A smartphone intervention with telemedicine support for management of post-traumatic stress disorder: A randomized trial

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Disclosures

• Consultant:
  - Healthtech
  - Meditech

• Employee:
  - Ontario Shores Centre for Mental Health Sciences
Learning Objectives

• At the end of this presentation participants will:
  - Understand the decision-making process involved in deciding to undertake this study
  - Be familiar with key components of the study protocol
  - Be able to identify challenges, opportunities, lessons learned and early outcomes
Principles in Choosing Target Clinic

• Address access problems
• Efficient use of resources
• Evidence-based treatments
• Opportunity for research
• Minimize clinical risk
• Impact on volumes
Addressing Access

Traumatic Stress Clinic
- Number of patients on waitlist YTD: 247
- Average wait (days): 391

Borderline Personality Skills Clinic
- Number of patients on waitlist YTD: 31
- Average wait (days): 281

Geriatric Outpatients (mood and anxiety disorders)
- Number of patients on waitlist YTD: 208
- Average wait (days): 107

Borderline Personality SR Clinic
- Number of patients on waitlist YTD: 70
- Average wait (days): 114

Mood and Anxiety Disorder Clinic
- Number of patients on waitlist YTD: 59
- Average wait (days): 32

Transitional Age Youth Clinic
- Number of patients on waitlist YTD: 12
- Average wait (days): 19

Women’s Mental Health Clinic
- Number of patients on waitlist YTD: 18
- Average wait (days): 16
Available Apps

• PTSD Coach Canada (free)
• Moodkit ($6.99 USD) for iOS
• MoodGym (free)
• Intellicare Hub (free)
• OCFighter for OCD (over $150- and RCT not completed yet)
• Beating the Blues ($75-)
• FearFighter (cost)
Traumatic Stress Clinic

Strengths

- Free Canadian-specific app available for iOS and Android through PTSD Coach Canada
- App is easy to use and is built on CBT principles
- Preliminary research reported user satisfaction, improved symptom control and better sleep (Kuhn E et al. Preliminary evaluation of PTSD Coach, a smartphone app for post-traumatic stress symptoms. Military Medicine 2014; 179; 12-18.)
- US-based app has research behind it showing utility in both clinician-guided and non-clinician-guided mode (Possemato et al. Using PTSD Coach in primary care with and without clinician support: a pilot randomized controlled trial. General Hospital Psychiatry 2016. 38: 94-89.)
- 60% of users engaged with the app on multiple occasions (Owen JE et al. mHealth in the Wild: Using Novel Data to Examine the Reach, Use, and Impact of PTSD Coach. JMIR Mental Health 2015. 2(1): e7.)

http://www.himss.org/ValueSuite
Traumatic Stress Clinic

• **Strengths**
  • Less diagnostic heterogeneity than other clinics
  • Supported use of the app requires minimal clinician time (4 X 20 minute sessions that can be delivered by telephone or in-person)
    • Opportunity to integrate with brief in-person or OTN visits which could support volumes
Traumatic Stress Clinic

• Weaknesses
  • Has not been studied in non-military populations
  • No ability to integrate app with Meditech
  • Query higher risk population that may have suicidal thoughts triggered by the app
Traumatic Stress Clinic

**Opportunities**

- If Pilot is successful could be used in conjunction with clinic to reduce wait-times and increase volumes
- May provide insights in how to deliver treatment to significantly more individuals affected by PTSD using same number of human resources
- Opportunity to study use of the app outside of Military populations
- Possibility to collaborate with military bases in the future – providing a unique service to the community and a different funding source
- Future grant opportunities
## Oversight

### Virtual Health Steering Committee

<table>
<thead>
<tr>
<th>Purpose</th>
<th>• Oversee the all Virtual Health initiatives at the decision making level</th>
</tr>
</thead>
</table>
| **Responsibilities** | • Review and resolve issues related to strategy, priorities, financial arrangement, and governance  
• Review recommendations presented from Project Leads  
• Ensure effective communications across all disciplines  
• Receive and review executive status reports from each project to monitor progress |
| **Decision-making authorities** | • Support decisions made by each project sponsors  
• All decisions made by the steering Committee are final and will be communicated back to the Project team. |
| **Frequency of involvement / expectation** | • Monthly |
Virtual Health Governance

