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Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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Fort Detrick, Maryland  21702-5012

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**Title:** Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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**Abstract:**
This was a randomized controlled treatment study to test a modification of Cognitive Processing Therapy (CPT) for PTSD in which CPT is interwoven with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study examined 100 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomized half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans also received comprehensive symptom, mental health, and neuropsychological assessments at 3 time points during the study. The investigation sought to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.
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INTRODUCTION:
This study focused 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 TBI, 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 randomized controlled trial integrated therapeutic approaches and tested a modification of CPT in which CPT was enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT was compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and current PTSD.

BODY:
The first fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study began on September 15, 2011. The study continued for a total of 6 fiscal years, ending on September 14, 2017. During the duration of the study, research accomplishments remained largely on target as outlined in the Statement of Work.

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

Task 1. Study Start Up, Months 1-12: Complete.

1a. Obtain regulatory approvals:
Initial approvals from the UCSD IRB and the VA Research and Development (VA R&D) committee were acquired. All necessary regulatory renewals and approvals were maintained and kept up-to-date during the duration of the study.

1b. Hire and train study staff:
The study coordinator, research assistants, graduate student researcher, and psychologist were hired in the first fiscal year. They promptly completed necessary VMRF and VA training in research ethics, safety and information security training, sexual harassment prevention training, and other required courses. The psychologist received training for CogSMART and the hybrid
treatment, SMART-CPT. The other staff were trained and approved on administration and scoring of the neuropsychological battery. All staff hired throughout the study remained up-to-date with all required training and approvals.

1c. Initial recruitment:
Recruitment efforts started during the first fiscal year of the study and continued through the fifth fiscal year. Recruitment activities included exchanging recruitment material with other study coordinators, placing brochures in VA clinics, utilizing the VA electronic board advertisement, maintaining contact with VA clinicians who provided referrals, utilizing an interest form in the Polytrauma clinic, and continually working with other research coordinators for referrals.

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:
Recruitment continued as described above through fiscal year 5. See table below for final enrollment numbers.

<table>
<thead>
<tr>
<th>Total Referrals</th>
<th>Enrolled</th>
<th>Withdrew</th>
<th>Declined/Do not qualify</th>
</tr>
</thead>
<tbody>
<tr>
<td>564</td>
<td>107</td>
<td>57</td>
<td>457</td>
</tr>
</tbody>
</table>

2b. Treatment:
A total of 107 participants were enrolled in the study over the course of the first 5 fiscal years. Of these, 1 was a pilot participant and was not included in final analyses, four were withdrawn after enrollment as further assessment revealed they did not meet all inclusion criteria, and two individuals enrolled but never presented for baseline assessment. Therefore, 51 participants were randomized to the SMART-CPT condition and 49 to the standard CPT treatment group. 53 participants completed all 12 treatment sessions. Fidelity checks revealed good treatment fidelity.

2c. Assessment:
105 participants completed the baseline assessment, 50 completed the immediate post-therapy assessment, and 38 completed the three-month post-therapy assessment and, therefore, completed all aspects of the protocol. All assessments were double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry.
Task 3. Data analysis, presentation, publication, months 60-72:

3a. Data Analysis:

Initial analyses used t-tests and chi-square analyses to examine whether treatment groups differed on baseline demographic variables, TBI injury variables, previous treatment history, symptom measures, and performance validity. In order to compare groups on neuropsychological measures at baseline, t-tests as well as ANCOVAs were employed with TOMM trial 2 as a covariate to control for effort. We also examined whether groups differed in rates of treatment completion and number of sessions attended using chi-square and t-tests. Initial analyses also used t-tests and chi-square analyses to examine whether those who completed the full twelve treatment sessions differed on baseline demographic variables, TBI injury variables, previous treatment history, symptom measures, and performance validity from those who did not complete all treatment sessions.

For the outcome measures of interest, data were analyzed using multilevel modeling (MLM). For the primary outcome of PTSD symptoms, all available PCL-S data from pretreatment to follow-up (15 possible time points) were used. Because those who completed treatment versus those who dropped out differed in baseline PTSD and post-concussive symptom severity, these scores were entered as covariates into the MLM predicting change in PCL-S scores at the 14 time points after baseline (starting at treatment session 1 and going through the follow-up assessment). Separate models tested each additional outcome measure of interest and included all available data (4 possible time points for NSI, 3 possible time points for BDI-II, QOLI-B, and all neurocognitive measures). Each MLM model included a random intercept and fixed effects of time, treatment group, treatment group x time interaction, as well as baseline PTSD and post-concussive symptom scores as covariates. Only the model predicting change in post-concussive symptoms did not include baseline NSI scores because they were included in the DV. TOMM trial 2 scores were also included as a covariate in models predicting changes in neuropsychological measures in order to control for effort. Finally, t-tests were used to compare groups on their treatment satisfaction, as measured by the CSQ. Results were considered significant at the level of p<.05. All analyses were conducted in SPSS version 23.0.

