

# A Randomized Stepped Care Intervention Trial Targeting Posttraumatic Stress Disorder for Surgically Hospitalized Injury Survivors

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**Objective:** To test the effectiveness of a stepped care intervention model targeting posttraumatic stress disorder (PTSD) symptoms after injury.

**Background:** Few investigations have evaluated interventions for injured patients with PTSD and related impairments that can be feasibly implemented in trauma surgical settings.

**Methods:** The investigation was a pragmatic effectiveness trial in which 207 acutely injured hospitalized trauma survivors were screened for high PTSD symptom levels and then randomized to a stepped combined care management, psychopharmacology, and cognitive behavioral psychotherapy intervention (n = 104) or usual care control (n = 103) conditions. The symptoms of PTSD and functional limitations were reassessed at 1, 3, 6, 9, and 12 months after the index injury admission.

**Results:** Regression analyses demonstrated that over the course of the year after injury, intervention patients had significantly reduced PTSD symptoms when compared with controls [group by time effect, CAPS (Clinician-Administered PTSD Scale):  $F(2, 185) = 5.50, P < 0.01$ ; PCL-C (PTSD Checklist Civilian Version):  $F(4, 185) = 5.45, P < 0.001$ ]. Clinically and statistically significant PTSD treatment effects were observed at the 6-, 9-, and 12-month postinjury assessments. Over the course of the year after injury, intervention patients also demonstrated significant improvements in physical function [MOS SF-36 PCS (Medical Outcomes Study Short Form 36 Physical Component Summary) main effect:  $F(1, 172) = 9.87, P < 0.01$ ].

**Conclusions:** Stepped care interventions can reduce PTSD symptoms and improve functioning over the course of the year after surgical injury hospitalization. Orchestrated investigative and policy efforts could systematically introduce and evaluate screening and intervention procedures for PTSD at US trauma centers. (Trial Registration: [clinicaltrials.gov](http://clinicaltrials.gov) identifier: NCT00270959)

**Keywords:** injury, physical function, PTSD, stepped care, surgical hospitalization, traumatic brain injury

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Each year, between 1.5 and 2.5 million American civilians require surgical hospitalization for the treatment of traumatic physical injury.<sup>1–3</sup> The symptoms of posttraumatic stress disorder (PTSD) and related comorbid conditions, such as depression and alcohol-use

problems, are common in physically injured patients with and without traumatic brain injury (TBI).<sup>4–10</sup>

After traumatic injury, PTSD and related comorbidities are associated with a broad profile of functional and health-related impairments.<sup>8,11–16</sup> A number of investigations have reported an association between high PTSD symptom levels and the development of postinjury impairments in physical functioning.<sup>6,12,13,17</sup> In a nationwide US study of injury survivors, PTSD and depression made an independent “dose”-related contribution to the inability to return to work after surgical hospitalization; 39% of individuals with no disorder versus 67% of individuals with 1 disorder and 78% of individuals with both disorders had not returned to work 12 months after injury.<sup>13</sup>

A body of evidence now suggests that trauma-exposed individuals, including injured trauma survivors, may respond to early cognitive behavioral therapy (CBT) and pharmacologic interventions.<sup>18–22</sup> Epidemiologic data, however, suggest that it may take months or years for trauma-exposed individuals with PTSD to enter treatment.<sup>23</sup> Effective intervention models that serve to initially engage and then link injured trauma survivors to evidence-based PTSD services are therefore key in the early mental health response to trauma.<sup>19,24</sup>

Large-scale randomized trials have established the effectiveness of collaborative care models that integrate care management, evidence-based pharmacotherapy, and CBT in the treatment of primary-care medical patients with depressive and anxiety disorders.<sup>25–29</sup> Few large-scale investigations have comprehensively targeted PTSD and related functional impairments among injured patients initially treated in inpatient trauma surgical settings.<sup>18,30–32</sup> Finally, no published investigations have assessed the effectiveness of stepped care interventions targeting PTSD for patients with TBI.

This investigation was a pragmatic randomized effectiveness trial designed to assess whether injured patients participating in a stepped collaborative care protocol would demonstrate reductions in the symptoms of PTSD, functional impairments, and comorbid conditions when compared with patients assigned to a usual care control condition. We hypothesized that patients receiving the collaborative-care intervention would demonstrate clinically and statistically significant reductions in the symptoms of PTSD over the course of the year after injury. We also hypothesized that intervention patients would demonstrate improved physical function as well as diminished depressive and alcohol-use symptoms. A secondary hypothesis was that the intervention would be equally effective in patients with and without TBI.

## METHODS

### Design and Setting<sup>33</sup>

The University of Washington Institutional Review Board approved all study procedures prior to initiating the protocol. Between April 2006 and September 2009, injured trauma survivors admitted to the University of Washington’s Harborview level I trauma center were approached at bedside for participation. After providing

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written informed consent, potential participants were screened twice for high PTSD symptom levels with the PTSD Checklist Civilian Version (PCL-C),<sup>34</sup> once while being surgical inpatients [median hospital days = 4, interquartile range (IQR) = 7], and again in the early days and weeks after hospital discharge (median days after index injury event = 13, IQR = 17), either in the outpatient surgery clinic or over the telephone. It was determined that with 100 patients randomized to each group, loss to follow-up of 20%, and a 2-tailed  $\alpha = 0.05$ , there would be >80% power to detect an effect size of  $\geq 0.4$  when analyzing PTSD symptoms as a continuous variable.<sup>35</sup>

Two-hundred seven patients who screened positive at both time points were randomized to the stepped collaborative care intervention (n = 104) or usual care control (n = 103) conditions. All patients received evaluations of PTSD, depression, and alcohol consumption, as well as functional impairments and health service utilization, at baseline in the surgical ward before randomization, and again after randomization at 1, 3, 6, 9, and 12 months post discharge.

