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14. ABSTRACT
During the past 12 months, this study has transferred approval from the WRAMC Dept. of Clinical Investigation IRB to the new facilities at WRNMMC. Study enrollment has achieved stated goals and further recruitment is no longer needed. Currently enrolled participants are actively engaged in study protocols and projected to complete study participation on time. These milestones correspond to the goals set by the study timeline and indicate that progress is occurring on schedule despite delays resulting from the transition to a new IRB at WRNMMC. At this time there are no significant findings to report.

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PTSD, TBI, ACT, cognitive-behavioral therapy, military populations

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Introduction

Combat leads to "psychological injury," including posttraumatic stress disorder (PTSD) and other anxiety disorders and depression, in at least a substantial minority of combatants (Hoge et al., 2004). In addition, many combatants in Iraq and Afghanistan are exposed to blasts or blows to the head that may lead to head injury, which can be followed by postconcussive symptoms (PCS; McAllister & Arciniegas, 2002). There is a strong need for treatment of the complex array of problems that follow combat, specifically for non-pharmacologic treatments as these are preferred by many veterans and military personnel. Current approaches are not effective and/or acceptable for all affected individuals, so finding new ways to deal with the sequelae of deployment is important. Acceptance and Commitment Therapy (ACT) is a psychotherapeutic approach that holds promise for this group. ACT is not tied to any particular symptom constellation, so it can be applied to a variety of presenting concerns. It has good face validity and conveys a compelling message, asking individuals to move forward in accordance with one's values regardless of limitations, and ACT offers an alternative for people who refuse exposure-based approaches. Because of the enthusiasm for the approach, ACT is being widely disseminated – but without evidence for its effectiveness for military trauma. There is evidence of its effectiveness for emotional distress in general (Forman et al., 2007) and for depression in particular (Zettle & Hayes, 1986; Zettle & Rains, 1989) but not in military samples or for deployment-related distress.

The primary objective of this multi-site randomized controlled trial is to determine if receiving ACT, as compared to a control psychotherapy, is associated with reduced distress at the end of treatment. We will also examine its impact on functioning and acceptability as well as the extent to which gains are maintained after treatment. We will gather preliminary information about the impact of ACT on symptoms specific to PTSD, depression and PCS to inform future studies. In addition, we will gather information about the acceptability of and response to ACT in active duty service people as compared to those receiving care from the VA. Although the project is separately funded and administered, it is being conducted within the structure of the DoD-funded PTSD/TBI Clinical Consortium (INTRuST Consortium).

The primary objective of this trial is to evaluate the efficacy of ACT for reducing symptoms in veterans of Operation Enduring Freedom and/or Operation Iraqi Freedom and/or Operation New Dawn (OEF/OIF/OND).

Objective 1: To determine if receiving ACT, as compared to PCT, is associated with reduced distress as measured by the BSI-18 General Symptom Index (GSI) at the end of treatment.
There are three secondary objectives of the trial. First, we are interested in determining whether or not the impact of ACT extends beyond reduced general distress to anger, a common problematic associated symptom, and functioning. Second, we have hypothesized that an advantage of ACT is its acceptability. Thus, we will evaluate how participants receive it. Finally, we are interested in the degree to which gains are maintained after treatment. Early maintenance

of treatment effects (3 months) will be assessed in the entire sample. Longer-term follow-up will be completed for the patients who enroll earlier to provide preliminary data about longer-term outcomes.

Objective 2: To determine if receiving ACT, as compared to PCT, is associated with reduced anger and functional impairment at the end of treatment.
Objective 3: To compare the acceptability of ACT and PCT for OEF/OIF/OND veterans.
Objective 4: To describe to what extent treatment gains are sustained after treatment with ACT.

This project also has exploratory objectives. We chose to include patients with a variety of deployment-related presenting complaints because we believe that this is more representative of the way in which ACT would be applied in practice and because we believe that the broad applicability of the intervention is a strength of the approach. Nonetheless, it will ultimately be useful to understand whether or not there are groups for whom ACT is more or less helpful. Although we cannot recruit enough participants in this trial to have adequately powered disorder-specific comparisons, we plan to collect preliminary data that can direct future research on this topic. Similarly, we believe that it is important to inform future work in which ACT may be applied to active duty military personnel.

