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TITLE: Telephone-Delivered Cognitive Behavioral Therapy for Chronic Pain Following Traumatic Brain Injury

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14. ABSTRACT The purpose of this study is to evaluate the efficacy of a telephone-delivered cognitive behavioral treatment (T-CBT) in Veterans with a history of traumatic brain injury (TBI) for the treatment of chronic pain in a randomized controlled trial (RCT). Specifically, the RCT will examine the immediate (at the end of treatment) and long-term (6-months from randomization) efficacy of T-CBT on average pain intensity (primary outcome), and pain interference, sleep, depression, global impression of change, and life satisfaction (secondary outcomes) relative to a telephone-delivered pain psycho-educational active control condition (T-Ed). The study uses a 2-group parallel design. The sample will include 160 OEF/OIF Veterans with a history of TBI and chronic pain recruited from the VA Puget Sound Health Care System (VAPSHCS). Recruitment and enrollment for the study is ongoing. Despite the delays in recruitment and enrollment, we believe we will be able to achieve our enrollment goals given 1) the commitment by VAPSHCS providers to help us achieve our recruitment goals, and 2) the large number of VAPSHCS patients that we project to be eligible and willing to participate.					
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Introduction

The purpose of this study is to evaluate the efficacy of a telephone-delivered cognitive behavioral treatment (T-CBT) in Veterans with a history of traumatic brain injury (TBI) for the treatment of chronic pain in a randomized controlled trial (RCT). Specifically, the RCT will examine the immediate (at the end of treatment) and long-term (6-months from randomization) efficacy of T-CBT on average pain intensity (primary outcome), and pain interference, sleep, depression, global impression of change, and life satisfaction (secondary outcomes) relative to a telephone-delivered pain psycho-educational active control condition (T-Ed) designed to control for time, dose, attention, and other nonspecific therapeutic effects such as therapeutic alliance. The study uses a 2-group parallel design. The sample will include 160 OEF/OIF Veterans with a history of TBI and chronic pain recruited from the VA Puget Sound Health Care System (VAPSHCS).

Keywords

Traumatic Brain Injury (TBI)
Chronic Pain
Veterans
Telephone-Delivered Treatment
Cognitive Behavioral Treatment (CBT)
Randomized Controlled Trial (RCT)

Overall Project Summary

Development:

Research staff began the initial recruitment and screening process with prospective subjects who are solely recruited from the VAPSHCS shortly thereafter in the final week of June 2014.

The study PI has convened study meetings with study investigators on a monthly basis to attend to pertinent recruitment and enrollment topics.

Preparation:

All steps with regards to preparation have been completed. Mr. Gertz and three VAPSHCS research staff members meet on a weekly basis to review study recruitment and enrollment and address potential issues as they have arisen.

Participant Enrollment and Data Acquisition:

Enrollment for this study began in July 2014. As of October 20, 2016 we have enrolled 204 participants from the VAPSHCS, our only recruitment site. Three participants have been enrolled yet have not begun the treatment phase. Staff members were unable to reach six participants following enrollment but prior to randomization. Two participants withdrew prior to randomization.

A total of 193 enrolled participants have been randomly assigned to one of the two study treatment interventions. Thirty-two participants are participating in the study treatment phase, 20 participants have completed the treatment phase and are in the follow-up period, and 114 participants have completed at least part of the six month assessment period. Eight participants withdrew during the treatment phase. Two participants withdrew at the post-treatment assessment period. One participant withdrew at the 6 month assessment period. Sixteen participants were lost to follow up at the six month assessment period.

Research staff members are conducting systematic medical record reviews of patients who have been seen by specific VAPSHCS providers who often work with Veterans with TBI. All Veterans deemed eligible based on this initial review are sent approach letters explaining the study. Research staff will also make follow-up calls to these Veterans if the Veteran does not initiate contact following the mailings.

Drs. Hoffman, Williams, and Ehde meet with clinical staff on a monthly basis, with weekly supervision when needed, to provide supervision and oversight regarding clinical matters. Mr. Gertz meets with research staff to discuss recruitment and enrollment strategies on a weekly basis. Finally, Dr. Hoffman conducts executive committee meetings on a monthly basis to address issues regarding both treatment and enrollment.

Operations and Maintenance:

Researchers continue to submit quarterly progress reports to the Department of Defense (DoD). Researchers have obtained continuing IRB approval from both the UW and VAPSHCS IRBs and recently received continuing review approval from HRPO. Research staff members continue to maintain personnel training files. Drs. Hoffman and Williams along with Mr. Gertz continue to supervise research staff to ensure adherence to procedures.

