Home-Telehealth vs. In Person Delivery of Evidence Based Psychotherapy for Combat PTSD

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• About 15 to 17% of current Iraq war veterans meet full diagnostic criteria for MH problems such as post-traumatic stress disorder (PTSD) (Hoge et al., 2004).

• *Exposure Based treatments (PE)* have good empirical support in treating PTSD (Foa 1997; Schnurr et al., 2007), and have been adopted by the VAMC

• Many Veterans and Active Duty Personnel face obstacles (stigma, logistical) in receipt of this treatment.

• It is therefore important to employ treatment delivery methods that address these obstacles and maximize the likelihood that all veterans who need treatment receive treatment

• *Home Based Telemedicine Meets this Need and can demonstrate ability to reach active duty and veteran populations “where they’re at”*
TWO Studies: Research Question(s)/Hypotheses

AIMS

• Compare delivery of Behavioral Activation/Therapeutic Exposure In Person vs. Home-Based Telemedicine
• Compare delivery of Prolonged Exposure In Person vs. Home-Based Telemedicine

HYPOTHESES

• Treatment delivered via home based telemedicine mediums will be ‘as good as’ in person treatment for PTSD and depression symptom relief.

• Participants in the Telepsychology treatment conditions will
  • incur lower costs
  • report greater satisfaction with treatment
  • evince lower attrition
Design and Methodology

**Design:** RCT, Non-Inferiority, repeated measures (pre, post, 3 & 6 month for VA Merit, 12 month for DOD)

**Participants:**; Combat PTSD, non-psychotic, non suicidal.

**TX Protocol:**
- DoD Study: BA-TE: 8, 1.5 hour sessions Behavioral Activation (BA) for depression & Therapeutic Exposure (TE) for PTSD
- VA Study: PE

**Measures:** Primary PCL, BDI for PTSD and Depression. Also included are process and cost

**Statistical Methods:** The 90% confidence interval (CI) approach was used to evaluate noninferiority of HBT mode of intervention delivery compared to IP mode of delivery. A mixed effects repeated measures longitudinal modelling approach (MMRM) was used to estimate the 90% CI for difference in baseline-adjusted least squares means (treatment effect sizes) at each post-intervention time point.
CONSORT Diagram BA-TE

Enrollment

Screened (n=1,237) → Assessed for eligibility (n=280) → Excluded (n=15)
- Not meeting inclusion criteria (n=15)

Randomized (n=265)

Allocation

Allocated to BA-TE-IP (n=134)
- Initiated BA-TE-IP (n=121)
- Completed BA-TE-IP (n=101)

Allocated to BA-TE-HBT (n=131)
- Initiated BA-TE-HBT (n=111)
- Completed BA-TE-HBT (n=95)

Follow-Up

Completed any follow-up (n=102)
- Completed any follow-up and initiated BA-TE-IP (n=101)
- Completed any follow-up and completed BA-TE-IP (n=91)
- Lost to follow-up (n=32)

Completed any follow-up (n=99)
- Completed any follow-up and initiated BA-TE-HBT (n=98)
- Completed any follow-up and completed BA-TE-HBT (n=93)
- Lost to follow-up (n=32)

Analysis

Analysed
- Intent to Treat (n=101)
- Per Protocol Completer (n=89)
- Excluded from analysis (randomization violation, n=1 data out of range n=5)

Analysed
- Intent to Treat (n=98)
- Per Protocol Completer (n=86)
- Excluded from analysis (randomization violation n=1, data out of range n=2)
## Final Sample Characteristics: BA-TE