## Participants

The investigators screened English-speaking women and men ages 18 and older who presented to Harborview with injuries severe enough to require inpatient surgical admission. Patients who required immediate psychiatric intervention (ie, self-inflicted injury, active psychosis), lived more than 100 miles from the trauma center, were currently incarcerated, or who had recent histories of severe violence and were likely to face criminal charges were excluded.

## Randomization

Randomization occurred in a 1:1 ratio according to a computer-generated random assignment sequence. A series of blocks of either 4 or 6 patients were generated using a random number generator. Research associates conducting all baseline screening assessments and follow-up interviews were blinded to block sizes and intervention or control status.<sup>33</sup>

## Stepped Collaborative Care Intervention

Patients randomized to the intervention condition received care from a trauma center-based mental health team over the course of the 12 months post injury. The intervention was designed to be feasibly delivered in the surgical inpatient ward, outpatient surgery clinics, and over the telephone, as patients re-engaged in primary care and community rehabilitation. The intervention included care management, as well as evidence-based pharmacotherapy and CBT components.<sup>33</sup> The intervention team included masters in social work (MSW) and nurse practitioner (NP) care managers who delivered the intervention in surgical hospital and outpatient settings.

In the early days and weeks post injury, intervention patients received continuous care management. Care managers coordinated care across surgical inpatient, primary-care, and community service delivery settings. To engage injured trauma survivors, care managers first elicited and attempted to problem-solve each patient's unique constellation of postinjury concerns. Behavioral activation psychotherapy elements, such as pleasant activities scheduling targeting sadness related to loss of preinjury function and postinjury anxious avoidance, were also part of routine postinjury care management.<sup>33,36,37</sup>

Care managers were trained in the delivery of evidence-based motivational interviewing (MI) intervention targeting problematic alcohol use and other high-risk behaviors associated with injury recurrence.<sup>10</sup> All intervention patients with positive blood alcohol concentration (BAC) results on admission or who at any point during the trial demonstrated symptoms of alcohol abuse/dependence received the MI intervention.

Patients randomized to the intervention condition discussed PTSD treatment preferences with the collaborative care team, thereby

informing the choice, timing, and delivery of medication, CBT, or combined treatment interventions. The medication intervention component aimed to initiate and maximize adherence to psychopharmacological treatments targeting PTSD and related disturbances, such as insomnia. The NP intervention team members prescribed medications under supervision by the study psychiatrist. Patients were advanced to and maintained on guideline-level therapeutic doses of serotonin-specific reuptake inhibitor (SSRI) antidepressant agents (eg, sertraline 75–200 mg, paroxetine 10–50 mg).<sup>19</sup> Patients were also started and advanced on medications targeting insomnia and related symptoms, such as posttraumatic nightmares (eg, prazosin 1 mg, trazadone 50 mg).<sup>19,38</sup> The CBT intervention was delivered by trained MSW team members and included psychoeducation, muscle relaxation, cognitive restructuring, and graded exposure.<sup>33,39</sup>

The intervention was designed as a stepped care procedure. Symptoms were repeatedly measured in intervention patients and higher-intensity care was available for patients with persistent or recurrent symptoms of PTSD. Care managers remained in contact with patients and used standardized scales to periodically reassess symptoms. Patient progression through the stepped care protocol was discussed during weekly measurement-based psychiatric supervision (DZ).

Preparatory training for the care management, behavioral activation, MI, CBT, and medication components consisted of (a) didactics focusing on the treatment manual contents, (b) role-plays with standardized patients, and (c) individual preceptorship sessions with expert supervisors in MI (CD), CBT (AW), and pharmacotherapy (DZ). The collaborative care team maintained detailed clinical notes and charted the nature and duration of all intervention activities.

## Usual Care Control Condition

Patients in the control condition underwent informed consent, PTSD screening, baseline surgical ward evaluation, and follow-up interviews. Prior investigation suggests that usual postinjury care includes routine outpatient surgical and primary-care visits, as well as the occasional use of specialty mental health services.<sup>31,33</sup>

## Assessments: PTSD Symptoms

Two measures were used to assess PTSD symptoms, the Clinician-Administered PTSD Scale (CAPS) and the PTSD Checklist Civilian Version (PCL-C).<sup>34,40</sup> The CAPS was administered at the 1-, 6-, and 12-month follow-up interviews, either in person or over the telephone. For both measures, a higher score indicates greater symptomatic distress. A cutoff of  $\geq 45$  and a rule requiring that symptoms occur at least monthly at the moderate intensity level were used to diagnose PTSD symptoms on the CAPS.<sup>40</sup> Total PTSD remission defined as a score of  $< 20$  and treatment response defined as a drop of  $\geq 10$  points were also ascertained with the CAPS.<sup>40</sup>

The PCL-C was used to screen injured trauma survivors with high PTSD symptom levels into the investigation and to follow up PTSD symptoms longitudinally at the 1-, 3-, 6-, 9-, and 12-month follow-up time points. A 2-step screening procedure was employed. Patients were first screened as surgical inpatients. Patients with an initial PCL-C score of  $\geq 35$  in the surgical ward received a second PCL-C screen in the days and weeks immediately after hospital discharge, either in outpatient surgery clinics or over the telephone. Patients who again screened high on the PCL-C with scores  $\geq 35$  were randomized into the study.

