Trauma Survivors Outcomes and Support (TSOS): A Policy-Relevant U.S. Trauma Care System Pragmatic Trial for PTSD and Comorbidity

Study Snapshot

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Abstract: Each year, more than 30 million Americans present to trauma centers, emergency departments, and other acute-care settings for treatment of physical injuries. Multiple long-term conditions, including posttraumatic stress disorder (PTSD), alcohol and drug use problems, depression and associated suicidal ideation, pain and somatic symptoms, and preexisting long-term medical conditions are endemic among survivors of physical trauma, including those with and without traumatic brain injuries (TBIs). PTSD and related comorbid conditions are associated with marked functional impairments and societal costs. Evidence-based treatments for PTSD and comorbidity exist but have yet to be broadly implemented throughout U.S. trauma care systems. The challenges presented by this constellation of PTSD and comorbid conditions in survivors of both TBI and non-TBI injuries require novel research approaches that cut across the traditional domains of multiple NIH Institutes.

The TSOS project will enable a series of innovations in the efficient development and implementation of a large-scale, policy-relevant, pragmatic randomized clinical trial targeting PTSD and comorbidity for injured patients cared for at U.S. trauma centers. The trial will be conducted at 24 level 1 trauma care centers across the United States.

TSOS Effectiveness-Implementation Hybrid Pragmatic Trial Framework

- RE-AIM Evaluation Framework
  - Adoption
  - Effectiveness
  - Implementation
  - Maintenance

- Clinical Trial Frameworks & Classic Theory

- Robust Sustainable Implementation Systems

- Policy
  - ACS/COT Context

- Multiple Comorbid Conditions
  - PTSD
  - Depression
  - Suicidal ideation
  - Alcohol use problems
  - Drug use problems
  - Traumatic brain injury
  - Chronic medical conditions

- Critical Intervention Elements
  - Care management
  - Motivational interviewing
  - Cognitive behavioral therapy elements
  - Medications
  - Primary care linkage

- Assessment of trauma center site adopter status
  - 24 sites included
  - Innovators, laggards, other sites excluded

- Diffusion of Innovation

- Stepped Wedge Cluster Randomized Trial
  - Control recruitment begins
  - Intervention left on, promoting sustainable implementation

- Diffusion of Innovation
  - Targets National Trauma Center Adoption

- American College of Surgeons policy summit targeting PTSD and comorbidity guidelines

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- Time
  - 2011
  - 2014
  - 2019

- May ACS/COT Policy Summit
  - ACS/COT PTSD Practice Guideline
  - Protocol Supported ACS/COT Policy Summit
### What We’ve Learned So Far

<table>
<thead>
<tr>
<th>Current Barriers</th>
<th>Level of Difficulty</th>
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</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>X</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty

#### Challenge

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
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<tbody>
<tr>
<td>Capabilities of the EHR systems were varied with no single administrative database</td>
<td>Asked all level 1 and 2 trauma centers to complete a survey regarding EHR capabilities and found that while some sites were able to automate PTSD screening, other sites needed to screen manually. Developed methods to work with all sites regardless of capability and created a 10-domain EHR screen for risk factors for PTSD and other comorbid conditions.</td>
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<tr>
<td>DSMB suggested that the study team ensure every site distributes a suicide hotline number to patients at baseline; however, only 1 of the 24 sites routinely gives a suicide hotline number</td>
<td>The study team did not implement this suggestion because in PCTs, the usual care condition is not malleable, and the goal is to compare the intervention with usual care.</td>
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#### Selected Publications & Presentations

<table>
<thead>
<tr>
<th>Date</th>
<th>Publication</th>
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<tbody>
<tr>
<td>June 2017</td>
<td>The Cumulative Burden of Mental, Substance Use, and General Medical Disorders and Rehospitalization and Mortality After an Injury, Psychiatr Serv, Zatzick et al.</td>
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<tr>
<td>April 2017</td>
<td>PCT Grand Rounds Presentation: Toward National Trauma Care Practice Change for PTSD &amp; Comorbidity: Lessons Learned from the TSOS Pragmatic Trial</td>
</tr>
<tr>
<td>April 2016</td>
<td>An effectiveness-implementation hybrid trial study protocol targeting posttraumatic stress disorder and comorbidity, Implement Sci, Zatzick et al.</td>
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