The 12-Month Effects of the Trauma Collaborative Care Intervention

A Nonrandomized Controlled Trial

Major Extremity Trauma Research Consortium (METRC)*

Background: Studies have suggested that patient-centered collaborative care in the early phases of recovery may assist providers and patients in managing the multifactorial consequences of injury and may lead to better outcomes. This cluster-controlled trial, conducted at 12 U.S. Level-I trauma centers, was designed to evaluate the impact of the Trauma Collaborative Care (TCC) program on 1-year outcomes following severe musculoskeletal injury.

Methods: Patients with high-energy orthopaedic trauma requiring surgical fixation were prospectively enrolled. Six sites implemented the TCC intervention as well as the Trauma Survivors Network (TSN), and the other 6 sites provided the standard of care. Participants were followed for 1 year, and a composite primary outcome measure composed of the Short Musculoskeletal Function Assessment (SMFA) Dysfunction Index, Patient Health Questionnaire-9 (PHQ-9), and Post-traumatic Stress Disorder Checklist (PCL) was assessed. A 2-stage, Bayesian hierarchical statistical procedure was used to characterize treatment effects. Sensitivity analyses were conducted to account for an error in the delivery of the intervention.

Results: There were 378 patients enrolled at 6 trauma centers implementing the TCC program, and 344 patients enrolled at 6 trauma centers providing usual care. Patient utilization of treatment components varied across the intervention sites: 29% of patients in the intervention group received all 5 key components (TSN handbook education, peer visits, recovery assessment, and calls before and after recovery assessment). Posterior estimates of the intention-to-treat effect suggested that the intervention did not have an appreciable effect: the odds of the composite outcome for the TCC group increased by 5% (95% credible interval, −40% to 63%). The estimates of the effect of receiving all 5 key intervention components were similar.

Conclusions: Despite prior work showing early positive effects, this analysis suggests that the TCC program as delivered did not have positive effects on patient outcomes at 1 year. It is not known whether programs that improve compliance or target specific subgroups would better meet the psychosocial needs of trauma survivors.

Level of Evidence: Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

Trauma is a major cause of disability. Despite substantial improvements in the delivery of trauma care in the acute setting, patients with severe orthopaedic injuries often experience long-term physical, psychological, and social consequences[1-4]. Previous studies have demonstrated that, when unmanaged, the development of symptomatic pain, depression, and posttraumatic stress disorder (PTSD)[5-12] early in the recovery process predicts poor long-term outcomes[13-17], although numerous other symptoms and risk factors may also play a role. These results suggest that patients sustaining severe orthopaedic trauma may benefit from interventions in the early phases of recovery addressing the psychosocial needs of patients and families.

Various models of intervention are designed to meet the complex psychosocial needs of patients with trauma[18], including intensive interventions matched to patient needs[19,20]. The Trauma Collaborative Care (TCC) intervention, guided by the Collaborative Care and Chronic Care Models[21,22], was developed to provide a comprehensive framework for patients and providers managing recovery in the orthopaedic trauma setting. The TCC emphasizes the need for patients to be engaged in their recovery and stresses the importance of addressing psychosocial

*A list of the Major Extremity Trauma Research Consortium (METRC) members is included in a note at the end of the article.

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H202).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H204).

factors that may influence long-term outcomes[23]. The TCC expands the programs and services provided by the Trauma Survivors Network (TSN), which includes evidence-based interventions: peer visitation, patient education, a self-management program, and peer support[18].

These analyses present the impact of the TCC program on outcomes at 1 year following the injury. Access to the TCC program was hypothesized to result in lower rates of poor function, depression, and PTSD.

Materials and Methods

In this cluster-controlled trial, the outcomes of study participants at 6 trauma centers implementing the TCC program were compared with those of participants at 6 centers providing usual care. The study design was previously described[23]. The protocol was approved by the institutional review boards of the study coordinating center, the 12 participating centers, and the U.S. Department of Defense Human Research Protection Office. The study was registered at ClincalTrials.gov (NCT01907893).

Patients with at least 1 major orthopaedic injury (denoted by an Abbreviated Injury Scale [AIS] score of ≥3) resulting from a moderate to high-energy mechanism and requiring surgical intervention were eligible for the study. Detailed eligibility requirements and consent procedures were previously described[23]. At intervention sites, the TCC program was initiated following consent. Participants in the intervention arm completed a recovery assessment at 6 weeks, which was administered by the TSN coordinators (TSN-Cs) as part of the TCC program. Participants in the control arm received a call at 6 weeks following discharge to complete the same battery of questions but did not receive feedback or additional follow-up. Follow-up interviews were conducted by telephone by an independent survey research firm at 6 and 12 months after the injury. Recruitment was completed between July 2013 and December 2014.

