TITLE: A Comparative Effectiveness Trial of Optimal Patient-centered Care for U.S. Trauma Care Systems

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Table of Contents

ABSTRACT

1. Background: Currently, high-quality patient-centered care is not the standard of care throughout U.S. trauma care systems. Injured trauma survivors treated in trauma care systems frequently receive fragmented care that is not coordinated across hospital, emergency department (ED), outpatient, and community settings. Postinjury care is frequently not individualized to integrate the patient's most pressing posttraumatic concerns and preferences into medical decision making.

2. Objective: The aim of this randomized comparative effectiveness trial was to compare 2 approaches to the delivery of patient-centered care for hospitalized injured trauma survivors: a novel patient-centered care transition service delivery model versus enhanced usual care that included notifications to nurses of trauma survivors' postinjury concerns.

3. Methods: The care transition intervention included a master's-level social worker who first elicited and then addressed each injured trauma survivor's posttraumatic concerns; whenever possible, the social worker attempted to integrate the trauma survivor's concerns and preferences into medical decision making, and problem solve with the patient. The intervention team provided 24 -hour cell phone contact, 7 days a week, that included text messaging services aimed to enhance care coordination and reduce emergency department visits. The primary outcome examined was the severity and domain of patient-identified postinjury concerns. Other primary outcomes examined included posttraumatic stress disorder and depressive symptom severity. Secondary outcomes examined included physical function, automated statewide health service use, satisfaction with the physical and emotional aspects of care, and injury risk behaviors. Regression analyses assessed intervention and control group outcome differences over time.

4. Results: Of the 171 patients, motor vehicle, pedestrian, or bicycle-related crashes represented approximately 50% of the injuries. Other events (e.g., falls, work injuries) represented approximately 36% of injuries. More than 80% patient follow-up was attained at

each time point. Concerns elicited from patients spanned physical health, work/finance, social, psychological, medical, and legal domains. Intervention patients demonstrated clinically and statistically significant reductions in the percentage of any severe postinjury concerns when compared with controls longitudinally (Wald chi-square = 11.29; P = 0.01) and at the 6-month study time point (Control [C] = 74%, Intervention [I] = 53%; Fisher exact test, P = 0.02). Comparisons of emergency department use data yielded clinically significant differences at the 6-month time point (1 or more 3- to 6-month ED visits; C = 30.2%, I = 16.5%; relative risk [95% confidence interval or CI] C versus I = 2.00 [1.09, 3.70], P = 0.03) that did not achieve significant differences over time when compared with baseline (F3,507 = 2.24, P = 0.08). The intervention did not significantly affect other symptomatic, risk behavior, or functional outcomes.

5. Conclusions: The investigation found that patients who received the intervention had a clinically and statistically significant reduction in the percentage of any severe postinjury concerns expressed over the course of the 6 months after injury hospitalization. Clinically important ED health service use reductions were observed, but the intervention did not affect other symptomatic or functional outcomes. These initial findings are provocative and could lead to further investigation to develop a body of knowledge that would inform sustainable American College of Surgeons' clinical guideline requirements for U.S. trauma care systems.

6. Limitations and subpopulation considerations: Because this was a multifaceted intervention, the investigation did not yield information about which components of the treatment were effective in targeting specific outcomes. No analyses were conducted to examine lasting intervention effects. The investigation did not find substantial age, ethnoracial, or traumatic brain injury group differences in treatment outcomes.

BACKGROUND

Each year in the U.S., more than 30 million individuals present to acute care medical trauma centers and emergency departments (EDs) for the treatment of traumatic physical injury.[1-6] Annually, 1.5 through 2.5 million Americans are so severely injured that they require inpatient

hospitalization.[1-5] Injured trauma survivors present to acute care medical settings after both intentional (e.g., gunshots, stabbings, physical assaults) and unintentional (e.g., natural disasters, motor vehicle crashes) injury events.[7] Estimates suggest that approximately 1.5 million American youths and adults experience traumatic brain injury (TBI) annually, although many of these patients may not require injury admissions.[8,9] Physical injury with and without TBI constitutes a major public health problem for both civilian and veteran trauma- exposed patient populations.[10,11] Traumatic injury is a leading cause of death for individuals younger than age 45 and accounts for 12% of medical expenditures in the United States.[1-3,5] In a nationwide U.S. study, more than 40% of injured trauma survivors reported they were unable to return to work 12 months after their hospital admission.[12] Globally, traumatic injury is estimated to account for approximately 9% of the world's burden of disease.[13-15]

In 2001, an Institute of Medicine report, Crossing the Quality Chasm, identified patient-centered care as 1 of the 6 specific components of high -quality care.[16] Increasingly, the adoption of a patient-centered model of health care delivery is being advanced as a critical goal of clinical medicine.[17,18] At the core of a patient-centered approach is the belief that patients' perspectives can be understood and ultimately integrated into medical decision making and comparative effectiveness research.[19-22]

A key element of trauma-focused patient-centered care is the empathic identification of each patient's individual needs, concerns, and values.[20,21] Another key element particularly relevant to the acute care medical context is the coordination of care transitions across inpatient, outpatient, and community service delivery settings.[16] Postinjury, the provision of a continuous helping relationship may help reduce care fragmentation and optimize acute care transitions.[20,21] Other elements of high-quality postinjury patient-centered care can include the incorporation of patient caregivers into care where appropriate and the integration of peer support interventions.[16,17,22]

Currently, the standard of care throughout U.S. trauma care systems does not incorporate high-quality patient-centeredness in practice.[21,23] Upon discharge from an acute trauma care setting, injured trauma survivors frequently experience disjointed and ineffective care as they transition into outpatient and community settings. Postinjury care often prioritizes

a medical practitioner's knowledge in medical decision making to the detriment of the patient's most pressing posttraumatic concerns and preferences.

Prior investigation has demonstrated the reliability and validity of patient-centered posttraumatic concern assessments.[20,21] These investigations have shown that the longitudinal trajectories of posttraumatic concerns mirror the trajectories of postinjury posttraumatic stress disorder symptoms and functional limitations.[20,21] Prior investigations have also established that greater concern severity and burden are risk factors for the longitudinal development of high levels of posttraumatic stress disorder symptoms over the course of the year after injury.[20,21]Commentary has encouraged increased incorporation of patients' perspectives, including addressing needs and concerns, into comparative effectiveness trials.[17,22] A key methodological approach in comparative effectiveness research is the development and implementation of pragmatic randomized clinical trials that are conducted in real-world practice settings, include representative patient populations, and target a broad spectrum of outcomes relevant to patients, providers, and policymakers.[24]

Several papers have suggested that research with trauma victims requires an increased attention to ethical considerations beyond the standard guidelines for conducting research with human participants.[25-29] Acutely injured patients often surrender control over emergency care decisions and frequently undergo treatment procedures about which they may have minimal awareness or understanding. Traumatically injured patients may, therefore, come to passively accept loss of autonomy as an unavoidable circumstance of their hospitalization. Also, the traumatic injury and subsequent medical procedures induce psychological distress, which could be exacerbated by research participation. An accumulating body of literature suggests that adequate protection against these risks can be enhanced by appropriate investigative methods in trauma-exposed populations.[25-29]

Care management treatment models are in place across U.S. health service delivery sectors and could incorporate enhancements to patient-centered care derived from comparative effectiveness trials.[30] Care management treatment models can target multiple aspects of patient-centered care delivery, including tailoring treatments to each patient's concerns and preferences and enhancing care coordination. In particular, by coordinating care

across inpatient acute care and emergency, outpatient surgical subspecialty, primary care, and community service delivery sectors, care management treatment models could reduce postinjury care fragmentation.[30,31] Few comparative effectiveness trials have assessed the delivery of high-quality patient-centered care for injured trauma survivors transitioning from inpatient trauma center settings to outpatient care and community rehabilitation.[21,32]

Additionally, relatively few investigations have made the needs and concerns of patients a central element of comparative effectiveness trial design by comprehensively incorporating patient-centered methods into screenings, treatment targets, and outcome assessments. In one of the few such randomized clinical trials, investigators randomized patients in a general medical practice to a standardized patient-centered need and concern elicitation intervention versus a care-as-usual comparator condition.[32]

At the time it was envisioned, the proposed comparative effectiveness model was novel in that, rather than targeting for improvement a specific physical or mental health disease entity, the investigation focused on eliciting and improving patients' posttraumatic concerns as well as the integration of each patient's unique constellation of needs and concerns into medical decision making. The project focused on the development and implementation of patient-centered care transitions, care management, and outcome evaluation among injured trauma survivors treated in acute care medical settings. The approach developed in the application could facilitate a more central role for patient perspectives in the design and implementation of comparative effectiveness research; ultimately, the findings have excellent potential to be leveraged across disease states and service delivery contexts.

Injured trauma survivors and their family members, frontline trauma center providers, and U.S. trauma care system policymakers need to better understand how a patient-centered care transition intervention can affect these key outcomes. A multidisciplinary team that includes patients, clinical investigators, frontline trauma center providers, and national trauma surgery policymakers implemented and evaluated the intervention.

This investigation was a comparative effectiveness trial designed to evaluate posttraumatic concerns, psychological symptoms, physical function, health service use, satisfaction with care, and injury risk behaviors in patients randomized to receive a patient-

centered care transition intervention versus enhanced usual postinjury care. The study hypothesized that patients who received the novel care transition intervention would demonstrate significant improvements in a broad spectrum of patient-centered outcomes, including reductions in the number and severity of individual patients' posttraumatic concerns, reductions in posttraumatic stress and depressive symptoms, improved physical function, more efficient patterns of health service use, enhanced satisfaction with care, and reductions in injury risk behaviors.

