Form "EAST Multicenter Study Proposal"
Details #2 (submitted 01/31/2023)

Please indicate if this is a...	New MCT proposal submission
If a revised proposal summarize the changes made to this proposal based on the feedback received:	
Study Title	Mental Health Screening and Referral: Evaluating Trauma Centers Protocols and Patient Outcomes
Primary Investigator:	Mary Elizabeth Schroeder
Institution that will be the primary site for the study:	Medical College of Wisconsin
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Are you a current member of EAST?	Yes
If you selected "No" above please identify a Sponsor that is an active EAST member:	
Use this area to briefly outline the burden of the problem to be examined.	Following injury, 10-42% of individuals develop posttraumatic stress disorder (PTSD), which can cooccur with major depression, anxiety, substance use and poor quality of life. In 2022, the American College of Surgeons (ACS) published the “2022 Standards for Resources for Optimal Care for the Injured Patient.” Standard 5.29 now requires Level I and II trauma centers to have a protocol for mental health screening and appropriate referral for psychopathology following trauma. However, while a handful of studies have examined percentages of trauma centers screening and providing intervention, no study has thoroughly reviewed the types of screening and interventions that are provided at trauma centers and how this may impact mental health outcomes. This is a significant gap as more than 80% of trauma centers express desire for guidance on how to implement screening and intervention services (Bulger et al. 2022), underscoring the need to provide evidence-based recommendations for trauma centers.

Briefly review what major published studies exist on the topic of the proposed project.

While literature exists describing prevalence rates of psychopathology or mental health sequalae following injury (e.g., Visser, et al., 2017; Zatzick, et al., 2008) as well as the screening and intervention practices for substance use (Kodadek, et al., 2020), minimal research describes the mental health screening and referral processes for specific trauma centers. For example, deRoon Cassini and colleagues (2019) provide a review of practices in screening, including automated screens and screening measures, as well as integrated mental health treatment. Their review provides five examples of mental health programs including personnel and funding, though this review did not provide outcome data. Similarly, Bulger and colleagues (2022) expanded understanding by conducting a national survey of centers assessing use of screening for mental health, substance use, and violence prevention. Notably, only 28% of responding centers endorsed screening for PTSD, with a majority of those sites then providing community referrals (76%). Currently, there is a gap in the literature exploring both screening and referral protocols as a continuum, and further, how these programs relate to outcomes for patients.

Use this area to briefly outline how this idea is innovative and it's anticipated impact.

This proposed prospective longitudinal study will assess trauma centers' current practices in screening and intervention to provide a better understanding of how Level I and II trauma centers are meeting the new requirement. Further, this study will evaluate differences in patient outcomes based on current screening and intervention practices, a study idea which has never been conducted in the literature. By assessing patient outcomes, we can develop evidence-based recommendations which will have significant impact for trauma centers that need to develop practices.

Describe what & how the proposed MCT will add to the existing body of knowledge & literature.

This MCT will impact the existing body of knowledge in two ways. First, this study will inform how trauma centers implement mental health screening and intervention programming by assessing the current state of trauma center practices. Developing evidence-based recommendations of screening and intervention is vital to the literature as centers begin to implement these new ACS guidelines. To better understand current practice, the first aim will assess the current screening and referral protocols of Level I and II trauma centers. This will include understanding what tools and services are utilized in combination, allowing us to categorize the level of mental health integration at each center. The current literature has descriptively presented national rates of mental health screening and intervention (e.g., Bulger et al., 2022). This has looked at use of automated screening and measures, as well as staff involved in services. However, to date, there is a paucity of research on mental health services at centers and patient outcomes including psychopathology, follow up care, and quality of life. The MCT will include centers with varying levels and models of mental health integration, allowing for assessment of patient outcomes based on types of programming and services provided as well as characteristics of trauma centers (e.g., level, mechanisms). For example, PI Schroeder has found that almost all patients with a penetrating mechanism of injury screen positive with automated screening tools, informing screening practice for trauma centers with high levels of penetrating injuries (Submitted to AAST). Extending this work, the proposed study can provide more specific and actionable recommendations for centers regarding both screening and intervention for centers based on their needs. Second, since trauma centers are implementing the ACS guidelines in different ways, this study will provide information on the differential impact of different practice models on mental health outcomes of trauma patients. We aim to use the current study as an initial evaluation of patient outcomes six months after trauma in order to assess if use of standardized screening protocols can improve access to care and subsequently improved mental health. Furthermore, given the scoping variability of intervention that may occur at trauma centers from referral to community resources to provision of inpatient mental health services, Aim 2 will also assess if greater mental health integration will lead to reduced psychopathology and improved quality of life 6 months after trauma. Examining an array of outcomes, including both psychopathology and quality of life, will determine the impact of screening and intervention practices.