Intervention

The TCC was a multicomponent, patient-focused intervention delivered by a TSN-C. Key components have been previously described[23]. All centers delivering the intervention also had a TSN program that was run by the TSN-Cs available to all hospital patients with trauma. During the inpatient stay, the TSN-C offered patient and family education, introduced TSN services, and offered peer support visits. Following discharge, in order to identify recovery challenges and guide the development of a personalized recovery plan, the TSN-C conducted a 6-week recovery assessment with the patient. Surgeons were educated to encourage patients to take action based on their recovery plan. The recovery plan included peer support, self-management information and resources, or referral for additional mental health services as options. Patients and families utilized each program component based on their needs and preferences. To facilitate patient engagement, the TSN-C offered patient coaching calls. The control sites agreed not to implement any additional related services, such as PTSD screening, for the duration of the study.

Primary and Secondary Outcomes

The primary study outcome was a binary composite outcome based on clinically meaningful impairment in any one of the following domains: patient-reported function (Short Musculoskeletal Function Assessment [SMFA] Dysfunction Index [with a cut-point of >27])[24], depression (Patient Health Questionnaire-9 [PHQ-9] score [with a cut-point of >9])[25,26], and PTSD (standard PTSD Checklist [PCL], Civilian Version score [with a cut-point of >35])[27]; these cut-points are standardized in the literature but were not specifically stated in our study outcomes on ClinicalTrials.gov. A binary composite outcome was chosen, as previous research has indicated that orthopaedic trauma impacts multiple domains and poor outcomes on any of these domains are associated with poor long-term return to work and participation in life activities[1-4]. The primary composite outcome and the composite measures examined individually, as well as the SMFA Bother Index[24], are reported here. We studied several other outcomes in our original study and those secondary outcomes will be reported in another article.

Participant engagement with the TCC program was logged by the TSN-Cs, who documented each interaction with the participant in a central database. Treatment fidelity was ensured through standardized training of the TSN-Cs, the development of an implementation manual of operations, and site visits with staff involved in program delivery. Investigators and TSN-Cs worked closely with hospital leadership to ensure that the delivery of all elements of the TSN was possible, and the coordinators participated in biweekly calls to discuss implementation challenges. The TSN-Cs also participated in 2 booster training sessions over the course of the program.

Statistical Analysis

The intention-to-treat effects of the TCC on the primary composite outcome at 12 months, as well as on the secondary individual measures, were evaluated using a 2-stage statistical procedure. This approach allowed us to account for clustering within sites and for differences in site-level baseline characteristics (see the Statistical Appendix for details). The same analytical approach was used in prior research evaluating the early effects of the TCC[28]. The first stage computed the standardized estimates (and the variance-covariance matrix) of the probability of the outcome at each site. This was to ensure that the differences in probabilities observed across sites are not attributable to observed variability in patient characteristics at baseline. The second stage used the results of the first stage as input into a Bayesian meta-analytic hierarchical model to compute the overall effects of the TCC across sites. Posterior medians, 95% highest posterior density credible intervals, and posterior probabilities of beneficial treatment effects are reported.

The effect of full receipt of all intervention components was also estimated. This analysis estimates the treatment effect had all intervention patients, contrary to fact, received the 5 components of the intervention (i.e., TSN handbook education, peer visits, recovery assessment, and calls before and after recovery assessment). The inference for a full receipt of intervention effects involves a similar 2-stage approach as that used

for intention-to-treat effects, with the exceptions that the regression model in the first stage is augmented with 5 indicator variables, 1 for the actual receipt of each component, that each interacted with a TCC site indicator, and that the second stage uses this augmented regression model (see the Statistical Appendix for details). Multivariate imputation by chained equations (MICE) with the random forest imputation method was used to impute missing values in the baseline covariates, creating 10 imputed data sets. Statistical analyses were performed using R, version 3.4.2 (R Project for Statistical Computing).

Sensitivity analyses were conducted to address an error that occurred in providing PTSD feedback to patients after the recovery assessment at 6 weeks after discharge. In the first sensitivity analysis, we examined the effect of the intervention stratified by reported or actual PCL categorizations at the recovery assessment. In the second sensitivity analysis, we examined the effect of the intervention stratified by the risk of PTSD.

