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# Randomized clinical trial of peer integrated collaborative care intervention after physical injury

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## ABSTRACT

**Objectives** The goal of the current study was to assess the effectiveness of a peer integrated collaborative care intervention for postinjury outcomes.

**Methods** Injury survivors ≥18 years of age were screened for post-traumatic stress disorder (PTSD) symptoms and severe postinjury concerns; screen-positive patients were randomized to the intervention versus enhanced usual care control conditions. The collaborative care intervention included peer support and care management. The intervention also included evidence-based pharmacotherapy and psychotherapeutic elements targeting PTSD. The COVID-19 pandemic interrupted recruitment between March and June 2020; in response to the COVID-19 pandemic, the peer component of the intervention went from in-person to virtual delivery. The primary outcomes were PTSD symptoms assessed with the Diagnostic and Statistical Manual of Mental Disorders fourth edition PTSD checklist, any severe postinjury concerns, and emergency department/inpatient utilization followed over the 12 months postinjury. Secondary outcomes included patient satisfaction with emotional healthcare.

**Results** A total of 450 patients were randomized to the intervention (n=225) and control (n=225) conditions; 124 patients (28%) were recruited and completed all study assessments prior to the onset of the COVID-19 pandemic, while 326 patients (72%) were recruited after and/or had one or more study follow-ups occur postpandemic onset. Mixed model regression revealed no statistically significant comparisons for any of the primary outcomes. In exploratory models that examined the impact of COVID-19, significantly improved PTSD symptoms were present at 3 months pre-COVID-19 relative to post-COVID-19. Intervention patients consistently demonstrated higher satisfaction with emotional aspects of healthcare ($F(5,1652)=2.87$, $p=0.01$).

**Conclusions** The intervention demonstrated no significant improvements in primary outcomes in the intent-to-treat sample. The peer integrated collaborative care intervention contributed to higher patient satisfaction with the emotional aspects of healthcare.

**Level of evidence** Level II, randomized clinical trial.

**Trial registration number** NCT03569878.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Few randomized clinical trial investigations have assessed the effectiveness of peer integrated collaborative care interventions for postinjury outcomes.

### WHAT THIS STUDY ADDS

⇒ Although the intervention demonstrated no significant improvements for primary outcomes, including post-traumatic stress disorder symptoms, severe patient concerns, and emergency department utilization when compared with enhanced usual care, the peer integrated collaborative care intervention was associated with higher patient satisfaction with emotional aspects of healthcare.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Interrupted by the COVID-19 pandemic, the study provides novel information on the integration of peers into trauma center-based collaborative care teams.

## INTRODUCTION

Traumatic physical injury requiring hospitalization is associated with risk for the development of post-traumatic stress disorder (PTSD) and related comorbidity.[1 2] After the injury, PTSD and associated comorbidities have been linked to substantial functional impairment, as well as patterns of increased emergency department and inpatient health service utilization.[3–7] Nationwide, acute care centers provide initial triage and, if indicated, admission for patients with traumatic physical injuries.[8 9]

Peer interventionists are becoming a mainstay of treatment delivery for multiple health conditions across diverse US healthcare systems.[10–14] However, unlike other areas of clinical medicine, acute post-injury interventions have yet to comprehensively integrate peer interventionists or clarify optimal roles for peer interventionists within a collaborative team.[14] A number of potential roles exist for integrating peers, including bedside support, empathic engagement, and care coordination.[14 15] Initial studies in the rehabilitation literature suggest that peer interventionists may aid care transitions after severe spinal cord and traumatic brain injury by serving to link acute care service delivery with outpatient and community resources; however, no large-scale acute care trials have integrated injured peers into acute care multidisciplinary teams.[14 16 17]

Collaborative care interventions hold promise for the integration of peer interventionists into multidisciplinary teams for the treatment of injured patients.[14 18–22] Collaborative care is a comprehensive, patient-centered strategy for treating medical and mental health comorbidity for injury survivors that combines medications and cognitive behavioral psychotherapy elements that have effectiveness in PTSD treatment with proactive postinjury care management that optimizes care transitions. A series of investigations have established the effectiveness of the collaborative intervention approach for injured trauma survivors; these investigations have used social work, nursing, psychologist, and physician providers to implement collaborative care.[18–22] Collaborative care has been suggested as one optimal approach for US trauma centers working to adhere to the recent American College of Surgeons Committee on Trauma requirements for mental health screening and referral for injured patients at risk for the development of PTSD.[8 9] The literature review, however, revealed no acute care medical investigations that have tested collaborative care interventions that integrate peers into a multidisciplinary treatment team.

This investigation sought to compare the effectiveness of a peer integrated collaborative care intervention versus an enhanced usual care control condition. The investigation hypothesized that peer intervention would significantly reduce PTSD symptoms, the severity of postinjury concerns expressed by patients, and emergency department and/or inpatient health service utilization.

The investigation was interrupted by the COVID-19 pandemic, and the peer intervention required substantial post-pandemic modification. Secondary analyses explored the differential effects of peer intervention treatment before versus after the onset of the COVID-19 pandemic.

## METHODS

### Design overview

The investigation aimed to integrate previously injured peers with frontline acute care providers as part of a multidisciplinary team (online supplemental file 1). Injured trauma survivors ≥18 years of age underwent a 10-domain electronic health record (EHR) evaluation for high levels of emotional distress (ie, PTSD symptoms and severe postinjury concerns).[23] Patients who had three or more EHR risk domains were then screened for scores ≥35 on the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) PTSD checklist and one or more severe postinjury concerns.[24] Screen-positive patients were randomized to intervention and control conditions. Intervention activity began at the bedside in the trauma center and continued for up to 6 months after the injury hospitalization. Follow-up occurred for all patients 1, 3, 6, 9, and 12 months after the index injury hospitalization. An institutional review board (00005068) approved all study procedures, including COVID-19 protocol modifications, and informed consent was obtained from each participant. Recruitment for the investigation began on August 7, 2018, and ended on July 8, 2022. The COVID-19 pandemic interrupted recruitment between March 13, 2020, and June 16, 2020. The Consolidated Standards of Reporting Trials (CONSORT) guideline was used to ensure proper reporting of methods, results, and discussion.[14]

### Patient recruitment

All potential patient participants underwent an EHR 10-domain PTSD evaluation, which has been previously described.[23] After informed consent was obtained, patients underwent a baseline inpatient screen for emotional distress; patients who scored ≥35 on the PTSD checklist and endorsed one or more severe post-traumatic concerns were randomized into the longitudinal portion of the investigation.[14 19 20 25]

Patients were excluded if they required immediate psychiatric intervention or were currently incarcerated. Patients who did not speak either English or Spanish were also excluded from the protocol; prior studies have documented over 40 different languages spoken by patients, making the translation of consent documents and scales in multiple different languages impractical. Patients were also excluded if they were not residents of Alaska, California, Oregon, or Washington.