All research assistants (RAs) were trained in the administration of the interviews. Training included attending workshops, watching training CDs/videos, mock interviews, and observed practice interviews with hospitalized surgical inpatients. Additional training was required for the administration of the CAPS structured clinical interview. Practice CAPS interviews were conducted and RA interviewers

received feedback and coaching until they consistently attained 100% reliability on CAPS PTSD criteria when compared with “gold standard” PhD expert raters. During the course of the study, 5% of CAPS interviews were audio-recorded and coded by expert raters. A pooled Kappa of 0.83 was attained for CAPS rating comparisons between study RAs and expert raters.

## Assessments: Other Clinical and Injury Characteristics

The 9-item Patient Health Questionnaire (PHQ)<sup>41</sup> was used to assess depressive symptoms. The Alcohol Use Disorders Identification Test-Consumption Items (AUDIT-C)<sup>42</sup> were used to assess alcohol use. The Medical Outcomes Study Short Form 36 (MOS SF-36) Physical Component Summary (PCS)<sup>43</sup> score was used to assess physical health and function. Prior trauma, preinjury PTSD symptoms, and preinjury alcohol abuse/dependence were assessed with items from the National Co-morbidity Survey investigations.<sup>44</sup> Previously developed items assessing postinjury health service use were administered at the baseline and at the 1-, 3-, 6-, 9-, and 12-month follow-up interviews.<sup>33</sup> Interview items contained self-report descriptions of current medication usage (ie, name, dosage, duration). We derived from these items the number of antidepressant prescriptions, attainment of guideline dosages, and adequate adherence to guideline level doses for  $\geq 25$  or more days. Other medication categories included medications targeting insomnia related to PTSD (ie, prazosin or trazadone). The number of psychotherapy visits was also assessed at each follow-up time point. Finally, items assessing satisfaction with general healthcare services and emotional healthcare services were included in all interviews.<sup>33</sup>

The investigation determined injury severity at baseline during the index admission from the medical record *International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) Codes* using the Abbreviated Injury Scale and Injury Severity Score.<sup>45</sup> TBI was also prospectively identified in the medical record and categorized by the following ICD-9-CM codes: 800.0–801.9, 803.0–804.9, 850.0–854.1, and 959.01.<sup>8,46</sup> TBI severity was coded based on a previously validated algorithm for hospitalized inpatients.<sup>8,46</sup> Laboratory toxicology results, insurance status, length of hospital and intensive-care unit stays, and other clinical characteristics were abstracted from the trauma registry and electronic medical record.

## Statistical Analyses

We first examined the intervention and control groups for differences in baseline demographic and clinical characteristics using  $\chi^2$  test for categorical variables and *t* test for continuous variables. We also examined patients with and without complete longitudinal data for differences in baseline characteristics.

Our primary analyses evaluated the symptoms of PTSD longitudinally over the course of the year after injury in the intention-to-treat sample of 207 randomized patients. The symptoms of related conditions, including depression and alcohol use, physical function, and health service utilization outcomes, were also examined in longitudinal intention-to-treat analyses. To determine whether patients in the 2 groups manifested different patterns of change in PTSD symptoms and other outcomes over the year after injury, we used mixed-effects random coefficient regression models employing SAS PROC MIXED for continuous variables and SAS PROC GLIMMIX for categorical variables.

In the models examining the PCL-C, PHQ-9, AUDIT-C, and PCS, repeated measurements of the continuous scale scores at the baseline, 1-, 3-, 6-, 9-, and 12-month time points were the dependent variables. For the models examining CAPS PTSD outcomes, the dependent variables were 1-, 6-, and 12-month repeated measurements

of the continuous CAPS total score and the dichotomized CAPS diagnosis, remission, and treatment response outcomes. Mixed-model regression was also used to determine whether intervention patients had differential patterns of psychotropic medication usage, psychotherapy visits, or satisfaction with care over the course of the year post injury.

For all dependent variables, we first fit models containing time categories, intervention, intervention by time interactions, and baseline symptomatic or functional status with and without covariates. Our final models adjusted for characteristics that significantly differed across groups either at baseline or longitudinally; the baseline characteristics included in all adjusted models as covariates were marital status, employment, insurance status, and years of education. For all regression models in the event of a nonsignificant interaction, the interaction term was removed and the models refit. In the event of a significant interaction or main effect of group, we examined adjusted simple main effects at each time point. To examine the impact of TBI on any observed treatment effects, we fit additional models that included the presence or absence of TBI injuries and their interaction with treatment group and time.

Finally, we performed sensitivity analyses. We included age, gender, and injury severity as additional covariates in all longitudinal outcome analyses, as these had been essential design variables in prior clinical studies.<sup>5,14</sup> We used SAS version 9.2 (SAS Institute, Cary, NC) for all analyses.

## RESULTS

Compared with all other patients admitted to the trauma center during the time period of the investigation, the 207 study patients were more likely to be female, less severely injured, intentionally injured, blood alcohol positive, younger, and had greater length of surgical hospitalization. The investigation achieved  $\geq 75\%$  follow-up at each assessment point (Fig. 1).

