Award Number: W81XWH-08-2-0047

TITLE: Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

PRINCIPAL INVESTIGATOR: Dr. Ronald Acierno

CONTRACTING ORGANIZATION: Charleston Research Institute
Charleston, SC  29401

REPORT DATE: April 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland  21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
1. REPORT DATE (DD-MM-YYYY) 01-04-2011
2. REPORT TYPE Annual
3. DATES COVERED (From - To) 1 APR 2010-31 MAR 2011

4. TITLE AND SUBTITLE Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women

5a. CONTRACT NUMBER
5b. GRANT NUMBER W81XWH-08-2-0047
5c. PROGRAM ELEMENT NUMBER
5d. PROJECT NUMBER
5e. TASK NUMBER
5f. WORK UNIT NUMBER

6. AUTHOR(S) Dr. Ronald Acierno
   E-Mail: ron.acierno@musc.edu

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Charleston Research Institute
   Charleston, SC 29401

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
   U.S. Army Medical Research and Materiel Command
   Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR’S ACRONYM(S)

11. SPONSOR/MONITOR’S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
    Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/10 and 3/31/11. This report focuses on the primary objectives for our third year including: a) recruitment and enrollment, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, and c) presentation of the project at two national conferences and submission and preparation of initial manuscripts. Additionally, we provide a detailed description of the study-related activities that occurred between 01/01/11 and 3/31/11.

15. SUBJECT TERMS
PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations

16. SECURITY CLASSIFICATION OF:
a. REPORT U
b. ABSTRACT U
c. THIS PAGE U

17. LIMITATION OF ABSTRACT UU
18. NUMBER OF PAGES 11
19a. NAME OF RESPONSIBLE PERSON USAMRMC
19b. TELEPHONE NUMBER (include area code)
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Body</td>
<td>2</td>
</tr>
<tr>
<td>Key Research Accomplishments</td>
<td>6</td>
</tr>
<tr>
<td>Reportable Outcomes</td>
<td>6</td>
</tr>
<tr>
<td>Conclusion</td>
<td>7</td>
</tr>
<tr>
<td>References</td>
<td>9</td>
</tr>
<tr>
<td>Appendices</td>
<td>9</td>
</tr>
</tbody>
</table>
INTRODUCTION:

The current project has two primary objectives: 1) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD symptoms in post-deployed OIF/OEF service men and women, and 2) determine whether or not this program delivered via telepsychology will be as effective as in-person treatment. Behavioral Activation and Therapeutic Exposure (BATE) is an eight-session, manualized treatment program. Using a between-groups, repeated measures design, study participants will be randomized to one of two treatment conditions: BATE delivered via telepsychology (BATE-T), or BATE delivered in-person (BATE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

BODY:

The major tasks of the S.O.W. include (1) recruit 200 active duty or veteran participants with PTSD or Sub-Threshold PTSD and randomly assign to either in person or televideo based treatment for PTSD; (2) collect measures of PTSD and other psychopathology, attendance, patient satisfaction and cost at pre-treatment, post-treatment, and follow-up. Note that our S.O.W. has been amended and approved to address the more prevalent problem of chronic PTSD by including up to 33% of Vietnam Veterans, in addition to OIF/OEF and Persian Gulf Veterans.

Report:

Between 04/01/2010 and 03/31/2011, 167 participants were screened and 47 were enrolled, bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 98. Additionally, 20 participants completed post-test assessment (47 total), 11 completed three-month follow-up (35 total), and 18 completed 12-month follow-up (19 total).

3 Year Point Data Analysis

Participants were predominantly male (88.4%), African American (51.2%) followed by Caucasian (41.9%), Hispanic (2.3%), and other (4.7%), married (46.5%), employed (58.1%), not disabled (61.4%), and had a mean age of 32.7 years (SD = 9.02). All participants endorsed symptoms consistent with either PTSD (62.8%) or subthreshold PTSD (37.2%) on the CAPs.

Clinical outcomes: Baseline to one-week post treatment

To evaluate the overall efficacy of BA-TE, we ran paired t-tests for the PTSD Checklist-Military Version (PCL-M) and Beck Depression Inventory, Second Edition (BDI-II) for the entire sample. As presented in Table 1, these analyses revealed
significant within subject pre- to post-treatment reductions on the primary symptom measures (PCL-M, \( t = 5.2, p < .001 \); BDI-II, \( t = 2.8, p = .008 \)).