Primary aim

Primary Aim 1: Create a descriptive assessment of current models of mental health screening and intervention at Level I and II trauma centers, that goes beyond simply prevalence rates of screening practices.

Primary Aim 2: Evaluate patient mental health and hospital outcomes based on trauma center's mental health screening and intervention protocols.

Secondary aims

Assess implementation rates of screening and referral protocols. Evaluate differences in hospital-based outcomes based on trauma center's mental health screening and intervention protocols.

Tertiary aim

Design

Prospective (observational with or without consent requirement)

Inclusion Criteria

Primary Aim 1 Inclusion Criteria: (1) Level I and II trauma centers.

Primary Aim 2 Inclusion Criteria: (1) Adults admitted to trauma center for traumatic injury

Exclusion Criteria

Primary Aim 1 Exclusion Criteria: Exclusion Criteria: (1) Level III and IV trauma centers given ACS guidelines requiring protocols for Level I and II centers.

Primary Aim 2 Exclusion Criteria: (1) younger than 18 years; (2) a moderate to severe traumatic brain injury (via chart diagnosis or imaging results, Glasgow Coma Scale score of 30 minutes of loss of consciousness, or >24 hours of posttraumatic amnesia); (3) self-inflicted injury; (4) inability to communicate; and (5) non-English speaking

Please describe, completely but succinctly, how the project will be conducted.

Primary Aim 1 Procedure

To complete Aim 1, centers that agree to participate will be sent survey measures regarding center and population characteristics as well as screening and referral protocols. Surveys will be completed via an email link which will be sent to division of trauma chiefs, trauma medical directors, or trauma program managers. Screening practices will be categorized as none, use of the automated screening tool, use of screeners such as the Injured Trauma Survivor Screen, or other screening practices unique to the center. Mental health referral practices will be categorized as integrated trauma psychology/mental health services, utilization of inpatient psychiatry or psychology (outside of trauma program), referral to outpatient services or other. The aim will allow for understanding of implementation rates such as percent of patients screened as well as utilization of mental health services during the initial hospitalization.

Primary Aim 2 Procedure

For the Aim 2, research personnel at each trauma center will review the census daily to determine potential eligible participants who can be approached for recruitment. Participants will be approached during admission to determine interest in participation. To facilitate recruitment, consent will be completed in hospital. After consent, participants will be sent an email/text link to complete brief baseline questionnaires during their hospital admission. Six months following their admission, participants will be called or sent email/text links to complete questionnaires either via phone or online. Participants will receive compensation for their time. Additionally, following consent medical charts will be reviewed by research personnel to collect descriptive and hospital data regarding admission (e.g., injury severity score, mechanism of injury, length of stay).

Primary Outcome

Primary Aim 1:

Screening protocol: Likert questionnaire including description of protocol, personnel and FTE

Referral protocol: Likert questionnaire including description of protocol, personnel and FTE

Primary Aim 2:

PTSD: Posttraumatic Stress Disorder Checklist for DSM-V

Quality of Life: Short Form-12

Access to treatment: Likert questionnaire evaluating receipt of referral and engagement in mental health treatment

Primary Aim 1:

Rates of screening and referral, likert questionnaires additional program demographics (e.g., funding)

Primary Aim 2:

Secondary Outcome(s)

Depression: Depression, Anxiety, Stress Scale (DASS-21)

Anxiety: DASS-21

Hospital outcomes: ED utilization, no show rates for follow up

Select the variables to be collected & analyzed:

Baseline Participating Institution Information,Demographics,Baseline Clinical Characteristics,Hospital Course,Treatments & Interventions,Outcomes of Interest

Additional variables:

We propose to test our aims through a prospective, longitudinal study. For Aim 1, trauma centers which elect to participate in the study will provide descriptive data via an email link to a RedCap survey regarding their current practices in mental health screening and intervention including screening tools, percent of screening administration, staffing, intervention tools used, referral resources.

Outline the data collection plan/tool succinctly

For Aim 2, we will enroll participants following admission to the trauma service. Our average time of recruitment will be approximately 3 days after injury (based on previous data from primary institution; e.g., Hunt, et al., 2021; deRoon-Cassini, et al., 2022). During baseline assessment and data collection, we will administer via email or text link RedCap survey measures of psychopathology and demographic questionnaires. At 6 month follow up, we will repeat baseline measures as well as measures assessing quality of life, psychosocial factors and engagement in healthcare. Medical records will be reviewed after each time point to obtain data related to attendance of appointments, healthcare utilization, complications, and treatment.

Has IRB approval been obtained at the primary site?

No

Is DUA required for participation in the study?