Data Management and Analysis:

Study databases have been completed. Research staff enters study data as it is collected from participants. Mr. Barber monitors the integrity of the research data on a regular basis.

Formative Evaluation:

The study PI and study personnel have not sought out our advisory partners as we have not needed any additional study assistance. We have continued to move forward in determining factors related to implementation. We hired a masters level social worker to address the need for additional clinical coverage and have worked extensively on our training materials as these will be necessary to move towards implementation. We plan to work on developing a training manual based on our success in training our new hire.

Problems Encountered:

Considerable effort and time were expended to submit the VA IRB application. We had initially anticipated that the length of time required for submission caused a delay in subject recruitment and enrollment by approximately 1-2 months. However, additional delays were encountered when it took the VAPSHCS regulatory committees a considerable amount of time to review and approve the application (study personnel submitted the application in early January, and received full approval from the R&D committee August 22, 2013). We anticipated at that time that the length of time that elapsed for full VAPSHCS approval (over eight months) caused a delay in subject recruitment and enrollment by an additional 3-4 months.

After receiving approval from the VAPSHCS IRB and regulatory committee, we submitted the HRPO IRB application August 8, 2013. We first received notice October 8, 2013 that our application underwent initial administrative review. On October 10, 2013 we addressed the items raised in the initial review, yet did not hear back from HRPO staff regarding any substantive steps taken to complete the approval process for a considerable amount of time. We were later told that a personnel change at HRPO had occurred and our application was not assigned to an alternate individual. Given the delays in review, there was also some confusion regarding the versions of the protocol document that was submitted to HRPO. It took until April 9, 2014 for the program manager, Ms. Kristen Katopol, to inform us that the approval authority at HRPO had given us approval to submit the revised protocol document to both the UW and VAPSHCS IRBs for approval. We received approval for the study protocol April 25, 2014 and May 14, 2014 from the UW and VAPSHCS IRBs, respectively. We then finally received full HRPO approval June 13, 2014 (10 months after submission).

We believe the significant delay in getting HRPO approval caused significant delays in study recruitment and enrollment. We anticipate that the length of time that elapsed for full HRPO approval (10 months) has caused a delay in subject recruitment and enrollment by an additional 8-9 months, such that we are 15 months behind on recruitment and enrollment.

We have been approved for a no cost extension in order to complete our full enrollment. We continue to pursue our goal for full enrollment despite the extensive delays and given a) the research team consists of members with extensive experience in subject recruitment, b) the research team hired an additional clinician to increase clinician availability, c) the expressed commitment by VAPSHCS providers to help study personnel achieve their recruitment goals, and d) the large number of patients within the VAPSHCS that we project to be eligible and willing to participate we remain hopeful of achieving our original enrollment goals.

Breaches in Confidentiality: During the past reporting period research staff inadvertently caused three breaches in the confidentiality of subjects. Specifically, on three different occasions research staff accidentally disclosed the identity (first and last name only) of a research subject to another subject via postal mailings.

The study team has concluded that the breaches were executed by one particular research staff member who was compromised by medical issues at the time. Study researchers have incorporated safeguard measures into study procedures to prevent this from happening in the future. In addition, study researchers have greatly limited the offending research staff member's tasks to reduce the chances of any future breaches.

Key Research Accomplishments

Recruitment and enrollment for the study continues despite the considerable delays in obtaining IRB approval from both the VAPSHCS and HRPO.

Conclusion

We plan to make the following progress during the no-cost extension of the research study.

Participant Enrollment/Data Acquisition:

Study personnel plan to recruit and enroll approximately 15-20 more subjects to enroll enough subjects to collect complete data from 160 randomized subjects. Further, study personnel will continue to collect study data from subjects both in-person and via telephone. The study PI and investigators will provide ongoing supervision to research and clinical staff, as well as facilitate regular meetings with research staff and investigators to address enrollment issues.

Research staff members will continue to conduct systematic medical record reviews of patients who have been seen by specific VAPSHCS providers who often work with Veterans with TBI until we reach our enrollment goal.

Dr. Williams has reached out to several VAPSHCS providers informing them of the study's enrollment goals and planned end of recruitment and enrollment by the end of December 2016.

Operations and Maintenance:

Dr. Hoffman, Dr. Williams and Mr. Gertz will continue to monitor study personnel performance to ensure adherence to procedures. In addition, Drs. Hoffman, Williams and Ehde will continue to conduct weekly meetings with study clinicians to address any clinical issues that may arise during treatment.

Data Management and Analysis:

Study personnel will continue to enter data as it is collected and conduct routine data checking.

Formative Evaluation:

The study PI and study personnel plan to consult with advisory partners and VA leadership to discuss transition planning related to implementation.