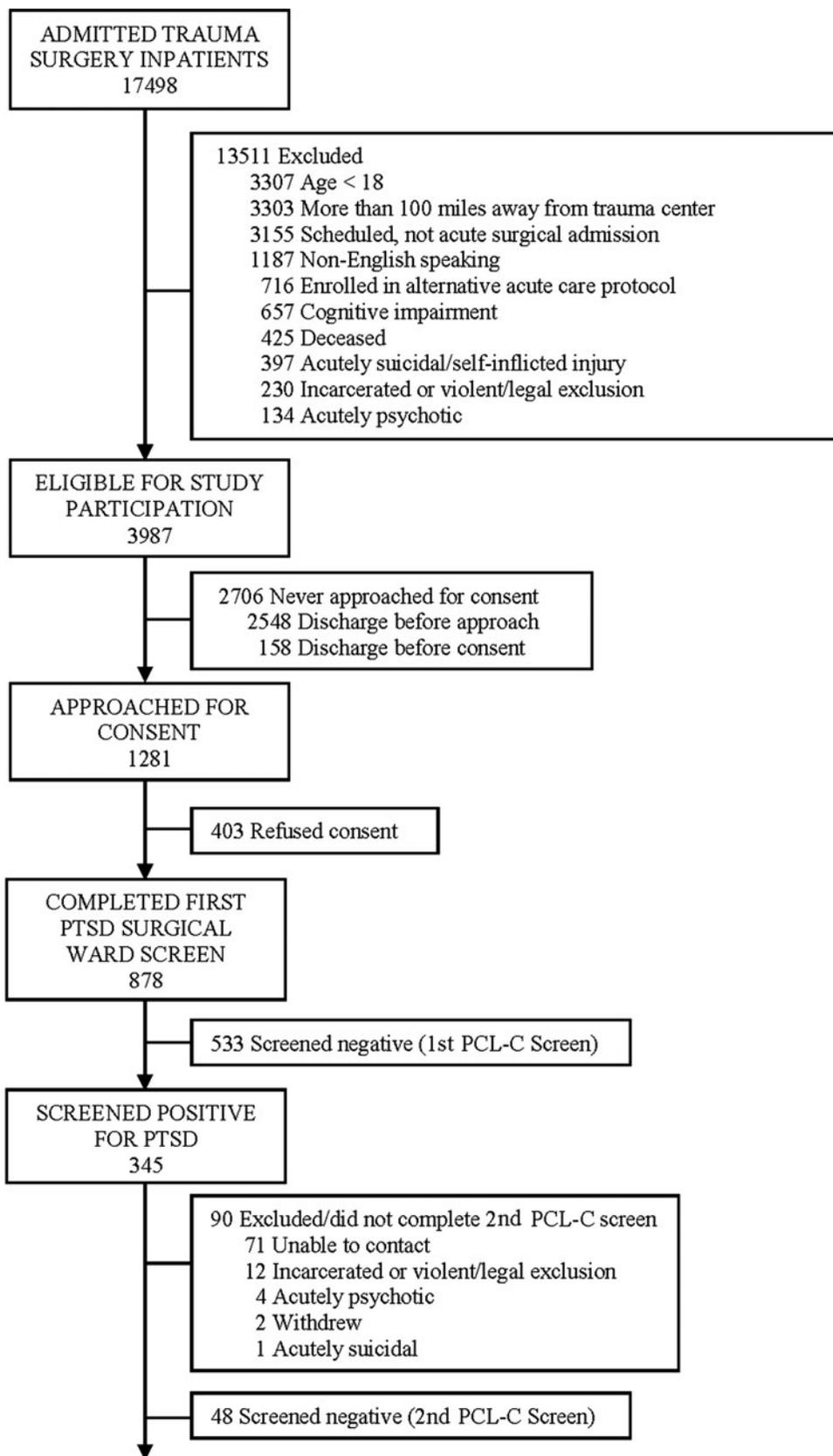
The 207 injured surgical inpatients recruited and randomized into the investigation were diverse, predominantly publically insured or uninsured patients with high levels of PTSD, depressive and alcohol-use symptoms, and substantial histories of preinjury trauma (Table 1). Patients in the intervention and control conditions did not substantially differ with regard to the percentage and distribution of TBI (Table 1).

## Intervention Implementation

Care managers spent a median of 13.2 hours (IQR = 13.3 hours) with each patient over the course of the year after injury. Care manager's time intensity in the stepped care procedure gradually decreased over the course of the year. Over 60% of care management activity occurred during the first 6 months post injury (median hours = 9.4, IQR = 8.6 hours). Eighty-four (81%) of the 104 intervention patients received NP medication evaluations. Seventy-eight (75%) of the 104 intervention patients were offered PTSD pharmacotherapy; 48 (62%) of these 78 patients accepted and maintained their medication regimens during the study. The majority (75%) of NP intervention hours also occurred during the first 6 months after the injury. Eighty intervention patients (77%) received 1 or more MI session targeting alcohol use and other high-risk behaviors. Ninety-three (89%) of the 104 intervention patients were assessed for multisession CBT. Twenty-five of these patients demonstrated adequate CBT readiness,<sup>33</sup> and were offered CBT; nine (36%) of these 25 patients received 4 or more CBT sessions.