Source of Funding

The study was funded by a grant from the Department of Defense Congressionally Directed Medical Research Program (W8XWH-10-2-0090). The sponsor had no role in the design or conduct of the trial; the collection, management, analysis, or interpretation of the data; or the preparation, review, or approval of the manuscript for submission.

Results

The screening, enrollment, and follow-up, as well as the baseline characteristics of 896 patients enrolled in the TCC study, have been described previously[23]. Except for education (60% of the controls had some college compared with 44% in the intervention group), the control and intervention groups were shown to be similar on key characteristics[23]. Among the 896 patients, 722 patients (81%) had the 12-month assessment within a visit window that spanned from 323 to 449 days after the injury; 378 patients enrolled at 6 trauma centers implementing the TCC program, and 344 patients enrolled at 6 trauma centers providing usual care. The mean assessment time (and standard deviation) was 373.4 ± 22.5 days for the intervention group and 368.7 ± 21.2 days for the control group. Table I shows differences in baseline characteristics between patients with 12-month outcome data and those without it because they either did not return for that follow-up (13%) or returned outside the designated time window (6%). Patients with missing data or data collected outside of the allowable follow-up window were more likely to be younger, be less educated, have non-private insurance, have no comorbidities, use tobacco, and have thoracic or spinal injuries.

There was substantial variability in the receipt of intervention components, as shown in Table II. The use of the early intervention components among patients in the intervention group with 12-month data (n = 378) ranged from 91% receipt of the recovery assessment to 56% receipt of a peer visit. This variation in utilization of intervention components was observed across all 6 intervention sites: TSN handbook (35% to 100%), peer visit (36% to 82%), early coaching calls (46% to 92%), coaching calls during recovery assessment (80% to 98%), and coaching calls after recovery assessment (62% to 73%). Only 29% of patients in the intervention arm received all 5 components (range across sites, 13% to 54%).

Table III shows the results of the intention-to-treat and full-receipt-of-intervention analyses for the composite primary outcome and the secondary individual measures; treatment effects are represented on an odds ratio scale (as the presence of the outcomes is undesirable, <1.0 favors TCC, >1.0 favors control). Site-specific estimates of the probability of each outcome can be found in Appendix A.

The posterior estimate of the intention-to-treat effect for the primary composite outcome was 1.05, suggesting a clinically unimportant benefit of the control group. The estimated intention-to-treat effects on the individual components were 0.99 for function, 1.27 for depression, and 1.16 for PTSD; and for the SFMA Bother Index, the estimated effect was 0.95. The associated 95% credible intervals included 1.0 for all outcomes; the highest posterior probability of benefit of the TCC for these outcomes was 59%.

The estimated effects of full receipt of the components of the intervention were the same as above or less favorable to the TCC, although all credible intervals again included 1.0.

As part of their initial coaching assessment, the patients in the intervention arm received information on the level of PTSD symptoms and a recommendation for action, as well as feedback on 8 other risk or protective domains. After the completion of the study, an error in the coding of the feedback portion of the recovery assessment was discovered, resulting in consistent underscoring of the PCL domain of the tool for 298 of the 397 participants in the intervention arm who completed the assessment. These participants received feedback that underreported their actual level of PTSD symptoms, and, of these individuals, 28% were incorrectly told that no further action was indicated (see Appendix B). No other domains of the recovery assessment were impacted.

In Appendix B, we report on sensitivity analyses to evaluate the effect of this error on our study findings. Drawing conclusions from the first sensitivity analysis is challenging because participants with more severe PTSD were more likely to receive inaccurate feedback. The second sensitivity analysis suggested generally worse effects for participants at low and medium risk for PTSD and generally better effects for participants at high risk for PTSD.