Results

Data is presented on 100 randomized Veterans enrolled in the study and completed baseline testing. 49 were randomized to the CPT-C condition and 51 to the SMART-CPT condition. There were no significant differences between groups on demographic factors, injury variables, symptom measures, neuropsychological measures, or rates of prior treatment at baseline (see Table 1), indicating that randomization was effective. 56.9% of the SMART-CPT group and 49% of the CPT-C group completed treatment (i.e., completed all 12 treatment sessions), though this difference was not statistically significant, χ² = .62, p = .548. Groups also did not differ in number of sessions attended, t(98) = -1.23, p = .222. No demographic differences between completers (n = 53) and non-completers (n = 47) were observed (all ps > .34). However, non-completers had significantly higher baseline PCL-S, t(96) = -2.76, p = .007, and NSI, t(96) = -3.66, p < .001, scores than completers.
Table 1. Mean (SD) or percentage for demographic, clinical, and baseline assessment characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Sample (N=100)</th>
<th>CPT (N=49)</th>
<th>SMART-CPT (N=51)</th>
<th>t, χ², or F (df)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>34.39 (7.89)</td>
<td>33.94 (7.27)</td>
<td>34.82 (8.50)</td>
<td>-.56 (98)</td>
<td>.578</td>
</tr>
<tr>
<td>Education, years</td>
<td>13.69 (1.83)</td>
<td>13.88 (1.65)</td>
<td>13.51 (1.98)</td>
<td>1.00 (98)</td>
<td>.317</td>
</tr>
<tr>
<td>Male, %</td>
<td>89.0%</td>
<td>87.8%</td>
<td>90.2%</td>
<td>χ²=.15 (1)</td>
<td>.758</td>
</tr>
<tr>
<td>Non-Caucasian, %</td>
<td>53%</td>
<td>59.2%</td>
<td>47.1%</td>
<td>χ²=1.48 (1)</td>
<td>.155</td>
</tr>
<tr>
<td>Loss of Consciousness, minutes a</td>
<td>4.50 (8.84)</td>
<td>5.49 (8.90)</td>
<td>3.61 (8.78)</td>
<td>1.05 (95)</td>
<td>.297</td>
</tr>
<tr>
<td>Number of TBIs</td>
<td>2.81 (1.92)</td>
<td>2.90 (1.99)</td>
<td>2.73 (1.87)</td>
<td>.44 (97)</td>
<td>.661</td>
</tr>
<tr>
<td>Percentage Service Connection</td>
<td>57.10 (38.70)</td>
<td>56.73 (37.88)</td>
<td>57.45 (39.84)</td>
<td>-.09 (98)</td>
<td>.927</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Completion, %</td>
<td>53.0%</td>
<td>49.0%</td>
<td>56.9%</td>
<td>χ²=.62 (1)</td>
<td>.548</td>
</tr>
<tr>
<td>Prior PTSD Treatment, %</td>
<td>57.0%</td>
<td>55.1%</td>
<td>58.8%</td>
<td>χ²=.14 (1)</td>
<td>.840</td>
</tr>
<tr>
<td>Prior Cognitive Rehabilitation, %</td>
<td>1.0%</td>
<td>2.1%</td>
<td>0%</td>
<td>χ²=1.03 (1)</td>
<td>.495</td>
</tr>
<tr>
<td>Total sessions completed</td>