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Home Based</th>
<th>Office Based</th>
<th>t / χ², p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>45.5 (SD=14.8)</td>
<td>46.1 (SD=14.7)</td>
<td>44.9 (SD=15.0)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>246 (91.8)</td>
<td>121 (45.7)</td>
<td>125 (47.2)</td>
</tr>
<tr>
<td>Female</td>
<td>19 (6.8)</td>
<td>10 (3.8)</td>
<td>9 (3.4)</td>
</tr>
<tr>
<td>Race/Ethnicity (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>133 (50.2)</td>
<td>68 (56.7)</td>
<td>75 (62.5)</td>
</tr>
<tr>
<td>Black</td>
<td>125 (47.2)</td>
<td>58 (21.9)</td>
<td>67 (25.3)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (1.5)</td>
<td>2 (0.8)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Others</td>
<td>3 (1.1)</td>
<td>2 (0.8)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Marital status (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>37 (14.5)</td>
<td>14 (5.5)</td>
<td>23 (9.0)</td>
</tr>
<tr>
<td>Married</td>
<td>167 (65.2)</td>
<td>88 (34.4)</td>
<td>79 (30.9)</td>
</tr>
<tr>
<td>Sep./Divorced</td>
<td>48 (18.8)</td>
<td>23 (9.0)</td>
<td>25 (9.8)</td>
</tr>
<tr>
<td>Widowed</td>
<td>4 (1.6)</td>
<td>2 (0.8)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Mean Years Education</td>
<td>12.2 (SD=4.3)</td>
<td>11.9 (SD=4.7)</td>
<td>12.6 (SD=4.0)</td>
</tr>
<tr>
<td>Employed (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>122 (50.8)</td>
<td>62 25.8</td>
<td>60 25.0</td>
</tr>
<tr>
<td>Yes</td>
<td>118 (49.2)</td>
<td>54 22.5</td>
<td>64 26.7</td>
</tr>
<tr>
<td>Service Connection Rating</td>
<td>34.6 (SD=38.7)</td>
<td>34.1 (SD=38.5)</td>
<td>35.0 (SD=39.1)</td>
</tr>
<tr>
<td>Baseline CAPS PTSD</td>
<td>203 (77.2)</td>
<td>102 (50.2)</td>
<td>101 (49.8)</td>
</tr>
</tbody>
</table>

- No significant differences on any baseline variables were evident.
- Additionally, attrition was 30% across treatment delivery medium.
- Two-variable χ² tests and one-way ANOVA revealed no group differences between completers and dropouts in terms of gender, race age, baseline BDI, or PCL scores.
Results: Behavioral Activation and Therapeutic Exposure

PCL: Difference in Baseline-Adjusted Means at Immediate Post, 3-months, 12-months
90% 2-sided CI (95% One sided CI)
Per Protocol Sample (n=184): Number sessions > 4
Results: Behavioral Activation and Therapeutic Exposure
CONSORT 2016 Flow Diagram (PE)

Enrollment

Screened (n=1314) → Assessed for eligibility (n=154)

Excluded (n=4)
- Not meeting inclusion criteria (n=4)

Randomized (n=150)

Allocation

Allocated to PE-IP (n=76)
- Initiated PE-IP (n=68) (ITT Sample)
- Completed 6 Sessions PE-IP (n=55) (PP sample)

Allocated to PE-HBT (n=74)
- Initiated PE-HBT (n=65) (ITT Sample)
- Completed 6 Sessions PE-HBT (n=43) (PP sample)

Follow-Up

Completed any follow-up (n=58) → Completed any follow-up (n=52)

Analysis

Analysed
- Intent to Treat (n=68)
- Per Protocol Completer (n=55)
- Excluded from analysis (n=0)

Analysed
- Intent to Treat (n=64)
- Per Protocol Completer (n=43)
- Excluded from analysis (missing randomization certification n=3)
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean / Total N (SD / %)</th>
<th>PE-HBT n (%)</th>
<th>PE-IP n (%)</th>
<th>F or X^2, p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>41.8 (SD=14.5)</td>
<td>40.7 (SD=14.9)</td>
<td>42.9 (SD=14.1)</td>
<td>0.74, 0.39</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>127 (96.2)</td>
<td>63 (98.4)</td>
<td>64 (94.1)</td>
<td>1.69, 0.20</td>
</tr>
<tr>
<td>Female</td>
<td>5 (3.8)</td>
<td>10 (1.6)</td>
<td>9 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>80 (60.6)</td>
<td>39 (60.9)</td>
<td>41 (60.3)</td>
<td>1.16, 0.76</td>
</tr>
<tr>
<td>Black</td>
<td>44 (33.3)</td>
<td>21 (32.8)</td>
<td>23 (33.8)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7 (5.3)</td>
<td>4 (6.3)</td>
<td>3 (45.4)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>1 (0.8)</td>
<td>0 (0.0)</td>
<td>1 (1.5)</td>
<td></td>
</tr>
<tr>
<td>Marital status (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>30 (23.3)</td>
<td>15 (23.8)</td>
<td>15 (22.7)</td>
<td>0.32, 0.96</td>
</tr>
<tr>
<td>Married</td>
<td>73 (56.6)</td>
<td>36 (57.1)</td>
<td>37 (56.1)</td>
<td></td>
</tr>
<tr>
<td>Sep./Divorced</td>
<td>23 (17.8)</td>
<td>11 (17.5)</td>
<td>12 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>3 (2.3)</td>
<td>1 (1.6)</td>
<td>2 (3.0)</td>
<td></td>
</tr>
<tr>
<td>Education (Years)</td>
<td>12.4 (SD=4.6)</td>
<td>12.2 (SD=4.9)</td>
<td>12.5 (SD=4.4)</td>
<td>0.09, 0.76</td>
</tr>
<tr>
<td>Employed (%)</td>
<td>55 (49.1)</td>
<td>26 (48.1)</td>
<td>29 (50.0)</td>
<td>0.04, 0.50</td>
</tr>
<tr>
<td>Baseline PCL</td>
<td>59.2 (11.2)</td>
<td>60.1 (11.3)</td>
<td>58.3 (11.1)</td>
<td>0.84, .36</td>
</tr>
<tr>
<td>Baseline BDI</td>
<td>27.7 (12.1)</td>
<td>27.5 (13.0)</td>
<td>27.9 (11.4)</td>
<td>0.01, .87</td>
</tr>
<tr>
<td>Mean Service Connection Rating</td>
<td>53.5 (SD=37.9)</td>
<td>55.8 (SD=35.7)</td>
<td>51.4 (SD=40.2)</td>
<td>0.32, 0.57</td>
</tr>
</tbody>
</table>
Results: Prolonged Exposure (per protocol N = 98)
Results: Prolonged Exposure (per protocol N = 98)