### Randomization

After completing the baseline assessment, randomization occurred in a 1:1 ratio according to a computer-generated random assignment sequence in blocks of either four or six patients, prepared by the study biostatistician. All individuals conducting follow-up interviews were blinded to patient intervention versus control group status (table 1).[14]

### Enhanced usual care control condition

The trauma surgery team notification of the patient emotional distress, with suggestions for mental health inpatient consultation (eg, social work, rehabilitation psychology, psychiatry consult, addiction intervention, chaplaincy, or other psychosocial consult service), constituted the enhanced usual care comparator condition. Routine screening of trauma surgical patients with the PTSD checklist, linked to nurse notification of patients with elevated scores, constituted an enhancement to usual care.

### Peer integrated collaborative care intervention

Previously injured peers worked alongside frontline acute care providers in the delivery of collaborative care. Peers were adults aged 18 and older who had survived a variety of traumatic life events that required hospitalization. One peer, an older adult white female, incurred polytrauma requiring intensive care unit (ICU) admission after being hit by debris during a hurricane. Another peer was a young adult African American male who was confined to a wheelchair after incurring a gunshot-related spinal cord injury. Another peer was a middle-aged Hispanic female who required multiple limb amputations after hospitalization for necrotizing fasciitis. A fourth peer was a young adult white female survivor of a mass shooting event in which she incurred multiple gunshot wounds.[14]

The team included peers as well as other study team members (eg, social workers and psychiatrists).[14] The collaborative care team worked to link injured patients' care from inpatient and emergency department settings to primary care and community services. Care coordination includes a series of intervention components that have been previously shown to improve acute care to primary care and community transitions and reduce unnecessary emergency department utilization.[7] Intervention team members actively linked patients to primary care providers. Intervention patients were also given the study team's 24/7 cell phone number and encouraged spontaneous calls or texts to answer any postinjury concerns that arose, including patient and family member questions regarding visiting the emergency department for postinjury concerns. Injured patients randomized to the collaborative care intervention were visited by the peer and/or other collaborative care team members while in the hospital. Peers and study team case managers elicited and targeted for improvement each patient's unique constellation of

**Table 1** Activities/treatment elements with hypothesized outcomes for patients randomized to the peer integrated collaborative care intervention versus enhanced usual care control conditions

| Peer integrated collaborative care intervention (n=225) | Enhanced usual care control (n=225) | Hypothesized outcome |
|---|---|---|
| Research assistant assesses postinjury concerns and symptomatic distress at baseline | Research assistant assesses postinjury concerns and symptomatic distress at baseline | Not applicable |
| Randomization | Randomization | Not applicable |
| Not received | Trauma surgery recommendation for mental health consultation | Not applicable |
| Peer interventionist and other clinical study team provide care management | Not received | Intervention demonstrates reductions in post-traumatic concern severity* and emergency department/inpatient utilization† relative to control group |
| Social work interventionist and other non-peer clinical study team members provide evidence-based cognitive behavioral therapy elements | Not received | Intervention group demonstrates reductions in post-traumatic stress disorder symptoms relative to controls |
| Psychiatrist recommends psychotropic medication prescriptions | Not received | Intervention group demonstrates reductions in post-traumatic stress disorder symptoms* relative to control group |
| Social worker, psychiatrist and or other non-peer clinical study staff provide 24/7 cell phone text and call coverage, that includes responses to Emergency Department Information Exchange alerts. | Not received | Intervention group demonstrates reductions in emergency department/inpatient utilization† relative to control group |
| Blinded follow-up telephone outcome assessment | Blinded follow-up telephone outcome assessment | Not applicable |

*Assessed at baseline, 1, 3, 6, 9, and 12 months after the injury hospitalization.
†Assessed continuously by automated electronic health record data over the 12 months after injury.

postinjury concerns. Elements of the intervention were delivered during routine postinjury patient encounters in trauma wards, emergency departments, outpatient clinics, community settings, over the telephone, and through secure web-based audio/video conferencing (eg, Zoom) or other electronic means.

Study team members also asked about treatment preferences and scheduled ongoing times to meet/call the patient. Whenever possible, and with the injured patient's permission, family members and other primary postinjury caregivers were incorporated into the care management intervention.

Collaborative care intervention team members were trained in the delivery of evidence-based cognitive behavioral therapy elements during routine postinjury patient encounters.[14] Psychopharmacological intervention, including the use of serotonin-specific reuptake inhibitors and serotonin norepinephrine reuptake inhibitor antidepressants, was also recommended in the treatment of patients with PTSD and/or depression symptoms. The medication intervention component aimed to initiate and ensure adequate follow-up of psychopharmacological antidepressant treatment targeting symptoms of PTSD and/or depression. The intervention also included a pharmacological component targeting PTSD-related sleep disturbances. A novel information technology feature, The Emergency Department Information Exchange system, allowed collaborative care team members to implement electronic healthcare records innovations, such as the creation of care plan notifications and the receipt of emergency department visit alerts.

## COVID-19 intervention modification

The central COVID-19 intervention change was the modification of the peer intervention element from in-person to exclusively virtual activities. The original pre-COVID-19 pandemic protocol had peers engaging study patients in person in the hospital and in outpatient clinic settings. The peers were supported by a social work interventionist who would orchestrate peer in-person interactions (eg, notify peers of a newly randomized patient and ensure that the peer interventionists were aware of inpatient rooms and/or outpatient clinic appointment meeting times and locations). In the prepandemic protocol, the study social worker also supported virtual peer engagement activities that included telephone and other virtual (eg, FaceTime) interactions. These intervention activities were in place from the initiation of intervention activities on August 7, 2018, through March 13, 2020. The peers were exclusively virtual after March 13, 2020. The rationale for the post-COVID-19 modification was that previously injured peers had a high COVID-19 disease vulnerability and could not safely perform in-person intervention activities. Separate mixed-method manuscripts further describe the disruptive impact that the COVID-19 pandemic had on peer intervention.[26–28]

## Outcome assessments

The PTSD checklist for DSM-IV was used to assess PTSD symptoms at baseline and 1-, 3-, 6-, 9-, and 12-month postinjury follow-up assessment time points.[24] The instrument yields a continuous PTSD symptom score, and a series of investigations have demonstrated the reliability and convergent and construct validity of the PTSD checklist across trauma-exposed populations.[23 24] At baseline, patients were asked to report their symptoms since the injury event, and at each follow-up interview, patients reported their PTSD symptoms over the prior month. Prior investigation has established the equivalence of the DSM-IV and DSM-V versions of the PTSD checklist across trauma-exposed patient populations, including physically injured trauma survivors.[29–31] Based on prior study team publications, a ≥10-point reduction in PTSD checklist scale scores from baseline to study endpoint was used to further describe clinically meaningful differences in the current investigation.[20] At the time of the study's inception, the study team had validated the 10-domain EHR evaluation with the DSM-IV version of the PTSD checklist; therefore, all primary surgical ward and follow-up assessments for the current study were performed with the DSM-IV version of the PTSD checklist.[14 23]

