

# What is the Best Use of the Planning Phase? Lessons Learned from the TSOS Pragmatic Trial

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# TSOS *Trauma Survivors Outcomes and Support*

- Stepped-wedge cluster trial **testing innovative intervention for patients with PTSD and comorbidity**
- 25 US level 1 trauma centers
- 635 physically injured trauma survivors
- Patients recruited with EHR PTSD screen
- Outcome was PTSD symptoms at 3-, 6-, & 12-months post-injury

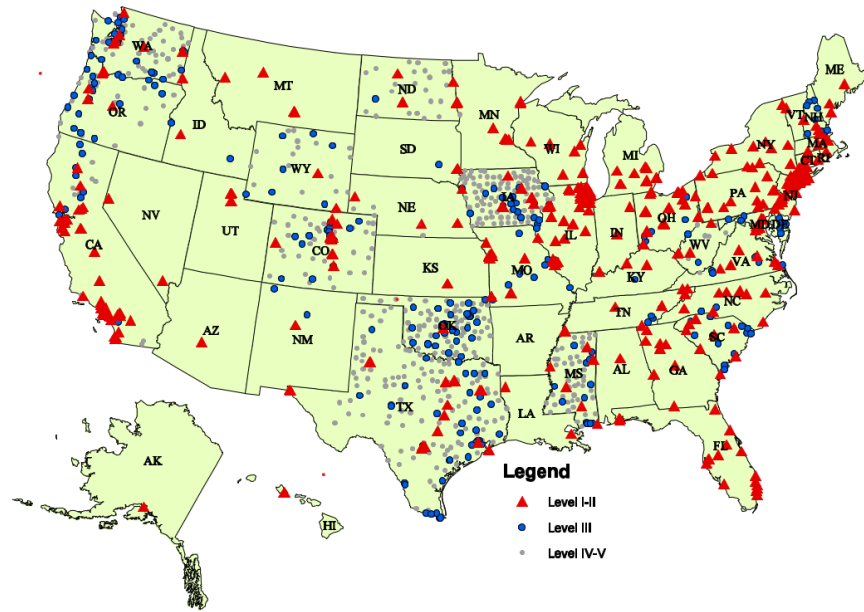


JAMA Surgery | **Original Investigation**

Stepped Collaborative Care Targeting Posttraumatic Stress Disorder Symptoms and Comorbidity for US Trauma Care Systems  
A Randomized Clinical Trial

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# Year 1 Planning Phase: Recruitment of TSOS Sites from the “Population” of US Level I Trauma Centers



# RE-AIM Conceptual Framework Informs TSOS Site Recruitment in Year 1: Early Adopter Centers

Zatzick et al. *Implementation Science* (2016) 11:58  
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Implementation Science

## STUDY PROTOCOL

Open Access

### An effectiveness-implementation hybrid trial study protocol targeting posttraumatic stress disorder and comorbidity



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#### Abstract

**Background:** Each year in the USA, 1.5–2.5 million Americans are so severely injured that they require inpatient hospitalization. Multiple conditions including posttraumatic stress disorder (PTSD), alcohol and drug use problems, depression, and chronic medical conditions are endemic among physical trauma survivors with and without traumatic brain injuries.

**Methods/design:** The trauma survivors outcomes and support (TSOS) effectiveness-implementation hybrid trial is designed to test the delivery of high-quality screening and intervention for PTSD and comorbidities across 24 US level I trauma center sites. The pragmatic trial aims to recruit 960 patients. The TSOS investigation employs a stepped wedge cluster randomized design in which sites are randomized sequentially to initiate the intervention. Patients identified by a 10-domain electronic health record screen as high risk for PTSD are formally assessed with the PTSD Checklist for study entry. Patients randomized to the intervention condition will receive stepped collaborative care, while patients randomized to the control condition will receive enhanced usual care. The intervention training begins with a 1-day on-site workshop in the collaborative care intervention core elements that include care management, medication, cognitive behavioral therapy, and motivational-

**Table 5** Organizational characteristics of TSOS study versus other US level I trauma centers (N = 222)<sup>a</sup>

Characteristic	TSOS TC n = 24 n (%)	Other TCs n = 198 n (%)	P
American College of Surgeons accredited	17 (70.8)	74 (37.4)	0.01
Region of country			0.40
Midwest	7 (29.2)	64 (32.3)	
South/Southeast	4 (16.7)	30 (15.2)	
Northeast/East	5 (20.8)	63 (31.8)	
West	4 (16.7)	28 (14.1)	
Central	4 (16.7)	13 (6.6)	
Rural status	3 (12.5)	24 (12.1)	1.0
Population served			0.03
Adult	7 (29.2)	92 (46.5)	
Adult and pediatrics	17 (70.8)	82 (41.4)	
Pediatrics	0 (0.0)	23 (11.6)	
Missing	0 (0.0)	1 (0.5)	
Teaching hospital	23 (95.8)	162 (81.8)	0.14
Council of teaching hospitals	22 (91.7)	143 (72.2)	0.04
University affiliation	24 (100.0)	189 (95.5)	0.60
Median (IQR)			
Number of interns/residents	327 (282)	224 (297)	0.11
Number of hospital beds	575 (296)	534 (318)	0.40
Number of inpatient admits	26,971 (16,311)	25,699 (14,978)	0.28

TC trauma center, IQR interquartile range

<sup>a</sup>Two of 224 sites were missing organizational data

# TSOS Baseline & Longitudinal Site Heterogeneity: Characteristics Impacting Trauma Centers' Ability to Roll-out the TSOS Protocol

## At Baseline

- Electronic health record/IT capacity
- Research experience
- PTSD intervention experience

## Differential Over Time

- Recruitment rates
- Regulatory lapses
- Leadership turnover
- Intervention quality

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# TSOS Lessons Learned

- Maximize diversity of site characteristics in the planning/piloting phase
- Work to capture as much information as possible across key pragmatic trial domains during piloting
- Hone pragmatic trial formative evaluation approach to continuously deliver essential details of the investigation's roll-out to study leadership team