Discussion

This study shows the impact of the TCC program on 1-year outcomes. Results did not show that the TCC had a meaningful impact on patient outcomes at 1 year when compared with the control group. A previous report showed that the TCC program had a small but positive effect on the outcomes of depression, pain, PTSD symptoms, and self-efficacy at 6 weeks[28]. Another study of the impact of the stand-alone TSN program, which did not include the collaborative care and risk assessment components of the intervention, observed a significant reduction

TABLE I Baseline Characteristics in Patients with and without 12-Month Outcomes

	Overall (N = 896)	With 12-Month Outcome (N = 722)	Without 12-Month Outcome (N = 174)
Sociodemographic characteristics			
Age* *(yr)*	38.2 ± 12.5	39.1 ± 12.7	34.6 ± 10.8
18 to 24 yr†	162 (18%)	129 (18%)	33 (19%)
25 to 34 yr†	217 (24%)	158 (22%)	59 (34%)
35 to 44 yr†	199 (22%)	154 (21%)	45 (26%)
45 to 54 yr†	210 (23%)	181 (25%)	29 (17%)
55 to 60 yr†	108 (12%)	100 (14%)	8 (5%)
Gender†			
Male	585 (65%)	465 (64%)	120 (69%)
Female	311 (35%)	257 (36%)	54 (31%)
Race or ethnicity†			
Hispanic	87 (10%)	67 (9%)	20 (11%)
Non-Hispanic non-white	188 (21%)	157 (22%)	31 (18%)
Non-Hispanic white	621 (69%)	498 (69%)	123 (71%)
Education†			
Less than high school	11 (1%)	11 (2%)	0 (0%)
High school or GED‡	416 (46%)	316 (44%)	100 (57%)
Some college or higher	464 (52%)	391 (54%)	73 (42%)
Refused to answer or unknown	5 (1%)	4 (1%)	1 (1%)
Usual major activity†			
Working	649 (72%)	515 (71%)	134 (77%)
Going to school	54 (6%)	47 (7%)	7 (4%)
Taking care of house	70 (8%)	60 (8%)	10 (6%)
Other	123 (14%)	100 (14%)	23 (13%)
Health insurance†			
None	192 (21%)	141 (20%)	51 (29%)
Medicaid	144 (16%)	110 (15%)	34 (20%)
Private	418 (47%)	352 (49%)	66 (38%)
Other	138 (15%)	116 (16%)	22 (13%)
Unknown	4 (<1%)	3 (<1%)	1 (<1%)
Marital status†			
Married (or cohabiting)	361 (40%)	299 (41%)	62 (36%)
Never married	372 (42%)	291 (40%)	81 (47%)
Widowed, divorced, or separated	161 (18%)	131 (18%)	30 (17%)
Refused to answer or unknown	2 (<1%)	1 (<1%)	1 (1%)
Self-efficacy* (0 to 60)	43.6 ± 12.5	43.8 ± 12.2	43.0 ± 13.7
Refused to answer, unknown, or missing†	38 (4%)	29 (4%)	9 (5%)
Patient Activation Measure†			
Disengaged and overwhelmed	49 (5%)	39 (5%)	10 (6%)
Becoming aware, but still struggling	93 (10%)	74 (10%)	19 (11%)
Taking action	394 (44%)	312 (43%)	82 (47%)
Maintaining behaviors and pushing further	349 (39%)	288 (40%)	61 (35%)
Refused to answer, unknown, or missing	11 (1%)	9 (1%)	2 (1%)
Multidimensional Scale of Perceived Social Support*	72.0 ± 11.4	72.2 ± 11.2	70.9 ± 12.0
Low acuity†	35 (4%)	28 (4%)	7 (4%)
Moderate acuity†	216 (24%)	170 (24%)	46 (26%)
High acuity†	643 (72%)	522 (72%)	121 (70%)

continued

TABLE I (*continued*)

