

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., Boston, MA

REPORT DATE: October 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development 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.**

<b>1. REPORT DATE</b> October 2023			<b>2. REPORT TYPE</b> Annual		<b>3. DATES COVERED</b> 30 Sep 2022 - 29 Sep 2023	
<b>4. TITLE AND SUBTITLE</b>  Massed Cognitive Processing Therapy for Combat-Related PTSD					<b>5a. CONTRACT NUMBER</b> W81XWH-17-2-0067	
					<b>5b. GRANT NUMBER</b> BA160492	
					<b>5c. PROGRAM ELEMENT NUMBER</b>	
<b>6. AUTHOR(S)</b> Jennifer Wachen, Ph.D.  E-Mail: Jennifer.wachen@va.gov					<b>5d. PROJECT NUMBER</b>	
					<b>5e. TASK NUMBER</b>	
					<b>5f. WORK UNIT NUMBER</b>	
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> Boston VA Research Institute, Inc. (BVARI)  150 S. Huntington Ave. Boston, MA 02130					<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012					<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>	
					<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>	
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited						
<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b>  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.						
<b>15. SUBJECT TERMS</b> Posttraumatic stress disorder, cognitive processing therapy, intensive outpatient therapy, combat trauma						
<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT</b>	<b>18. NUMBER OF PAGES</b>	<b>19a. NAME OF RESPONSIBLE PERSON</b>	
<b>a. REPORT</b> U	<b>b. ABSTRACT</b> U	<b>c. THIS PAGE</b> U			<b>USAMRDC</b>	
			UU	11	<b>19b. TELEPHONE NUMBER (include area code)</b>	

## Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Accomplishments.....	4
4. Impact.....	9
5. Changes/Problems.....	9
6. Products, Inventions, Patent Applications, and/or Licenses.....	9
7. Participants & Other Collaborating Organizations.....	9
8. Special Reporting Requirements.....	11
9. Appendices.....	11

**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

<b>Major Task 1: Prepare Research Protocol</b>	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
<b>Major Task 2: Hiring and Training of Study Staff</b>		
<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	12/31/22
<b>Major Task 3: Participant Recruitment, Therapy, Participant Evaluation</b>		
<i>Milestone: 1st participant consented, screened and</i>	4/30/18	3/5/19

enrolled		
Milestone: Treatment completed	3/31/21	1/24/22
Milestone: Assessments at all time points completed	6/30/21	12/31/22
Milestone: Report findings comparing CPT treatment formats.	9/30/21	
Milestone: Report findings of predictors of treatment outcome.	9/30/21	
Milestone: Report findings of treatment tolerability.	9/30/21	
<b>Major Task 4: Data Analysis</b>		
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. The submission to close out the study at WRNMMC is underway, as data collection is complete, there is no further contact with participants, and no identifiable data will be analyzed.
- 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 18 October 2023. The next report will be submitted in September 2025.
- 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 continuing review approval for WRNMMC was submitted to HRPO in January 2023 and receipt was acknowledged.

#### **Major Task 2: Hiring and Training of Study Staff**

- Coordinate with Sites for training and supervising Therapists and Independent Evaluators throughout study:  
--Assessments were completed 31 December 2022.

#### **Major Task 3: Participant Recruitment, Therapy, Participant Evaluation**

- Coordinate with Sites for all study steps, data collection and database requirements:  
--Data entry has been completed in the REDCap database.  
--Site PIs, study Co-Investigators, and research staff participate in monthly teleconferences. Topics include regulatory submissions and administration, database management, and data analysis planning.
- Complete assessments at baseline, one month, and 4 months posttreatment:  
--Data collection is now complete. As of September 30, 2023, 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 48 one-year follow-up assessments have been completed.

- Evaluate the efficacy of massed CPT compared to standard CPT.  
--The study team continues to meet regularly with the statistical consultants on the project. Preliminary analysis on the primary hypotheses have been conducted. See Data Analysis task below for more information on the status of analysis of the research aims.
- Examine predictors of treatment outcome.  
--Discussions with the statistical team on these analyses are ongoing. They are in the process of scoring multiple measures of treatment predictors across multiple datasets and exploring options for modeling and analysis.
- Evaluate the tolerability of massed versus standard administration of CPT.  
--The statistical team is in the process of reconciling the data from multiple datasets to analyze these outcomes from the daily and weekly session measures. Once the dataset is finalized, analyses to explore this research aim may begin.

#### **Major Task 4: Data Analysis**

- Perform all analyses according to specifications, share finding with all investigators.  
--Data analysis for the study is ongoing. Preliminary analysis of the primary study hypothesis has been conducted. Data from the one year follow up assessment are in the process of being integrated into the dataset so final analyses on the primary hypotheses may be completed. The statistical team is in the process of reconciling the data from multiple datasets to analyze the secondary outcomes from the daily and weekly session measures to address hypotheses 4 and 5. Once the dataset is finalized, analyses to explore these research aims may begin.  
Please see Appendix 2 for a description of the analyses and results conducted to date. A summary of the completed analyses is included below:

**Hypothesis 1:** Massed CPT (MCPT) was found to be non-inferior to standard CPT on the CAPS-5 and PCL-5 at all time points using the pre-specified 10-point non-inferiority margin ( $p < .01$ ). PTSD symptoms improved over time from baseline to 4-months posttreatment in both conditions and were sustained at 12-month follow up.

**Hypothesis 2:** MCPT was found to be non-inferior to standard CPT on outcomes of depression and suicidality using the reliable change index ( $p < .0001$ ). Analyses on additional secondary outcomes is ongoing.

