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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	*4/30/18*	*3/5/19*

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.*	 *3/31/21* *6/30/21* *9/30/21* *9/30/21* *9/30/21*	 *1/24/22*
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: The continuing review was submitted to WRNMMC IRB in July 2022 and approval was granted on 8 September 2022.
- Coordinate with Sites for VA Boston IRB review: 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. The biennial status report was approved by VA Boston IRB on 27 September 2021. The next report will be submitted in September 2023.
- 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 8 October 2021.

Major Task 2: Hiring and Training of Study Staff

- Coordinate with Sites for training and supervising Therapists and Independent Evaluators throughout study:
  -- Therapists continued to receive weekly ongoing supervision from Drs. Wachen, Morris, and Galovski until completion of the treatment portion of the study in January 2022.
  --Independent evaluators continue 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, supervision, database maintenance, and data security.

- Subject recruitment and treatment:
  --Study recruitment was completed on 22 October 2021 when the final participant was consented and our target sample size (N=140) was reached. As of September 29, 2022, 231 potential participants were screened, 177 were consented and completed baseline assessments, and 140 were eligible and randomized to treatment. The final cohort (the 19th cohort) of the standard condition was completed on 24 January 2022. As of September 29, 2022, 110 participants have completed treatment, 19 never began, 10 dropped out, and 1 withdrew from the study.

- Complete assessments at baseline, one month, and 4 months posttreatment:
  --As of September 30, 2022, 177 baseline assessments were completed, resulting in 140 participants eligible for study participation. As of 30 Sept, 89 Week-5 assessments, 77 Week-10 assessments, 71 Week-17 assessments, and 44 one-year follow-up assessments have been completed. One year follow-up assessments are ongoing for the remaining enrolled participants.

Major Task 4: Data Analysis

- Coordinate with Sites for monitoring data collection rates and data quality
  --Data cleaning and database reconciliation is underway with the statistical team.

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 received consultation and supervision from Drs. Wachen and Morris.
- All study therapists and independent evaluators completed the online NCPTSD CAPS training.
- 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 presented in November 2021.

How were the results disseminated to communities of interest?

- A poster examining baseline secondary variables of moral injury and functional well being was presented at the 37th Annual Meeting of the International Society for Traumatic Stress Studies. This poster was selected as a featured poster by the Moral Injury Special Interest Group.
  - Mazzulo, N. N., Cole, A., Morris, K., Galovski, T., Dondanville, K., Schwartz, C., & Wachen, J. S. (2021, November). *The Relationship Between Moral Injury and Well-Being in Active-Duty Service Members.* Poster presentation at the 37th Annual Meeting of the International Society for Traumatic Stress Studies. Online conference.
- Two manuscripts authored by Drs. Wachen and Morris were accepted for publication in the special series of *Cognitive and Behavioral Practice* on the topic of "Intensive Delivery of Cognitive Behavioral Therapies for Anxiety, Mood, and Trauma-Related Disorders" in June 2022. These publications featured a case series of a cohort of participants from the MCPT condition and clinical insights gained from delivering massed CPT with service members.

- Morris, K., Schwartz, C., Galovski, T. E., Dondanville, K., & Wachen, J. S. (2022). Massed cognitive processing therapy in active duty military: A Case Series. *Cognitive and Behavioral Practice.* Advance online publication. doi:10.1016/j.cbpra.2022.04.004

- Wright, E. C., Wachen, J. S., Yamokoski, C. A., Galovski, T. E., Morris, K., Goetter, E. M., Klassen, B. J., Jacoby, V., Zweibach, L., Sornborger, J., Dondanville, K. A., & Fina, B. A. (2022). Clinical and administrative insights from delivering massed trauma-focused therapy to service members and veterans. *Cognitive and Behavioral Practice.* Advance online publication. doi:/10.1016/j.cbpra.2022.06.005

What do you plan to do during the next reporting period to accomplish the goals?
Tasks for next reporting period (months 61-64):

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 Independent Evaluators throughout study: Independent evaluators will continue to receive supervision from the assessment team through the completion of the one-year follow-up data collection.

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 assessments at one-year posttreatment: Remaining randomized consented participants will complete one-year follow-up assessments via telehealth.

Major Task 4: Data Analysis

- Perform all analyses according to specifications, share finding with all investigators: Coordinate with statistical team to continue data cleaning and begin analysis of primary outcomes of first three posttreatment assessment points.

4. IMPACT:

- Nothing to report at this time.

5. CHANGES/PROBLEMS

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

- Based on feedback received at the In Progress Review meeting in September 2020 suggesting a longer-term follow up period, we requested an additional one-year no-cost extension in June 2022 to complete the one-year follow-up assessment period for all participants. The one-year no-cost extension was approved to extend the funding period through 29 Sept 2023. We anticipate no delays in completing the project within this timeframe.

6. PRODUCTS

- Morris, K., Schwartz, C., Galovski, T. E., Dondanville, K., & Wachen, J. S. (2022). Massed cognitive processing therapy in active duty military: A Case Series. *Cognitive and Behavioral Practice.* Advance online publication. doi:10.1016/j.cbpra.2022.04.004

- Wright, E. C., Wachen, J. S., Yamokoski, C. A., Galovski, T. E., Morris, K., Goetter, E. M., Klassen, B. J., Jacoby, V., Zweibach, L., Sornborger, J., Dondanville, K. A., & Fina, B. A. (2022). Clinical and administrative insights from delivering massed trauma-focused therapy to service members and veterans. *Cognitive and Behavioral Practice.* Advance online publication. doi:/10.1016/j.cbpra.2022.06.005

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, Training and supervision*

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 and supervision*

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:	3
Contribution to Project:	*Study therapist, baseline 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:	*Ashton Rouska*
Project Role:	Independent evaluator
Nearest person month worked:	2
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