions, space and resources, training and supervision, hiring, database development, and data security.
- Begin subject recruitment and treatment:
 - The study had a steady stream of referrals since recruitment began in March 2019. However, due to the COVID-19 pandemic, recruitment was temporarily halted following completion of the ninth cohort of the MCPT condition on 13 March 2020.

--On May 1, 2020, an IRB modification was submitted and currently enrolled participants in the standard CPT condition were offered the option to continue treatment via telehealth, and two additional participants completed treatment.

-- On 8 July 2020, WRNMMC IRB approval was granted to consent new participants via telehealth, and the study was able to proceed fully remotely. As of 30 September 2020, 154 potential participants were screened, 111 were consented and completed baseline assessments, and 94 were eligible and randomized to treatment. The first 11 cohorts of the MCPT condition have been completed. Cohort 10 was completed on 7 August 2020 and Cohort 11 was completed on 9 October 2020 via telehealth. The 12th cohort is scheduled to begin on 7 December 2020. As of 30 September 2020, 4 additional participants were pending consent and 64 participants had completed treatment.

- **Complete assessments at baseline, one month, and 4 months posttreatment:**

--As of September 30, 2020, 111 baseline assessments have been completed, resulting in 94 participants eligible for study participation. Follow-up assessments are ongoing for enrolled participants. As of 30 Sept, 44 Week-5 assessments, 35 Week-10 assessments, and 27 Week-17 assessments have been completed. Follow up rates have improved for recent cohorts due to improved procedures including advanced scheduling and increased accessibility due to telehealth administration.

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

- The Research Coordinator, Allison Cole, received training in the REDCap database.
- 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.

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 37-39):

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

- **Coordinate with Sites for training and supervising Therapists and Independent Evaluators throughout study:** Therapists will continue to receive ongoing weekly supervision from Drs. Wachen, Morris, and Galovski. Independent evaluators will continue to receive weekly training from the assessment team.

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.
- **Continue subject recruitment:** Recruitment for the study will continue until the proposed sample size is reached.

- Continue treatment of consented participants in standard and massed CPT conditions:
Treatment of participants in the standard and massed CPT conditions will continue via telehealth.
- Continue assessments at baseline, one month, and 4 months posttreatment:
Randomized consented participants will complete follow-up assessments at all major timepoints via telehealth.

4. IMPACT:

- Nothing to report at this time.

5. CHANGES/PROBLEMS

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

- Due to the COVID-19 epidemic, enrollment to new participants was put on hold as of March 16, 2020. We received IRB approval to begin enrolling new participants via telehealth on July 8, 2020, and the study has made a smooth transition to completing all tasks remotely. However, we lost several months of recruitment and enrollment, which delayed the timeline of the study. We have resumed enrollment and continue to receive potential participants from our existing referral sources. The rate of recruitment has slowed somewhat as a result of less direct contact with referral sources due to working remotely. We plan to continue regular communication with our recruitment sources and will increase outreach efforts as needed in hopes of maintaining our previous recruitment rate. We intend to request a one-year no-cost extension to complete the projected enrollment.

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>4.8</i>
Contribution to Project:	<i>Protocol development, Coordination of IRB submission, Hiring, Training</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>Julian Burke, MA</i>
Project Role:	<i>Research Coordinator</i>
Nearest person month worked:	9
Contribution to Project:	<i>Coordination of IRB submission, Recruitment, Participant tracking, daily study operations</i>

Name:	<i>Allison Cole, B.S.</i>
Project Role:	<i>Research Assistant</i>
Nearest person month worked:	12
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:	9
Contribution to Project:	<i>Study therapist, baseline assessor</i>

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

Name:	<i>Harry McCleary, Ph.D.</i>
Project Role:	<i>Study Therapist</i>
Nearest person month worked:	12
Contribution to Project:	<i>Study therapist, assessor</i>

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

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

Name:	<i>Sarah Kleiman Ph.D.</i>
Project Role:	Assessment supervisor
Nearest person month worked:	0.5
Contribution to Project:	<i>Training and supervision of evaluators</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 (through April 2020)

Location of Organization: Tacoma, WA

Collaboration: Grant management at Fort Belvoir site

Organization Name: Henry Jackson Foundation (as of May 2020)

Location of Organization: Bethesda, MD

Collaboration: Grant management at Fort Belvoir site

8. SPECIAL REPORTING REQUIREMENTS:

See Quad Chart

9. APPENDICES

Quad Chart