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS IN THE DESIGN AND CONDUCT OF RESEARCH AND DISSEMINATION OF FINDINGS[33]

The study multidisciplinary stakeholder team included clinical investigators (N = 5), patients (N = 6), patient advocates (N = 2), frontline trauma center providers (N = 5), and trauma center policymakers (N = 4). More than a decade before the initiation of the study, members of the study team began to ask representative samples of injured trauma survivors to voice their most pressing postinjury concerns and needs.[20,21] Four years before the initiation of the study, the clinical investigator, patient, patient advocate, frontline trauma center provider, and trauma center policymaker study team members collaborated to develop national trauma center guidelines for patient-centered and psychosocial care. In May 2011, the multi-stakeholder study team organized an American College of Surgeons' policy summit that focused on mental health and patient-centered care for U.S. trauma care systems. As part of this policy summit, patient members of the team presented in their own words their experiences of traumatic injury and recovery. While giving injured trauma survivors a "voice" at the summit, these narratives did not move surgical policymakers to develop requirements or clinical guidelines for patient-centered care. In contrast, at the May 2011 summit, presentations that included information from randomized comparative effectiveness trials and standardized outcome assessments convinced surgical policymakers to develop U.S. trauma care system policy mandates and best practice guidelines for managing related posttraumatic stress disorder (PTSD) and alcohol use problems. The stakeholder team realized that, to optimally integrate patient-centered care into U.S. trauma care systems, they would need to use the best scientific methods that capture the highest-quality data; the now completed PCORI proposal is

the product of the multidisciplinary stakeholder team's effort.[34]

The composition of the study team (e.g., the patient and peer advocacy stakeholder group) changed over the course of the 3-year protocol. One senior patient co-investigator and 1 senior peer advocate co-investigator had substantial input into all phases of the PCORI project. At the beginning of the project, these 2 stakeholders gave input on the study design and reviewed study instruments and protocols. Over the course of the study, regular telephone conferences (e.g., monthly) between these stakeholders and the principal investigator provided opportunities for ongoing input in the study implementation. These 2 stakeholder coinvestigators encouraged the investigation to incorporate a friend and family intervention component, as well as to develop the peer pilot intervention.

For the peer pilot intervention, an additional injured peer was recruited to become the lead interventionist. This project member was a physical injury survivor who was trained by MD/PhD members of the study team to take the lead in the peer interventionist role. Over the course of the pilot study, the peer interventionist intervened with 4 peer pilot intervention cases and presented her experience of the pilot at the end-of-study policy summit. Three additional patient and peer advocate stakeholders participated in the end-of-study summit development and implementation. Thus, a diverse group of stakeholders contributed to the planning, implementation, and policy summit phases of the study protocol.

The study team, which included the clinical investigators, frontline trauma center providers, patient and peer advocate stakeholders, and national trauma center policymakers, as well as PCORI program staff, planned and successfully conducted a Patient-Centered Care Policy Summit with the American College of Surgeons Committee on Trauma; the summit was held on September 23, 2016, at the American College of Surgeons Policy offices.35 The study team orchestrated the review of 2 other comparative effectiveness trials at the policy summit (1 PCORI-sponsored trial and 1 Department of Defense–sponsored trial).36,37 The American College of Surgeons is currently considering clinical care recommendations for the incorporation of patient-centered care within U.S. trauma care systems. The patient stakeholders and peer advocates voiced the importance of patient engagement in care within U.S. trauma systems. The patients and peer advocates also voiced the importance of future

investigations that assessed the impact of including injured peer interventionists as part of multidisciplinary trauma center teams.

METHODS

Study Design

The investigation—a randomized comparative effectiveness trial—evaluated 2 readily implementable approaches to the delivery of patient-centered care for injured trauma survivors treated acutely in hospitals and emergency departments. The 2 compared approaches—a novel patient-centered care transition service delivery model versus nurse notification of patient concerns and emotional distress that constituted a modest enhancement to usual care—were selected in part because they can be feasibly implemented in the acute care medical context. The care transition intervention included a master's-level social worker who first elicited and then addressed each injured trauma survivor's unique constellation of posttraumatic concerns; whenever possible, the social worker attempted to integrate patient concerns and preferences into medical decision making. The study incorporated automated electronic health record (EHR) screening for high levels of emotional distress as well as computerized decision support and caseload supervision. The intervention team also provided patients with the opportunity for 24-hour, 7-days-per-week cell phone contact that included text messaging. This intervention element aimed to enhance care coordination across acute care inpatient and surgical subspecialty and primary care outpatient service delivery sectors, as well as reduce unnecessary emergency department use. Patients' posttraumatic stress and depressive symptoms,[38,39] functional impairment,40 and satisfaction with care[30,41,42] were assessed at baseline in the surgical ward and again 1, 3, and 6 months after the injury. Patients' health service use was assessed over the course of the 12 months after injury.[43]

Forming the Study Cohort

Patients included in the study were female and male survivors of intentional and unintentional injuries, aged ≥ 14, who were admitted to the University of Washington's Harborview level I trauma center (Harborview) inpatient surgical ward or emergency department for ≥ 24 hours. A

previously developed electronic health record screen was used to assess the population of admitted injured trauma survivors at risk of developing high levels of emotional distress.44 The screen used 10 data elements that are both associated with increased risk for PTSD and readily available in any robust electronic health record.

Consenting patients who scored ≥ 3 on the EHR screen were subsequently evaluated for study participation. Patients included in the study were required to have ≥ 3 posttraumatic concerns at the time of their baseline interview as well as substantial postinjury emotional distress as manifested by a score of ≥ 35 on the PTSD Checklist, a score of ≥ 10 on the 9-item Patient Health Questionnaire (PHQ-9), or a score of ≥ 1 on the PHQ-9 item 9 suicide assessment.[38]

Patients were excluded only if they required immediate psychiatric intervention (i.e., self-inflicted injury, active psychosis), were not Washington State residents, or were currently incarcerated; non-English-speaking patients were also excluded from the protocol. The University of Washington Institutional Review Board approved all study procedures prior to protocol initiation and each participant provided written informed consent. For adolescent participants, parental consent was obtained before adolescent assent. Study recruitment occurred over an 18-month period, from March 2014 through September 2015.

When patients declined to participate, the recruiter asked the patient why they did not want to participate. The answers were recorded verbatim and then categorized into 1 of 5 refusal reasons/categories: inconvenience, privacy concerns, not interested, undo distress, and refusal without giving a reason. Randomization occurred in a 1:1 ratio according to random assignments of blocks of 4 or 6 patients that were computer-generated by the investigation's biostatistician. Team members conducted randomization. The research assistants who conducted all baseline assessments and follow-up interviews were blinded to block sizes and intervention or control group status.

Study Setting

Harborview is the major level I trauma center for the Pacific Northwest; Harborview admits

patients from throughout the WWAMI (Washington, Wyoming, Alaska, Montana, and Idaho region). Harborview has a large annual admission volume (approximately 6000-7000 injured trauma survivors annually); otherwise, its organizational characteristics are similar to other U.S. academic level I trauma centers.24 These features made Harborview an ideal setting for developing and implementing the comparative effectiveness trial.

Table 1. Protocol Elements Received by Patients in the Patient-centered Care Transition Intervention Versus Enhanced Usual Care Control Study Arms

Patient-centered Care Transition Service Intervention	Enhanced Usual Care Control
Research assistant (RA) elicitation of postinjury concerns in baseline interview	RA elicitation of postinjury concerns in baseline interview
RA notifies nurse of patient's postinjury concerns and levels of psychological distress	RA notifies nurse of patient's postinjury concerns and levels of psychological distress
Randomization with allocation concealment	Randomization with allocation concealment
Masters of Social Work (MSW) interventionist reviews baseline interview concerns and reapproaches patient to further elicit and begin to address postinjury concerns	Not received
MSW coordinates care from trauma center to primary care and community	Not received
MSW orchestrates stepped-up care for persistent symptoms	Not received
RA conducts blinded follow-up telephone assessment of postinjury concerns and symptomatic and functional outcomes	RA conducts blinded follow-up telephone assessment of postinjury concerns and symptomatic and functional outcomes

Interventions

Table 1 outlines the recruitment, intervention, and follow-up elements of both conditions. The research assistants performed the baseline recruitment and concern elicitation for both intervention and control conditions. Similarly, research assistants blinded to the conditions performed the 1-, 3-, and 6-month concern assessments.

The research assistants received comprehensive training that included shadowing the principal investigator during routine Harborview consultation liaison clinical encounters. They also shadowed the principal investigator and coinvestigators for training on approaching injured patients on the ward to obtain informed consent and conduct interviews. Research

assistants also were trained to deliver the 1-, 3-, and 6-month follow-up interviews; these trainings included practice in the elicitation of the posttraumatic concern items. Finally, drift assessments and recalibration retraining were periodically performed for the research assistants who conducted baseline and follow-up interviews.

The investigation compared 2 approaches for delivering patient-centered care to hospitalized injured trauma survivors with high levels of posttraumatic emotional distress: a novel patient-centered care transition service delivery model versus enhanced usual care that consisted of nurse notification of patients' postinjury concerns. The 2 approaches were selected in part because they can be feasibly implemented in the acute care medical context. Below, the 2 approaches are described in detail.