	Overall (N = 896)	With 12-Month Outcome (N = 722)	Without 12-Month Outcome (N = 174)
Missing†	2 (<1%)	2 (<1%)	0 (0%)
Preinjury health history			
Veterans RAND-12			
Overall health status†			
Excellent	254 (28%)	212 (29%)	42 (24%)
Very good	322 (36%)	257 (36%)	65 (37%)
Good	209 (23%)	159 (22%)	50 (29%)
Fair	90 (10%)	75 (10%)	15 (9%)
Poor	21 (2%)	19 (3%)	2 (1%)
Physical Component Summary*	51.5 ± 9.9	51.2 ± 10.1	52.7 ± 8.8
Mental Component Summary*	53.2 ± 10.6	53.2 ± 10.5	53.1 ± 10.9
Body mass index* *(kg/m²)*	29.5 ± 7.2	29.7 ± 7.1	29.0 ± 7.8
<25 kg/m²†	253 (28%)	196 (27%)	57 (33%)
25 to 30 kg/m²†	304 (34%)	244 (34%)	60 (34%)
31 to 35 kg/m²†	166 (19%)	133 (18%)	33 (19%)
>35 kg/m²†	173 (19%)	149 (21%)	24 (14%)
No. of major comorbidities†			
0	460 (51%)	358 (50%)	102 (59%)
1	252 (28%)	204 (28%)	48 (28%)
≥2	184 (21%)	160 (22%)	24 (14%)
Tobacco use†			
Current use	340 (38%)	257 (36%)	83 (48%)
Former use	176 (20%)	141 (20%)	35 (20%)
No use	376 (42%)	321 (44%)	55 (32%)
Refused to answer or unknown	4 (<1%)	3 (<1%)	1 (1%)
Injury and treatment characteristics			
Mechanism†			
Motor vehicle and occupant	369 (41%)	289 (40%)	80 (46%)
Motor vehicle and bicyclist or pedestrian	122 (14%)	99 (14%)	23 (13%)
Motor vehicle and motorcyclist	178 (20%)	144 (20%)	34 (20%)
Fall	132 (15%)	113 (16%)	19 (11%)
Firearm	31 (3%)	24 (3%)	7 (4%)
Other	64 (7%)	53 (7%)	11 (6%)
Injuries (AIS ≥3), by type†			
Head	177 (20%)	136 (19%)	41 (24%)
Face	67 (7%)	48 (7%)	19 (11%)
Neck	12 (1%)	9 (1%)	3 (2%)
Thorax	346 (39%)	264 (37%)	82 (47%)
Abdomen	203 (23%)	156 (22%)	47 (27%)
Spine	243 (27%)	184 (25%)	59 (34%)
Upper extremity	388 (43%)	318 (44%)	70 (40%)
Lower extremity	828 (92%)	668 (93%)	160 (92%)
Unspecified	8 (1%)	7 (1%)	1 (1%)
Injury Severity Score* *(points)*	16.8 ± 10.2	16.5 ± 10.0	18.3 ± 11.0
<13 points†	365 (41%)	299 (41%)	66 (38%)
13 to 17 points†	192 (21%)	158 (22%)	34 (20%)
18 to 24 points†	167 (19%)	140 (19%)	27 (16%)

continued

TABLE I (*continued*)

	Overall (N = 896)	With 12-Month Outcome (N = 722)	Without 12-Month Outcome (N = 174)
25 to 34 points†	129 (14%)	95 (13%)	34 (20%)
≥35 points†	43 (5%)	30 (4%)	13 (7%)
Length of hospital stay* *(days)*	12.2 ± 10.5	11.8 ± 10.0	13.6 ± 12.2
<7 days†	254 (28%)	208 (29%)	46 (26%)
7 to 13 days†	387 (43%)	313 (43%)	74 (43%)
14 to 20 days†	145 (16%)	123 (17%)	22 (13%)
≥21 days†	110 (12%)	78 (11%)	32 (18%)
Had intensive care unit stay†			
Yes	370 (41%)	294 (41%)	76 (44%)
No	526 (59%)	428 (59%)	98 (56%)
No. of operating room trips*	2.6 ± 2.6	2.5 ± 2.6	2.8 ± 2.8

*The values are given as the mean and the standard deviation. †The values are given as the number of patients, with the percentage in parentheses. ‡GED = general equivalency diploma.

in depression at 6 months[29]. However, based on the results reported here, these early positive impacts were not observed at the 12-month follow-up.

It is surprising that evidence-based strategies, including the TSN[24], self-management[30], and collaborative care models[31,32], that have individually demonstrated efficacy were not efficacious when offered as a set of optional services. One factor that may have undermined the impact of this program was the highly variable and generally low utilization of TCC services, although the negative results observed in the full-receipt-of-intervention analysis suggest that this effect may have been limited. Although 96% of participants with follow-up data received at least 1 service, only 29% of the population received all 5 core services. Although study participants were not required to use all TCC services, they were encouraged to do so through the recovery assessment and coaching sessions. Low utilization of all services in this cohort replicates previous reports[28,29] indicating that the use of various TCC services varies among participants. Previous studies in this population found that there are unmet needs for support and mental health services[13]. Commonly reported barriers to psychosocial service utilization are the lack of support for using services, a low perceived need for psychosocial care, stigma, and limited resources[33,34]. Although patient stakeholders were actively engaged in the design of this program, further studies on the delivery of this class of intervention with input from patients and families may improve uptake. In implementation science, the impact of low intervention uptake on study outcomes is termed a type-III error. This type-III error is an inaccurate conclusion that a program is ineffective because of the failure of the intervention to be delivered as designed[35]. The current study results, paired with low program use by study participants, suggest that we still do not fully understand the impact of the program on patients with orthopaedic trauma.

