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Problem-Solving Treatment for Service Members with Mild TBI: A Randomized Controlled Trial

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Disclosure

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- The views expressed herein are those of the presenter and do not reflect the official policy of the Department of the Army, Department of Defense, or the U.S. Government.
  - I have no relevant financial relationships to disclose.
  - I do not intend to discuss off-label/ investigative (unapproved) use of commercial products or devices.
  - The description of programs in this presentation is for descriptive purposes only and not intended to promote any individual program.
Learning Objectives

- To understand the common challenges to treating soldiers who have sustained mild TBI on deployment.

- To be exposed to a new intervention model incorporating telehealth and problem-solving therapy.

- To learn the results of a randomized controlled trial comparing telephone-based problem-solving therapy to an education-based intervention.
Background

Mild Traumatic Brain Injury (MTBI) sustained on deployment

Increased Risk

Persistent Post-concussive Symptoms (PPCS) and emotional distress

(Hoge et al., 2008; Schneiderman, Braver, & Kang, 2008)

Image source: www.dvidshub.net
The Problem

- There are no *standardized* treatments for PPCS and its common co-morbidities.
- There are numerous potential barriers to treatment (Seal et al., 2010):
  - Duty restrictions
  - Access to care
  - Inadequate financial resources
  - Stigma of receiving treatment
  - Fear for impact on military career
- **Our Goal**: Create and evaluate a treatment for PPCS that was easily accessible, feasible for wide dissemination, and accepted by service members.
Rationale Guiding Our Intervention

- **Cognitively based**
  - Cognitive and cognitive behavioral treatments may increase long-term resilience.

- **Problem-solving therapy**
  - Past studies suggest it is effective at addressing a variety of psychological problems, medical problems, and chronic pain.
  - It is patient-centered and usually well accepted by military and veteran populations.

- **Telehealth**
  - A promising approach to treatment to help overcome access barriers – virtually everyone has access to a telephone.
  - Past studies have established the feasibility of telehealth approaches in civilians across the spectrum of TBI, even in the presence of cognitive impairment. (Bell et al., 2005; Bell et al., 2011)
The Intervention

- We developed a manualized, telephone-delivered, problem-solving therapy-based (PST) intervention (Bell et al., 2015)
- A Concussion Support Specialist (CSS) was assigned to guide them through the intervention.
- CSSs conducted up to 12 biweekly phone calls over six months.
  - Each call was approximately 30-45 minutes.
- PST was taught using didactic information and examples.
- Problems of focus were selected by participants.
  - A structured worksheet was used to select problems
  - Direct guidance was provided when needed.
Steps of PST

A = Assess
(Define it, characterize it, understand it.)

B = Brainstorm
(List ‘em all, anything goes.)

C = Consider and Choose
(Determine pros and cons of each solution, then choose.)

D = Do it
(Develop a plan, use concrete steps, and operationalize.)

E = Evaluate
(Did it work? If not, why?)

F = Fight On
(Return to earlier steps, improve it, or keep it up!)
Intervention – Modules

- Modules were created and available for common problems.
  - Depression
  - Anxiety/post-traumatic symptoms
  - Insomnia
  - Headache

- Modules included assessment, education, and therapeutic strategies.
  - Based on behavioral activation, cognitive behavioral therapy, and problem-solving therapy

- Designed to last 2-4 sessions

- After completion of a module, it was determined if referral for additional treatment was needed.
Study Methods

- Service members sustaining mTBI in combat (Operation Iraqi Freedom, Operation Enduring Freedom, Operation New Dawn) within the past two years were eligible.
  - Moderate or severe TBI were excluded.
- Enrolled from Womack or Madigan Army Medical Centers (WAMC & MAMC, respectively)
  - Affirmative screening at a post-deployment health examination AND
  - Positive screening on the “2+10 TBI Screening Questionnaire” or the Military Acute Concussion Evaluation (MACE)
- Criteria were intentionally minimally restrictive.
- Participants were randomized to either PST or Education Only (EO).
  - PST group also received educational materials.
- “Usual care/treatment as usual” was not interrupted.
Education Only

