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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. Standard delivery of CPT consists of 12 individual sessions over 6 weeks. 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. A one-year follow-up will assess maintenance of treatment gains.

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. A one-year follow-up will assess maintenance of treatment gains.

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:
  --Amendment #12 adding Noel Mazzulo as Research Coordinator replacing Julian Burke was submitted on 28 January 2021 and approved by WRMMC IRB on 19 February 2021.
  --Amendment #13 was submitted on 29 March 2021 and approved by WRNMMC on 6 May 2021. Contents of this amendment included: Adding a one-year follow-up assessment point in which compensation will be given for completion of the survey portion and adds a new assessment on CPT use, removing the URICA at the one-year follow-up, modification of the healthcare utilization form, removal of the witness signature from the consent form, and changing the phone number and email address on the recruitment flyer.
  --Amendment #14, adding a new study checklist and changing the protocol to offer to mail participants payment or allow them to pick up the payment in person for their long-term follow-up participation rather than email the payment was submitted on 3 June 2021 and approved by WRNMMC on 14 June 2021.
  --Amendment #15 adding the statement "DOD funding and USAMRDC representatives are also eligible to review research record" to section 16 of the consent was submitted on 30 June 2021 and approved by WRNMMC on 22 July 2021.
  --The continuing review was submitted to WRNMMC IRB in July 2020 and approval was granted on 9 September 2021.
- 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. A status report will be submitted in October 2021.
- 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 21 October 2020.

--On 19 May 2021, HRPO was notified about the modification adding a one-year follow-up assessment point and adding compensation in the form of a $50 electronic generic cash card for completion of the survey portion of the one-year follow-up assessment when completed off duty hours. HRPO acknowledged receipt on 14 June 2021 with no further action required.

Major Task 2: Hiring and Training of Study Staff

- Provide initial training of therapists by expert CPT consultants: Drs. 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 conducted assessments of study cases. Rachel Micol was hired to serve as an additional independent evaluator. She is fully trained in CAPS assessment. Upon the departure of Murphy Danahy and Sonya Kang in July 2021, Ashton Rouska, an advanced graduate student assessor, began training. He is now fully trained and is completing study assessments.
- 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, database maintenance, and data security.
- Begin subject recruitment and treatment:
  --Recruitment and treatment have been ongoing. As of 30 September 2021, 225 potential participants were screened, 171 were consented and completed baseline assessments, and 134 were eligible and randomized to treatment. The first 18 cohorts of the MCPT condition have been completed. The 19th cohort is scheduled to begin on 25 October 2021. As of 30 September 2021, 103 participants had completed treatment.
- Complete assessments at baseline, one month, and 4 months posttreatment:
  --As of September 30, 2021, 171 baseline assessments have been completed, resulting in 134 participants eligible for study participation. Follow-up assessments are ongoing for enrolled participants. As of 30 Sept, 81 Week-5 assessments, 67 Week-10 assessments, 54 Week-17 assessments, and 20 one-year follow-up 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.
- 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.
- Research Coordinators Allison Cole and Noel Mazzulo submitted a poster for presentation at the International Society for Traumatic Stress Studies annual conference. The poster was accepted and will be presented in November 2021.

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 49-51):

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, 4 months, and one-year 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

- The study timeline was delayed due to a pause in enrollment early from March-July 2020 as a result of the COVID-19 pandemic. The study has made a smooth transition to telehealth and enrollment is nearing completion. Additionally, based on feedback received at the In Progress Review meeting in September 2020 suggesting a longer-term follow up period, we requested a one-year no-cost extension in April 2021 to complete the projected enrollment and add a one-year follow-up assessment period for all participants. The one-year no-cost extension approved in May 2021 to extend the funding period through 29 Sept 2022.

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:	*4.8*
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:	*Nichole Noel Mazzulo, MS*
Project Role:	*Research Coordinator*
Nearest person month worked:	12
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:	6
Contribution to Project:	*Coordination of IRB submission, Database development, study preparation*

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:	*Sarah Kleiman Ph.D.*
Project Role:	Assessment supervisor
Nearest person month worked:	0.5
Contribution to Project:	*Training and supervision of evaluators*

Name:	*Rachel Micol Ph.D.*
Project Role:	Independent evaluator
Nearest person month worked:	2
Contribution to Project:	*Conducting study assessments*

Name:	*Murhpy Danahy*
Project Role:	Independent evaluator
Nearest person month worked:	3
Contribution to Project:	*Conducting study assessments*

Name:	*Sonya Kang*
Project Role:	Independent evaluator
Nearest person month worked:	3
Contribution to Project:	*Conducting study assessments*

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: Henry Jackson Foundation
Location of Organization: Bethesda, MD
Collaboration: Grant management at Fort Belvoir site

8. SPECIAL REPORTING REQUIREMENTS:

See Quad Chart attached.

9. APPENDICES

Quad Chart