There is a need for alternative strategies to improve long-term outcomes of patients following orthopaedic trauma. One approach would be to use risk stratification strategies. Castillo

TABLE II Use of Intervention Components Among Intervention Patients with 12-Month Outcomes (N = 378)*

Intervention Services	Intervention Patient Group (N = 378)	Site G (N = 93)	Site H (N = 58)	Site I (N = 55)	Site J (N = 90)	Site K (N = 45)	Site L (N = 37)
TSN handbook	291 (77%)	93 (100%)	36 (62%)	19 (35%)	74 (82%)	33 (73%)	36 (97%)
Peer visit	211 (56%)	76 (82%)	29 (50%)	24 (44%)	38 (42%)	16 (36%)	28 (76%)
Early call	245 (65%)	76 (82%)	34 (59%)	30 (55%)	41 (46%)	30 (67%)	34 (92%)
Recovery assessment	345 (91%)	91 (98%)	50 (86%)	44 (80%)	81 (90%)	43 (96%)	36 (97%)
Post-recovery assessment calls	259 (69%)	63 (68%)	36 (62%)	37 (67%)	63 (70%)	33 (73%)	27 (73%)
Received all 5 services	108 (29%)	45 (48%)	16 (28%)	7 (13%)	12 (13%)	8 (18%)	20 (54%)

*The values are given as the number of patients served, with the percentage in parentheses.

TABLE III Results of the Intention-to-Treat Analysis and Estimated Effect If All Patients Had Received All Components of the Intervention

12-Month Outcomes	Groups	Probability*	Treatment Effect	
			Odds Ratio†	Posterior Probability of Beneficial Treatment Effect
Composite outcome‡	Control§	0.68 (0.60, 0.75)	Reference	
	Intervention#	0.69 (0.61, 0.76)	1.05 (0.60, 1.63)	42.51%
	Full intervention**	0.72 (0.61, 0.81)	1.18 (0.56, 2.02)	28.81%
SMFA Dysfunction Index > 18.2	Control	0.65 (0.57, 0.72)	Reference	
	Intervention	0.65 (0.56, 0.73)	0.99 (0.55, 1.53)	52.51%
	Full intervention	0.69 (0.59, 0.79)	1.21 (0.60, 2.03)	25.48%
SMFA Bother Index > 23.7	Control	0.53 (0.45, 0.61)	Reference	
	Intervention	0.52 (0.44, 0.60)	0.95 (0.57, 1.45)	58.82%
	Full intervention	0.54 (0.43, 0.65)	1.03 (0.55, 1.68)	46.02%
Depression (PHQ-9) > 9	Control	0.29 (0.22, 0.37)	Reference	
	Intervention	0.34 (0.27, 0.41)	1.27 (0.72, 1.96)	16.09%
	Full intervention	0.36 (0.26, 0.46)	1.37 (0.68, 2.28)	13.53%
PTSD (PCL) > 35	Control	0.38 (0.31, 0.46)	Reference	
	Intervention	0.42 (0.33, 0.51)	1.16 (0.66, 1.81)	27.30%
	Full intervention	0.42 (0.30, 0.54)	1.16 (0.57, 1.93)	29.92%

*The values are given as the probability, with the 95% credible interval in parentheses. †The values are given as the odds ratio, with the 95% credible interval in parentheses. ‡The composite outcome is defined to be positive if SMFA Dysfunction Index > 18.2 or SMFA Bother Index > 23.7 or Depression (PHQ-9) > 9 or PTSD (PCL) > 35; the composite outcome would be missing if any of the 4 items is missing. §Control indicates treatment as usual. #Intervention indicates TSN handbook education, peer visits, coaching calls to be delivered after admission and prior to 6-week recovery assessment, recovery assessment, and post-recovery assessment calls. **Full intervention indicates the estimate of the effect if patients had received all components of the intervention.

et al. reported that patients with trauma can be effectively stratified into risk categories early in the course of recovery[17]. This risk stratification could guide the allocation of psychosocial support services. The result of our second sensitivity analysis suggested generally worse effects for those at low and medium risk for PTSD and generally better effects for those at high risk for PTSD. Although these analyses suggest the possibility of using risk assessment to tailor interventions to subgroups, the sample sizes are too small to reliably inform the deployment of scarce resources available to trauma systems for these types of services.