The baseline and follow-up interviews began with the assessment of each patient's unique constellation of postinjury concerns.[25 32 33] The concern question asks, 'Of everything that

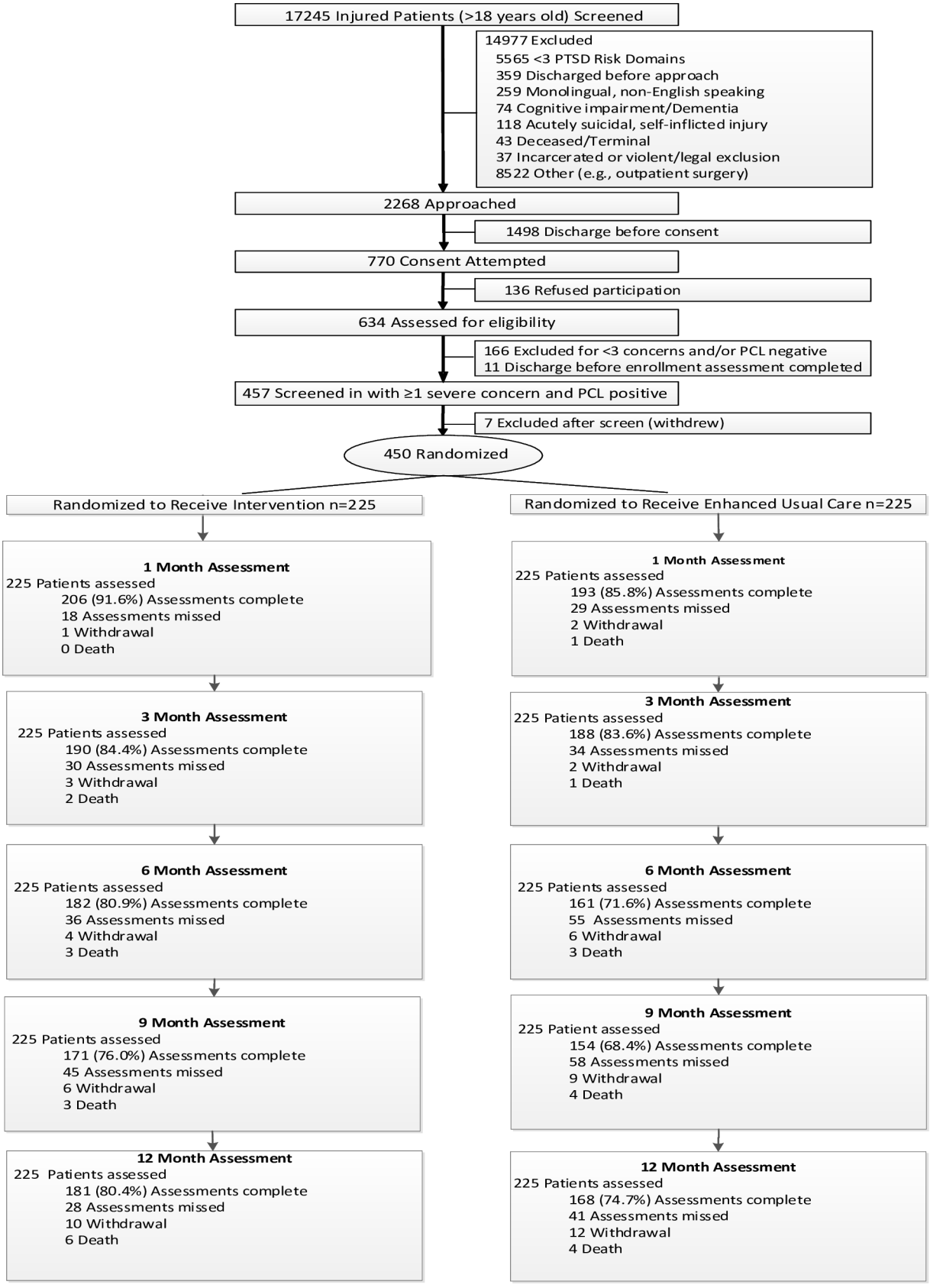


**Figure 1** Patient flow through trial.

has happened to you since you were injured, what concerns you the most?' Following each concern elicitation, patients are asked to rate the severity of the concern on a scale from one to five, with one being not at all concerning and five being extremely concerning. A severe concern was defined as a concern rated as a five by the patient.[25 32 33] Prior psychometric investigations

**Table 2** Baseline patient characteristics

| Characteristics | No. (%) of patients | | |
|---|---|---|---|
| | All (n=450) | Usual care (n=225) | Peer intervention (n=225) |
| Electronic heath record variables | | | |
| Sex: female | 220 (48.9) | 109 (48.4) | 111 (49.3) |
| Intensive care unit admission | 192 (42.7) | 100 (44.4) | 92 (40.9) |
| Prior inpatient hospitalization | 168 (37.3) | 84 (37.3) | 84 (37.3) |
| Tobacco use | 163 (36.2) | 84 (37.3) | 79 (35.1) |
| Psychiatric diagnosis | 154 (34.2) | 80 (35.6) | 74 (32.9) |
| PTSD diagnosis | 36 (8.0) | 15 (6.7) | 21 (9.3) |
| Positive blood alcohol concentration/drug use | 278 (61.8) | 146 (64.9) | 132 (58.7) |
| Demographic | | | |
| Age, mean (SD), years | 38.9 (15.3) | 38.5 (15.5) | 39.3 (15.1) |
| Race* | | | |
| White | 237 (52.7) | 125 (55.6) | 112 (49.8) |
| Black | 70 (15.6) | 32 (14.2) | 38 (16.9) |
| American Indian | 20 (4.4) | 6 (2.7) | 14 (6.2) |
| Asian | 9 (2.0) | 4 (1.8) | 5 (2.2) |
| Pacific Islander | 8 (1.8) | 3 (1.3) | 5 (2.2) |
| Mixed | 55 (12.2) | 26 (11.6) | 29 (12.9) |
| Other | 51 (11.3) | 29 (12.9) | 22 (9.8) |
| Hispanic* | | | |
| Yes | 109 (24.3) | 53 (23.6) | 56 (25.0) |
| No | 340 (75.7) | 172 (76.4) | 168 (75.0) |
| Education | | | |
| Less than high school | 59 (13.2) | 28 (12.5) | 31 (13.8) |
| High school/GED | 223 (49.8) | 110 (49.1) | 113 (50.5) |
| Associate degree | 83 (18.5) | 42 (18.8) | 41 (18.3) |
| Bachelor's or graduate degree | 83 (18.5) | 44 (19.6) | 39 (17.4) |
| Marital status | | | |
| Married/living with partner | 117 (26.0) | 52 (23.1) | 65 (28.9) |
| Employed | 294 (66.4) | 161 (72.2) | 133 (60.5) |
| Insurance | | | |
| Private | 109 (29.0) | 62 (33.0) | 47 (25.0) |
| Public | 249 (66.2) | 116 (61.7) | 133 (70.7) |
| None | 18 (4.8) | 10 (5.3) | 8 (4.3) |
| Acute care injury and medical | | | |
| Intentional injury | | | |
| Assault | 18 (4.0) | 6 (2.7) | 12 (5.3) |
| Stabbing | 21 (4.7) | 8 (3.6) | 13 (5.8) |
| Firearm | 59 (13.1) | 26 (11.6) | 33 (14.7) |
| Unintentional injury | 352 (78.2) | 185 (82.2) | 167 (74.2) |
| Injury severity category | | | |
| 0–8 | 77 (17.1) | 32 (14.2) | 45 (20.0) |
| 9–15 | 154 (34.2) | 84 (37.3) | 70 (31.1) |
| ≥16 | 219 (48.7) | 109 (48.4) | 110 (48.9) |
| Traumatic brain injury† | | | |
| None | 369 (82.0) | 183 (81.3) | 186 (82.7) |
| Mild | 29 (6.4) | 17 (7.6) | 12 (5.3) |
| Moderate | 41 (9.1) | 20 (8.9) | 21 (9.3) |
| Severe | 11 (2.4) | 5 (2.2) | 6 (2.7) |
| Number of comorbid medical conditions | | | |
| 0 | 98 (24.1) | 51 (25.5) | 47 (22.8) |
| 1 | 91 (22.4) | 42 (21.0) | 49 (23.8) |
| 2 | 59 (14.5) | 29 (14.5) | 30 (14.6) |
| ≥3 | 158 (38.9) | 78 (39.0) | 80 (38.8) |
| Days in hospital, mean (SD) | 11.5 (14.5) | 12.1 (15.2) | 10.9 (13.8) |