## Process of Care

When compared with control patients, collaborative care intervention patients were significantly more likely to receive evidence-based PTSD pharmacotherapy. Intervention patients were



significantly more likely to have received an adequate dosage of antidepressant medication [adjusted main effect, odds Ratio (OR) = 2.32, 95% confidence interval (CI) = 1.20–4.50]. Intervention patients were also significantly more likely to use PTSD insomnia medications (adjusted group by time interaction, Wald  $\chi^2 = 19.57$ ,  $P < 0.001$ ). There were no observed significant group, time, or group by time effects for pain medications, benzodiazepines, or psychotherapy visits over the course of the year after injury.

Intervention patients were significantly more likely to report being very satisfied with their general healthcare (adjusted main effect, OR = 2.00, 95% CI = 1.01–3.96) and emotional healthcare services (adjusted main effect, OR = 2.93, 95% CI = 1.84–4.67) when compared with control patients.

### Symptomatic and Functional Outcomes

The intervention group demonstrated clinically and statistically significant reductions in the symptoms of PTSD over the course of the year after injury (Fig. 2). Regression analyses demonstrated significant CAPS [adjusted  $F(2, 185) = 5.50$ ,  $P < 0.01$ ] and PCL-C [adjusted  $F(4, 185) = 5.45$ ,  $P < 0.001$ ] group by time interaction effects over the course of the year. The intervention also achieved a statistically and clinically significant impact on CAPS PTSD treatment response criteria over the course of the year after injury (adjusted

main effect, OR = 1.93, 95% CI = 1.00–3.70). PTSD remission criteria also demonstrated significant reductions over the course of the year [adjusted group by time interaction,  $F(2, 306) = 5.41$ ,  $P < 0.01$ ]. No significant treatment effects were observed for PTSD diagnostic criteria over the course of the year (adjusted main effect, OR = 1.39, 95% CI = 0.77–2.51).

The intervention achieved clinically and statistically significant symptom reductions on the CAPS and PCL-C continuous PTSD symptom scores at the 6-, 9-, and 12-month postinjury time points (Table 2). Effect sizes for PTSD were temporally associated with treatment intensity, and peaked at the 6-month postinjury time point; effect sizes at the 6- and 12-month time points ranged from 0.32 to 0.65 (Table 2).

Intervention patients demonstrated significant improvements in physical function [adjusted  $\beta = 3.10$ , standard error (SE) = 0.99,  $P < 0.01$ ] over the course of the year. The intervention effects for physical function achieved statistical significance at the 3-, 6-, and 9-month postinjury time points (Table 2).

For alcohol consumption (adjusted  $\beta = -0.52$ , SE = 0.30,  $P = 0.08$ ) and depression (adjusted  $\beta = -1.4$ , SE = 0.76,  $P = 0.07$ ), trend level effects were observed. Regression revealed that patients with TBI responded equally well to the stepped care intervention as those without TBI. Analyses revealed no significant interaction of TBI by