These results must be considered in light of several important limitations. A cluster randomized design was precluded because some sites had previous experience in implementing the TSN, resulting in an imbalance in the intervention and control groups. Patients in the intervention cohort were less educated, with 44% having some college compared with 60% of patients in the control cohort. Although efforts were made to balance the sites and participants and to control for key variables, unobserved covariates, such as access to psychosocial services and community resources, and residual confounding remain possible sources of bias. Historical trends at a regional or site level, as well as cointerventions, may have occurred and may have been missed despite our efforts to monitor sites throughout the study. Expectation effects due to the awareness of study assignment by clinicians and research staff at participating hospitals were an additional potential source of bias, as they could have influenced care. However, it is less likely that they would have influenced outcomes, as they were collected by an independent research organization.

The error in the delivery of feedback on the PTSD assessment and the recommendation for action at the time of the recovery assessment may have impacted the study outcomes and may have potentially biased results toward the null hypothesis. When the error was discovered, the study team developed and implemented a mitigation plan, which was approved by the institutional review boards at all participating centers. We also conducted sensitivity analyses to understand the impact of this error. The net effect of these efforts was a delay in the reporting of the study results. Due to small strata-specific sample sizes and confounding, it is not possible to draw definitive conclusions about whether the intervention had differential effects on 1-year outcomes based on PTSD risk subgroups.

Despite showing early positive effects at 6 weeks[28], the results of this analysis did not support our hypothesis that the TCC program would result in lower rates of poor function, depression, and PTSD. Rather, the findings suggest that the TCC as delivered does not have appreciable effects on 1-year outcomes in this patient population. Given the resource

intensity of this comprehensive intervention, alternative models need to be explored to address the psychosocial challenges of individuals following orthopaedic trauma.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H203). ■

NOTE: METRC consists of the METRC Writing Group Members and METRC Corporate Authors. The following individuals in both groups meet ICMJE criteria for authorship. Site affiliations are as of the time of the study unless otherwise noted.

The METRC Writing Group Members include Stephen T. Wegener, PhD, ABPP, Johns Hopkins School of Medicine; Katherine P. Frey, PhD, RN, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health; Michael J. Bosse, MD, Carolinas Medical Center, Department of Orthopaedic Surgery, Atrium Health Musculoskeletal Institute; Yanjie Huang, ScM, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health; Joshua L. Gary, MD, McGovern Medical School at The University of Texas Health Science Center at Houston; Robert V. O'Toole, MD, University of Maryland, R Adams Cowley Shock Trauma Center; Andrew N. Pollak, MD, University of Maryland, R Adams Cowley Shock Trauma Center; H. Claude Sagi, MD, FACS, Tampa General Hospital (now at University of Cincinnati College of Medicine); Todd O. McKinley, MD, Indiana University Health Methodist Hospital; Heather A. Vallier, MD, MetroHealth Medical Center; Kristin R. Archer, PhD, DPT, Vanderbilt University Medical Center; William T. Obremskey, MD, MPH, Vanderbilt University Medical Center; Robert A. Hymes, MD, Inova Fairfax Hospital; Clifford B. Jones, MD, FACS, Orthopaedic Associates of Michigan, Spectrum Health; Eben A. Carroll, MD, Atrium Health Wake Forest Baptist; David J. Hak, MD, Denver Health and Hospital Authority (now at Hughston Orthopedic Trauma); Andrew H. Schmidt, MD, Hennepin Healthcare Research Institute; Elizabeth Wysocki, MS, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health; Susan C. Collins, MSc, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health; Daniel O. Scharfstein, ScD, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health (now at University of Utah); Anna B. Newcomb, PhD, MSW, Inova Fairfax Hospital; Renan C. Castillo, PhD, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health; and Ellen J. MacKenzie, PhD, METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health.