Continued

Table 2 Continued

| Characteristics | No. (%) of patients | | |
|---|---|---|---|
| | All (n=450) | Usual care (n=225) | Peer intervention (n=225) |
| Clinical assessments | | | |
| Prior serious traumas before injury admission, mean (SD)‡ | 5.1 (3.4) | 5.0 (3.3) | 5.2 (3.5) |
| Postinjury concerns | | | |
| Number of severe, mean (SD) | 3.4 (1.9) | 3.4 (2.0) | 3.3 (1.7) |
| Baseline PCL-C total score, mean (SD)§ | 49.4 (11.3) | 49.5 (11.4) | 49.3 (11.3) |
| Baseline PCL5 blended total score, mean (SD) | 36.7 (13.6) | 36.7 (13.5) | 36.6 (13.8) |
| Baseline PHQ-9 depression total score, mean (SD)§ | 12.9 (5.6) | 12.8 (5.3) | 12.9 (5.9) |
| PHQ-9 item nine suicide positive¶ | 109 (24.7) | 50 (22.6) | 59 (26.7) |
| Preinjury AUDIT-C score, mean (SD) | 3.3 (2.9) | 3.3 (3.0) | 3.3 (2.8) |
| Preinjury self-report drug use** | | | |
| Stimulants†† | 78 (17.5) | 40 (17.8) | 38 (17.3) |
| Opioids | 26 (5.9) | 15 (6.7) | 11 (5.0) |
| Marijuana | 254 (57.3) | 129 (57.6) | 125 (57.1) |
| Preinjury Short Form-12 Physical Component Summary score, mean (SD) | 49.8 (10.7) | 50.2 (10.3) | 49.4 (11.1) |
| Preinjury Short Form-12 Mental Component Summary score, mean (SD) | 44.5 (12.1) | 43.7 (12.3) | 45.3 (12.0) |
| Patient satisfaction | | | |
| Physical health care | 382 (87.0) | 192 (86.5) | 190 (87.6) |
| Emotional health care | 321 (75.7) | 169 (77.2) | 152 (74.2) |

Risk factors for persistent PTSD symptoms include: (1) ≥5 preinjury traumas, (2) PTSD diagnosis from inpatient EHR screen, (3) non-white race from inpatient EHR, (4) ≥3 medical comorbidities, (5) stimulants, and (6) intentional injury.
*Patients were asked to self-identify racial/ethnic group classifications as provided by the investigators. One study participant was missing race data and was included in the other category. Three study participants were missing ethnicity data.
†Traumatic brain injury severity was coded on the basis of a previously validated algorithm for hospitalized inpatients that assigned MAXAIS head injury scores of 1–2 to mild, 3 to moderate, and 4 or higher to severe.
‡Derived from the 3-month interview trauma history screen; this value may underestimate the rates of prior PTSD symptoms as patients who were missing data were included in the no PTSD symptom group.
§For PCL-C and PHQ-9 baseline assessments, inpatients were asked to report symptoms since the injury event.
¶PHQ-9 item 9 suicide+ is score of 1 or greater.
**Single item self-report dichotomized as none versus at least monthly use.
††Stimulants include cocaine and amphetamines.
AUDIT-C, The Alcohol Use Disorders Identification Test-Consumption Items; ICU, intensive care unit; PCL-C, PTSD checklist civilian version; PHQ, Patient Health Questionnaire; PTSD, post-traumatic stress disorder.

documented that the severity of postinjury concerns mirrors the longitudinal trajectory of PTSD symptoms and functional impairments.[25 32 33]

Emergency department and inpatient health service utilization after discharge was assessed using the Emergency Department Information Exchange.[7] Emergency Department Information Exchange is a novel clinical informatics tool that aggregates real-time emergency department and inpatient visits for the population of patients presenting to any emergency department in Alaska, California, Oregon, and Washington, as well as other US states. Recent study team investigations document the reliability and validity of Emergency Department Information Exchange emergency department assessments.[7]

The investigation used the Patient Health Questionnaire (PHQ-9) to assess depressive symptoms[34] and the Medical Outcomes Study Short Form 12/36 (MOS SF) to assess physical and mental health function.[35] Items assessing satisfaction with physical and emotional healthcare after injury were adapted from previous studies of care management interventions for patients in primary and acute care medical settings.[19] A single item assessing satisfaction with emotional aspects of care asked, 'How satisfied were you with the healthcare available to you for personal or emotional problems since your injury?' Likert scale responses for the item included five choices: 1 'very dissatisfied', 2 'dissatisfied', 3 'neither satisfied or dissatisfied', 4 'satisfied' and 5 'very satisfied'. The item was dichotomized with the percentage satisfied including patients that responded 'very satisfied' or 'satisfied'. Information on the use of antidepressants and PTSD sleep medications was collected by patient self-report at the 1-, 3-, 6-, 9- and 12-month time points by blinded follow-up interviewers. Medical record data was used to derive injury severity scores and injury mechanisms.[36] Laboratory toxicology results, insurance status, length of hospital and ICU stays, and other clinical characteristics were also obtained from medical record data. The amount of time spent with each patient was recorded in the Research Electronic Data Capture (REDCap) tool by providers when they documented each patient encounter.