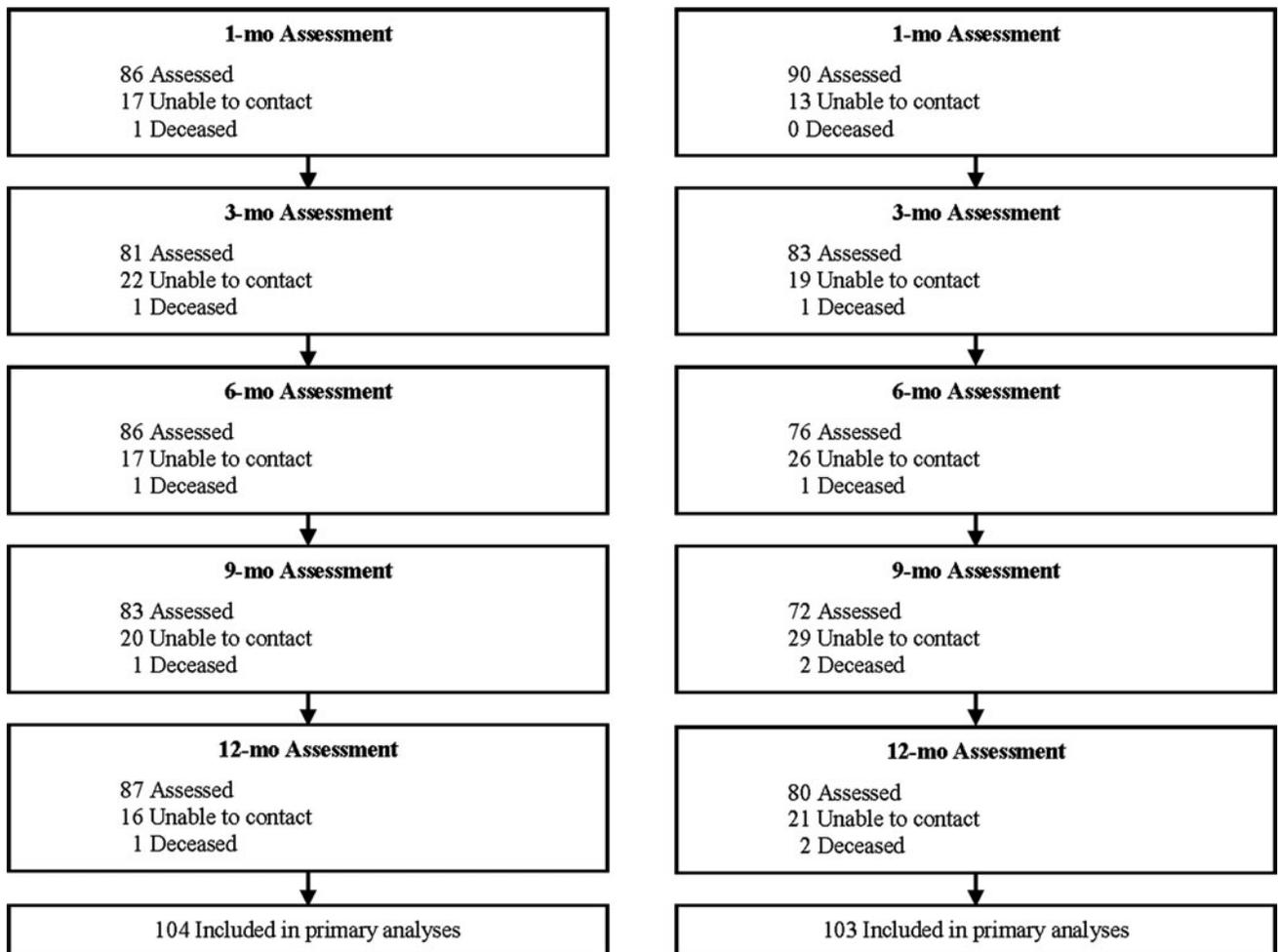


FIGURE 1. Patient flow through the trial. PTSD indicates posttraumatic stress disorder; PCL-C, PTSD Checklist Civilian Version.

TABLE 1. Baseline Patient Characteristics

Characteristics	No. Patients (%)		
	All (N = 207)	Intervention (N = 104)	Usual Care (N = 103)
<b>Demographic</b>			
Age, mean (SD), years	38.5 (13.1)	39.4 (13.4)	37.7 (12.8)
Female	99 (47.8)	54 (51.9)	45 (43.7)
<b>Race/ethnicity</b>			
White	124 (59.9)	63 (60.6)	61 (59.2)
Black	38 (18.4)	21 (20.2)	17 (16.5)
American Indian	27 (13.0)	14 (13.4)	13 (12.6)
Asian	12 (5.8)	4 (3.9)	8 (7.8)
Hispanic	6 (2.9)	2 (1.9)	4 (3.9)
Education, mean (SD), years	13.1 (2.2)	13.2 (2.5)	12.9 (1.9)
<b>Marital status*</b>			
Married/living with partner	52 (25.1)	37 (35.6)	15 (14.6)
Employed	96 (46.4)	43 (41.3)	53 (51.5)
<b>Insurance</b>			
Private	45 (21.7)	22 (21.1)	23 (22.3)
Public	111 (53.6)	58 (55.8)	53 (51.5)
None	51 (24.6)	24 (23.1)	27 (26.2)
<b>Acute care injury and medical</b>			
<b>Injury severity category</b>			
0–8	46 (22.2)	21 (20.2)	25 (24.3)
9–15	93 (44.9)	50 (48.1)	43 (41.7)
≥16	68 (32.9)	33 (31.7)	35 (34.0)
<b>Traumatic brain injury</b>			
None	128 (61.8)	64 (61.5)	64 (62.1)
Mild	55 (26.6)	29 (27.9)	26 (25.3)
Moderate/severe	24 (11.6)	11 (10.6)	13 (12.6)
Intentional injury	47 (22.7)	24 (23.1)	23 (22.3)
<b>Number of comorbid medical conditions</b>			
0	126 (60.9)	56 (53.8)	70 (68.0)
1	47 (22.7)	27 (26.0)	20 (19.4)
2	20 (9.6)	11 (10.6)	9 (8.7)
≥3	14 (6.8)	10 (9.6)	4 (3.9)
<b>Days in intensive care unit</b>			
0	137 (66.2)	76 (73.0)	61 (59.2)
1	37 (17.9)	14 (13.5)	23 (22.3)
≥2	33 (15.9)	14 (13.5)	19 (18.5)
Days in hospital, mean (SD)	9.0 (10.4)	8.4 (7.7)	9.5 (12.6)
<b>Clinical</b>			
Serious prior traumas before injury admission, mean (SD)	5.7 (2.8)	5.9 (2.8)	5.5 (2.8)
Preinjury PTSD symptoms	130 (62.8)	66 (63.5)	64 (62.1)
Baseline 1st PCL-C screen total score, mean (SD)†	50.6 (10.5)	50.5 (10.5)	50.8 (10.5)
Baseline PHQ-9 depression total score, mean (SD)†	13.9 (5.5)	13.7 (5.8)	14.1 (5.2)
Preinjury alcohol abuse or dependence	74 (36.3)	36 (35.6)	38 (36.9)
Preinjury AUDIT-C score, mean (SD)	3.4 (3.3)	3.0 (2.9)	3.8 (3.6)
Positive blood alcohol on admission	73 (35.3)	30 (28.8)	43 (41.7)
Urine toxicology screen positive for stimulants (amphetamine and/or cocaine)	23 (11.1)	14 (13.5)	9 (8.7)
Urine toxicology screen positive for marijuana	34 (16.4)	20 (19.2)	14 (13.6)

\* $P < 0.05$ . All other comparisons were not statistically significant.

†For PCL-C and PHQ-9 baseline assessments, inpatients were asked to report symptoms since the injury event.