- 12 informational brochures provided upon enrollment
- Addressed problems of mTBI and deployment
  - Stress
  - Substance abuse
  - Pain and headache
  - Sleep disorders
  - Anger
  - Depression
  - Cognitive problems
  - Relationships
  - Money and finances
  - Post-traumatic stress
  - Physical recovery
  - Returning to work
- Based on peer-reviewed civilian literature
  - Reviewed for military appropriate content by MAMC Education Coordinator
- Additional copies were mailed or e-mailed every two weeks throughout the duration of the study.
Assessments and Hypotheses

- In-person baseline assessment at time of enrollment collected demographic information, injury history, and medical history.
- All other baseline and follow-up assessments were completed by a blinded Outcomes Examiner via telephone.

Hypotheses:
- Primary Objectives – Six-month follow-up:
  - PST will result in lower levels of PPCS than EO.
  - PST will result in lower levels of emotional distress than EO.
- Exploratory Objectives
  - PST will result in greater improvements than EO in general health and physical well-being, sleep quality, mental health, resiliency, day-to-day functioning, and social functioning, at six-month follow-up.
  - PST will be accepted and preferred over EO.
  - Gains will be maintained at 12-month follow-up.
Measures

Primary Objectives:
- PPCS: Rivermead Post-Concussion Symptoms Questionnaire (RPSQ)
- Emotional Distress: Brief Symptom Inventory-18 (BSI-18)

Exploratory Objectives:
- EuroQol
- PTSD Checklist – Military Version (PCL-M)
- Pittsburgh Sleep Quality Index (PSQI)
- Patient Health Questionnaire-9 (PHQ-9)
- Connor Davidson Resilience Scale-10 (CD-RISC)
- Brief Inventory for Functioning Evaluation (B-IFE)
- Alcohol Use Disorders Identification Test (AUDIT)
- Sheehan Disability Scale
- Short Form – 12, version 2 (SF-12)
- Life Events Checklist
- Columbia-Suicide Severity Rating Scale (C-SSRS)
- Cornell Service Index (CSI)
- Client Satisfaction Questionnaire (CSQ-8)
Analyses

Primary Outcomes

- **Mixed Effects Regression Analyses**
  - Conducted separately on each primary outcome variable
  - **DV** = Outcome Score (RPSQ or BSI-18)
  - **IV** = Time (Baseline vs. 6-month), Treatment Arm (PST vs. EO), and Time x Arm Interaction
  - Covariates (e.g., stratification variables, other unbalanced variables at baseline)

- **Sensitivity analysis** to examine imbalance between completers and dropouts

Exploratory Analyses

- **Similar Mixed Effects Regression Analyses** as used in Primary Outcomes
Study Participants

356 Participants Randomized

178 Randomized to PST
119 (67%) completed at least four sessions “Completers”
At 6-months
138 (78%) assessed
25 Unable to contact
  5 Refused
  1 Deployed
  7 Withdrew
  2 Deceased
143 assessed at 12-months