BDI: Difference in In-Person vs Telepsych

N=98

Delta_BDI

Difference in Outcome (Estimated Effect Size)

-10

-5

0

5

Post

Month 3

Month 6

-2.4

-2

-0.3
Switching Gears:

- Satisfaction
- Cost
- Dropout
Satisfaction

- Good relationship w/provider: 70.8%
- Good Care: 91.7%
- Recommend HB TMH to other Veterans: 79.2%
- Fewer missed/rescheduled appts: 45.8%
- Overall Satisfaction: 75.0%
Costs of the intervention include
- therapist
- VA clinic space
- mileage cost for face to face and all but mileage cost for telehealth.

Benefits include
- differences between post and pre intervention inpatient costs
- outpatient costs
- pharmaceutical VA costs
- mileage savings for telehealth patients.

Costs and benefits were adjusted to 2016 dollar values using the U.S. Department of Labor Consumer Price Index.
Cost-Benefit of PTSD Telehealth treatment in Veterans

- Student t tests were used to examine unadjusted differences in total cost and total benefits of the telehealth PTSD treatment relative to face to face.
- The cost of the intervention per Veteran was then compared with the estimated annual benefit per Veteran for the PTSD telehealth intervention relative to face to face.
- 100 Veterans were randomized to each group with 51 in face to face and 49 in telehealth.
Cost-Benefit of PTSD Telehealth treatment in Veterans

- The estimated total cost of the PTSD intervention per Veteran was not significantly different between telehealth ($457) and face to face ($474).

- The unadjusted estimated mean benefit (total cost difference and mileage between post and pre intervention) for telehealth relative to face to face was $3,640.

- The telehealth intervention appears to be extremely cost effective for PTSD with a negligible difference in the cost and a very large benefit for the VA in reduced healthcare costs and mileage.
Dropout:

A slightly disturbing trend

- Dropout was the same for both conditions: about 25% in BA=TE and about 20% in PE.

- Non sig, but a higher proportion of telemed participants *consistently* reported more problems with exposure therapy procedures.
BTPS SUBCATEGORY 2: TREATMENT DEMANDS; ITEM LEVEL ILLUSTRATION

- Tx inc stress
- Tx was work
- Sess uncomf
- Couldn't tol think
- Couldn't tol assign
- Imag felt bad
- Worry lose control

In Person
Telemedicine
But...On the positive side...

- Dropout was delayed in the telemedicine group.
NUMBER OF SESSIONS UNTIL DROPOUT

In Person

Telemedicine
Summary:

Hypothesis: Telemedicine will be associated with lower dropout rate

- Was not supported, and NO differential rate of dropout was observed.

- HOWEVER, Participants receiving exposure therapy via telemedicine tended to complete more sessions prior to dropping out.
Summary

Hypothesis: Telemedicine participants will report fewer problems, less discomfort, and lower cost treatment than In Person participants

- No statistically significant differences in tx demands were observed across conditions.
- However, AMONG DROPOUTS, some non-significant differences:
  - 11.8% of in person vs. 21.1% of telemedicine reported imaginal exposures made them feel bad.
  - 20.0% of in person vs. 41.2% of telemedicine reported feeling worried about losing control during exposure;
  - 40.0% of in person vs. 58.3% of telemedicine indicated that they could not tolerate assignments to go out in public.

- A very strong cost advantage for telemedicine
Summary

The Main Hypothesis: Home based telemedicine is non inferior to in person care

- Fully supported across both measures of PTSD and depression.
- The therapeutic results of Home based telemedicine treatment of PTSD and depression by behavioral activation and therapeutic exposure are as good as in person treatment.