Table 1: Efficacy of BA-TE across all patients

<table>
<thead>
<tr>
<th>Scale</th>
<th>Pre-Tx Mean</th>
<th>Post-Tx Mean</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCL-M (n = 45)</td>
<td>58.8 (13.15)</td>
<td>46.8 (17.9)</td>
<td>5.2</td>
<td>.000</td>
</tr>
<tr>
<td>BDI-II (n = 45)</td>
<td>23.8 (10.4)</td>
<td>18.8 (13.2)</td>
<td>2.8</td>
<td>.008</td>
</tr>
</tbody>
</table>

Note. Pre-Tx and Post-Tx columns are presented as means (standard deviations). Tx = treatment; PCL-M = PTSD Checklist – Military; BDI-II = Beck Depression Inventory – II

A series of 2x2 repeated measures ANOVAs were used to evaluate changes in PTSD and MDD symptom severity as a result of treatment, with time (Pre/Post PCL-M scores and BDI-II) serving as the within subjects factor, and condition (IP/HBT) serving as the between-subjects factor. As expected, one way ANOVAs failed to find differences across condition on any measures of baseline PTSD (CAPS, \( F = .036, p = .851 \); PCL-M, \( F = .066, p = .799 \)); MDD (BDI-II, \( F = .116, p = .735 \)); or Substance use/abuse (DAST, \( F = 3.61, p = .065 \); AUDIT, \( F = .126, p = .724 \)). As illustrated in Figures 1 and 2, consistent with hypotheses, analyses revealed significant reductions in PTSD (PCL-M, \( F = 25.04, p < .001 \)) and MDD symptoms over time (BDI-II, \( F = 7.46, p = .009 \)) but no significant time by condition interactions (PCL-M, \( F = 3.12, p = .579 \); BDI-II, \( F = .036, p = .850 \)).

Figure 1. PTSD symptoms by time and condition

Note. PCL-M: PTSD Checklist – Military; BDI-II: Beck Depression Inventory – II; IP: In-person; HBT: Home-based telehealth
Trends at three-month follow-up

To date, 35 participants have completed the three-month follow-up assessment. Although tests of significance across condition are premature at this stage of the study, initial data suggest that participants maintain therapeutic gains three months post-treatment completion.

Table 2: Mean BDI-II and PCL-M Scores at Baseline, Post-Treatment, and 3-Month Follow-up

<table>
<thead>
<tr>
<th>Assessment Time Frame</th>
<th>Base (n=43)</th>
<th>Post (n=40)</th>
<th>3 month (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall BDI-II Mean</td>
<td>23.85</td>
<td>18.4</td>
<td>17.84</td>
</tr>
<tr>
<td>(SD= 10.98)</td>
<td>(SD=12.81)</td>
<td>(SD=12.93)</td>
<td></td>
</tr>
<tr>
<td>Overall PCL-M Mean</td>
<td>58.4</td>
<td>46.10</td>
<td>47.4</td>
</tr>
<tr>
<td>(SD=14.6)</td>
<td>(SD=17.8)</td>
<td>(SD=17.8)</td>
<td></td>
</tr>
</tbody>
</table>

Note. Base: One week prior to session 1; Post: One week post session 8; 3 month: 3 months post session 8; PCL-M: PTSD Checklist, Military; BDI-II: Beck Depression Inventory, Second edition; SD= standard deviation; n=number of participants.

Process Outcomes

We ran a series of independent t tests to determine whether treatment satisfaction (CPOSS-VA), credibility, and service delivery perceptions differed across groups. As
illustrated in Tables 3, 4 and 5, participants in both conditions were highly satisfied with the treatment and mode of delivery and generally found the treatment to be credible. However, contrary to hypotheses, participants reported comparable treatment satisfaction, credibility, and service delivery perceptions scores across condition. Further, as illustrated in Tables 5 and 6, participants displayed comparable attrition rates.

Table 3: Overall Satisfaction with Services by Condition

<table>
<thead>
<tr>
<th>Item</th>
<th>In Person</th>
<th>Tele</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx Helpfulness</td>
<td>4.4</td>
<td>4.5</td>
<td>-0.18</td>
<td>0.868</td>
</tr>
<tr>
<td>Tx Quality</td>
<td>4.4</td>
<td>4.5</td>
<td>-0.60</td>
<td>0.550</td>
</tr>
<tr>
<td>Rec to a friend?</td>
<td>4.3</td>
<td>4.1</td>
<td>-0.76</td>
<td>0.449</td>
</tr>
</tbody>
</table>

*Items from the CPOSS VA (4=Very Good; 5=Excellent); IP=In-person, HBT=Home-based telehealth

