



Trauma Survivors Outcomes & Support (TSOS): Progress, Barriers & Lessons Learned

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Trauma Survivors Outcomes & Support (TSOS)



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TSOS UH3 Overview

- Barriers scorecard
- Progress toward study completion
- Generalizable lessons learned

Barriers Scorecard: Trauma Survivors Outcomes & Support (TSOS)

Barrier	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

TSOS Study Design

- 25 US trauma centers
- Stepped wedge cluster randomization
- All sites begin recruiting controls
- Intervention “turned on” at each site
- 40 patients per/site goal (960 pts. total)
- Patients provide informed consent
- Baseline PTSD & comorbidity assessment
- 3, 6 and 12 month follow-up interviews

TSOS Progress

- Patient recruitment completed fall 2018
- Baseline data cleaned and analyzed
- 1027 Patients consented/screened
- 635 patients randomized
 - 370 Control
 - 265 Intervention
- Stepped wedge intervention ends spring 2019
- Follow-up ongoing
 - 80% 3 month follow-up
 - ~75% 12 month follow-up

TSOS Next Steps & Timeline

- Summer 2019 complete trauma registry data collection & cleaning
- Fall 2019 complete 12-month follow-up
- Fall & winter 2019-2020 data cleaning and analyses
- June 2020 American College of Surgeons' policy summit
- Summer 2020 primary outcome paper submission
- 2021 data sharing begins

TSOS Lessons Learned

- Helpful to have a pragmatic approach to the monitoring of trial implementation processes
- Retrospectively, site staff and provider turnover was associated with major challenges during the study roll-out
- Going forward, the observation that some patients did not engage in the intervention may inform secondary hypotheses/analyses