<td>7.96 (4.74)</td>
<td>7.37 (4.95)</td>
<td>8.53 (4.51)</td>
<td>-1.23 (98)</td>
<td>.222</td>
</tr>
<tr>
<td>Average time per session, minutes</td>
<td>79.58 (19.19)</td>
<td>72.64 (16.20)</td>
<td>83.96 (19.65)</td>
<td>-3.57 (92)</td>
<td>.001</td>
</tr>
<tr>
<td>Symptom Severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCL-S</td>
<td>59.35 (10.65)</td>
<td>61.06 (9.92)</td>
<td>57.63 (11.17)</td>
<td>1.61 (96)</td>
<td>.111</td>
</tr>
<tr>
<td>NSI</td>
<td>46.56 (14.12)</td>
<td>48.61 (14.92)</td>
<td>44.51 (13.10)</td>
<td>1.45 (96)</td>
<td>.151</td>
</tr>
<tr>
<td>BDI-II</td>
<td>27.68 (10.27)</td>
<td>27.29 (9.62)</td>
<td>28.06 (10.96)</td>
<td>-.37 (95)</td>
<td>.714</td>
</tr>
<tr>
<td>Cognitive b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WRAT Reading</td>
<td>97.02 (10.00)</td>
<td>97.08 (10.63)</td>
<td>96.96 (9.44)</td>
<td>F=.27 (1,95)</td>
<td>.603</td>
</tr>
<tr>
<td>WAIS-IV Processing Speed Index</td>
<td>91.51 (13.21)</td>
<td>90.10 (15.18)</td>
<td>92.88 (10.93)</td>
<td>F=.22 (1,94)</td>
<td>.639</td>
</tr>
<tr>
<td>CVLT-II 1-5 Learning Total</td>
<td>45.37 (9.93)</td>
<td>43.35 (9.72)</td>
<td>47.39 (9.83)</td>
<td>F=3.25 (1,95)</td>
<td>.075</td>
</tr>
<tr>
<td>CVLT-II SDFR</td>
<td>-.54 (.96)</td>
<td>-.67 (.93)</td>
<td>-.40 (.98)</td>
<td>F=.85 (1,95)</td>
<td>.358</td>
</tr>
<tr>
<td>CVLT-II LDFR</td>
<td>-.69 (1.13)</td>
<td>-.86 (1.07)</td>
<td>-.52 (1.19)</td>
<td>F=.79 (1,95)</td>
<td>.376</td>
</tr>
<tr>
<td>WAIS-IV Digit Span</td>
<td>8.36 (2.59)</td>
<td>8.35 (2.53)</td>
<td>8.38 (2.67)</td>
<td>F=.64 (1,96)</td>
<td>.426</td>
</tr>
<tr>
<td>D-KEFS Trail-Making</td>
<td>8.85 (2.78)</td>
<td>8.73 (2.77)</td>
<td>8.96 (2.81)</td>
<td>F=.02 (1,94)</td>
<td>.879</td>
</tr>
<tr>
<td>Number-Letter Switching</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-KEFS Color Word Inhibition</td>
<td>7.80 (4.04)</td>
<td>7.66 (4.45)</td>
<td>7.94 (3.65)</td>
<td>F=.05 (1,93)</td>
<td>.829</td>
</tr>
<tr>
<td>WCST-64 Total Errors</td>
<td>48.08 (8.90)</td>
<td>48.06 (8.93)</td>
<td>48.10 (8.97)</td>
<td>F=.04 (1,94)</td>
<td>.835</td>
</tr>
<tr>
<td>TOMM Trial 2</td>
<td>47.45 (4.54)</td>
<td>46.69 (5.29)</td>
<td>48.18 (3.58)</td>
<td>-1.65 (98)</td>
<td>.103</td>
</tr>
<tr>
<td>TOMM Retention Trial</td>
<td>46.80 (5.54)</td>
<td>45.94 (6.59)</td>
<td>47.63 (4.20)</td>
<td>-1.53 (98)</td>
<td>.128</td>
</tr>
<tr>
<td>QOLI-B General Life Satisfaction</td>
<td>4.07 (1.30)</td>
<td>4.19 (1.21)</td>
<td>3.96 (1.38)</td>
<td>.86 (95)</td>
<td>.390</td>
</tr>
</tbody>
</table>