Patient-Centered Care Transition Service Delivery Condition

Care management treatment strategies have been flexibly used to target medical/surgical and psychiatric disorders in medical settings.[42,45,46] The study team had previously developed care management approaches in comparative effectiveness trials that targeted postinjury mental health conditions and associated improvement in functional outcomes.[30,31]

The care management intervention element of this trial specifically targeted each patient's unique constellation of postinjury concerns. Care management procedures were derived from previously implemented acute care medical care management interventions.[30,31] For patients randomized to the care management condition, the Masters of Social Work (MSW) intervention team member visited them by the bedside in the hospital ward or by the gurney in the emergency department. The research assistant elicited the patients' concerns; as follow-up to the research assistant concern elicitation, the MSW care manager independently elicited and targeted for improvement each patient's unique constellation of posttraumatic concerns and needs. The care manager asked about treatment preferences and scheduled ongoing times to meet or call the patient during the initial days and weeks postinjury. Treatment preferences the care manager might have discussed with the patients included the option of receiving continued care from specialty surgical providers versus receiving care from a new or preexisting primary care provider. For mental health specialty care, treatment preferences might have

included the option of receiving ongoing counseling from the care manager versus an early, stepped-up referral to a community mental health provider who could address more intensive emotional distress or counseling needs. The care manager might also assist in locating a community provider who could address patients' psychotropic medication needs. The care manager also gave the patients the study team's 24-hour/7 days per week telephone contact number and encouraged the patients to text or call with questions, needs, and concerns. Care management patients were given a choice of treatment options, and the care manager shared information and deliberated medical treatment decisions with each patient to develop a patient-informed, individually tailored treatment plan.[19] For care management patients with high levels of postinjury mental health symptoms, psychiatric consultation and community mental health referrals were made available.

As in prior study team trials, stepped-up care was available for patients with specific postinjury symptomatic presentations. For patients with alcohol use problems or other risk behaviors, the care manager delivered a motivational interviewing intervention.[30,31] For patients with high levels of PTSD and/or depressive symptoms, the care manager delivered cognitive behavioral therapy elements.[47] Psychopharmacologic consultation and community referral was also recommended as stepped-up care procedures for symptomatic patients. Patients received the intervention over the course of the 6 months after the injury event.

Nurse Notification Enhanced Usual Care Control Condition

Patients in the control condition underwent informed consent, both electronic health record and in-person PTSD screenings, baseline surgical ward evaluation, and blinded follow-up interviews. At the termination of the surgical ward/emergency department interviews, the study research assistant contacted the nurses of all patients in the usual care arm of the investigation. With each patient's nurse, the research assistant reviewed the nature and severity of the individual patient's posttraumatic concerns and, if pertinent, level of emotional distress. Nurse notification of patient concerns constitutes an enhancement to usual trauma center/emergency department posttraumatic care. Nurse notification was selected because it represented an optimal, feasibly implemented comparator condition for comparative effectiveness trials targeting American College of Surgeons' policy.[48] Of note, while existing

guidelines recommended that nurses follow up on patients concerns, competing time demands may have preempted some of these efforts for enhanced usual care patients.

Prior investigation suggests that usual posttraumatic care after hospital discharge includes routine surgical, primary care, and emergency department visits, as well as the occasional use of specialty mental health services.[30,31] In this investigation, all usual care emergency department use was captured using the Emergency Department Information Exchange System (EDIE).[43]

Follow-up

Emergency department health service use was assessed using the EDIE to collect population-based usage data over the course of the 12 months after the injury; this follow-up outcome assessment extended 6 months beyond patients' exposure to the intervention. Patients' posttraumatic concerns, symptomatic, risk behavior, and functional outcomes were assessed by patient self-report at baseline and again 1, 3, and 6 months after the injury event. Research assistants collected these assessments through telephone interviews, which have been found to be reliable and valid in the assessment of injured trauma survivors.[42,49,50] To minimize bias, the research assistants who conducted the telephone follow-up interviews were blinded to the patients' study group assignments.[51]

Study Outcomes

Table 2 describes the timing and administration of all study outcome assessments. Further detail of specific assessments and measures is provided below.

Table 2. Study Assessments and Timing of Administration

Measure	BL*	1 M	3 M	6 M
Posttraumatic concerns[20,21]	x	x	x	x
PTSD Checklist Civilian Version[38]	x	x	x	x
Patient Health Questionnaire Depression Scale[39]	x	x	x	x
Physical functioning (Medical Outcomes Study Short Form-12/36)[40]	x	x	x	x
Satisfaction with care[30,41,42]	x	x	x	x
Alcohol Use Disorders Identification Test[58]	x	x	x	x
Drug Abuse Screening Test[59]	x	x	x	x
Violence/weapon carriage[60]	x	x	x	x
Reactions to research participation[26]				x
Traumatic event narrative[20,21]	x	x	x	x

Injury Severity Score[61]	x			
Traumatic brain injury and chronic medical conditions[49]	x			
Rivermead Post-Concussion Symptoms Questionnaire[62]		x	x	x
Cognitive screen[66]	x	x	x	x
Short Form McGill Pain Questionnaire[65]	x	x	x	x
National Comorbidity Survey Trauma History Screen[64]		x		
Stressful Life Events Screening Questionnaire[63]			x	x
Demographic characteristics[20,21]	x			
Medication use[20,21]	x	x	x	x
Technology aptitude readiness [20,21]	x	x	x	x
Work status[20,21]	x	x	x	x
Intervention acceptability[20,21]				x
Automated emergency department health service use[43,57]	Up to 12 M			

*BL = Baseline

Primary Outcomes

Posttraumatic concern severity and domain.[20,21] As in prior study team investigations,[20,21] the baseline and follow-up interviews began with the assessment of each patient's unique constellation of postinjury concerns. The baseline, 1-, 3-, and 6-month concern assessment asked each patient, "Of everything that has happened to you since you were injured, what concerns you the most?" Patients could express an unlimited number of concerns. At each follow-up time point, research assistants reassessed the presence or absence of previously endorsed concerns. Following each concern elicitation, patients were asked to rate the severity of the concern on a scale from 1 to 5, with 1 being not at all concerning and 5 being extremely concerning. Based on a prior study team investigation, a severe concern was defined as a concern that the patient rated as a 5.[20,21] The study team assessed whether each patient expressed 1 or more severe concerns at each time point; the study team used this dichotomized assessment in the outcome analyses. The study team also calculated the average severity rating for all concerns for each individual patient at each time point, and used this continuous variable in the outcome analyses.

Procedures for coding the posttraumatic concern domains were derived from previously described content analytic methods.[20,21] A previously developed code book that described concern domains and coding procedures was used.[20,21] The initial concern question and its explanation constituted the unit of analysis. Raters independently coded each concern into 1 of

the previously established concern domains.[20,21] The frequency of patients reporting themes from 1 or more domains along with the concern severity was tabulated.[20,21] Approximately 10% (80/735) of concerns were coded by 2 raters. A kappa statistic was used to assess interrater reliability, with values ranging from 0.77 to 0.78.

Posttraumatic stress disorder symptoms (PTSD Checklist). The PTSD Checklist, a 17-item self-report questionnaire, was used to assess PTSD symptoms.[38] The instrument yields both a continuous PTSD symptom score and a dichotomized diagnostic cut point for symptoms consistent with a Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) diagnosis of PTSD.[52] A series of investigations have demonstrated the reliability and convergent and construct validity of the PTSD Checklist across trauma- exposed populations.[38,53,54] Increasing symptom scores on the PTSD Checklist have been linked to such important postinjury outcomes as reductions in physical function and impairments in the return to work.[12] At baseline, patients were asked such questions as, “Since the event in which you were injured, how often have you been bothered by repeated, disturbing memories, thoughts, or images of the event in which you were injured?” Patients were then asked to respond using a 5-point Likert scale (1 = “Not at all” to 5 = “Extremely”). PTSD symptoms for the month prior were assessed again during the 1-, 3-, and 6-month follow-up interviews. In a prior investigation with injured trauma survivors conducted by the study team, Cronbach’s alpha for the 17-item scale was 0.92.30,42 In a study of injured motor vehicle crash survivors, a correlation of 0.93 was documented between the PTSD Checklist total score and the gold standard Clinician-Administered PTSD Scale diagnostic scale.[53]

Depressive symptoms (PHQ-9).[39] The investigation used the PHQ-9 to assess depressive symptoms. The instrument yields both a continuous depressive symptom score and a dichotomized diagnostic cut point for symptoms consistent with a DSM-IV diagnosis of depression. The PHQ-9 item asks specifically about suicidal ideation and/or intent. The PHQ-9 has established reliability and convergent and construct validity when used to assess patients in general medical settings.39 At baseline, patients were asked such questions as, “In the past month, how often have you been bothered by little interest or pleasure in doing things?” Patients were then asked to respond using a 4-point Likert scale (0 = “Not at all” to 3 = “Nearly

all the time"). During the 1-, 3-, and 6-month follow-up interviews, the PHQ-9 was administered for the month prior to the interview. In a prior investigation with injured trauma survivors conducted by the study team, Cronbach's alpha for the 9-item scale was 0.97.[30,42]

Secondary Outcomes

Physical function and quality of life outcomes (Medical Outcomes Study Short Form 36 [MOS SF-36]).[40] The investigation used the SF-36 to assess functioning and quality of life outcomes. The 8 domains assessed included physical function, pain, general health, role physical function, role emotional function, vitality, social function, and mental health. The SF-36 has established reliability and validity and the measure has been used extensively with traumatically injured populations.[40,42,55,56] The study team used the Physical Component Summary (PCS) subscale to assess postinjury physical function. In prior investigations conducted by the study team, Cronbach's alpha for the MOS SF-36 PCS was 0.90.[30,42]

Emergency department health service use. Emergency department health service use was assessed using the Emergency Department Information Exchange System, developed by Collective Medical Technologies.[43,57] EDIE is a novel clinical informatics tool that aggregates emergency department visits in real time for the population of patients who present to any emergency department in Washington and Oregon. EDIE is currently integrated into the medical record at the University of Washington and Harborview Medical Center. For the purposes of this trial, EDIE allowed a population-based, 12-month follow-up of all emergency department visits across Washington and Oregon for the intent-to-treat sample of intervention and control patients.