No

If applicable, list the primary contact (name/email) to contact to initiate & execute DUA:

Identify the individuals that will primarily be responsible for data collection process:

Individuals responsible for initial recruitment will be dependent on each participating trauma center, though these can be completed by any trained research personnel. Following recruitment and consent, as data collection will occur through online surveys, the primary institution will utilize a team of one research fellow and 1-3 research assistants to engage in data collection. Similarly, the primary institution's research team will organize hospital data from each institution. The PI and Co-PI will supervise recruitment and provide support as needed.

Is there a primary statistician assigned to assist the PI w/design & data analysis?

Yes

If no, how was study design/power analysis determined/who will handle analysis once complete?

Include detailed description of the data analysis plan:

To conduct Aim 1, descriptive analyses will demonstrate the differences in implemented models of screening and follow up at trauma centers. Trauma center data including MOI rates, volume, patient demographics and level of designation will be presented.

To conduct Aim 2, analysis of variance will be conducted to determine if differences in programming leads to differential outcomes at 6 months. Levels of programming was determined by variability in models of care, it is anticipated that there will be 4 types of models: 1) centers with no protocols for screening or intervention, 2) centers with screening and community referral, 3) centers with screening and outpatient referral, 4) centers with screening and inpatient referral. Analyses will evaluate differences specifically on PTSD, quality of life, depression, anxiety and stress while also controlling for hospital factors such as level of center, high rates of penetrating trauma. To assess secondary and tertiary aims, ANOVAs will also examine if there are significant differences in hospital outcomes, including rates of screening/referral practices, ED utilization, and follow up rates.

Include Power Analysis:

Power analysis using G*Power was conducted for Aim 2's analysis of covariance to determine potential sample size. Using an effect size of .25, with a power of .9, and alpha value of .05, it was determined that a sample of 338 participants across all sites would be needed if there were 4 groups of distinct protocols (1) centers with no protocols for screening or intervention, 2) centers with screening and community referral, 3) centers with screening and outpatient referral, 4) centers with screening and inpatient referral). This also includes controlling for trauma center level and high or low penetrating trauma.

Please note what your enrollment procedure for this study entails:

The primary site has extensive background in conducting prospective, longitudinal research with the patient population. Further, the site has led a AAST sponsored multi-institutional trial to validate the Injured Trauma Survivor Screen (Hunt, et al., 2021). Potential participants admitted to the trauma service will be screened via medical record to determine eligibility. Potentially eligible participants will be approached primarily while in the hospital or called post-discharge if unable to approach while inpatient. If participants are interested in the study, informed consent will be obtained and a text or email will be sent containing the baseline survey link.

Outline consent procedures here, if applicable:

If patients express interest in participation, trained research personnel will review the informed consent form with the participant highlighting confidentiality, risks/benefits and voluntary participation. Given level of information gathered and longitudinal aspects of study, written consent will be obtained.

Please indicate what resources are available at the primary study institution:

Presence of a dedicated statistician,Research personnel ,Availability of data collectors

Include a brief listing of key references:

1.deRoon-Cassini TA, Bergner CL, Chesney SA, Schumann NR, Lee TS, Brasel KJ, Hillard CJ. Circulating endocannabinoids and genetic polymorphisms as predictors of posttraumatic stress disorder symptom severity: heterogeneity in a community-based cohort. Translational Psychiatry. 2022 Feb 1;12(1):48.

2.deRoon-Cassini TA, Hunt JC, Geier TJ, et al. Screening and treating hospitalized trauma survivors for posttraumatic stress disorder and depression. J Trauma Acute Care Surg. 2019;87:440–450.

3.Hunt JC, Herrera-Hernandez E, Brandolino A, Jazinski-Chambers K, Maher K, Jackson B, Smith RN, Lape D, Cook M, Bergner C, Schramm AT. Validation of the injured trauma survivor screen: an American association for the surgery of trauma multi-institutional trial. Journal of Trauma and Acute Care Surgery. 2021 May 1;90(5):797-806.

4.Kodadek LM, Freeman JJ, Tiwary D, et al. Alcohol-related trauma reinjury prevention with hospital-based screening in adult populations: An Eastern Association for the Surgery of Trauma evidence-based systematic review. J Trauma Acute Care Surg. 2020;88:106–112.

5.Visser E, Gosens T, Den Oudsten BL, et al. The course, prediction, and treatment of acute and posttraumatic stress in trauma patients: A systematic review. J Trauma Acute Care Surg. 2017;82:1158–1183.

6.Zatzick D, Jurkovich GJ, Rivara FP, et al. A national US study of posttraumatic stress disorder, depression, and work and functional outcomes after hospitalization for traumatic injury. Ann Surg. 2008;248:429–437.