Objective 5: To assess whether or not ACT as compared to PCT is associated with decreased disorder-specific symptoms in subgroups with PTSD, Major Depression and post-concussive symptoms.

Objective 6: To gather preliminary information regarding the acceptability of and response to ACT in active duty service people as compared to those receiving care from the VA.

Objective 7: To compare the impact of the interventions on posttraumatic growth, hope, guilt and insomnia and to evaluate potential mediators of change.

Body

The overall study is a randomized controlled trial of Acceptance and Commitment Therapy (ACT). However, WRAMC subjects will participate only in one arm of the study, a pilot study in which all service members will receive ACT therapy and there will be no control group or need for randomization. The following is an overview of the approved study design that is currently being implanted across all study sites:

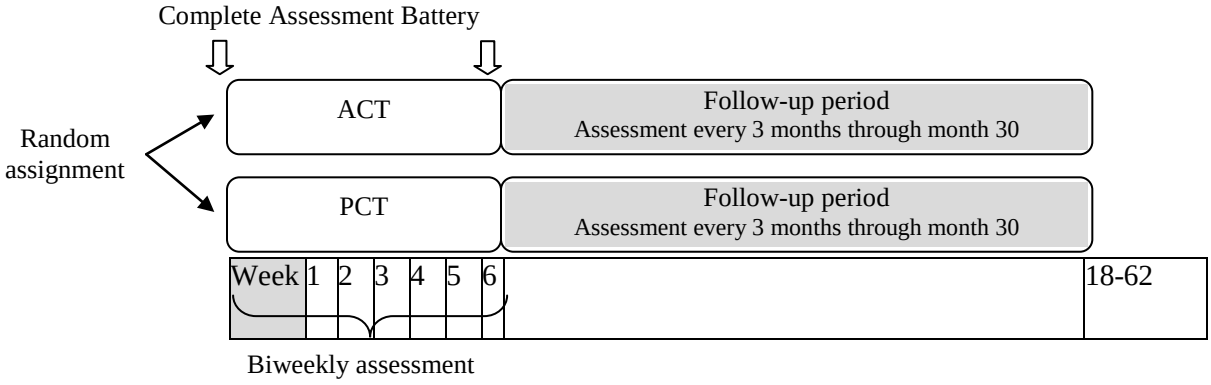

Figure 1: Study Timeline

Screening Visit: Informed Consent and Eligibility Assessment

- Review of study, obtain Informed Consent, sign HIPAA Authorization.
- Semi-structured clinical interview and neuropsychological screening by study assessor to determine eligibility.
- Participant completes self-administered questionnaires. Active duty respondents at Walter Reed are not eligible to receive the $25 dollar incentive that civilian study participants will receive at the other study locations.

Visits 1-12 Treatment Sessions

- Participant completes full assessment battery before session 1 (except credibility, which is given at the end of session 1) and after session 12. Participant receives twelve 60-minute one-on-one treatment sessions of ACT over 6-10 weeks (ideally 2 sessions per week but additional weeks are permissible if needed).
- Periodic brief assessment before sessions 3,5,9 and 11.
- Follow-up treatment sessions and assessments will be scheduled by the therapist with the subjects at the conclusion of each session in accordance with the treatment and assessment schedule. If a subject fails to return for scheduled follow-up, three attempts will be made to contact the subject by phone in accordance with the attached telephone script before the subject is considered to have been withdrawn from the study.

Post- treatment Follow-Up

- Participant completes self-administered questionnaires (via mail or by telephone) every 3 months for up to 12 months after the last session attended. See appendix L for script and cover letter.