Satisfaction with care. Items that assessed satisfaction with posttraumatic care were adapted from previous studies of care management interventions for patients in primary and acute care medical settings.[30,41,42]

Alcohol and drug use problems and other injury risk behaviors. The study team used the Alcohol Use Disorders Identification Test (AUDIT), a 10-item screening instrument for the early identification of problem drinkers,[58] to assess alcohol use problems. At baseline, the AUDIT evaluated drinking behaviors in the year prior to the injury. The reliability and validity of the AUDIT are well established in traumatic injury populations and the scale has been widely used

as a screening instrument in general medical settings.[58] The Drug Abuse Screening Test was used to assess drug use problems.[59] A single item assessed whether patients had a recent history of weapon carrying.[60]

Reactions to research participation. Over the past 2 decades, the study team has developed research methods that allow for the empirical assessment of reactions to research participation, including participant burden.[26] These methods involve asking all research participants key questions that weigh the costs and benefits of research study participation. The participants were asked to respond to the four following statements: "Had I known in advance what participating would have been like, I still would have participated"; "I gained something positive from participating"; "Participating upset me more than I expected"; and "I felt free to skip questions and/or parts of the study." Patient participants could respond with "True," "Mostly true," "Uncertain," "Mostly false," or "False." All 171 patient participants were asked these items at baseline in the surgical ward and again during the 1-, 3-, and 6-month follow-up interviews.

Other assessments. The investigation determined injury severity at baseline during the index admission from the medical record International Classification of Disease Codes (ICD-9-CM) using the Abbreviated Injury Scale and Injury Severity Score.[61] Traumatic brain injury and chronic medical conditions were also prospectively identified in the medical record.[49] Race, ethnicity, and gender were assessed through patient self-report. Laboratory toxicology results, insurance status, length of hospital and intensive care unit stays, and other clinical characteristics were abstracted from the electronic health record and trauma registry. The study included many other assessments of clinical, demographic, and injury characteristics, which are listed in Table 2.[62-66]

Data Collection and Sources

A previously developed electronic health record screen was used to assess the population of admitted injured trauma survivors at risk for developing emotional distress.[44] The screen used 10 data elements that are both associated with increased risk for posttraumatic stress disorder and readily available in any robust electronic health record system. In a prior investigation, when the 10 data elements were used to predict scores on the PTSD Checklist of ≥ [35], the

electronic health record screen demonstrated adequate sensitivity (0.71), specificity (0.66), and area under the receiver operating characteristic curve (0.72).[44] Consenting patients who scored ≥ 3 on the electronic health record screen were subsequently evaluated for their number of posttraumatic concerns. The 10 data elements include an ICD-9-CM PTSD diagnosis, other ICD-9-CM psychiatric diagnosis, other ICD-9-CM substance use diagnosis or positive blood alcohol on admission, tobacco use, female gender, nonwhite ethnicity, uninsured, public or veteran insurance status, intentional injury (e.g., physical assault, stabbing, gunshot or other violent trauma), and intensive care unit admission and EHR documentation of any prior trauma center visits.

The research assistant administered the concern assessment to each consenting patient; the assessment asked, "Of everything that has happened to you since you were injured, what concerns you the most?" Subsequent open-ended items further explored the nature and severity of each concern. Patients could express an unlimited number of concerns. Following the administration of these open-ended questions, patients were asked to rate the severity of each concern on a scale from 1 to 5, with 1 being not at all concerning and 5 being extremely concerning. Next, patients were administered the PTSD Checklist (PCL-C) and the PHQ-9. Patients were screened into the randomized portion of the study if they had ≥ 3 concerns and either a score ≥ 35 on the PCL-C, a score ≥ 10 on the PHQ-9, or a response ≥ 1 on item 9 of PHQ-9. These screen-in criteria were used because, in previous investigations, injured trauma survivors with ≥ 3 concerns and high scores for PTSD and/or depression demonstrated the greatest symptomatic and functional impairment over the course of the year after injury and thus may derive the greatest benefit from study intervention procedure.

Upon recruitment, patients were asked to provide at least 2 contact information items for themselves (e.g., phone number and mailing address). Recruiters probed patients for as many contact information items as possible, including alternate contact sources such as family or friends. If a patient could no longer be reached through his or her personal contact information, follow-up interviewers contacted the patient's alternate contact sources to either collect new contact information for the patient or pass a message on to them. If interviewers were unable to reach patients after repeatedly trying to contact them through the information

provided at recruitment, the follow-up interviewers searched for new information in the following ways: Check Harborview medical records for new information; search Yellow Pages; use search engines (e.g., Google, Bing); or search social media (e.g., Myspace, Facebook, Google+). Patients who could not be contacted or were deceased were considered lost to follow-up.

Analytical and Statistical Approaches

The study hypothesized that the novel care transition intervention, when compared with nurse notification, would be associated with significant improvements in patient-centered outcomes, including standardized assessments of the severity of individual patients' posttraumatic concerns. The study also hypothesized that intervention patients would demonstrate reductions in the percentage of concerns across medical/physical and mental health domains. The study also hypothesized that patients who received the intervention would demonstrate reductions in posttraumatic stress disorder and depressive symptoms when compared with patients receiving enhanced usual care. Secondary outcomes compared across intervention and control conditions included physical function, injury risk behaviors, physical and emotional satisfaction with care, and automated statewide health service use. Exploratory analyses assessed the impact of the intervention on outcomes for patients with and without a traumatic brain injury. To further assess for treatment effect heterogeneity, gender, ethnicity, and age were tested as interactions with treatment effects.

A detailed analytic plan was created prior to the conduct of data analyses. The prespecified primary outcome analysis began with assessments of concern severity and domains. Two concern severity variables were used as the dependent variable in the outcome analyses: the dichotomous assessment of whether each patient expressed 1 or more severe concerns at each time point and the continuous assessment of the average severity rating for all concerns of each individual patient at each time point. For the concern assessments, the study team used both the full sample of N = 171 patients and the subsample of patients who endorsed enduring concerns at each time point (N = 102). Changes in concern domains over time were also assessed.

Next, the primary outcome analysis examined changes over time across groups for PTSD

and depressive symptoms. The analysis plan specified the secondary outcomes to be assessed, including physical function, health service use, satisfaction with care, and injury risk behaviors.

The investigation used mixed effects regression models to test hypotheses.[67-69] The effect of major interest was the time by treatment group interaction term. Regression models included time categories, intervention, and intervention by time interactions. Other analyses adjusted for relevant clinical and demographic characteristics, including age, gender, race, and traumatic brain injury. Longitudinal data collected prospectively from injured trauma survivors was characterized by correlated intra-individual observations, missing data, and dropouts. Mixed-effects random-coefficient regression methods were selected because of their superior ability to model longitudinal data with these characteristics. The study team used SAS version 9.4 and SPSS version 24.0 for all analyses.

Some attrition was expected in the study sample. Prior studies by the investigative group have consistently achieved follow-up completion rates ≥ 80% between 6 and 12 months postinjury.[30,31] Assumptions about the nature of missing data are important to the type of statistical analysis chosen. Full information maximum likelihood estimates from mixed random-effects models at least accommodate missing data that are missing at random (MAR); MAR data depend on previously observed variables.[67,70-72] The study team used statistical logistic models to determine which, if any, demographic or clinical characteristics, including treatment group membership, were predictive of subject attrition. Any factors observed to explain trends in missing data were used as covariates in subsequent analyses. Past studies found no sources of consistent variation to explain missing data.[23,24] Based on the relatively low attrition rates and the inability to find consistent variation in past investigations, the study team believes that MAR is a reasonable assumption.

Criteria and standards for the approach to treatment effect heterogeneity were derived from the PCORI Methodology Report published for public comment on July 23, 2012.[73] Because of the limited information in the prior literature and the lack of large studies with subgroup analyses, the approach to heterogeneity of treatment effect (HTE) was considered somewhere between a descriptive and exploratory HTE analysis. Prior analyses suggest that patients of different ages, genders, and ethnicities who have traumatic brain injuries may experience

varying impacts of traumatic injury regarding PTSD symptoms, depressive symptoms, and physical function outcomes.[42,74-79] However, none of these investigations have previously established variations in posttraumatic concerns or severity in response to these subgroup factors. Therefore, the study adopted a descriptive/exploratory approach to the heterogeneity of treatment effect analyses. To explore for treatment effect heterogeneity, the study team examined treatment effect by time interactions for gender, age, traumatic brain injury, and ethnoracial group. It was understood a priori that the study would not be adequately powered to examine differences across these multiple subgroups.

Conduct of the Study

Please reference previous sections on the methods and outcome variables for explication of the study protocol. First, the study added an injured trauma survivor family and friend protocol element at the behest of the patient and patient advocate stakeholders on the investigative team. Second, in the third year of the study, a small (n = 4) injured peer interventionist intervention was conducted, also at the recommendation of the patient and patient advocate stakeholders.

RESULTS

Assessment of the Study Population Generalizability to the Trauma Registry External Population for Sampling

Compared with all other patients admitted to the trauma center during the investigation period, the 171 randomized study patients were significantly more likely to be female, nonwhite, more severely injured, hospitalized in the intensive care unit (ICU), and have a greater overall length of hospital stay (Table 3).