Table 4: Treatment Credibility by Condition

<table>
<thead>
<tr>
<th>Item</th>
<th>In Person</th>
<th>Tele</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tx Logical</td>
<td>7.4</td>
<td>7.1</td>
<td>0.31</td>
<td>0.758</td>
</tr>
<tr>
<td>Tx Reduce Symptoms</td>
<td>5.8</td>
<td>5.7</td>
<td>0.20</td>
<td>0.841</td>
</tr>
<tr>
<td>Rec to a friend?</td>
<td>7.6</td>
<td>6.6</td>
<td>0.78</td>
<td>0.226</td>
</tr>
<tr>
<td>Reduce Other Fear</td>
<td>7.0</td>
<td>6.1</td>
<td>0.74</td>
<td>0.187</td>
</tr>
</tbody>
</table>

* Items from the Treatment Credibility Scales (1=Not at all; 5=Moderately Confident; 10=Very Confident)

Table 5: Service Delivery Perceptions by Condition

<table>
<thead>
<tr>
<th>Item</th>
<th>In Person</th>
<th>Tele</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>4.1</td>
<td>4.6</td>
<td>-0.47</td>
<td>0.639</td>
</tr>
<tr>
<td>Quality of communication</td>
<td>4.6</td>
<td>4.5</td>
<td>0.77</td>
<td>0.446</td>
</tr>
<tr>
<td>How far drive if IP?</td>
<td>3.2</td>
<td>2.6</td>
<td>1.64</td>
<td>0.109</td>
</tr>
<tr>
<td>How far drive if tele?</td>
<td>2.2</td>
<td>2.0</td>
<td>0.36</td>
<td>0.724</td>
</tr>
<tr>
<td>Use service again</td>
<td>4.3</td>
<td>4.1</td>
<td>0.75</td>
<td>0.459</td>
</tr>
<tr>
<td>Overall satisfaction</td>
<td>4.3</td>
<td>4.7</td>
<td>-1.67</td>
<td>0.102</td>
</tr>
</tbody>
</table>

* Items from the Service Delivery Perceptions Questionnaire (For items 1, 2, & 5: 1=Very Uncomfortable/Poor/Very Unlikely; 5=Very Comfortable/ Excellent/Very likely; for items 3 & 4: 1=0-10 miles; 2=11-20 miles; 3=21-40 miles; 4=41-60 miles; 5=over 60 miles)
KEY RESEARCH ACCOMPLISHMENTS:

- Ninety-eight participants have been enrolled to date; 47 participants have completed treatment.

- Team representatives established relationships with clinicians at our two primary care clinic annexes located in the Trident Hospital and the Charleston Naval Weapons Station. Since these collaborations began, we have received over 50 referrals to the study and have enrolled 13 participants.

- An amendment to the statement of work to allow the enrollment of Vietnam and Persian Gulf veterans into the study was approved.

- Three manuscripts were accepted for publication (see next section).

- We presented preliminary findings at several national conferences (see next section).

REPORTABLE OUTCOMES:

- Three manuscripts were accepted for publication and are currently in press:


- The research team presented at many national conferences:


CONCLUSION:

Recruitment has increased dramatically with the activation of a second recruitment site. Moreover, the recent inclusion of Vietnam Veterans two weeks ago will additionally enhance recruitment success. This inclusion was predicated on the fact that virtually all active duty and Veteran service men and women who seek services for PTSD do so more than 6 months post-symptom presentation. As such, the prototypic PTSD case treated in Active Duty and Veteran populations is Chronic PTSD. This inclusion modification will allow us to speak to the effectiveness of telemedicine delivered BA-TE with both distal and recent chronic populations.

Preliminary results are consistent with current literature that suggests behavior therapies can be safely and effectively implemented via home-based telehealth technology and that telehealth service delivery yields reductions in symptomatology that are comparable to in-person service delivery. Further, participants who receive behavior therapy via telehealth report comparable treatment satisfaction, credibility, and service
delivery perceptions to patients who receive exposure therapy via conventional in-person service delivery.

Thus far, study findings are encouraging. On measures of both PTSD and MDD, within group improvements are evident, but no differences between telemedicine and in person conditions are evident. The latter findings are tempered, however, because power is still low relative to that suggested as necessary in non-inferiority designs. Nonetheless, lack of significant differences between modalities, with significant improvement within both modalities is worthy of note.
REFERENCES:

None

APPENDICES:

The 3 research articles and 9 presentations are available upon request.