Publications, Abstracts and Presentations

A publication on the intervention approach is in draft.

Inventions, Patents and Licenses

None to report.

Reportable Outcomes

None to report.

Other Achievements

None to report.

References

None

Appendices

We have included a Quad Chart for this particular study as requested by the CDMRP.

Telephone-Delivered Cognitive Behavioral Therapy for Chronic Pain Following Traumatic Brain Injury



PI: Jeanne M. Hoffman, Ph.D.

Org: University of Washington

Award Amount: \$3,085,185

Log#: PT110602, Applied Neurotrauma Research Award with Clinical Trial

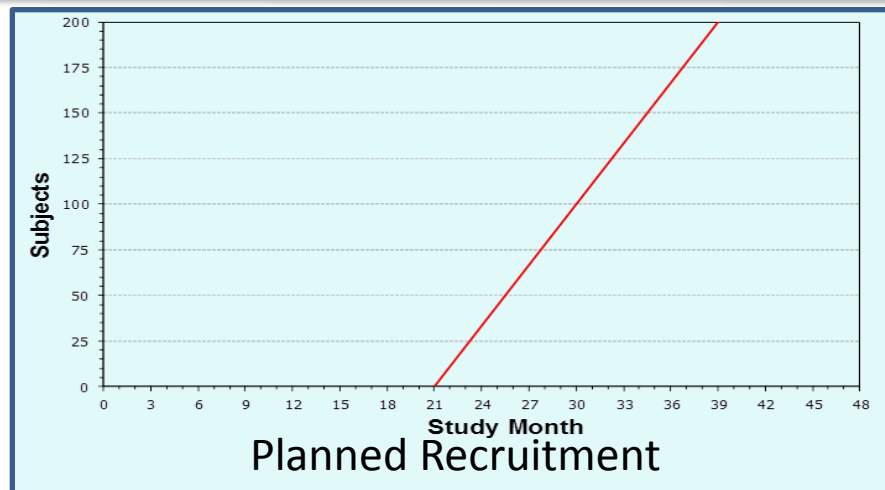
Award # W81XWH-12-2-0109

Study/Product Aim(s)

- We will evaluate the efficacy of telephone-delivered cognitive behavioral therapy (T-CBT) for reducing average pain intensity relative to telephone-delivered education intervention (T-Ed) in Veterans with a history of TBI.
- We will determine the efficacy of T-CBT relative to T-Ed in reducing pain interference, sleep problems, and depression, as well as improving global impression of change and life satisfaction.
- We will determine whether treatment effects are maintained 6 months after randomization.
- We will conduct a formative evaluation to identify key factors relevant to future dissemination and implementation of the intervention into the VA.

Approach

The sample will include 160 OEF/OIF/OND Veterans with a history of TBI and chronic pain recruited from the VA Puget Sound Health Care System (VAPSHCS). Participants will be randomized to either T-CBT or T-Ed (2 group parallel design). Each treatment will consist of eight 60-minute sessions conducted over the telephone over 8-16 weeks. Information about pain and the other commonly co-occurring conditions described above will be collected before, mid treatment, post treatment and at 6 months following randomization.



Accomplishment: Investigators have accomplished all preparation and development components of the study. We began participant recruitment in Month 21.

Timeline and Cost

Activities	CY	13	14	15	16
IRB approval, finalize protocol, Intervention manual, develop databases					
Participant Enrollment/Data Acquisition					
Formative Evaluation					
Publication/Dissemination					
Estimated Total Budget (\$K)		\$653	\$879	\$893	\$661

Updated: 20/10/2016

Goals/Milestones

CY13 Goal – Development and Preparation

- ☒ IRB Approval
- ☒ Finalize study protocol, intervention manual, databases

CY14 Goals – Participant Enrollment/ Data Acquisition

- ☒ Enroll 75 subjects
- ☒ Assess important factors that contribute to formative evaluation

CY15 Goal – Participant Enrollment/ Formative Evaluation

- ☒ Enroll 100 subjects
- ☐ Collect data current practice-formative evaluation
- CY16 Goal – Participant Enrollment/ Formative Evaluation/Dissemination**
 - ☐ Complete enrollment and data acquisition (total of 200 enrolled subjects)
 - ☐ Produce manual and training program- formative evaluation
 - ☐ Disseminate study findings in primary paper

Comments/Challenges/Issues/Concerns

- Participant enrollment delayed 12-15 months by prolonged VAPSHCS IRB/HRPO approval process.

Budget Expenditure to Date (Through 20/10/2016)

Projected Expenditure: \$3,085,185

Actual Expenditure: \$2,697,616