A PRAGMATIC STEPPED-WEDGE HYBRID EFFECTIVENESS-IMPLEMENTATION TRIAL EVALUATING ENGAGEMENT AND COLLABORATIVE MANAGEMENT TO PROACTIVELY ADVANCE SEPSIS SURVIVORSHIP (ENCOMPASS)



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BACKGROUND

Sepsis survivors experience high morbidity and mortality, and healthcare systems lack effective strategies to address patient needs after hospital discharge

Atrium Health

The Sepsis Transition and Recovery (STAR) program is a navigator-led, telehealthbased multicomponent strategy to provide proactive care coordination and monitoring of high-risk patients using evidence-driven, post-sepsis care tasks

OBJECTIVES: To evaluate the effectiveness of STAR to improve outcomes for sepsis patients and to examine contextual factors that influence STAR implementation.

METHODS

- Study Overview: Hybrid type I effectivenessimplementation design to test clinical effectiveness & gather implementation data
- Design: Two-arm, pragmatic, stepped-wedge cluster-randomized trial with embedded implementation evaluation (Fig 1, Table 1)
- Setting: Eight hospitals in North Carolina
- Patients: 4032 adults hospitalized with sepsis
- Comparison: Usual care (UC; i.e., routine transition support, outpatient care) vs added STAR program support (Fig 2, Table 2)
- Randomization: Each hospital begins in UC and transitions to STAR in random sequence
- Main Effectiveness Outcome: Composite of mortality and readmission within 90 days

Figure 1: Overview of ENCOMPASS Stepped-Wedge Trial Conducted between July 2020 and June 2023



June 2023			Evaluation of STAR Program Implementation			
7 8	3		CFIR Construct Assessed	Evaluation tool		Timi
		_			Pre	Per
	uation 3	Post-Implementation Evaluation	Outer setting (Patient Needs and resources, Cosmopolitanism, external policies/incentives)	CFIR interviews	х	х
	ion Evalu		Inner Setting (networks/ communication, implementation climate, readiness)	CFIR interviews	х	х
	Implementati		Intervention (evidence strength, relative advantage, adaptability, trialability, complexity)	CFIR Interviews	х	х
			Individuals (knowledge and beliefs about intervention, self-efficacy)	Surveys		х
			Process (execution)	Ethnography		Х
2023		3	Other outcomes will include Reach, Adoption, and Maintenance navigator use per eligible patient, risk predicted events for those			

promptly address issues during transition

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Table 1: Overview of Outcome Measures for

tenance (e.g., or those enrolled, number of providers with patients enrolled), Effectiveness (e.g., 90-day mortality or readmission), and Cost (assessed from health system and societal perspectives)

TRIAL STATUS | NCT04495946

Between July 2020 and April 2021, 1,121 patients have been enrolled (28% of target) Pre-implementation CFIR-guided qualitative assessments identified multi-faceted facilitators and barriers to STAR program implementation, mapped to ERIC strategies to adapt ongoing implementation efforts

IMPLICATIONS

Timing

Peri Post

х х

х х

х х

6

Link to next

care setting

90 days after

hospital discharge

 ENCOMPASS will provide practical information to advance understanding of how to integrate post-sepsis management across care settings and facilitate implementation, dissemination, and sustained utilization of best-practice postsepsis management strategies in other heterogeneous healthcare delivery systems

Table 2: Monitoring Targets Evidence-Based **Post-Sepsis Care Recommendations**

Identification and treatment referral for new functional or cognitive deficits

Review for adjustment of medications

Surveillance for treatable conditions that may lead to poor outcomes

Referral to palliative care when appropriate

ACKNOWLEDGEMENTS

This project is supported by National Institute of Nursing Research of the National Institutes of Health under award number R01NR018434



Figure 2: Patient Trajectory Through the STAR Program

