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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 to study start up, including regulatory approvals and treatment manual development. Initial recruitment and enrollment of participants began in the final quarter of the year; six Veterans are currently enrolled and active in the protocol. There is no data to report at this time.					
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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 is being compared to standard CPT in a group of 90 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. Both treatments entail 12 weekly visits to the VA hospital lasting 50-75 minutes and three additional assessment visits lasting approximately 3.5 hours each. Assessment of diagnosis, symptom severity, quality of life, and subjective and objective assessments of cognition are administered at baseline (prior to treatment onset), immediately post-treatment (i.e., three months after baseline), and three months post-treatment (i.e., six months after baseline). Treatment satisfaction is assessed mid-treatment (i.e., six weeks) and immediately post-treatment. Treatment compliance, attendance, and symptom severity is assessed weekly during the twelve-week intervention component.

BODY:

This annual report details the first year of a four year project. This year, the project was in its preparatory stages and focused on such tasks as obtaining and maintaining regulatory approvals, hiring and training study staff, purchasing equipment and materials, finalizing the treatment manual and procedures, and initial participant recruitment.

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

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

1a. Obtain regulatory approvals:

Initial approvals from the UCSD IRB were acquired on May 19, 2011 and these approved documents were forwarded to Susie Stubbs at HRPO for further review. Documents were revised, amended and resubmitted to the UCSD IRB for final approval. UCSD IRB granted final approval for this project on December 22, 2011. Concurrent to the UCSD IRB submissions were necessary submissions to the VA Research and Development (VA R&D) committee. The VA R&D committee granted final approval for this project on August 11, 2011. Since the initial approval from UCSD IRB was granted on May 19, 2011, during this past year we applied for a renewal of this project with the UCSD IRB and the renewal was approved on May 17, 2012. A minor amendment to the consent was submitted and approved on May 25, 2012. This amendment simply allows us to ask participants if they would like to receive more information about additional PTSD and TBI research in the future. The IRB renewal approval and the consent amendment were also submitted to and approved by the USAMRMC HRPO on May 23, 2012. Renewed VA R&D approval was also granted on July 12, 2012. Additional minor amendments to the protocol have been requested and approved including updating study staff lists, clarifying that sessions would be audiorecorded (as opposed to audiotaped, as initially indicated), and adding recruitment materials. These approvals were granted on September 11, 2012. These minor amendments did not change the study in any substantial way, did not alter the risk level of the study, and did not warrant any changes to the consent form.

1b. Hire and train study staff:

- i. In addition to the co-investigators, this project planned for a fulltime study coordinator, a study psychologist, and research assistant. In late October of 2011, the study coordinator and research assistant were hired. They promptly completed necessary VMRF and VA training in research ethics, safety and information security training, sexual harassment prevention training, and other required courses. Both were also trained on administration and scoring of the neuropsychological battery and were subsequently tested and approved for independent administration of the assessment battery by Dr. Lisa Delano-Wood, a co-investigator on this project.
- ii. In late June of 2012, we had a staff change in the research assistant position; a part-time graduate student researcher and a part-time research assistant were hired to jointly fill this position in August 2012. Both RA's underwent all required trainings and have also been approved for independent administration of the assessment battery and all other job related duties.
- iii. Our study psychologist was hired in early February of 2012 and completed all required training activities. She was already formally trained in Cognitive Processing Therapy

(CPT) and has now received training for CogSMART as well as the hybrid treatment, SMART-CPT. She will update her training in CPT in October of 2012.

1c. Initial recruitment:

- i. Preliminary recruitment efforts started during the May of 2012, in the form of attending traumatic brain injury consortium meetings to present our study and exchange recruitment material with other study coordinators.
- ii. Primary recruitment in VA PTSD and TBI clinics began in August 2012. This effort has been very fruitful; please refer to the table below for details.

Table 1 Recruitment efforts for 1st fiscal year

Total Referrals	Enrolled	Pending	Declined
12	6	5	1

- iii. To further enhance recruitment, in the last quarter of the first year we created a brochure and a VA electronic board advertisement; these have been approved by the UCSD IRB and are ready for implementation.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals were obtained/renewed and are current and up to date.
- All study staff have been hired and trained.
- A treatment manual for the investigational manualized treatment, SMART-CPT, was completed and is in use in the trial.
- Six Veterans have been enrolled in the trial to date.

REPORTABLE OUTCOMES:

- The working version of the SMART-CPT manual was created
- Ni Sun, employed as a research assistant on this project from October 2011-June 2012, was accepted into a doctoral program in clinical psychology based in part on her experience working on this project.
- Funding provided by this study allowed the hiring of Sarah Jurick as a graduate student researcher who will provide significant research staff stability as she will be working on the study for the entire four year duration.
- No additional outcomes, papers or presentations have yet resulted from this award given the largely start-up nature of the first funding year.

CONCLUSION:

In summary, “Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD”, is proceeding very much on schedule and all tasks detailed in the statement of work, including obtaining and maintaining regulatory approvals, hiring and training study staff, completion of the SMART-CPT manual, and initial recruitment efforts, have been completed. Recruitment outcomes include 12 referrals and 6 Veterans enrolled in the last quarter of the first year. To date, we have not encountered any significant problems and are proceeding very much on schedule with our SOW. At this time, there are not any known barriers to continuing to move forward on schedule and are optimistic that our initial successful recruitment efforts can be maintained for the duration of the study.

REFERENCES:

N/A

APPENDICES:

N/A