

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

Study Snapshot

Principal Investigator: Douglas Zatzick, MD

Co-Investigators: Gregory Jurkovich, MD; Patrick Heagerty, PhD; Joan Russo, PhD; Erik Van Eaton, MD; Doyanne Darnell, PhD

Sponsoring Institution: University of Washington School of Medicine

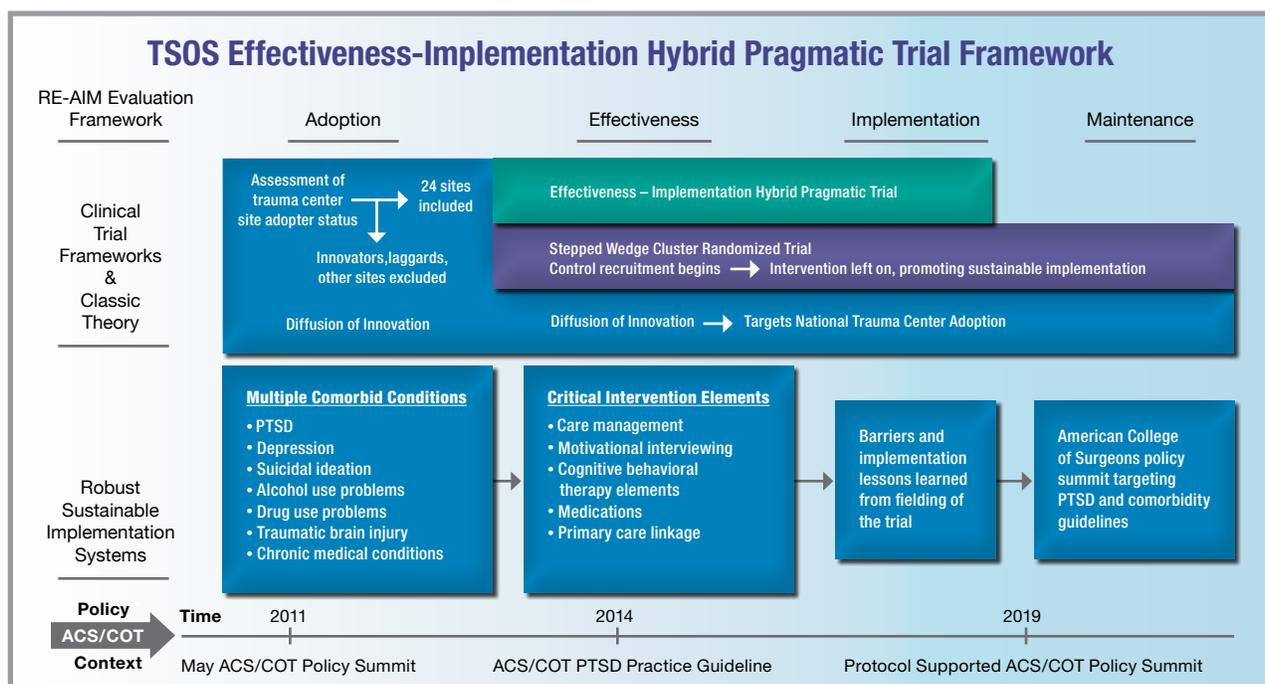
ClinicalTrials.gov: [NCT02655354](https://clinicaltrials.gov/ct2/show/study/NCT02655354)

NIH Institute Oversight: National Institute of Mental Health (NIMH)

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.



What We've Learned So Far

Current Barriers	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/ subjects			X		
Engagement of clinicians and health systems		X			
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)				X	
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations		X			

1 = little difficulty
5 = extreme difficulty

Challenge	Solution
Capabilities of the EHR systems were varied with no single administrative database	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.
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	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.

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