Table 3. Trauma Registry Population versus Study Patient Comparisons

Variable	Trauma Registry (N = 9481)	Total Sample (N = 171)	X^2, Fisher's exact test, or *t*	*p*
Age, years, mean (SD)	42.8 (23.2)	42.4 (16.0)	$t(9462) = 0.38$	0.79
Female, n (%)	2925 (31.5)	97 (56.7)	$X^2(1) = 49.25$	< .0001
Race/ethnicity, n (%)			$X^2(5) = 45.42$	< .0001
White	6564 (70.5)	96 (56.1)		
Black	798 (8.6)	27 (15.8)		
Native American	225 (2.4)	22 (12.9)		
Asian	565 (9.1)	9 (5.3)		
Hispanic/Latino	850 (9.1)	12 (7.0)		
Pacific Islander	65 (0.7)	5 (2.9)		
Insurance, n (%)			$X^2(2) = 3.82$	0.15
Private	441 (4.9)	5 (3.0)		
Public	8307 (92.3)	163 (96.4)		
None	254 (2.8)	1 (0.6)		
Acute care injury and medical Injury severity				
Mean (SD)	11.5 (11.1)	15.1 (11.3)	$t(9479) = –4.13$	< .0001
0-8	4345 (46.7)	53 (31.0)	$X^2(2) = 23.63$	< .0001
9-15	2393 (25.7)	44 (25.7)		
≥ 16	2572 (27.6)	74 (43.3)		
Traumatic brain injury, n (%)			$X^2(2) = 5.60$	0.13
None	6410 (68.9)	123 (71.9)		
Mild	1215 (13.1)	28 (16.4)		
Moderate/severe	1685 (18.1)	20 (11.7)		
Intentional injury	844 (9.1)	22 (12.9)	$X^2(1) = 5.28$	0.07
Days in ICU, n (%)			$X^2(1) = 13.40$	< .0001
0	5331 (57.3)	74 (43.3)		
1+	3979 (42.7)	97 (56.7)		
Days in hospital for injury, mean (SD)	6.0 (10.9)	11.3 (11.7)	$t(9430) = 5.92$	< .0001

Note: Intentional injury includes gunshots, physical assault, and stabbings.

Comparison of Demographic, Clinical, and Injury Characteristics Between Intervention and Control Groups

For the 171 randomized patients, the mean age was 42.4 years (SD = 16.0) and 56.7% (n = 97) of patients were female (Table 4). Race and ethnicity were self-reported: 56.1% (n = 96) of patients identified as white, 15. 8% (n = 27) identified as African American, 12. 9% (n = 22) identified as American Indian, 7.0% (n = 12) identified as Hispanic, 5.3% (n = 9) identified as Asian, and 2.9% (n = 5) identified as Pacific Islander. Injury events in the population included falls (31.6%, n = 54), motor vehicle crashes (23.4%, n = 40), motorcycle crashes (12.9%, n = 22), pedestrian accidents (10.5%, n = 18), physical assaults (7.6%, n = 13), gunshots (4.1%, n = 7), bicycle accidents (3.5%, n = 6), stabbings (2.3%, n = 4), work injuries (1.2%, n = 2), sports injuries

(0.6%, n = 1), and other (2.3%, n = 4). Intervention patients were less likely than control patients to have 1 or more chronic preinjury medical conditions (chi-square [3] = 9.23; $p < 0.05$); no other significant differences existed between intervention and control patients on any demographic, clinical, or injury characteristics.

Table 4. Baseline Patient Characteristics

Variable	Total (N = 171)	Intervention (n = 85)	Usual Care (n = 86)	X^2, Fisher Exact Test, or $F_{(df)}$	*p*
Age, mean (SD)	42.4 (16.0)	41.2 (16.1)	43.6 (16.0)	$F_{1,169} = 0.93$	0.34
Female, n (%)	97 (56.7%)	50 (58.8%)	47 (54.7%)		0.64
Race/ethnicity, n (%)				$X^2(5) = 6.13$	0.29
White	96 (56.1%)	46 (54.2%)	50 (58.2)		
Black	27 (15.8%)	12 (14.1%)	15 (17.4)		
Native American	22 (12.9%)	9 (10.6%)	13 (15.1)		
Asian	9 (5.3%)	7 (8.2%)	2 (2.3)		
Hispanic/Latino	12 (7.0%)	7 (8.2%)	5 (5.8)		
Pacific Islander	5 (2.9%)	4 (4.7%)	1 (1.2)		
Education, years, mean (SD)	13.1 (2.5)	13.1 (2.4)	13.1 (2.7)	$F_{1,167} = 1.00$	
Married/living with partner, n (%)	40 (23.5%)	20 (23.8%)	20 (23.2%)		0.96
Employed, n (%)	78 (48.8%)	41 (52.6%)	37 (45.1%)		0.43
Insurance, n (%)				$X^2(2) = 1.20$	0.45
Private	5 (3.0%)	2 (2.4%)	3 (3.5%)		
Public	163 (96.4%)	81 (96.4%)	82 (96.5%)		
None	1 (0.6%)	1 (1.2%)	0 (0.0%)		
Acute care injury and medical injury severity					
Mean (SD)	15.1 (11.3)	15.6 (11.5%)	14.6 (11.1%)	$F_{1,169} = 0.36$	0.55
0-8	53 (31.0%)	25 (29.4%)	28 (32.6%)	$X^2(2) = 0.25$	0.88
9-15	44 (25.7%)	23 (27.1%)	21 (24.4%)		
≥ 16	74 (43.3%)	37 (43.5%)	37 (43.0%)		
Traumatic brain injury, n (%)				$X^2(3) = 0.21$	0.98
None	123 (71.9%)	60 (70.6%)	63 (73.3%)		
Mild	28 (16.4%)	15 (17.6%)	13 (15.1%)		
Moderate/severe	20 (11.7%)	10 (11.8%)	10 (11.6%)		
Intentional injury, n (%)	22 (12.9%)	13 (15.3%)	10 (11.6%)	$X^2(2) = 0.50$	0.78
Comorbid medical conditions out of 16				$X^2(3) = 12.36$	0.006
0	103 (60.2%)	56 (65.9%)	47 (54.7%)		
1	40 (23.4%)	18 (21.2%)	22 (25.6%)		
2	14 (8.2%)	5 (5.9%)	9 (10.5%)		
≥ 3	14 (8.2%)	6 (7.1%)	8 (9.3%)		
Days in ICU, n (%)					0.88
0	74 (43.3%)	36 (42.4%)	38 (44.2%)		
1+	97 (56.7%)	17 (20.0%)	10 (11.8%)		
Days in hospital for injury, mean (SD)	11.3 (11.7)	12.0 (13.6)	10.7 (9.4)	$F_{1,169} = 0.56$	0.46
Serious prior traumas before injury, mean (SD)	4.2 (3.0)	4.5 (3.2)	3.9 (2.8)	$F_{1,169} = 1.23$	0.27
Psychiatric symptom severity and substance use					
Preinjury PTSD symptoms, n (%)	113 (67.3%)	55 (66.3%)	58 (68.2%)		0.46
Baseline PCL-C total score, mean (SD)	42.7 (11.2)	42.5 (11.3)	42.9 (11.2)	$F_{1,169} = 0.05$	0.82
Baseline PHQ-9 total score, mean (SD)	14.5 (4.3)	14.3 (4.5)	14.8 (4.2)	$F_{1,169} = 0.53$	0.47
SF-12/36 Mental Health Score, mean (SD)	47.3 (9.9)	48.7 (9.3)	45.9 (10.3)	$F_{1,169} = 3.36$	0.07
SF-12/36 Physical Health Score, mean (SD)	48.5 (9.1)	48.5 (9.2)	48.4 (9.1)	$F_{1,169} = 0.01$	0.93
Preinjury AUDIT-C Gender Group Positive, mean (SD)	83 (48.8)	41 (48.8)	42 (48.8)		1.00
Preinjury AUDIT-C score, mean (SD)	3.5 (3.2)	3.4 (3.2)	3.7 (3.2)	$F_{1,168} = 0.55$	0.46
Positive blood alcohol on admission, n (%)	39 (22.8%)	16 (18.8%)	23 (26.7%)	$X^2(2) = 1.62$	0.44

Urine toxicology screen positive for stimulants (amphetamine and/or cocaine), n (%)	7 (4.1%)	4 (4.7%)	3 (3.5%)	$X^2(2) = 0.16$	0.92
Urine toxicology screen positive for marijuana, n (%)	3 (1.8%)	1 (1.2%)	2 (2.3%)	$X^2(2) = 0.64$	0.73

Note: Intentional injury includes gunshots, physical assault, and stabbings. AUDIT-C = Alcohol Use Disorders Identification Test; PCL-C = PTSD Checklist Civilian Version; PHQ-9 = Patient Health Questionnaire; SF-12/36 = Medical Outcomes Study Short Form Health Survey.

