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Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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14. ABSTRACT
This study is a randomized trial of a hybrid treatment for Iraq and Afghanistan Veterans with a history of mild to moderate TBI (mTBI) and PTSD. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mTBI can impede recovery from PTSD. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of cognitive processing therapy (CPT), an empirically supported treatment for PTSD, in which CPT is enhanced with compensatory cognitive rehabilitation principles. The enhanced CPT, called SMART-CPT is being compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mTBI and PTSD. Half of the participants are randomly assigned to receive standard CPT and half to receive SMART-CPT. This year was dedicated recruitment, enrollment, and treatment, with 107 Veterans enrolled and 50 who have completed active components of the protocol, to date.

15. SUBJECT TERMS
TBI, PTSD, cognitive rehabilitation, CPT

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INTRODUCTION:

This study focuses on helping Iraq and Afghanistan Veterans who have a history of mild to moderate traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) benefit fully from interventions for both conditions. PTSD and TBI occur together frequently in Iraq and Afghanistan Veterans, a combination of conditions which often complicates recovery from either condition. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mild to moderate TBI can impede recovery from PTSD. Prior research has shown that cognitive rehabilitation programs that focus on teaching about what is typical after a head injury, providing people with expectation of positive recovery, and teaching strategies that allow individuals to compensate for their cognitive deficits are effective for treating the thinking symptoms resulting from mild to moderate TBI. These practice standards have been organized into a manualized treatment, Cognitive Symptom Management and Rehabilitation Therapy (CogSMART), which teaches Veterans ways to compensate for cognitive difficulties. Psychotherapies that focus on changing thoughts and behaviors related to a traumatic event, such as Cognitive Processing Therapy (CPT), are effective treatments for PTSD and are the standard of care for treatment of the disorder. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of CPT in which CPT is enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT will be compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and PTSD. Half of the participants will be randomly assigned to receive standard CPT and half to receive SMART-CPT.

BODY:

September 15, 2015 to September 14, 2016 was the fifth fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study. The focus in the fifth fiscal year was on recruitment, enrollment, assessment, treatment, and follow up.

The following are accomplishments as outlined in the Statement of Work:

Task 1. Study Start Up, Months 1-12: Complete, see prior annual report.

Task 2. Recruitment, Enrollment and Treatment and Assessment, months 13-40, extended with a one year no-cost extension through month 60:

2a. Ongoing recruitment of participants:

In the fifth fiscal year of this study, the study coordinator was focused on final recruitment efforts that concluded at the end of January 2016. The coordinator attended meetings in VA-based TBI and PTSD treatment clinics and has been in frequent contact with other study coordinators to facilitate study recruitment. The study coordinator has also responded to a steady flow of referrals from clinical providers within the PTSD clinics in the La Jolla, Mission Valley and Oceanside VA locations.
In addition to recruitment, the coordinator also focused on retention and follow-up assessments requiring steady communication with participants to ensure protocol timeline adherence.

The table below depicts recruitment efforts for the fifth fiscal year as well as final recruitment.

Final Recruitment and Enrolment:

Total Referrals	Enrolled	Withdrew	Declined/Do not qualify
564	107	57	457

The reasons for withdrawal vary; the most common are leaving this treatment to focus on treatment(s) for other medical or mental health comorbidities, feeling overcommitted/scheduling difficulties due to work, family, and/or school obligations, relocation, and clinical ambivalence/avoidance regarding treatment expressed by multiple no-shows or last minute cancelations in a row.

2b. Treatment:

Of the 13 participants enrolled in the fifth fiscal year (only one quarter was dedicated to new enrollments), 12 participants engaged in treatment. In total, 53 participants were randomized to the SMART-CPT condition and 54 to the standard CPT treatment group. 38 participants completed all aspects of the study, including all treatments and assessment sessions (including extended post-treatment assessment). Fifty-four participants completed all 12 therapy sessions. Fidelity checks of therapy sessions were ongoing during the past fiscal year. We have not had a serious adverse event in the fifth year of this project.

2c. Assessment:

In the fifth fiscal year all who were enrolled completed pre-treatment assessments, 11 completed post-treatment assessments, and 11 completed extended follow-up assessments. To date, 105 enrolled participants have undergone the pre-treatment assessment consisting of neuropsychological, mood, and symptom ratings. Fifty participants have undergone the post-treatment assessment, and 38 have completed the extended follow-up assessment and fully completed the study. All assessments have been double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry and that any errors are not perpetuated.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals were renewed and are current and up to date.
- 107 Veterans have been enrolled in the trial
- 105 Veterans have completed baseline assessment
- 50 Veterans have completed all active components of the protocol
- 38 Veterans have completed all components of the study (which includes the extended follow-up)

REPORTABLE OUTCOMES:

Published manuscripts:

Jak, A. J., Aupperlee, R., Rodgers, C. S., Lang, A. J., Schiehser, D. M., Norman, S. B., & Twamley, E. W. (2015). Evaluation of a hybrid treatment for Veterans with comorbid traumatic brain injury and posttraumatic stress disorder: Study protocol for a randomized controlled trial.