**Note:** Minutes of loss of consciousness from the worst injury reported. All comparisons between cognitive variables were conducted using ANCOVAs controlling for TOMM Trial 2. CPT=Cognitive Processing Therapy; SMART-CPT=Cognitive Symptom Management and Rehabilitation Therapy combined with CPT; TBI=traumatic brain injury; PTSD=posttraumatic stress disorder; PCL-S=PTS-D Checklist – Specific Trauma; NSI=Neurobehavioral Symptom Inventory; BDI-II= Beck Depression Inventory - Second Edition; WRAT= Wide Range Achievement Test; WAIS-IV=Wechsler Adult Intelligence Scale – Fourth Edition; D-KEFS= Delis Kaplan Executive Function System; WCST-64=Wisconsin Card Sorting Test – 64 Card Version; TOMM=Test of Memory Malingering; QOLI-B=Quality of Life Interview-Brief Version
Symptom Change

Table 2 presents the relevant MLM model parameter estimates, p values, and effect sizes for each analysis conducted. Estimates of effect sizes are reported as r values (small = 0.10; medium = 0.30; large = 0.50). Both groups showed clinically significant decreases in PTSD and post-concussive symptoms, but with no significant group x time interaction. PCL-S scores dropped by a clinically significant average of 19 points and showed a statistically significant main effect of time, $b = -1.26, t(318.83) = -12.47, p < .001, r = .57$. However, there was no group x time interaction ($p = .085$). Similarly, for post-concussive symptom reporting, NSI scores dropped a clinically significant average of 13 points from baseline to follow-up, resulting in a main effect of time, $b = -.46, t(62.40) = -4.05, p < .001, r = .46$, but no group x time interaction ($p = .784$). In terms of depression symptoms, the BDI-II dropped a clinically significant average of 11 points and there was a main effect of time, $b = -.43, t(54.60) = -5.42, p < .001, r = .59$, but no group x time interaction ($p = .633$).

Quality of Life

There was a main effect of time, but no group or group x time interaction, on the majority of QOLI-B indicators. On the QOLI-B, there was a main effect of time for ‘General Life Satisfaction’, $b = .03, t(70.24) = 2.81, p = .006, r = .32$, satisfaction with ‘Daily Activities & Functioning’, $b = .03, t(62.97) = 3.54, p = .001, r = .41$, satisfaction with ‘Family’, $b = .03, t(50.36) = 3.24, p = .002, r = .42$, and satisfaction with ‘Health’, $b = .02, t(73.40) = 2.68, p = .009, r = .30$, but no group x time interactions (all $p$s >.33). However, for satisfaction with ‘Work & School’ there was group x time interaction, $b = -.05, t(10.41) = -3.51, p = .005, r = .74$ such that the CPT-C group expressed greater job satisfaction over the study visits compared to the SMART-CPT group.

Objective Cognitive Functioning

Regarding processing speed, there was no main effect of time, nor group x time interaction ($p$s >.07) as measured by the WAIS-IV Processing Speed Index. In the domain of attention and working memory, there was a group x time interaction, $b = .07, t(67.79) = 2.67, p = .010, r = .31$, as measured by WAIS-IV Digit Span Total scaled score, such that attention and working memory improved more over time in the SMART-CPT group than the CPT-C group (see Figure 1). For verbal learning (CVLT-II Trials 1-5 T-score), there was a group x time interaction, $b = .32, t(66.19) = 2.74, p = .008, r = .32$, showing that verbal learning improved more over time in the SMART-CPT group than the CPT-C group (see Figure 1). For immediate verbal recall (CVLT-II short delay free recall z-score), there was a group x time interaction, $b = .03, t(83.05) = 2.18, p = .032, r = .23$, in which immediate verbal recall improved more for those in the SMART-CPT group relative to those in the CPT-C group (see Figure 1). For delayed verbal recall (CVLT-II long delay free recall z-score), there was a main effect of time, $b = .02, t(73.24) = 2.69, p = .009, r = .30$, but no group x time interaction ($p = .248$).
In terms of executive functioning, for problem solving specifically (WCST-64 Total Errors T-score), there was a significant group x time interaction, $b = .27, t(94.78) = 2.38, p = .019, r = .24$, such that the SMART-CPT group showed greater improvement over time in problem solving than the CPT-C group (see Figure 1). For cognitive flexibility (D-KEFS Trail Making Number Letter Switching scaled score), there was a main effect of time, $b = .08, t(65.59) = 3.93, p < .001, r = .44$, but no group x time interaction ($p = .830$). For inhibition (D-KEFS Color Word Interference Inhibition scaled score), there was a main effect of time, $b = .08, t(83.69) = 2.56, p = .012, r = .27$, but no group x time interaction ($p = .737$).

None of the cognitive findings changed when controlling for TOMM retention trial instead of TOMM trial 2. Additionally, when excluding those who performed below cutoff on two of three effort measures at any of the three assessment time points ($n = 24$; below 45 on TOMM trial 2 or retention or below 15 on CVLT-II forced-choice), all cognitive findings were successfully replicated with the exception of CVLT-II short delay free recall z-score which dropped to a trend for the group by time interaction, $b = .02, t(75.50) = 1.69, p = .096, r = .19$.