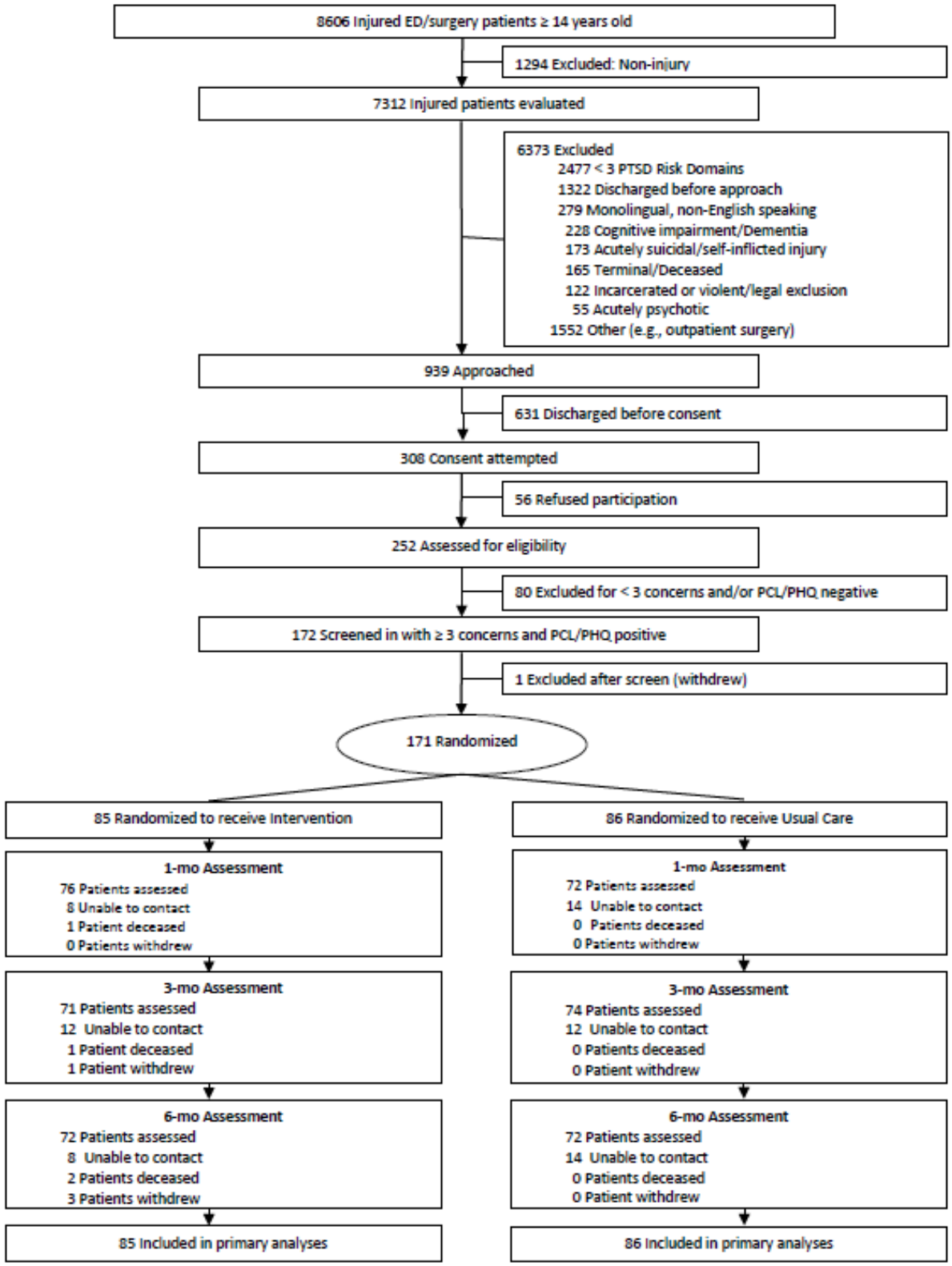
Presentation of the CONSORT Patient Flow Through Protocol

Fifty-six patients declined to enroll in the project. Of those who declined, 21 patients identified the time commitment and/or inconvenience of the protocol as their reason for declining, 11 patients were concerned about their privacy, 11 patients stated they were not interested, 7 patients felt that taking part in the study would cause them distress, and 6 patients refused to give a reason for not wanting to participate.

The investigation attained ≥ 80% follow-up at each time point for patients randomized to the intervention and control conditions (Figure 1). Of the 171 patients, 26% were missing 1 or more assessment at the 1-, 3-, or 6-month time point.

Observation from the CONSORT diagram (Figure 1) and additional analyses that broke down lost to follow-up categories revealed some differences across the 2 groups that the study team believes did not achieve clinical significance because of the relatively small number of patients in each group. Three patients in the intervention group, but no patients in the control group, withdrew from the study. Two patients in the intervention group, but no patients in the control group, died during the 6-month protocol. Fourteen patients in the control group and 8 patients in the intervention group were not able to be contacted at the 6-month time point. Of the patients who were missing follow-up data, 7 control patients and 5 intervention patients completed only the baseline interview, zero control patients and 2 intervention patients completed only the baseline and 1-month interviews, and 8 control patients and 6 intervention patients completed only the baseline, 1-, and 3-month interviews.

Figure 1. Patient Flow Through Protocol (CONSORT)



Regression analyses that systematically assessed patterns of missing data revealed that only gender was associated with missing assessments (61% of men versus 38% of women; P < 0.01). Men and women were equally balanced, however, across intervention and control group conditions (Table 4).

Intervention Implementation

On average, the total time spent with each intervention subject was 6.49 hours (SD = 4.57 hours). More than half of patient clinical encounters occurred over the telephone. Approximately 95% of patients (81/85) had at least 1 care management telephone contact over the course of the 6 months after the injury. Approximately 65% (55/85) of patients communicated with the study by text messaging; 63.5% (54/85) of patients sent texts to the study team's 24/7 cell phone and 64.7% (55/85) of patients received texts from the study team. Of patients, 94% (80/85) had any voicemail communication with the study team; 87.1% (74/85) left a voice message for the study team and 94.1% (80/85) received at least 1 voice message from the care manager interventionist or other study team members.

Approximately one-third of intervention patients (n = 27) received 1 or more motivational interviews targeting alcohol use. Most intervention patients (N= 76) were engaged in the delivery of cognitive behavioral therapy elements. Also, the need for psychopharmacologic intervention was assessed in most intervention patients (N = 74).

Primary Outcome: Posttraumatic Concerns

Patients in both the intervention and control groups reported a variety of concerns that spanned the 6 previously articulated content domains (Table 5). Regression analyses in both the intent-to-treat sample and the subsample of patients with enduring concerns demonstrated significant reductions in the percentage of any severe concerns in intervention patients when compared with controls. At the 3-month postinjury time point, 71.4% of control patients versus 76.2% of intervention patients endorsed 1 or more severe concerns. At the 6-month postinjury time point, 73.7% of control patients versus 52.4% of intervention patients endorsed 1 or more severe concerns (Fischer's exact test P = 0.02; Table 6). For the continuous analyses of mean concern severity, significant reductions among intervention patients relative to controls were observed in the subsample with enduring concerns but not in the intent-to-treat sample (Table 6). No significant differences in concern domains were observed for intervention and control group patients over time (Table 6).

Table 5. Posttraumatic Concern Domains: Definitions and Examples

Concern Domain	Definition	Example
Physical health	The physical health domain included patient concerns regarding bodily injury, pain, and self-care. Concerns coded in this category reflected that the patient was worried about current and future health, how the event was impairing physical function, and being able to take care of self.	"My pain has decreased; my right knee still hurts. I hit them on the dashboard, and my neck still hurts and my chest still hurts on occasion. It hurt last Friday when I went bowling. I'm in a bowling league, and that was the first strenuous activity I did and now all my injuries hurt."
Work and finance	Work and finance concerns focused on the patient's posttraumatic employment, finances, housing, education, and food acquisition. Concerns coded in this category reflected that the patient was worried about issues related to day-to-day sustenance for self and family.	"My job and my bills. I work at the metro and I'm only covered for 16 weeks under the FMLA [Family and Medical Leave Act], and I've been out of work for 2 months, and I'm just now getting the surgery, which starts the healing process all over, and I just found out last night that the radial nerve damage was worse than what they thought, and I'll have to come back for a second surgery and if my arm doesn't work, and I need to do another FMLA or something, but I just can't afford to lose my job. I have car notes, car insurance, cell phone bills, and the little savings I had is gone and I'm starting to panic."
Social	Social concerns encompassed thoughts and feelings regarding the health and emotional status of family and friends. This domain included both positive and negative concerns regarding people in the patient's social network.	"I guess I'm wondering if in the future if I'm going to be able to run and play and act normal with my kids. Will I be able to walk down the aisle or will I be in a wheelchair for the rest of my life?"
Psychological	Patient psychological concerns included expressions of posttraumatic symptomatic distress, such as anxiety and depression. Other psychological themes included struggles with substance abuse, existential reflections, and concerns regarding safety and disfigurement.	"I think that I'm having a lot of anxiety about my injury. With a lot of emotion attached to it and fear."
Medical	Medical concerns related themes about patient interactions with care providers and the health care system. Concerns coded in this domain reflected that the patient was worried about having medical needs adequately covered, including payment issues.	"The discharge from the hospital was botched badly. I tried to get home health care services and my caregiver forbade it even though she knew I was terrified to go outside, and I still am terrified to go outside. I was not sent home with anything that I needed in regards to the care for my wounds, and I was not weaned off or given a schedule to be weaned off the pain medication I was on, so I went cold turkey."
Legal	Legal concerns included questions regarding attribution for the traumatic event and patient interactions with the police, courts, or other criminal justice agencies.	"I'm worried I'll get in trouble, I'm hurting, and I'll probably go to prison or something."

Primary Outcome: PTSD and Depressive Symptoms

No clinically or statistically significant differences between intervention and control group patients were observed for the PCL-C and PHQ-9 longitudinally over the course of the 6 months after the injury (Table 7). Similarly, intervention and control group patients did not demonstrate significant 1-month, 3-month, or 6-month differences in either PTSD or depressive symptom levels.