Contemporary Clinical Trials, 45(B), 210-216. doi:10.1016/j.cct.2015.10.009

Boyd, B., Rodgers, C., Aupperle, R., & Jak, A.J., Case Report on the Effects of Cognitive Processing Therapy on Psychological, Neuropsychological, and Speech Symptoms in Comorbid PTSD and TBI, Cognitive and Behavioral Practice (2015), http://dx.doi.org/10.1016/j.cbpra.2015.10.001

Jurick, S.M., Twamley, E.W., Hays, C.C., Orff, H.J., & **Jak, A.J.** (accepted for publication). Post-concussive Symptom Over-reporting in Iraq and Afghanistan Veterans. To appear in *Journal of Rehabilitation Research and Development.*

Jak, A.J., Crocker, L., Aupperle, R., Clausen, A., & Bomyea, J. (accepted for publication). Neurocognition in PTSD: Treatment Insights and Implications. To appear in *Current Topics in Behavioral Neurosciences: Behavioral Neurobiology of PTSD.*

Manuscripts in progress:
Crocker, L.D., Jurick, S.M. Hays, C.C., Jak, A.J. (under review). The Role of Depression and PTSD Symptoms in Cognitive Functioning in Veterans with a History of Mild Traumatic Brain Injury.

Jurick, S.M., Crocker, L.D., Sanderson-Cimino, M.E., Keller, A., Trenova, L., Boyd, B., Twamley, E. W., Rodgers, C.S., Schiehser D., Aupperle, R. & Jak, A.J. (under review). Relationships between symptom clusters of post-traumatic stress and cognition in Veterans with a history of mild traumatic brain injury.

Presentations:
Jak, A.J., (2016, August). Benefits of mental health treatment in Individuals with comorbid history of TBI. In P. Uy (Chair), *Traumatic brain injury as a chronic health condition.* Symposium conducted at the American Psychological Association Annual Convention, Denver, CO.

Rauch, A. A., Hoffman, S., Jurick, S. M., Keller, A., Sanderson, M., Crocker, L., Johnson, C., Trenova, L., & Jak, A. J. (August 2016). Examination of social relations and working memory in Iraq and Afghanistan Veterans with a history of mild to moderate TBI and PTSD. Poster presented at the 2016 American Psychological Association Convention, Denver, CO.

Keller, A. V., Jurick, S.M., DeFord, N.E., Sanderson-Cimino, M. E., Crocker, L. D., Rauch, A.A., Hoffman, S.N., Trenova, L.S., Boyd, B.L., & Jak, A.J. (August 2016). Depressive symptom clusters and cognitive functioning in OEF/OIF Veterans with comorbid PTSD/TBI. Poster presented at the 2016 American Psychological Association Convention, Denver, CO.

Crocker, L.D., Jurick, S.M., Hays, C.C., Jak, A.J. (2016). The role of Depression and PTSD symptoms in cognitive functioning in Veterans with a history of Mild Traumatic Brain Injury. Presented at the 44th annual meeting of the International Neuropsychological Society, Boston, MA.

Jurick, S.M., Sanderson, M., Crocker, L., Johnson, C., Trenova, L., Keller, A., Rauch, A. & Jak, A.J. (February 2016). Examination of cut scores on the validity subscale of the Neurobehavioral Symptom Inventory in Iraq and Afghanistan Veterans with a history of mild to moderate traumatic brain injury. Presented at the 44th annual meeting of the International Neuropsychological Society, Boston, MA.

Jak, A.J., Crocker, L. D., Jurick, S. M., Boyd, B., Sanderson-Cimino, M., Keller, A. V., Trenova, L. S., Aupperle, R., Rodgers, C. S., Lang, A.J., Schieshser, D., & Norman, S., Twamley, E. W. (under review). Neuropsychological outcomes following hybrid treatment for Veterans with comorbid TBI and PTSD. Submitted for presentation at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.

Jurick, S. M., Crocker, L. D., Sanderson-Cimino, M., Keller, A. V., Hoffman, S. N., Rauch, A. A., Trenova, L. S., Boyd, B., Schiehser, D., Aupperle, R., Twamley, E. W., Rodgers, C. S., & Jak, A. J. (under review). Contributions to Executive Dysfunction in Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) Veterans with Post-Traumatic Stress Disorder and Traumatic Brain Injury History. Submitted for presentation at the 45th Annual Meeting of the International Neuropsychological Society, New Orleans, LA.

CONCLUSION:

In summary, “Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD”, has adhered to the tasks outlined in the statement of work, however, we extended the recruitment tasks for one year to accommodate for a drop-out rate that was higher than anticipated. This past fiscal year allowed us to over recruit and enroll 13 additional participants and the study is now closed to enrollment. In our fifth fiscal year, we were able to complete all recruitment/enrollment, assessments (baseline and follow-up), and therapy procedures. We continue to maintain regulatory compliance and approvals with the VA IRB and the US Army HRPO. In the fifth year, we have not encountered any serious adverse events. Work supported by this award has also led to five presentations (with two additional under review) and three publications (with one additional publication that was accepted last year that now is published) this fiscal year, all listed in the Reportable Outcomes of this report.