## Data analyses

First, intervention and control group differences in baseline characteristics were examined. Next, intervention and control group differences were examined over time for the primary and secondary outcomes in the intent-to-treat sample using mixed-effect regression models (n=450).[37] Separate mixed-effect regression models were run individually for the PTSD symptoms, any severe concerns, emergency department/inpatient health service use primary outcomes and patient satisfaction, PHQ-9, and MOS SF physical and mental health function secondary outcomes. Repeated measurements of the baseline, 1-,

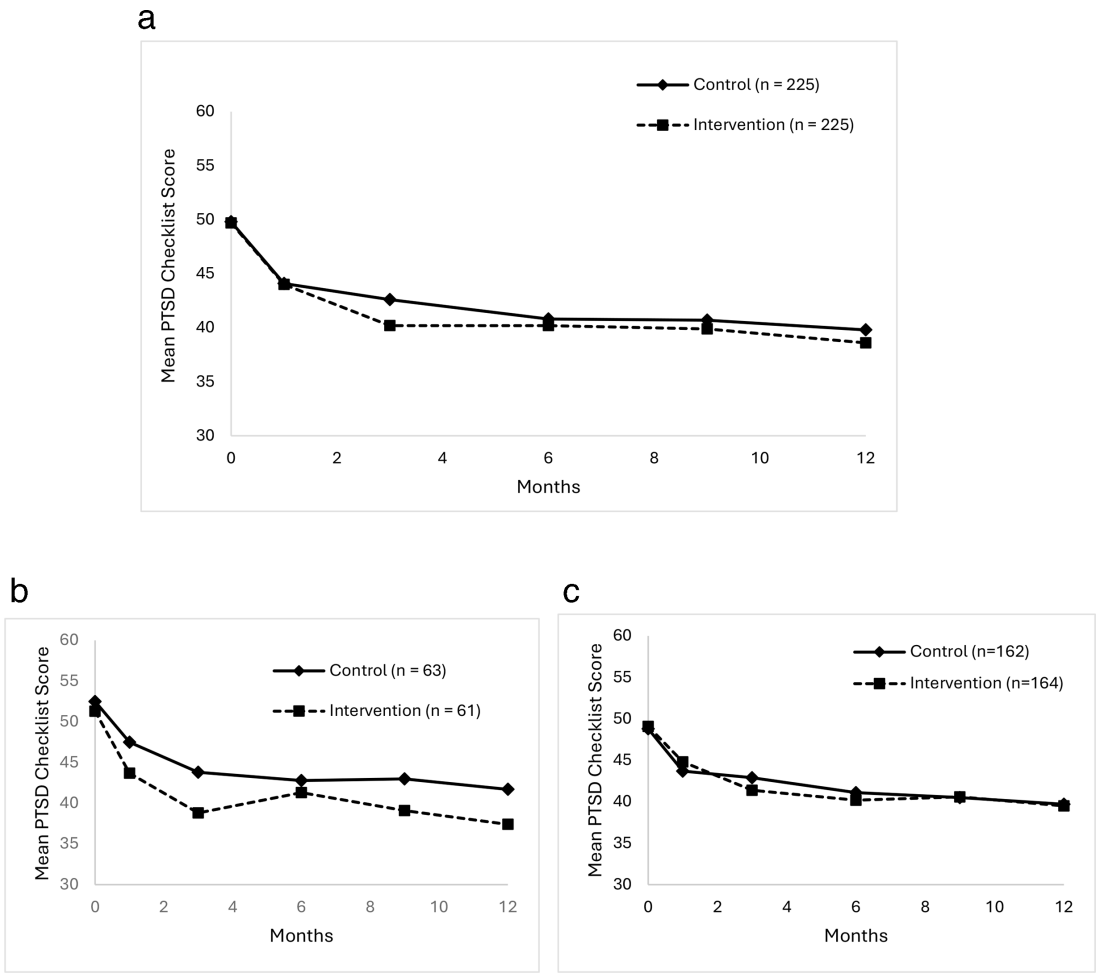


**Figure 2** (a) PTSD symptom levels over time: all participants (n=450). (b) PTSD symptom levels over time: pre-COVID-19. (c) PTSD symptom levels over time: post-COVID-19. PTSD, post-traumatic stress disorder.

3-, 6-, 9-, and 12-month primary and secondary outcome assessments were the dependent variables. For all dependent variables, the study team fit models containing time categories (six time points), intervention (intervention vs control), and intervention by time interactions, with no covariates. Multiple models were run in order to examine group-by-time interaction effects as well as main effects. Time, group, and group-by-time interaction were specified as fixed effects. Individual patient time was specified as a random effect. Effect sizes and/or relative risks were also calculated. For the PTSD symptom outcome, an analysis was also performed that compared the number of intervention versus control patients that experienced a clinically relevant ≥10-point reduction in PTSD checklist symptoms recorded from baseline to the final 12-month follow-up time point; the number needed to treat was derived from this comparison.[14]

Next, the study team developed exploratory data analytic approaches that could model the impact of the COVID-19 pandemic. The study team used data derived from COVID-19-focused qualitative studies undertaken during the pandemic to inform the dichotomization of randomized patients into pre-COVID-19 and post-COVID-19 cohorts.[26] A total of 124 patients (61 intervention and 63 control, 28% of the total sample) were recruited and completed all study assessments prior to the onset of the COVID-19 pandemic, while 326 patients (164 intervention and 162 control, 72% of the total sample) were recruited after and/or had one or more study follow-ups occur post-pandemic onset. To explore differential patterns of treatment response introduced by the COVID-19 pandemic, mixed-effects regression models that included the three-way interaction of treatment, by time, and by COVID-19 cohort were performed. These regression models also incorporated comparisons of both intervention and control group effects, as well as isolated comparisons of pre-COVID-19 and post-COVID-19 intervention group effects at each time point.

Sample size estimates for all primary outcomes were derived from prior investigations.[18–21] The investigation was not adequately powered for additional, exploratory COVID-19 analyses. The study team used SAS V.9.4 (SAS Institute) and SPSS V.25 (SPSS Software IBM) for the analyses.