Virtual Health Steering Committee

Members

Mozzaz
  Lead: Ricardo Thomas

Big White Wall
  Lead: Beth Brannon

Virtual Health
  Lead: Ilan Fischler

Patient Portal
  Lead: Sarah Kipping
PTSD Coach

• A pilot randomized controlled trial of PTSD Coach with a community sample of trauma survivors (N = 49) with PTSD symptoms found that those assigned to use PTSD Coach for 4 weeks (n = 25) saw a significant (p < .05) reduction of PTSD symptoms (PCL M change = 7.8; SD = 16.0) whereas those serving on a waitlist (N = 24) did not (PCL M change = 3.5, SD = 8.8)

• Clinician-Supported (CS) PTSD Coach was shown to be superior to a self-managed PTSD Coach intervention (i.e. app only)
  • 70% of participants in the CS group showed a reduction in symptoms compared to only 38% in the self-managed group
PTSD Coach

• Incorporates evidence-based assessment, psychoeducation and CBT intervention strategies
• The app has four main functions
  • 1) Learn
  • 2) Self-assessment
  • 3) Manage symptoms
  • 4) Find support.
Our Study

- Investigate the effectiveness of CS PTSD Coach at reducing PTSD symptoms while individuals are waiting for treatment at a specialty traumatic stress clinic
- Single-site, two-arm, parallel RCT
- 80 participants (40 per group) will be recruited
- Eligibility Criteria:
  - On the waiting list for the Ontario Shores traumatic stress clinic
  - Score $\geq 31$ on the PCL-5
  - Have access to a smartphone or tablet to which they are willing to download the PTSD Coach Canada app
  - No active suicidal ideation
Our Study

• Intervention consists of four 20-30 minute sessions focused on instructions for app use, setting symptom reductions goals, and assigning specific PTSD Coach activities (i.e., assessments, management strategies, psycho-educational readings) for completion between sessions.
• All sessions completed via Guestlink or OTN.
• Primary outcome:
  - Change in PTSD severity using the PCL-5 scale.
• Secondary outcomes:
  - Clinically Significant Change in PTSD severity (those who have PCL-5 score < 31 at end of study).
  - Change in depression severity (using PHQ-9).
  - App use.
  - Goals.
  - Fidelity.
**Preliminary Results**

**Table 1: Baseline characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>67</td>
<td>34</td>
<td>33</td>
</tr>
<tr>
<td>Age (years)</td>
<td>42.0 (9.2)</td>
<td>42 (10.3)</td>
<td>42 (8.1)</td>
</tr>
<tr>
<td>Multiple diagnoses</td>
<td>48 (72%)</td>
<td>25 (74%)</td>
<td>23 (70%)</td>
</tr>
<tr>
<td>PTSD Onset</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 year</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>1-5 years</td>
<td>25 (37%)</td>
<td>14 (41%)</td>
<td>11 (33%)</td>
</tr>
<tr>
<td>6-9 years</td>
<td>14 (21%)</td>
<td>11 (32%)</td>
<td>3 (9%)</td>
</tr>
<tr>
<td>≥10 years</td>
<td>8 (12%)</td>
<td>3 (9%)</td>
<td>5 (15%)</td>
</tr>
<tr>
<td>No response</td>
<td>20 (30%)</td>
<td>6 (18%)</td>
<td>14 (42%)</td>
</tr>
<tr>
<td>PCL-5</td>
<td>53.9 (10.3)</td>
<td>53.1 (11.0)</td>
<td>54.7 (9.7)</td>
</tr>
<tr>
<td>PHQ-9</td>
<td>19.6 (4.5)</td>
<td>19.9 (4.5)</td>
<td>19.2 (4.5)</td>
</tr>
</tbody>
</table>
## Preliminary Results

<table>
<thead>
<tr>
<th>Visit Complete</th>
<th>Intervention</th>
<th>Control</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>34</td>
<td>33</td>
</tr>
<tr>
<td>Clinic 1</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td>Clinic 2</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Clinic 3</td>
<td>4</td>
<td>N/A</td>
</tr>
<tr>
<td>Clinic 4</td>
<td>6</td>
<td>N/A</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Drop-out</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
## Preliminary Results

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>PCL-5</td>
<td>52.4 (12.8)</td>
<td>48.8 (18.3)</td>
</tr>
<tr>
<td>PHQ-9</td>
<td>21.0 (5.9)</td>
<td>19.1 (6.2)</td>
</tr>
</tbody>
</table>
Early Lessons

• Low study recruitment rate for individuals on waitlist for long periods of time
• Study attrition at numerous handoff points (waitlist call – research assistant call – clinician call)
• Many participants use Guestlink on their smartphone making toggling back and forth between app and Guestlink challenging
Questions?