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Brief Overview

Summary
A pragmatic clinical trial integrating a telehealth group-based mindfulness stress reduction program into primary care settings for persons with chronic low back pain

Study design
- Pragmatic randomized controlled trial
- One year follow-up

Population
- 450 patients with chronic low back pain ≥18 years of age
- Three healthcare systems: Boston Medical Center, UPMC, North Carolina

Comparison
- Intervention group: 225 participate in 8-week Mindfulness Based Stress Reduction program
- Control group: 225 receive usual primary care

Outcomes
- Mindfulness vs Usual Care
  - Baseline, w8, m6, m12
  - Pain Intensity & Pain Interference (PEG, Primary Outcome)
  - Psychological function
  - Physical function
  - Healthcare utilization
  - Pain medication/opioid use
## Current Status

<table>
<thead>
<tr>
<th>Description</th>
<th>All Sites (N/N, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number screened eligible</td>
<td>801/1247, 64%</td>
</tr>
<tr>
<td>Number screened ineligible</td>
<td>443/1247, 36%</td>
</tr>
<tr>
<td>Number consented</td>
<td>452/801, 56%</td>
</tr>
<tr>
<td>Number consented but withdrawn before randomization</td>
<td>31/452, 7%</td>
</tr>
<tr>
<td>Number assigned to cohort</td>
<td>376/421, 89%</td>
</tr>
<tr>
<td>Number completed baseline</td>
<td>379/421, 90%</td>
</tr>
<tr>
<td>Number randomized</td>
<td>366/421, 87%</td>
</tr>
</tbody>
</table>
## Barriers Scorecard

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Level of Difficulty*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enrollment and engagement of patients/subjects</strong></td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td><strong>Engagement of clinicians and health systems</strong></td>
<td>×</td>
</tr>
<tr>
<td><strong>Data collection and merging datasets</strong></td>
<td>×</td>
</tr>
<tr>
<td><strong>Regulatory issues (IRBs and consent)</strong></td>
<td>×</td>
</tr>
<tr>
<td><strong>Stability of control intervention</strong></td>
<td>×</td>
</tr>
<tr>
<td><strong>Implementing/delivering intervention across healthcare organizations</strong></td>
<td>×</td>
</tr>
<tr>
<td><strong>Maintaining integrity of mindfulness program</strong></td>
<td>×</td>
</tr>
</tbody>
</table>

*Your best guess! 1 = little difficulty 5 = extreme difficulty*
Top Challenges

• Keeping up the momentum of recruitment

• Engagement in the intervention

• Preparing for the final phase of the trial
Recent Generalizable Lesson Learned

Stakeholders such as a community advisory board can have a lasting and positive impact on a trial.
Data Sharing Plan

Data available to other investigators under a formal data-sharing agreement that:

(1) Demonstrates commitment to use data for research purposes only

(2) Demonstrates commitment to use appropriate information technology systems to keep data secure

(3) Demonstrates commitment to returning or destroying data after analyses are complete

(4) Outlines the intended use of data with specific variables outlined and analyses described

(5) Demonstrates data will only be shared provided IRB approval is obtained or evidence of IRB exemption is received
What data from OPTIMUM will be shared?

• Group-level data

• Individual-level data with potential exclusions
Current Data Sharing Obstacles

• The process for creating datasets that are understandable to those unfamiliar with the data

• Deciding what data should require permission to use vs data that is freely available
Thank You