## RESULTS

A total of 450 patients were randomized to peer integrated collaborative care (n=225) and enhanced usual care control (n=225) conditions (figure 1). For the 1- and 3-month assessments, for both intervention and control patients, the study attained ≥80% follow-up. For the 6-, 9-, and 12-month assessments, for both intervention and control patients, the study attained ≥68% follow-up. Patients randomized into the investigation had substantial histories of preinjury trauma (table 2). The only characteristic that significantly differed between the pre-COVID-19 and post-COVID-19 patient groups was a significantly increased frequency of firearm injury survivors recruited into the study after the pandemic onset

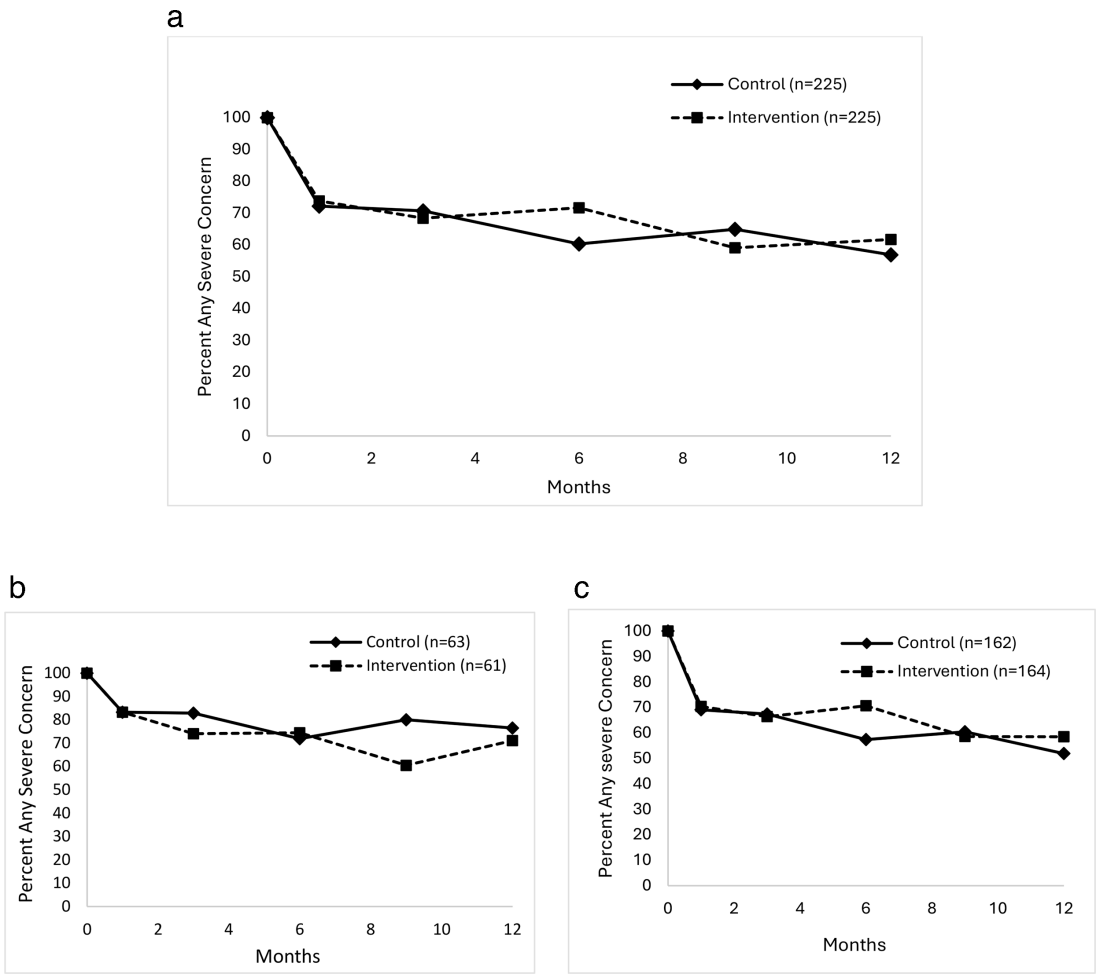


**Figure 3** (a) Any severe concern over time: all participants (n=450). (b) Any severe concern over time: pre-COVID-19. (c) Any severe concern over time: post-COVID-19.

(pre-COVID-19: 9% vs post-COVID-19: 17%, $\chi^2$ (1)=6.24, p=0.01).

## Intervention team activity and time

94% of intervention patients (211/225) were visited by a collaborative team member during the inpatient hospital admission. Each injured patient was assigned an individual peer, and 83% of intervention patients (186/225) had one or more peer visits. On average, a total of 368 min (SD (SD) = 356 min; median=275 min, IQR=355 min) was spent with each intervention patient; overall, peers spent 134 min (SD=202 min; median=40 min, IQR=150 min) with each intervention patient. Pre-COVID-19, the total intervention team time was approximately 503 min (SD=407 min; median=355, IQR=480), with peers averaging 207 min (SD=264 min; median=120 min, IQR=270 min) per patient. Post-COVID-19, the total intervention team time was significantly less at 317 min (SD=291 min; median=233 min, IQR=303 min), with peers averaging 107 min (SD=166 min; median=40 min, IQR=100 min) per patient.

## Primary outcomes

Post-traumatic stress symptom levels, as assessed with the PTSD checklist, were elevated at the time of the index physical injury admission and gradually diminished over the course of the month's postinjury for patients randomized to both the peer intervention and enhanced usual care control group conditions (figure 2a). Mixed model regression analyses revealed no statistically significant changes in PTSD symptoms between peer intervention and usual care control group patients over time (group-by-time interaction, F(5,1780)=0.82, p=0.54; average intervention vs control effect size=0.08). Additionally, 111/180 (61.7%) of intervention patients demonstrated a ≥10-point reduction from baseline to 12 months on the PTSD checklist, compared with 89/168 (53.0%) of control patients ($\chi^2$ (1) = 2.7, p=0.10; number needed to treat=11.5).

All patients began the study with at least one severe postinjury concern (figure 3a). The number of peer intervention and usual care control group patients expressing one or more severe concerns gradually decreased over the course of the weeks and months postinjury. Mixed model regression analyses revealed no statistically significant changes in the expression of one or more severe concerns between peer intervention and usual care control group patients over time (main effect, F(1,1358)=0.29, p=0.59; average intervention vs control relative risk (RR)=1.03, 95% CI 0.92 to 1.14).

All patients began the study with an index inpatient admission (figure 4a). Emergency department/inpatient visits decreased for peer intervention and usual care control group patients over the course of the year after injury. Emergency department/inpatient health service utilization did not demonstrate significant between-group differences over time (main effect,