**Treatment Satisfaction**

As determined by the Client Satisfaction Questionnaire, participants in the SMART-CPT group ($M = 29.65$) expressed slightly more overall satisfaction with treatment than the CPT-C group ($M = 27.86$), though the difference was not statistically significant, $t(27.52) = -1.78, p = .086$. Regarding specific items on the CSQ, those in the SMART-CPT group ($M = 3.87$) rated “how satisfied are you with the amount of help you received” significantly higher than the CPT-C group ($M = 3.43; t(27.58) = -2.48, p = .020$), though no other item was differentially endorsed between groups.
## Table 2. Estimates for effects of group, time, and group x time interaction

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>Group</th>
<th>Time</th>
<th>Group x Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b (SE)</td>
<td>p</td>
<td>r</td>
</tr>
<tr>
<td><strong>Symptom Self-report</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCL-S</td>
<td>.79 (1.95)</td>
<td>.685</td>
<td>.04</td>
</tr>
<tr>
<td>NSI</td>
<td>-.86 (2.63)</td>
<td>.745</td>
<td>.04</td>
</tr>
<tr>
<td>BDI-II</td>
<td>3.02 (1.56)</td>
<td>.056</td>
<td>.20</td>
</tr>
<tr>
<td><strong>QOLI-B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General Life Satisfaction</td>
<td>-.39 (.25)</td>
<td>.115</td>
<td>.16</td>
</tr>
<tr>
<td>Daily Activities &amp; Functioning</td>
<td>-.34 (.19)</td>
<td>.078</td>
<td>.18</td>
</tr>
<tr>
<td>Family</td>
<td>.03 (.31)</td>
<td>.929</td>
<td>.01</td>
</tr>
<tr>
<td>Health</td>
<td>-.23 (.22)</td>
<td>.292</td>
<td>.11</td>
</tr>
<tr>
<td><strong>Objective Cognitive Functioning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WAIS-IV Processing Speed Index</td>
<td>1.23 (2.51)</td>
<td>.625</td>
<td>.05</td>
</tr>
<tr>
<td>WAIS-IV Digit Span Total</td>
<td>-.61 (.48)</td>
<td>.208</td>
<td>.14</td>
</tr>
<tr>
<td><strong>Verbal Learning/Memory</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVLT-II 1-5 Learning Total</td>
<td>2.79 (2.01)</td>
<td>.168</td>
<td>.14</td>
</tr>
<tr>
<td>CVLT-II SDFR</td>
<td>.19 (.19)</td>
<td>.317</td>
<td>.10</td>
</tr>
<tr>
<td>CVLT-II LDFR</td>
<td>.19 (.21)</td>
<td>.382</td>
<td>.08</td>
</tr>
<tr>
<td><strong>Executive Function</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WCST-64 Total Errors</td>
<td>.34 (1.82)</td>
<td>.851</td>
<td>.02</td>
</tr>
<tr>
<td>D-KEFS Trails Switching</td>
<td>-.20 (.49)</td>
<td>.683</td>
<td>.04</td>
</tr>
<tr>
<td>D-KEFS Inhibition</td>
<td>-.27 (.77)</td>
<td>.731</td>
<td>.03</td>
</tr>
</tbody>
</table>

Figure 1
3b. Dissemination of Results:

Dissemination of results began in the second fiscal year and will continue past the period of funding due to lengthy submission and review processes. Consistent with our statement of work, this study has resulted in multiple presentations, talks, and manuscripts. Additionally, a SMART-CPT Treatment Manual is available and sent upon request. For a complete list of manuscripts and presentations, please see section ‘Reportable Outcomes’ below.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals obtained and maintained
- 107 Veterans enrolled in the trial
- 6 published manuscripts; 7 manuscripts under review/in preparation
- 25 presentations
- 1 treatment manual
- Both CPT and SMART-CPT result in clinically significant reductions in PTSD and post-concussive symptomatology and improvements in quality of life.
- SMART-CPT results in additional improvements in the neuropsychological domains of attention/working memory, learning, memory, and novel problem solving and in patient satisfaction.
- SMART-CPT reduces PTSD and neurobehavioral symptoms and also provides added value by improving attention/working memory, learning, memory, and problem solving.

REPORTABLE OUTCOMES:

Manuscripts:


Presentations:


Jak, A.J. (2016, August). Caregiving for individuals with traumatic brain injury. In L. Brown (Chair), Trauma and caregiving: Complicated situations and solutions. Symposium conducted at the American Psychological Association Annual Convention, Denver, CO.