AUDIT-C indicates Alcohol Use Disorders Identification Test—Consumption Items; PCL-C, PTSD Checklist Civilian Version; PHQ, Patient Health Questionnaire; PTSD, posttraumatic stress disorder; SD, standard deviation.

treatment group for PTSD, physical function, or other conditions. Finally, sensitivity analyses did not substantially alter the magnitude, pattern, or significance of the observed treatment effects.

## DISCUSSION

This investigation documents the effectiveness of a stepped collaborative care intervention in reducing PTSD symptoms in surgically hospitalized trauma survivors over the course of the year after physical injury. Intervention patients had a significantly more favorable course of PTSD recovery over the year, as evidenced by diminished symptom severity. PTSD treatment effects were tem-

porally associated with intervention intensity and were optimized at the 6-month postinjury time point. At the 12-month postinjury study endpoint, intervention patients continued to demonstrate clinically and statistically significant reductions in PTSD symptoms when compared with usual care control patients. Intervention patients received higher-quality posttraumatic care, which included more frequent prescriptions for adequate dosages of evidence-based PTSD pharmacotherapy and also greater satisfaction with general medical and emotional healthcare services.

A series of prior descriptive investigations have established an association between PTSD symptoms and a broad spectrum of

**TABLE 2. Symptomatic and Functional Outcomes for Patients in Collaborative Care (n = 104) Versus Usual Care Control (n = 103) Conditions**

Outcome Assessment	Baseline Mean† (95% CI)		1 Month Mean† (95% CI)		3 Months Mean† (95% CI)		6 Months Mean† (95% CI)		9 Months Mean† (95% CI)		12 Months Mean† (95% CI)		ES§
	CC	UC	CC	UC	CC	UC	CC	UC	CC	UC	CC	UC	
CAPS‡	—	—	57.2 (52.3–62.2)	59.0 (53.9–64.2)	—	—	42.9 (37.0–48.8)	56.7** (50.7–62.7)	—	—	38.6 (32.5–44.6)	47.2* (41.2–53.3)	0.53
PCL-C‡¶	51.2 (48.9–53.4)	52.0 (49.5–54.5)	50.2 (47.4–52.9)	51.1 (48.2–54.0)	45.9 (42.9–48.9)	48.6 (45.5–51.8)	40.6 (37.3–43.9)	49.9** (46.6–53.1)	40.2 (36.8–43.5)	45.5** (42.2–48.7)	37.4 (34.0–40.7)	42.5* (39.3–45.7)	0.65
PHQ-9‡¶	13.4 (12.3–14.6)	14.2 (13.0–15.5)	12.5 (11.3–13.7)	13.2 (11.9–14.5)	11.7 (10.5–13.0)	13.0 (11.5–14.5)	8.7 (7.4–10.1)	11.3** (9.9–12.8)	9.7 (8.3–11.2)	11.4 (9.9–12.9)	8.4 (7.1–9.7)	10.1 (8.6–11.7)	0.43
AUDIT-C‡	3.1 (2.5–3.8)	3.9 (3.2–4.6)	1.4 (1.0–1.8)	1.9 (1.2–2.5)	1.9 (1.4–2.4)	2.7* (2.0–3.4)	2.0 (1.4–2.6)	2.8 (2.1–3.5)	2.4 (1.8–3.0)	2.6 (1.9–3.2)	2.0 (1.5–2.6)	2.4 (1.8–3.0)	0.28
SF-36 PCS‡	49.1 (46.5–51.7)	50.6 (47.8–53.4)	34.6 (32.0–37.3)	32.4* (29.9–34.9)	39.0 (36.3–41.7)	34.8** (32.4–37.2)	42.4 (39.6–45.3)	37.8** (35.2–40.4)	43.2 (40.2–46.1)	39.8* (37.2–42.5)	43.7 (41.0–46.5)	41.2 (38.5–43.9)	0.56

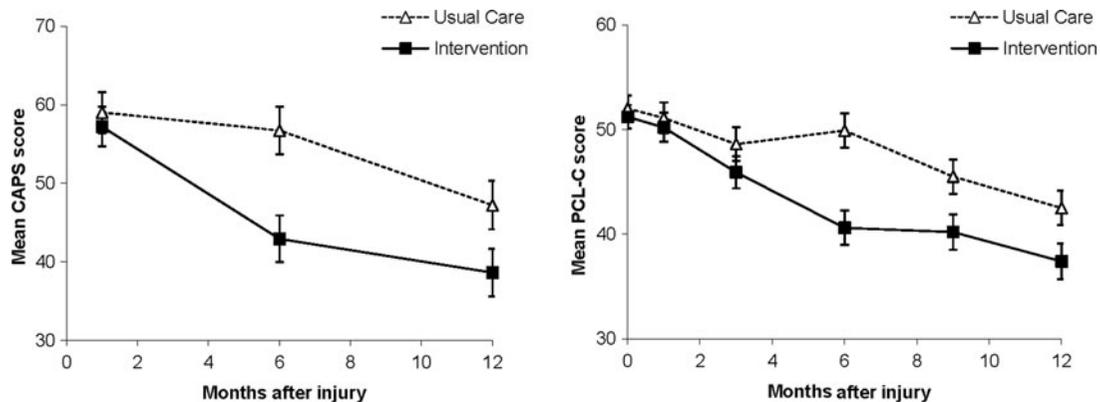
†Means are adjusted for marital status, employment, insurance status, and years of education; t tests were used to compare the symptoms and functional status of intervention and control groups.  
‡P-value: \* <0.05; \*\* <0.01.

§Effect sizes were calculated as the difference in group means divided by the pooled standard deviation.