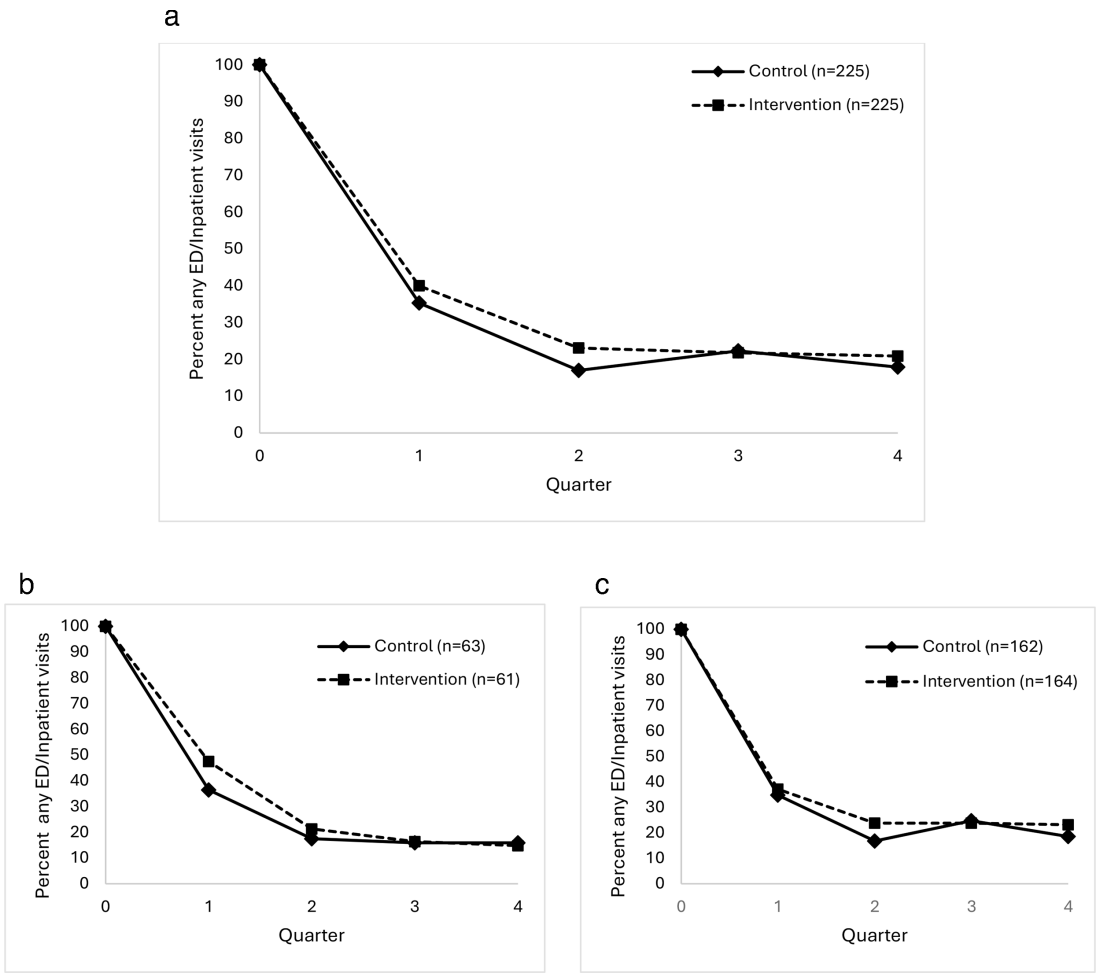


**Figure 4** (a) Per cent any ED/inpatient visits: All participants (n=450). (b) Per cent any ED/inpatient visits: pre-COVID. (c) Per cent any ED/inpatient visits: post-COVID. ED, emergency department.

F(1,1344)=1.82, p=0.18; average intervention vs control RR=1.14, 95% CI 0.94 to 1.39).

In exploratory regressions that modeled the impact of pre-COVID-19 and post-COVID-19 treatment effects, differential change was evident for some of the primary outcomes (figures 2b,c and 3b,c and 4b,c). Intervention patients demonstrated significantly greater rates of PTSD symptom reduction at the 3-month time point pre-COVID-19 (Beta=−12.5, 95% CI −16.2 to −8.8, p<0.001) compared with intervention patients post-COVID-19 (Beta=−7.7, 95% CI −9.8 to −5.5, p<0.001, difference=4.8, 95% CI 0.6 to 9.1, p=0.03). Pre-COVID-19 intervention patients demonstrated reductions in the expression of one or more severe concerns at the 9-month postinjury time point relative to control patients who did not attain statistical significance (RR=0.76, 95% CI 0.56 to 1.01, p=0.06). Post-COVID-19, control patients demonstrated significant reductions in one or more severe concerns at the 6-month postinjury time point relative to intervention patients (RR=1.23, 95% CI 1.02 to 1.48, p=0.03). Emergency department/inpatient health service utilization did not substantially differ for peer intervention and usual care control group patients pre-COVID-19 versus post-COVID-19 (figure 4b,c). For the emergency department/inpatient utilization outcome, mixed model regression revealed no statistically significant differences for the pre-COVID-19 and post-COVID-19 cohorts (pre-COVID-19 RR=1.11, 95% CI 0.68 to 1.82, p=0.67) versus post-COVID-19 RR=1.16, 95% CI 0.92 to 1.46, p=0.22, difference p=0.91).

## Secondary outcomes

Intervention patients consistently demonstrated higher satisfaction with emotional aspects of healthcare when compared with control patients (figure 5, group-by-time interaction, F(5,1652)=2.87, p=0.01). Higher satisfaction ratings achieved statistical significance for intervention patients compared with control patients from baseline to 3 months (RR=1.37, 95% CI 1.16 to 1.62) and from baseline to 6 months (RR=1.22, 95% CI 1.03 to 1.46). No other secondary outcomes, including the PHQ-9 or MOS SF physical or mental health function, demonstrated statistically significant comparisons across groups. There were no significant differences between intervention (36%) and control (28%) patients for any postinjury antidepressant use ($\chi^2$ (1) = 2.62, p=0.10). Also, there were no significant differences between intervention (18%) and control group (16%) patients for any PTSD sleep medication use ($\chi^2$ (1) = 0.40, p=0.53).

## DISCUSSION

This comparative effectiveness trial sought to compare outcomes for emotionally distressed injured patients randomized to a collaborative care intervention that integrated peers into a multidisciplinary treatment team versus an enhanced usual care control condition. The peer integrated collaborative care intervention was markedly impacted by the onset of the COVID-19 pandemic during the trial.