Table 6. Posttraumatic Concerns Severity and Domains over Time

Concern Measure	Baseline N =171	1 Month N = 143	3 Month N = 126	6 Month N = 120	Test Statistic: Mixed Model Regression
Concern Severity					
≥ 1 Severe Concern	n (%)	n (%)	n (%)	n (%)	N = 171 complete sample Wald Chi-Square = 11.29, df = 3, p = 0.01 N = 102 with enduring concerns F(3,300) = 3.93, p < 0.01
Control	80 (93.0)	55 (79.7)	45 (71.4)	42 (73.7)	
Intervention	83 (97.6)	59 (79.7)	48 (76.2)	33 (52.4)	
Mean Concern Severity	m (sd/se)	m (sd/se)	m (sd/se)	m (sd/se)	N = 171 complete sample Wald Chi-Square = 3.37, df = 3, p = 0.34 N = 102 with enduring concerns F(3,300) = 3.31, p = 0.02
Control	4.52 (0.53)	4.26 (0.83)	4.00 (0.95)	3.94 (0.98)	
Intervention	4.56 (0.53)	3.95 (0.92)	3.89 (1.09)	3.70 (1.05)	
Concern Domains					
Concern Domains	Baseline N =171	1 Month N =171	3 Month N =171	6 Month N =171	Test Statistic: Mixed Model Regression
	n (%)	n (%)	n (%)	n (%)	
Physical Health					
Control	80 (93.0)	55 (75.3)	52 (70.3)	44 (62.0)	Wald Chi-Square = 5.53, df = 3, p = 0.52
Intervention	75 (88.2)	63 (82.9)	52 (73.2)	51 (70.8)	
Work - Finances					
Control	60 (69.8)	43 (58.9)	42 (56.8)	38 (53.5)	Wald Chi-Square = 2.22, df = 3, p = 0.53
Intervention	56 (65.9)	43 (56.6)	30 (42.3)	32 (44.4)	
Psychological					
Control	46 (53.5)	27 (37.0)	30 (40.5)	29 (40.8)	Wald Chi-Square = 6.73, df = 3, p = 0.08
Intervention	45 (52.9)	42 (55.3)	30 (42.3)	32 (44.4)	
Social					
Control	39 (45.3)	26 (35.6)	19 (25.7)	19 (26.8)	Wald Chi-Square = 2.21, df = 3, p = 0.53
Intervention	41 (48.2)	28 (36.8)	14 (19.7)	13 (18.1)	
Medical					
Control	34 (39.5)	23 (31.5)	24 (32.4)	16 (22.5)	Wald Chi-Square = 2.29, df = 3, p = 0.51
Intervention	31 (36.5)	23 (30.3)	21 (29.6)	20 (27.8)	
Legal					
Control	10 (11.6)	9 (12.6)	10 (13.5)	9 (12.7)	Wald Chi-Square = 0.95, df = 3, p = 0.81
Intervention	4 (4.7)	5 (6.6)	5 (7.0)	4 (5.6)	

Note. p = probability; m = mean; sd = statistical deviation; se = standard error; df = degrees of freedom

Table 7. Symptomatic and Functional Outcomes Over time

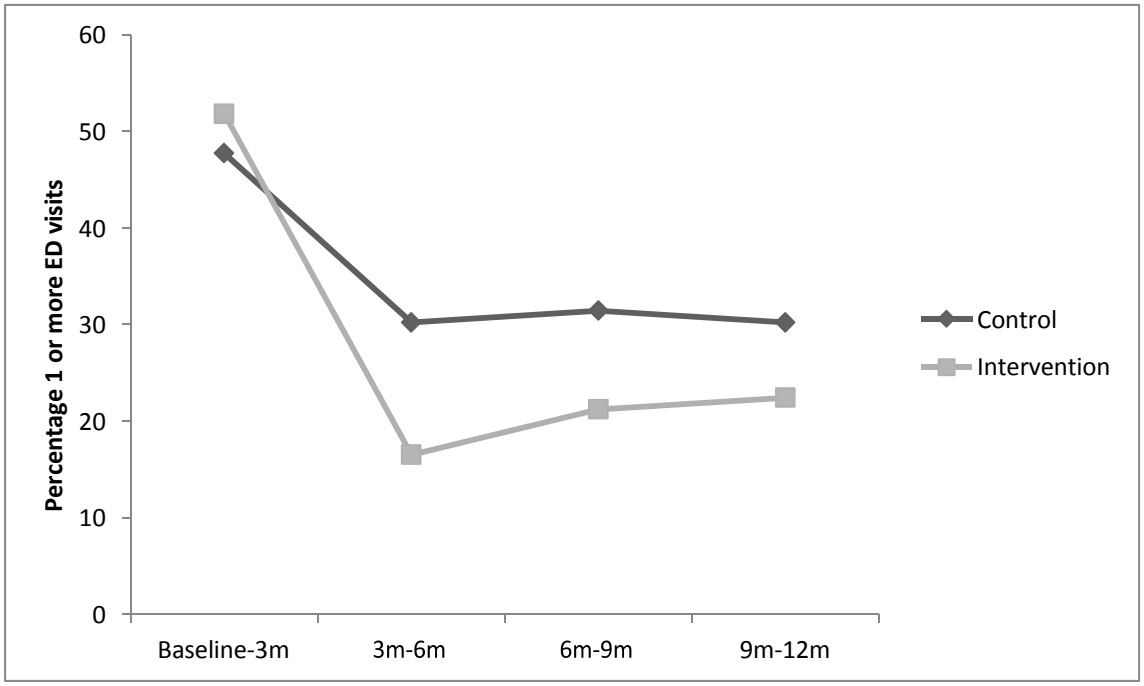
Concern Measure	Baseline m (sd) or n (%)	1 Month m (sd) or n (%)	3 Month m (sd) or n (%)	6 Month m (sd) or n (%)	Test Statistic: Mixed Model Regression	*p*
PCL-C, m (sd)					Wald Chi = 3.01, df = 3	0.39
Control	42.9 (11.2)	41.7 (14.3)	40.7 (14.7)	39.3 (14.7)		
Intervention	42.5 (11.3)	43.7 (14.9)	38.7 (13.7)	38.6 (16.0)		
PHQ-9, m (sd)					Wald Chi = 4.25, df = 3	0.23
Control	14.8 (4.2)	12.1 (6.2)	11.7 (7.2)	10.7 (6.4)		
Intervention	14.3 (4.5)	13.2 (6.5)	10.8 (6.9)	9.3 (6.8)		
PHQ-9 Item 9, n (%)					Wald Chi = 4.02, df = 3	0.26
Control	19(22.1)	13(18.1)	21(28.8)	16(22.5)		
Intervention	22(25.9)	18(24.3)	14(20.0)	17(23.6)		
AUDIT, m (sd)					Wald Chi = 0.18, df = 3	0.98
Control	7.3(8.8)	2.6(6.9)	3.2(6.3)	4.2(7.0)		
Intervention	5.8(6.9)	1.3(3.7)	1.5(2.9)	2.7(5.4)		
DAST, m (sd)					Wald Chi = 3.24, df = 3	0.36
Control	2.0(1.9)	1.4(1.2)	1.4(1.4)	1.3(1.0)		
Intervention	2.2(2.0)	1.3(1.2)	1.3(1.1)	1.5(1.4)		
Weapon Carriage, n (%)					Wald Chi = 4.44, df = 3	0.22
Control	7(8.2)	4(5.6)	7(9.6)	5(7.1)		
Intervention	12(14.3)	3(4.1)	5(7.0)	9(12.9)		
SF-12/36, m (sd)					Wald Chi = 3.52, df = 3	0.32
Control	48.4 (9.1)	38.3 (10.4)	39.3 (9.9)	39.9 (9.9)		
Intervention	48.5 (9.2)	37.1 (10.9)	39.8 (8.0)	42.3 (8.4)		

Note: AUDIT = Alcohol Use Disorders Identification Test; DAST = Drug Abuse Screening Test; PCL-C = PTSD Checklist Civilian Version; PHQ-9 = Patient Health Questionnaire; SF-12/36 = Medical Outcome Study Short Form Health Survey.

Secondary Outcomes

There were no significant group differences in physical functioning as assessed by the MOS SF-36 over the course of the 6 months after the injury (Table 7). Correspondingly, intervention and control group patients did not demonstrate baseline, 1-month, 3-month, or 6-month differences in physical function. Patients in the 2 groups demonstrated no significant differences in alcohol-, drug-, or violence-related injury risk behaviors over time. Comparisons between intervention and control patients on measures of physical and emotional satisfaction with care did not attain statistical significance.

Figure 2. One or More Emergency Department Visits Over Time



Note: N = 171 at all-time points; ED = emergency department; m = month.

Emergency Department Health Service Use

Patients in the intervention group demonstrated clinically important reductions in emergency department visits over the course of the year after injury hospitalization (Figure 2). The intervention was associated with clinically significant cross-sectional differences (1 or more 3- to 6-month ED visits; C = 30.2%, I = 16.5%; relative risk [95% CI] C versus I = 2.00 [1.09, 3.70], P = 0.03) that did not achieve longitudinal statistical significance ($F_{3,507}$ = 2.24, P = 0.08).

Because patients in the intervention group were less likely to have 1 or more chronic conditions, and chronic conditions may influence emergency department use, regression models were adjusted for chronic conditions. In these adjusted models, the intervention remained associated with nearly identical clinically significant cross-sectional differences (P = 0.03) that again did not achieve longitudinal statistical significance (P = 0.08).