178 Randomized to EO
Mean # sessions completed: 6.6±4.6 (range 0-12; median 7)
At 6-months
166 (93%) assessed
  4 Unable to contact
  6 Refused
  2 Deployed
157 assessed at 12-months
## Participant Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>All randomized subjects (n=356)</th>
<th>Randomized to Telephone PST (n=178)</th>
<th>Randomized to Education Only (n=178)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Recruitment Site</td>
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</tr>
<tr>
<td>Madigan AMC – n(%)</td>
<td>110 (31%)</td>
<td>55 (31%)</td>
<td>55 (31%)</td>
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<tr>
<td>Womack AMC – n(%)</td>
<td>246 (69%)</td>
<td>123 (69%)</td>
<td>123 (69%)</td>
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<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean (SD)</td>
<td>29.39 (7.23)</td>
<td>29.25 (7.20)</td>
<td>29.99 (7.27)</td>
<td>0.76</td>
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<tr>
<td>Gender – n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Male</td>
<td>332 (93.26%)</td>
<td>166 (93.26%)</td>
<td>166 (93.26%)</td>
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</tr>
<tr>
<td>Race – n (%)</td>
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<tr>
<td>Black or African American</td>
<td>29 (8.15%)</td>
<td>15 (8.43%)</td>
<td>14 (7.87%)</td>
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<tr>
<td>White</td>
<td>274 (76.97%)</td>
<td>137 (76.97%)</td>
<td>137 (76.97%)</td>
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<td>Other</td>
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<td>26 (14.62%)</td>
<td>27 (15.17%)</td>
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<tr>
<td>Ethnicity – n (%)</td>
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<tr>
<td>Hispanic or Latino</td>
<td>65 (18.26%)</td>
<td>36 (20.22%)</td>
<td>29 (16.29%)</td>
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<td>Non Hispanic or Latino</td>
<td>289 (81.18%)</td>
<td>141 (79.21%)</td>
<td>148 (83.15%)</td>
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<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>13.4 (1.81)</td>
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<td>13.34 (1.78)</td>
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<td>Military Status</td>
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<tr>
<td>Regular</td>
<td>332 (93.26%)</td>
<td>167 (93.82%)</td>
<td>165 (92.7%)</td>
<td>0.625</td>
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<td>Deployments to Combat Zone</td>
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<td>Mean (SD)</td>
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<td>2.47 (1.91)</td>
<td>2.41 (1.72)</td>
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<td>Range</td>
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<td>(1, 10)</td>
<td>(1, 9)</td>
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## Primary Outcomes – RPSQ

<table>
<thead>
<tr>
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<th>Total</th>
<th>Telephone PST</th>
<th>Education Only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Month 6</td>
<td>Baseline</td>
</tr>
<tr>
<td><strong>Mean (sd)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 6</td>
<td>355</td>
<td>304</td>
<td>177</td>
</tr>
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</table>

### Primary Outcomes – BSI-18

<table>
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<tr>
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<th>Total</th>
<th>Telephone PST</th>
<th>Education Only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Month 6</td>
<td>Baseline</td>
</tr>
<tr>
<td><strong>Mean (sd)</strong></td>
<td>57.23 (9.9)</td>
<td>56.118 (11.819)</td>
<td>57.275 (10.075)</td>
</tr>
<tr>
<td><strong>n</strong></td>
<td>356</td>
<td>304</td>
<td>178</td>
</tr>
</tbody>
</table>

![Graph showing the comparison of means across conditions with p=.013](graph.png)

Exploratory outcome analyses

- Significant positive effects of PST for:
  - Depression (Patient Health Questionnaire-9; p = 0.032)
  - Sleep quality (Pittsburgh Sleep Quality Index; p = 0.012)
  - General physical well-being (Short Form -12; p = 0.031)

Satisfaction

- PST was also rated higher than EO for the quality and kind of help, as well as the amount of help received (p<.05).

Maintenance

- Benefits were NOT evident at 12-months.
Summary

Large scale intervention study found positive effects at 6-months post-treatment…

- Telephone based problem-solving therapy was effective for certain aspects of post-deployment difficulty.
  - Levels of emotional distress were reduced.
  - Physical well-being, depression, and quality of sleep were particularly responsive to this intervention.
- PST was well-received by active duty service members, and generally preferred over EO.

However, gains/improvements were not maintained at 12-months post-treatment.
Conclusions

- Interventions such as telephone-PST may hold several potential advantages for treating service members sustaining mTBI:
  - Client-centered
  - Avoids access to care barriers
  - Increases privacy
  - Does not focus on “feelings”
  - Avoids stigmatizing treatment
  - Can address a wide range of problems:
    - Financial and occupational stressors (e.g., employment), interpersonal conflicts, and role/duty limitations due to physical/cognitive impairments

Image source: KR Bell, 2014
Limitations and Future Directions

- RPSQ contains a wide range of problems, and a total score may have masked improvements in specific areas.
  - E.g., somatic, emotional, and/or cognitive symptoms
- Loss to follow-up was larger in the PST group than the EO group.
  - Could bias results in either direction
- No minimal level of symptomology was required.
  - Could limit generalizability to more distressed groups
- Maintenance of effects was not observed.
  - Uncertain of dose effect
  - Determine appropriate length of treatment
  - Use of booster sessions
Collaborators

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