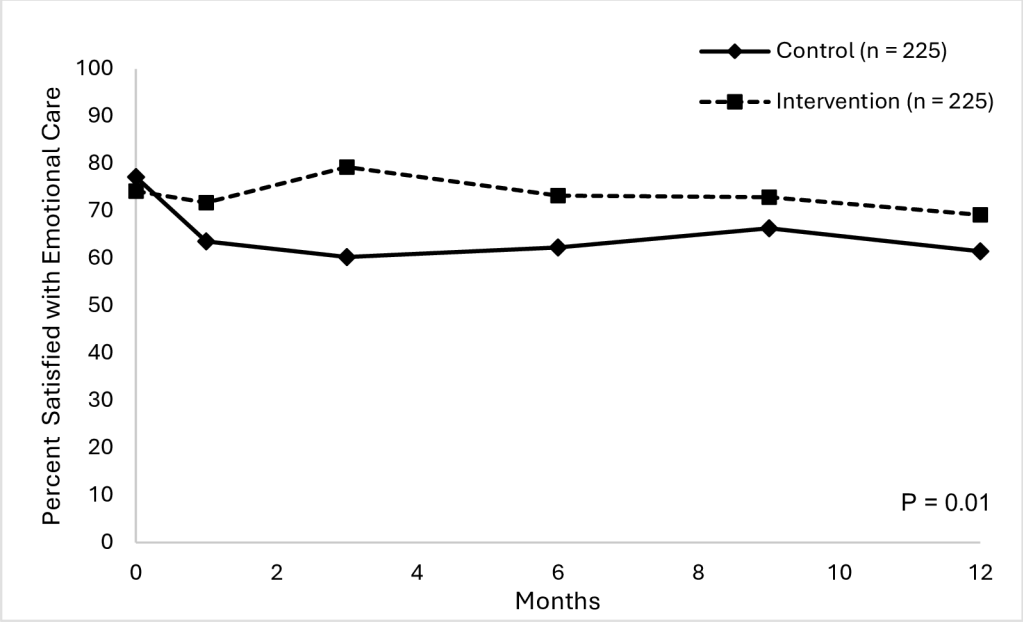


**Figure 5** Satisfaction with emotional aspects of healthcare: all participants (n=450).

In the intent-to-treat analysis, none of the primary outcomes, including PTSD symptoms, patient concern severity, and emergency department/inpatient health service utilization, demonstrated significant differences over time for patients randomized to the peer integrated collaborative care intervention versus enhanced usual care control conditions. Regarding secondary outcomes, peer intervention patients consistently reported improved satisfaction with emotional aspects of healthcare when compared with control patients. No significant between-group differences were observed for any other secondary outcomes.

In exploratory analyses that compared pre-COVID-19 and post-COVID-19 treatment effects, intervention patients demonstrated significantly improved PTSD symptom changes at the 3-month time point pre-COVID-19 versus post-COVID-19. Pre-COVID-19 intervention patients demonstrated reductions in one or more severe concerns at the 9-month postinjury time point relative to control patients that did not attain statistical significance. Post-COVID-19, control patients demonstrated significant reductions in one or more severe concerns at the 6-month postinjury time point relative to intervention patients.

A series of investigations now document that early interventions targeting the symptoms of PTSD can be effective.[2 38–42] In the current study, despite no observed PTSD treatment effect in the intent-to-treat sample, the peer integrated collaborative care intervention appears to have had a differential impact on patients pre-COVID-19 versus post-COVID-19; significantly improved PTSD intervention responses were observed in the pre-COVID-19 cohort at the 3-month postinjury time point.

One prior clinical trial investigation suggested that early postinjury intervention could significantly reduce severe patient concerns.[25] The current investigation trial did not replicate this finding. In the current investigation, post-COVID-19 patients randomized to the usual care control condition demonstrated statistically significant concern reductions at the 6-month postinjury time point. A prior clinical trial also found intervention-associated reductions in emergency department/inpatient health services utilization 27 months after an index injury admission.[7 25] The current COVID-19 impacted trial did not replicate this prior finding.

Prior investigations have documented intervention improvements in patient satisfaction with care associated with collaborative care interventions.[19] The current investigation corroborates and extends this observation by demonstrating improved intervention patient satisfaction with emotional aspects of healthcare both before and after the COVID-19 pandemic.

The peer intervention became exclusively virtual after the onset of the pandemic. Postpandemic, the peer interventionists required social work facilitation of virtual visits, which may have diminished spontaneous peer and patient interactions. Prior investigations of follow-up among injury survivors suggest person-to-person telephone contact versus online virtual contact enhances patient engagement.[43] Future investigation could assess whether in-person versus virtual peer activity is associated with differences in patient engagement. Observations derived from these studies could further inform the question of whether in-person versus virtual peer intervention activity contributed to the observed differential pre-COVID-19 versus post-COVID-19 treatment effects.[43]

The investigation and the pivot required for the COVID-19 pandemic highlight the challenges faced for clinical trials when exogenous events that constitute mass trauma exposures, such as the COVID-19 pandemic or extreme climate-related events, impact clinical trial designs targeting response to individual-level trauma, including physical injury requiring hospitalization.[27 44–46]

This investigation has limitations. This trial tested a multifaceted intervention and was interrupted by the COVID-19 pandemic. The COVID-19 pandemic introduced variable levels of exogenous stress and potential psychological trauma to all study participants and split the sample into two distinct cohorts. These considerations limited the sample size for testing hypotheses for the primary outcomes, including PTSD symptoms, postinjury concerns, and emergency department/inpatient health service utilization, as well as for important subgroup analyses. For example, recent investigations suggest collaborative care intervention may be more effective for racially and ethnically diverse injury survivors.[47] The current investigation, however, could not corroborate or extend these prior findings secondary to COVID-19-introduced cohort considerations. The investigation

is also limited by the inability to track in detail the time allocations and services delivered to patients in the enhanced usual care control condition. It is possible that enhancements to usual care, such as receiving a trauma center mental health referral, could have constituted an active intervention and contributed to the observed lack of an intervention effect for the three primary outcomes. An additional study limitation is the observation of significantly increased percentages of firearm injury survivors recruited post-COVID-19. Another limitation is that a mid-study electronic medical record transition may have contributed to some inaccuracies in the categorical tabulation of exclusions prior to the study team approach, at the primary hospital site. Reasons/etiologies for emergency department/inpatient visits were not able to be tabulated for the investigation. The study was additionally limited by the inability to comprehensively match peer and patient demographic and injury characteristics. Also, 24/7 patient contacts beyond the Monday through Friday 08:00–17:00 time window are not reported in the manuscript. It is acknowledged that for the post-traumatic concerns, a newer/novel patient-reported assessment, the investigation does not report on clinically meaningful intervention and control group differences. Finally, some of the COVID-19 exploratory analyses rely on data from single time points derived from multiple comparisons.

Beyond these considerations, the current investigation suggests that peer integrated collaborative care interventions hold some promise for enhancing satisfaction with emotional healthcare for injured patients treated at US trauma centers. Future clinical trials and methodological investigations may be required to assess the impact of mass trauma exposures on interventions with established effectiveness, such as collaborative care delivered within trauma care systems.

**Contributors** DFZ had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Conception and study design: DFZ, EMB, PT, LP, and RM. Literature review: DFZ, KA, CC, and AE. Data acquisition: DFZ, AE, MI-S, JR, JW, JS, CC, KA, NB, TK and PR. Data analysis and interpretation: DFZ, JR, JW, and PH. Drafting of the manuscript: DFZ, CC, and KA. Critical revision: all authors. Obtained funding: DFZ, PT, and RM. DFZ is the guarantor.

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**Competing interests** DFZ has provided forensic expert consultation/testimony related to posttraumatic stress disorder for the Washington State Attorney General, the City of Seattle, and other agencies/firms. No other disclosures were reported.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by the University of Washington Institutional Review Board, ID number: STUDY00005068. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; internally peer reviewed.

**Data availability statement** The study data will be shared; details of data sharing are currently being worked out by the investigative team.



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