**Hypothesis 3:** There were no significant differences in treatment completion based on treatment condition. This is likely due to the overall very low rates of treatment attrition in both conditions ( $n = 8$  in standard CPT,  $n = 3$  in MCPT). Additionally, there were no significant differences in rate of recovery in MCPT and standard CPT, such that MCPT was not superior. This may also be due to the good levels of treatment adherence in the standard CPT group, such that by the 5-week assessment, most participants were near completion of the full treatment protocol and both groups showed similar improvement.

Preliminary conclusions: CPT delivered in a massed format is non-inferior to standard spaced CPT, suggesting that massed treatment may be offered as an effective option for the treatment of PTSD in military personnel.

- Hypothesis 1: Massed CPT (MCPT) was found to be non-inferior to standard CPT on the CAPS-5 and PCL-5 at all time points using the pre-specified 10-point non-inferiority margin ( $p < .01$ ). PTSD symptoms improved over time from baseline to 4-months posttreatment in both conditions and were sustained at 12-month follow up.

- Hypothesis 2: MCPT was found to be non-inferior to standard CPT on outcomes of depression and suicidality using the reliable change index ( $p < .0001$ ). Analyses on additional secondary outcomes is ongoing.
- Hypothesis 3: There were no significant differences in treatment completion based on treatment condition. This is likely due to the overall very low rates of treatment attrition in both conditions ( $n = 8$  in standard CPT,  $n=3$  in MCPT). Additionally, there were no significant differences in rate of recovery in MCPT and standard CPT, such that MCPT was not superior. This may also be due to the good levels of treatment adherence in the standard CPT group, such that by the 5-week assessment, most participants were near completion of the full treatment protocol and both groups showed similar improvement.
- Preliminary conclusions: CPT delivered in a massed format is non-inferior to standard spaced CPT, suggesting that massed treatment may be offered as an effective option for the treatment of PTSD in military personnel.
- Work with team for dissemination of findings (presentations, publications, DOD).  
--The methods paper for this study is currently under review. Abstracts based on preliminary data analyses were submitted to the ISTSS and ABCT annual meetings. The study team is conducting preliminary work on manuscript drafts while awaiting final statistical results.

#### **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 and have contributed to the study design manuscript.

#### **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
- Dr. Wachen presented an invited address on the preliminary study findings at the 7<sup>th</sup> Annual Combat PTSD Conference, San Antonio, TX.
  - Wachen, J.S. (2022, November). Massed cognitive processing therapy for combat-related PTSD. Invited presentation at the 7<sup>th</sup> Annual Combat PTSD Conference, San Antonio, TX.
- A poster comparing the experiences of service members engaging in intensive and standard CPT was presented at the 38th Annual Meeting of the International Society for Traumatic Stress Studies in November 2022.
  - Wachen, J. S., Morris, K., Mazzulo, N. N., Cole, A., Galovski, T. Kehle-Forbes, S., & Dondanville, K. (2022, November). In their own words: Service members' perspectives on engaging in massed vs. standard cognitive processing therapy. Poster presentation at the 38th Annual Meeting of the International Society for Traumatic Stress Studies. Atlanta, Georgia.
- A manuscript authored by Drs. Wachen and Morris was submitted to *Contemporary Clinical Trials* in August 2023, describing the design and methodology of the first randomized clinical trial testing whether CPT delivered in an intensive format is non-inferior to standard delivery of CPT.
  - Wachen, J. S., Morris, K. L., Galovski, T. E., Dondanville, K. A., Resick, P. A., & Schwartz, C. (2023). Massed cognitive processing therapy for combat-related posttraumatic stress disorder: Study design and methodology of a non-inferiority randomized controlled trial. *Contemporary Clinical Trials*, 107405

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

**Tasks for next reporting period (months 72-75):**

**Major Task 4: Data Analysis**

- Coordinate with Sites for monitoring data analysis:  
 --The study team will work with the statistical consultants to compile final database of all assessment points, clean data, and continue data analysis for primary and secondary outcomes.

- Perform all analyses according to specifications, share finding with all investigators.  
--Data from the one year follow up assessment has been integrated into the dataset so final analyses may be completed. The statistical team is in the process of reconciling the data from multiple datasets to analyze the secondary outcomes from the daily and weekly session measures to address hypotheses 4 and 5. Once the dataset is finalized, analyses to explore these research aims may begin.
- Work with team for dissemination of findings (presentations, publications, DOD).  
--The study team will continue preliminary work on manuscript drafts and presentation submissions while awaiting final statistical results.

**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 compilation of multiple study databases reflecting multiple survey administrations (including daily surveys for the MCPT group) over several different modalities (in-person and via electronic survey) took longer than anticipated. As a result, data analysis was delayed and is still underway. We requested and received an additional one-year no-cost extension through 29 Sept 2024. 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

	<i>submission, Training and supervision</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 and supervision</i>

Name:	<i>Nichole Noel Mazzulo, MS</i>
Project Role:	<i>Research Coordinator</i>
Nearest person month worked:	<i>12</i>
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:	<i>6</i>
Contribution to Project:	<i>Coordination of IRB submission, Database development, study preparation</i>

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

<b>Name:</b>	<i>Katy Dondanville, Psy.D.</i>
Project Role:	<i>Co-Investigator</i>
Nearest person month worked:	<i>1</i>

Contribution to Project:	<i>Protocol development, expert consultation</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:** 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**

Appendix 1: Quad Chart

Appendix 2: Preliminary results for main outcomes