At this time, the WRNMMC site has enrolled its goal number of 20 participants, approx. 1/3 of which are in the follow-up phase while the rest are still actively participating. Recruitment has been discontinued as a result of meeting enrollment goals on schedule. Across all study sites, 263 participants have been enrolled, while 55 have completed active participation and entered the follow-up data collection phase. Local site data is being sent at regular intervals to the lead site at UC San Diego, however statistical analysis has not yet begun.

Key Research Accomplishments

Goals for year 2 of this three year study are detailed below along with a description of how these goals were met.

Patient Recruitment & Enrollment Phase (Months 7 – 24): (1) Identify and recruit potential participants (n ≅ 40 total per VA clinic, N = 158; n ≅ 20 total at Walter Reed); (2) monitor enrollment progress at clinics; (3) provide ongoing adherence checks and supervision for therapists (Drs. Walser & Bolton); (4) collect data from study participants in accordance with analysis plan; (5) collect and report adverse events and serious adverse events; (6) conduct regular data monitoring for quality assurance; (7) ongoing analyses as requested by DSMB.

-- Recruitment began in April 2011 with the first participant enrolling at WRAMC in May 2011. Recruitment presentations were given at key department meetings to increase rate of patient referrals and advertisement brochures describing the study treatment and participation opportunities were distributed at key wards within the WRNMMC ecosystem. At time of reporting, our site has successfully enrolled our

target number of participants (n=20). Data collection is ongoing and local data is copied and sent at monthly intervals back to lead site for database entry.

External audit performed by Data Safety & Monitoring Board (DSMB) to ensure all regulatory requirements are met (Months 12-24): Medical and Regulatory monitors will perform full audits at each local site to ensure (1) data collection is proceeding in a uniform fashion across all sites; (2) all safety and regulatory responsibilities are adhered to; (3) protocol deviations, adverse events and serious adverse events are being documented and reported.

-- During April 2012 a monitor from the DSMB performed an on-site audit at WRNMMC. The findings revealed that all regulatory approval was up to date, the study treatment was being administered according to the approved protocols, and there were no cases of unreported or undocumented safety concerns. As a result, no necessary follow-up actions or corrections were issued.

Ongoing study coordination and management tasks (Months 1-36): (1) Hold monthly teleconferences between site PI's, study therapists and site coordinators; (2) Submit any protocol amendments for IRB approval at local sites; (3) maintain continuing review with local IRBs; (4) Provide lead site with copies of all regulatory documentation; (5) transmit data at regular intervals to lead site for database entry; (6) adhere to all regulatory and funding reporting requirements.

-- Regular teleconferences continue to be held every 2-4 weeks between PI's, coordinators and therapists. No protocol amendments were made during the current reporting period. The continuing review has been submitted to the WRNMMC IRB and has received approval. All locally collected data is copied and transmitted to the lead site at the end of each month. Regulatory and funding reporting requirements continue to be fulfilled.

Reportable Outcomes

Although target recruitment has been achieved, data collection is still ongoing. Data analysis is set to begin during months 30-36 of the study lifespan. As such there are no reportable outcomes at this time.

Conclusions

This multi-year, multi-site study is designed to determine the efficacy of Acceptance and Commitment Therapy (ACT) in the treatment of distress and impairment related to combat exposure. Such a therapy would prove useful to both VA clinics and active-duty health care providers due to its low cost, ease of training and implementation, and broad range of application. To date, this is the only study that has looked at the efficacy of this therapeutic model in a military population. The eventual results of this study will be greatly instrumental in determining whether such a therapeutic model can be effectively implemented in a military setting or on other populations that experience similar types of distress and impairment (i.e.

emergency first responders, disaster relief workers, etc). Such an outcome could have a significant impact on the availability and quality of mental health treatment and care available to the growing number of combat veterans.

At this time, data collection is ongoing while sites approach their recruitment goals. WRNMMC has reached target enrollment but data collection will continue as participants move toward the follow-up phase of the study. The primary goal moving forward into Year 3 of the study timeline is to continue the protocol with active participants until each reaches their follow-up and closeout dates. Ongoing efforts to disseminate information about the study at relevant conferences and professional meetings will be increased as data collection continues.

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