Exploration of Treatment Effect Heterogeneity

The investigation did not find any significant treatment group by time interaction effects for race,

age, or traumatic brain injury across outcome domains. For gender, a significant group by time by emergency department use interaction was identified such that at the 3- to 6-month postinjury time point, women in the intervention group were significantly more likely to demonstrate reductions in emergency department use ($F_{3,501} = 3.08$, $P < 0.05$).

Reactions to Research Participation Items

For the first item, "Had I known in advance what participating would have been like, I still would have participated," 97% of participants responded favorably with "True" or "Mostly true" at baseline in the surgical ward. In the follow-up interviews, between 93% and 98% of participants responded favorably to this item. For the item "I gained something positive from participating," between 84% and 87% responded "True" or "Mostly true" over the 4-time points. For the item "Participating upset me more than I expected," 77-89% responded "False" or " Mostly false" over the 4 study time points. For the item "I felt free to skip questions and/or parts of the study," between 93% and 99% of patients responded "True" or " Mostly true" over the 4 study time points.

DISCUSSION

Decisional Context

This investigation contributes to the evolving literature on patient-centered early interventions for injured trauma survivors who are initially treated in surgical inpatient settings and then require continuous care transitions. The investigation demonstrates the feasibility and suggests the effectiveness of a patient-centered care transition intervention in reducing posttraumatic concern severity and reducing postinjury emergency department health service use. This initial investigation could have important implications for U.S. trauma care systems nationally. Trauma centers could consider customizing trauma care programs to incorporate elements of patient-centered care. Key program elements for consideration include the provision of a continuous helping relationship that links the trauma center to community services and includes eliciting and addressing patients' most pressing needs and concerns after injury.

The Study Results in Context

The comparative effectiveness trial was novel in that posttraumatic concerns constituted a primary

trial screening and intervention focus. The results of this investigation suggest that a patient-centered care transition intervention significantly reduces the severity of concerns expressed by injured trauma survivors. Patients in the intervention group demonstrated significant reductions in the percentage of any severe concerns expressed over the course of the 6 months after the injury. These reductions were most prominent at the 6-month endpoint, when approximately half of intervention patients expressed at least 1 severe concern as compared with three-quarters of control patients.

The literature review revealed 1 other investigation that used a patient-generated concern construct as a primary intervention target. In 1 of the few such randomized clinical trials, McLean and Armstrong randomized patients in a general medical practice to a standardized patient-centered need and concern elicitation intervention versus a care as usual comparator condition.32 Patients randomized to the concern elicitation condition reported increased satisfaction with health care visits.

The trial was also innovative because it used a population-based emergency department registry, EDIE, to track health care use outcomes associated with the care transition intervention. The investigation found substantial reductions in emergency department use among patients receiving the care transition intervention, even when adjusting for the presence of preexisting chronic medical conditions. Over the course of the year after injury, intervention group patients demonstrated clinically significant cross-sectional reductions in emergency department use that did not achieve longitudinal statistical significance.

Prior investigations by the study team have used stepped collaborative care interventions with care management components to effectively target postinjury PTSD symptoms and associated functional impairments.30,31 This investigation was innovative because postinjury concerns were directly targeted and followed as a distinct patient-centered outcome. Although the intervention reduced posttraumatic concern severity, concern domain, PTSD and depressive symptoms, physical function, and injury risk behaviors were not significantly affected. For treatment process measures, the care transition intervention was not associated with increased psychotropic medication usage or enhanced care satisfaction. The social worker interventionists' clinical directives differed from those in recent acute care collaborative care trials that have successfully targeted care processes and

symptomatic and functional outcomes; in this investigation, the social worker often focused on eliciting and targeting for improvement posttraumatic concerns rather than symptomatic targets.30,31 The pattern of postinjury severe concern reduction from 3 to 6 months deserves further comment. In observing the 3- and 6-month postinjury concerns results, at the 3-month time point, the intervention and control group are nearly equivalent in the percentage of any severe postinjury concerns expressed. At the 6-month time point, however, a separation occurs between the 2 groups, with the intervention manifesting reductions in the percentage of any severe concerns relative to the control group. Thus, there is a difference in the direction and magnitude for severe concerns across intervention and control groups between the 3- and 6-month time points.

Interestingly, the 3- to 6-month pattern of reduction in the severity of any severe concerns mirrors the pattern of 3- to 6-month intervention and control group differentiation in prior stepped collaborative care trials that have targeted PTSD.30,31 Future investigations could further explore the observation that, regardless of the primary outcome target, multifaceted interventions in acutely injured trauma survivors may require 3-6 months of intervention activity to achieve clinically and statistically significant differentiation between intervention and control group patients.

Implementation of Study Results

Based on the study team's experience of the investigation's rollout, the study team believes that the intervention can be feasibly delivered by frontline trauma center providers. On average, the intervention required just over 6 hours of interventionist time per patient; this time commitment could present a barrier to implementation among frontline acute care providers. Other barriers include the need for 24/7 cell phone coverage.

Generalizability

The investigation is hypothesized to be highly generalizable to other U.S. level I trauma centers. The characteristics of the Harborview level I trauma center, beyond admission volume, are typical of other U.S. level I trauma center sites. Prior behavioral interventions initiated at Harborview have

demonstrated excellent national implementation potential.24,30,31,80 Also, patients with PTSD are more likely to be female and from diverse backgrounds, which may explain some of the differences between the study sample and the external population for sampling at the Harborview level I trauma center.

Subpopulation Considerations

The investigation did not detect substantial differences in intervention effects by traumatic brain injury status, race/ethnicity, gender, or age. The investigation may have been underpowered to detect treatment effect heterogeneity.

Study Limitations

Because this intervention was multifaceted, the investigation did not yield information regarding which components of the treatment were effective in targeting specific outcomes. Thus, the study team can only postulate that the patient-centered care management procedures may have targeted reductions in concern severity, while telephone availability and care coordination may have been associated with observed reductions in emergency department health service use. Future investigations could test specific intervention components in relation to hypothesized outcome effects, or they could attempt to disentangle the effects of these individual components of the multifaceted intervention.47 Also, the intervention extended to the 6-month injury time point and the investigation did not conduct a formal posttreatment outcome assessment. The study was conducted at a single level I trauma center and may not generalize to diverse U.S. trauma care systems nationally. The results also may not generalize to acute care emergency department settings nationwide. The investigative sample was relatively small and included a large subpopulation of ethnically diverse women. The study team acknowledges that an enhancement to usual postinjury care, which included nurse notification of patient postinjury distress, was used as the comparator condition.

Finally, these findings are limited by challenges in the naturalistic follow-up of posttraumatic concerns over time. Although attempts were made to capture concerns at each time point, patients

had difficulty with comprehensively listing all their endorsed concerns. Further methodologic refinement of concern coding and quantitative analyses could be a productive area for future investigations. The study team also notes that although a systematic process was in place to train the research assistants to conduct the baseline and follow-up interviews, no reliability estimates or kappa statistics were obtained that specifically addressed concordance for the concern elicitation procedure. However, the study team has no reason to believe that systematic differences would occur in the way concerns were elicited for patients in the intervention and control conditions by blinded research assistants. Therefore, the study team believes there would be minimal overall impact of variations in concern elicitation for the results of the comparative effectiveness trial.

Future Research

Patient stakeholder study team members have voiced the importance of peer- integrated injury interventions. On September 23, 2016, the study team convened a PCORI-sponsored policy summit with the American College of Surgeons' Committee on Trauma, the regulatory governing body for U.S. trauma care systems nationally. A major summit recommendation was that additional research on peer-integrated interventions was required to inform American College of Surgeons' regulatory policy. A possible future research direction would be a comparative effectiveness trial of a multidisciplinary team care transition intervention that integrates injured trauma survivor peer interventionists.

CONCLUSIONS

The investigation randomized 171 patients to intervention (n = 85) and nurse notification group conditions (n = 86). Intervention patients demonstrated clinically and statistically significant reductions in the percentage of any severe postinjury concerns when compared with nurse notification patients longitudinally (Wald chi-square = 11.29; P = 0.01) and at the 6-month study time point (C = 74%, I = 53%; Fisher exact test, P = 0.02). Comparisons of emergency department use data yielded clinically significant cross-sectional differences (1 or more 3- to 6-month ED visits; C = 30.2%, I = 16.5%; relative risk [95% confidence interval or CI] C versus I = 2.00 [1.09, 3.70], P = 0.03) that did not achieve longitudinal statistical significance (F3,507 = 2.24, P = 0.08). The

intervention did not significantly affect symptomatic, risk behavior, or functional outcomes.

To the study team's knowledge, this is the first care management intervention to document reductions in patient postinjury concerns at the 6-month postinjury time point. Also, this is the first investigation to report an association between reductions in statewide emergency department use and a patient-centered care transition intervention.

The investigation has many limitations that contextualize the study findings. The intervention extended to the 6-month injury time point and the investigation did not conduct a formal posttreatment outcome assessment. Because the intervention was multifaceted, the investigation did not yield information regarding which components of the treatment were effective in targeting specific outcomes. The investigation did not find substantial gender, age, ethno-racial, or traumatic brain injury group differences in treatment outcomes; however, the investigation may have been underpowered to detect these subgroup differences.

In May 2011, the study team convened an American College of Surgeons' policy summit and patient stakeholders voiced the need for patient-centered care transition interventions. This comparative effectiveness trial provides initial evidence that a patient-centered care transition intervention can reduce patient concern severity and diminish emergency department use. These initial findings are provocative and could lead to further investigation to develop a body of knowledge that would inform sustainable American College of Surgeons' clinical guideline requirements for U.S. trauma care systems.

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