¶For PCL-C and PHQ-9 baseline assessments, patients were asked to report symptoms since the injury event.

||For AUDIT-C and SF-36 PCS baseline assessments, patients were asked to report symptoms prior to the injury event.

AUDIT-C indicates the Alcohol Use Disorders Identification Test—Consumption Items; CAPS, Clinician-Administered PTSD Scale; CC, collaborative care; CI, confidence interval; ES, effect size; PCL-C, PTSD Checklist Civilian Version; PHQ-9, Patient Health Questionnaire 9 Item Depression Scale; SF-36 PCS, Medical Outcomes Study Short-Form Health Survey 36 Physical Component Summary Score; UC, usual care.



**FIGURE 2.** PTSD symptom severity by treatment group on the Clinician-Administered PTSD Scale (CAPS) and PTSD Checklist Civilian Version (PCL-C). Means with standard errors are presented. Means are adjusted for marital status, employment, insurance status, and years of education.

functional impairment, including role and physical limitations.<sup>6,12,13,15,17</sup> To our knowledge, this is the first clinical trial with acutely injured trauma survivors to demonstrate improvements in physical function among patients receiving stepped collaborative care interventions. A substantial proportion of the low-income, diverse surgical inpatients recruited into the trial were not working prior to the injury event; therefore, we were not able to directly target return to work as part of the stepped collaborative care intervention procedure.

Literature review suggests that this is the first stepped collaborative care trial to specifically target TBI patients with PTSD and related comorbidities. The intervention appears to have been equally effective in reducing PTSD symptoms, and physical limitations, among injured patients with and without TBI.

One large-scale primary-care collaborative trial targeting PTSD and related anxiety disorders found 6- and 12-month PTSD treatment effects comparable with the current investigation.<sup>47</sup> The PTSD treatment effects observed in the current investigation are toward the middle end of the continuum reported for effective multisection early psychological PTSD interventions developed in efficacy trials.<sup>21</sup> A possible explanation for this observation is that to enhance the generalizability of the investigative results to populations of surgically hospitalized patients, this pragmatic trial included subjects regardless of patient characteristics that are typically excluded in many PTSD clinical trials, including injury comorbidity, concurrent active substance abuse/dependence, and histories of multiple prior traumas. A meta-analysis of 37 primary-care intervention trials reported comparable or lower collaborative care treatment effects for depression (OR = 0.25, 95% CI = 0.18–0.31),<sup>29</sup> as was observed for PTSD in the current trial 12 months post injury.

The stepped care intervention approach implemented in this trial suggests that primary reliance upon lower-intensity treatments embedded within care management procedures yields the greatest potential overall population impact.<sup>48,49</sup> Early stepped care intervention components readily deliverable to large populations of trauma center patients include problem-solving around each patient's unique constellation of postinjury concerns and behavioral activation elements embedded within routine postinjury care management.<sup>36</sup> Similarly, early pharmacologic intervention targeting initial PTSD-related insomnia may have greater potential breadth of applicability, treatment effects, and overall population impact, when compared with sustained treatment with SSRI pharmacologic agents.<sup>22,38</sup> More intensive and challenging-to-deliver procedures, such as session-based

CBTs, could be reserved for smaller subgroups of injured patients with recalcitrant or recurrent PTSD symptoms.<sup>36,50</sup> Future pragmatic trials of stepped care interventions targeting PTSD could also test whether intervention elements with greater breadth of applicability could be delivered earlier on after the injury with sustained 6- and 12-month treatment effects.

There are important considerations in interpreting the results of this investigation. Because this was a multifaceted intervention, the study did not yield information regarding which components of the stepped care procedure were most influential in reducing symptoms and improving function. Aspects of the stepped care intervention including the 2-stage PTSD screening procedure and the intensive-care management treatment protocol may be too resource intensive to ever have a broad reach across US trauma centers; subsequent investigation could develop more efficient screening and stepped-care intervention procedures with greater breadth of applicability and overall population impact.<sup>48,51</sup> An additional limitation of the study is that the investigation did not follow up with injured patients who had initial low symptom scores on the PCL-C. Prior investigations suggest that early PTSD screening efforts may miss some individuals who develop high PTSD symptom levels in the months after the event.<sup>52</sup> Finally, the TBI results can be seen as preliminary, as the overall sample size, combined with a rate of TBI of approximately 40%, limited our ability to assess TBI interaction effects.

Beyond these considerations, this investigation contributes to an evolving literature on early multidisciplinary PTSD interventions for injured trauma survivors treated initially in surgical inpatient settings and who require the establishment of continuous care through surgical and primary-care outpatient services.<sup>18</sup> With regard to the trauma center context, the investigation integrated many components of practical clinical trials.<sup>53</sup> This included the recruitment of a diverse clinical sample from a level I trauma center practice setting, intervention delivery by social work and nurse practitioner acute-care providers, and the measurement of a broad range of policy-relevant outcomes.<sup>54</sup> The American College of Surgeons has demonstrated the capacity to mandate screening and intervention procedures for alcohol-use problems at US trauma centers based on the results of empirical investigations.<sup>10,54,55</sup> By establishing the feasibility and effectiveness of the stepped collaborative care model in diminishing PTSD symptoms and improving postinjury physical function, the investigative findings could influence the development of guidelines for the sustainable implementation of PTSD screening and intervention procedures at trauma centers nationwide.<sup>54</sup>

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