While our recruitment and enrollment has been consistent with our proposed rate in the SOW, we experienced a higher than expected final attrition rate (53%). Although high, it is nonetheless well aligned with dropout rates reported in the literature for OEF/OIF Veterans, in particular (e.g., Chard, et al., 2010). It also reflects difficulties with treatment dropout noted by an Institute of Medicine Report (Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Initial Assessment, 2012) that may be related, in part, to high rates of comorbidities in the target population as well as trauma-related avoidance. We have targeted a representative treatment seeking sample by including those individuals with relatively recent sobriety and mental health comorbidities, and do not exclude participants based solely on the presence of suicidal ideation. This results in a more challenging, though realistic, treatment sample. Those in the experimental SMART-CPT arm, which targets comorbid post-concussive symptoms, continue to remain in treatment longer (average 10.2 sessions) than those in standard CPT (average 7.3 sessions), suggesting that concurrently addressing comorbidities may improve treatment adherence.

Because we have now completed all data collection, scoring, and entry, and had sufficient budgetary funds, we requested and received a second one-year no-cost extension to move into the final stage of this project of database management, data analysis, interpretation, and dissemination of results. The SOW tasks related to final data analysis and dissemination will now be completed in fiscal year 6.

REFERENCES:

Chard, K.M., Schumm, J.A., Owens, G.P., and Cottingham, S.M. (2010). A comparison of OEF and OIF veterans and Vietnam veterans receiving cognitive processing therapy. *Journal of Traumatic Stress, 23,* 25-32.

APPENDICES:

None

Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

Jak W81XWH-11-1-0641

PI: Amy Jak, Ph.D. **Org:** Veterans Medical Research Foundation **Award Amount:** $2,075,453

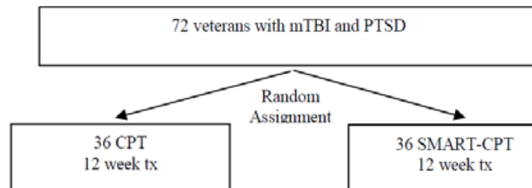
Study Aim(s)

Primary Aim 1: To investigate the efficacy of SMART-CPT in reducing emotional and neurobehavioral symptom severity in veterans with comorbid TBI and PTSD.

Primary Aim 2: To investigate the extent of cognitive changes in veterans with comorbid PTSD and TBI following treatment with SMART-CPT.

Approach

Randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interweaved with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study will examine 72 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomize half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans will also receive comprehensive symptom, mental health, and neuropsychological assessments at 3 timepoints during the study. The investigation seeks to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.



Fidelity measures:

Random 10% of CPT and SMART-CPT sessions coded l fidelity; 20% of other assessments double scored/entered

Baseline Assessment (immediately prior to tx):
CAPS, PCL, WARCAT NSI
Neuropsychological functioning QOLI

3-month Assessment (immediately following 12 week tx):
CAPS, PCL NSI CSQ
Neuropsychological Functioning QOLI

6-month Assessment (three months post-tx):
CAPS, PCL NSI
Neuropsychological Functioning QOLI

Weekly assessment of symptoms (PCL and NSI) and treatment compliance

Accomplishments: total of 107 enrolled, 50 completed all active study components, 13 research presentations, 3 publications

Timeline and Cost

Activities	12	13	14	15	16	17
Study Start Up						
Recruitment, Enrollment, Assessment, Treatment						
Ongoing recruitment, treatment, data entry						
Data Analysis, Dissemination of Results						
Estimated Budget ($K)	**$491**	**$514**	**$530**	**$540**	**$0**	**$0**

Updated: (October 11, 2016)

Goals/Milestones (Refer to previous reports for FY12-15)

FY12 Goals – Study Start Up

FY13 Goals – Recruitment, Enrollment, Treatment, and Assessment

FY14 Goals – Ongoing recruitment, treatment protocol, data entry

FY15 Goals – Ongoing recruitment, treatment protocol, data entry

FY16 Goals – Continued recruitment, Assessments, Treatment

☑ Recruitment/enrolment completed

☑ Assessments

☑ Treatment

FY17 Goals – Analysis, Presentation, Publication, Dissemination

☐ Data Analysis

☐ Dissemination of Results

Comments/Challenges/Issues/Concerns

Entering a 2nd 1-year NCE to proceed to final stage – data analysis and dissemination; salaries/benefits needs have decreased due to changes in tasks, they will be covered by the remaining balance of this grant. Actual expenditure under budget since hiring was not complete until midway through FY12 and Co-I funding changes in FY13-14

Budget Expenditure to date

Projected Expenditure: $2,075,453 Actual Expenditure:$1,757,878.38