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A Policy-Relevant US Trauma Care System Pragmatic Trial for Posttraumatic Stress Disorder and Comorbidity (Trauma Survivors Outcomes and Support [TSOS])

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ClinicalTrials.gov Identifier
NCT02655354

Sponsoring Institution
University of Washington School of Medicine

NIH Institute Providing Oversight
- National Institute of Mental Health (NIMH)

DATA AND RESOURCE SHARING

- Data sharing checklist
- **Primary study results:** Zatzick D, Jurkovich G, Heagerty P, et al. Stepped collaborative care targeting posttraumatic stress disorder symptoms and comorbidity for US trauma care systems: a randomized clinical trial. JAMA Surg. 2021;156(5):462-470. doi: 10.1001/jamasurg.2021.0131. PMID: 33688908.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Every year, 2.5 million to 3.0 million people in the United States experience an injury severe enough to require hospitalization. Many patients have symptoms of posttraumatic stress disorder (PTSD) and may have associated comorbid conditions, such as depressive symptoms and alcohol and drug use disorders. Few multicenter studies have evaluated the effectiveness of early interventions for traumatically injured patients with symptoms of PTSD.

DESIGN AND SETTING

Stepped-wedge, cluster randomized clinical trial with 635 hospitalized adult survivors of physical injury at 25 level I trauma centers in the United States between January 2016 and November 2019.

INTERVENTION AND METHODS

After an initial screen of the electronic health record to identify patients with a high likelihood of PTSD distress, followed by a formal screen using the PTSD Checklist (PCL-C), patients with high levels of distress underwent randomization, baseline evaluation, and follow-up interviews at 3, 6, and 12 months. Patients in the control group received usual care plus nurse notification about the patient's high level of distress. Patients in the intervention group received collaborative care consisting of evidence-based medication, cognitive behavioral therapy, and case management. Patients in the intervention group whose PTSD symptoms persisted after initial treatment received stepped-up care, such as medication adjustments or additional psychotherapeutic elements. The primary outcome was PTSD symptoms measured by the PCL-C at 3, 6, and 12 months after the injury. Prespecified subgroup analyses examined effects of baseline risk factors on enduring PTSD symptoms and the relationship between the quality of protocol implementation and study outcomes.

FINDINGS

After 6 months, but not at 3 or 12 months, the intervention group experienced a significant reduction in PTSD symptoms as compared with the control group. The treatment effect was greater for patients with higher baseline PTSD risk and for patients treated at sites with good or excellent protocol implementation. The subgroup of patients who had firearm injuries and who were treated at sites with good or excellent protocol implementation had among the largest 6-month treatment effects and had significant treatment effects at 12 months.

CONCLUSIONS AND RELEVANCE

A stepped collaborative care intervention was associated with significant PTSD symptom reductions at 6 months. Greater baseline risk for PTSD and good or excellent protocol implementation were associated with greater treatment effects.

GENERALIZABLE LESSONS

Challenge	Solution
Multiple site-level factors that influenced intervention quality and treatment outcomes (such as variability in site leadership stability) yet were not captured in baseline structured assessments	The study team developed the Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE) method for capturing pragmatic trial implementation processes. RAPICE allows for secondary analyses that assess associations between site implementation processes and individual-level treatment effects.
Biostatistics and study design issues	Working with the lead statistician and the Biostatistics and Study Design Core Working Group helped to avoid significant barriers.
Lag time between publication of pragmatic trial results and integration of research findings into US trauma care systems	An end-of-study policy summit ensured integration of trial findings into American College of Surgeons Committee on Trauma policy within approximately the 5-year grant cycle.

"A common theme that can come up during the UH3 year (or at other points during a pragmatic trial rollout) is that orchestrating all aspects of the trial can be a bit like trying to take a sip of water out of a leaking fire hydrant." — Doug Zatzick

"At those most trying moments in the rollout of your pragmatic trial (for example in TSOS there was a 4-month regulatory hold on recruitment across all 25 sites during the final stepped-wedge wave), being able to step back and reflect on the idea that, this too shall pass..." — Doug Zatzick

ADDITIONAL RESOURCES

- Article: An Effectiveness-Implementation Hybrid Trial Study Protocol Targeting Posttraumatic Stress Disorder and Comorbidity
- Article: Leveraging a Health Information Exchange to Examine the Accuracy of Self-Report Emergency Department Utilization Data Among Hospitalized Injury Survivors
- Article: A Pragmatic Approach to Psychometric Comparisons Between the DSM-IV and DSM-5 Posttraumatic Stress Disorder (PTSD) Checklists in Acutely Injured Trauma Patients
- Article: Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE) in Pragmatic Clinical Trials of Mental Health Services Implementation: Methods and Applied Case Study
- NIH Pragmatic Trials Collaboratory Steering Committee Meeting Presentation (2020): Trauma Survivors Outcomes & Support (TSOS): Progress, Barriers & Lessons Learned

Access the complete set of TSOS resources.