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.


Injury. Presented at the 44th annual meeting of the International Neuropsychological Society, Boston, MA.


Crocker, L.D., Jurick, S.M., Boyd, B., Rodgers, C.S., Twamley, E.W., Schiehser, D.M., & Jak, A.J. (April, 2015). Treatment of veterans with comorbid PTSD and TBI using a hybrid approach. Paper presented as part of the symposium ‘Addressing the needs of combat veterans with co-occurring head injury and mental health symptoms: Clinical trial outcomes for individuals with TBI and psychological distress’ at the annual meeting of the Anxiety and Depression Association of America Conference, Miami, FL.


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 to accommodate for a drop-out rate that was higher than anticipated. We maintained regulatory compliance and approvals with the VA IRB and the US Army HRPO. Work supported by this award led to 6 published manuscripts, 7 manuscripts under review/in preparation, 25 presentations, and 1 treatment manual, all listed in the Reportable Outcomes of this report. The results of this trial also serve as the basis for a new CDMRP PH/TBI proposal that seeks to add additional modules to SMART-CPT to target pain symptoms as a mechanism to attenuate the high dropout rate of this otherwise efficacious treatment.

Traumatic injuries that lead to mental health conditions and include a history of concussion are complex, and interdisciplinary or multifactorial treatment is recommended. Combining CPT for PTSD symptom reduction with components of CogSMART for neuropsychological symptoms effectively targets a highly prevalent co-morbidity in OEF/OIF/OND treatment seeking Veterans with trauma (both physical and psychological) histories. It does so without negatively impacting satisfaction or treatment retention even though sessions are longer. Treatments and trials related to PTSD and comorbidities are acknowledged gaps identified by the VA/DoD Treatment Guidelines for PTSD and SMART-CPT helps fill that knowledge gap. These data support the use of SMART-CPT, allowing for focus on overlapping etiologies, concurrent treatment of intertwined PCS and PTSD symptoms, and ability to simultaneously address factors that may contribute to persistent symptoms. SMART-CPT results in equivalent mental health and neurobehavioral symptom reduction as compared to standard CPT, but with additional benefit to neuropsychological performance. Additionally, SMART-CPT can be delivered in less time than administering both treatments separately. Because the psychological and fiscal costs of PTSD and TBI are high, (particularly within OEF/OIF/OND Veterans) as are healthcare utilization rates, even small improvements in efficiency of service delivery and retention of Veterans in treatment can result in notable healthcare cost reductions. Augmenting a standard mental health intervention for PTSD with compensatory cognitive strategies is feasible and provides added value to improving attention, memory, and problem solving symptoms while maintaining efficacy of PTSD symptom reduction. Combining therapeutic approaches in the clinical treatment of comorbid PTSD and TBI by enhancing an existing empirically supported PTSD intervention with cognitive rehabilitation principles also can defragment care and significantly improve treatment for this clinically complicated group.
APPENDICES:

Quad Chart attached as a separate document.
Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD
Jak W81XWH-11-1-0641
PI: Amy Jak, Ph.D.  Org: Veterans Medical Research Foundation

**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 interwoven with compensatory cognitive rehabilitation principles (CogSMART) to create a hybrid treatment, SMART-CPT. The study examined 100 veterans diagnosed with both PTSD and a history of mild to moderate TBI and randomized half to receive standard CPT and half to receive SMART-CPT for 12 weekly sessions. Veterans also received comprehensive symptom, mental health, and neuropsychological assessments at 3 timepoints during the study. The investigation sought to improve treatment outcomes for combat-related psychological health and develop an evidence-based intervention for treatment of comorbid TBI and PTSD.

**Timeline and Cost**

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<thead>
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<th>Activities</th>
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<th>14</th>
<th>15</th>
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<tr>
<td>Study Start Up</td>
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<td>Recruitment, Enrollment, Assessment, Treatment</td>
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<td>Data Analysis, Dissemination of Results</td>
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**Estimated Budget ($K)**

|                         | $491 | $514 | $530 | $540 | XX  | XX  |

**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/enrollment completed

☑ Assessments

☑ Treatment

**FY17 Goals** – Analysis, Presentation, Publication, Dissemination

☑ Data Analysis

☑ Dissemination of Results

**Comments/Challenges/Issues/Concerns**

2nd 1-year NCE to proceed to final stage – data analysis and dissemination; 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: $1,909,413

*Updated: (December 14, 2017)*