METRC Corporate Authors include: *Atrium Health Wake Forest Baptist*: Anna N. Miller, MD (now at Barnes-Jewish Hospital at Washington University Medical Center); Danielle Yemiola Drye, EdS, MA (now at METRC Coordinating Center at the Johns Hopkins Bloomberg School of Public Health); James Brett Goodman, MBA; Martha B. Holden, AAS, AA; *Carolinas Medical Center, Department of Orthopaedic Surgery, Atrium Health Musculoskeletal Institute:* Joseph R. Hsu, MD; Madhav A. Karunakar, MD; Rachel B. Seymour, PhD; Stephen H. Sims, MD; Eileen Flores, MSW, LCSW (now at American Trauma Society); Christine Churchill, MA; *Denver Health and Hospital Authority:* Corey Henderson Trujillo, MS; *Florida Orthopedic Institute:* Anjan R. Shah, MD; *Hennepin County Medical Center:* Jerald R. Westberg, BA; *Indiana University Health Methodist Hospital:* Greg E. Gaski, MD (now at Inova Fairfax Hospital); Laurence B. Kempton, MD (now at Carolinas Medical Center, Department of Orthopaedic Surgery, Atrium Health Musculoskeletal Institute); Anthony T. Sorkin, MD; Walter W. Virkus, MD; *Inova Fairfax Hospital:* Melissa A. Porrey, LPC, NCC (no longer affiliated); *McGovern Medical School at The University of Texas Health Science Center at Houston*: Andrew Choo, MD; Sterling J. Boutte, BS; Matthew C. Galpin, CRC (now at REDCap Cloud); *MetroHealth Medical Center:* Sarah B. Hendrickson, MEd; Mary A. Breslin, MPH; *Orthopaedic Associates of Michigan, Spectrum Health:* Debra L. Sietsema, PhD, MSN (no longer affiliated); *University of Maryland, R Adams Cowley Shock Trauma Center:* Timothy Zerhusen, MD; Katherine Joseph, MPH (now at American Trauma Society); Andrea L. Howe, BA; and *Vanderbilt University Medical Center:* Susan W. Vanston, PT, MS.

The authors thank Cesar S. Molina, MD, University of Louisville, for drafting, enrolling, and interacting with patients.

References

1. Finkelstein E, Corso PS, Miller TR. The incidence and economic burden of injuries in the United States. New York: Oxford; Oxford University Press; 2006.

2. Alghnam S, Wegener ST, Bhalla K, Colantuoni E, Castillo R. Long-term outcomes of individuals injured in motor vehicle crashes: a population-based study. Injury. 2015 Aug;46(8):1503-8.

3. Halcomb E, Daly J, Davidson P, Elliott D, Griffiths R. Life beyond severe traumatic injury: an integrative review of the literature. Aust Crit Care. 2005 Feb;18(1):17-8: 20-4.

4. Marshall GN, Miles JN, Stewart SH. Anxiety sensitivity and PTSD symptom severity are reciprocally related: evidence from a longitudinal study of physical trauma survivors. J Abnorm Psychol. 2010 Feb;119(1):143-50.

5. Archer KR, Abraham CM, Obremskey WT. Psychosocial factors predict pain and physical health after lower extremity trauma. Clin Orthop Relat Res. 2015 Nov; 473(11):3519-26.

6. Dahm J, Ponsford J. Long-term employment outcomes following traumatic brain injury and orthopaedic trauma: a ten-year prospective study. J Rehabil Med. 2015 Nov;47(10):932-40.

7. Davydow DS, Zatzick DF, Rivara FP, Jurkovich GJ, Wang J, Roy-Byrne PP, Katon WJ, Hough CL, Kross EK, Fan MY, Joesch J, MacKenzie EJ. Predictors of posttraumatic stress disorder and return to usual major activity in traumatically injured intensive care unit survivors. Gen Hosp Psychiatry. 2009 Sep-Oct;31(5):428-35.

8. Holbrook TL, Anderson JP, Sieber WJ, Browner D, Hoyt DB. Outcome after major trauma: 12-month and 18-month follow-up results from the Trauma Recovery Project. J Trauma. 1999 May;46(5):765-71, discussion 771-3.

9. Kiely JM, Brasel KJ, Weidner KL, Guse CE, Weigelt JA. Predicting quality of life six months after traumatic injury. J Trauma. 2006 Oct;61(4):791-8.

10. Rosenbloom BN, Khan S, McCartney C, Katz J. Systematic review of persistent pain and psychological outcomes following traumatic musculoskeletal injury. J Pain Res. 2013;6:39-51.

11. Zatzick D, Jurkovich GJ, Rivara FP, Wang J, Fan MY, Joesch J, Mackenzie E. A national US study of posttraumatic stress disorder, depression, and work and functional outcomes after hospitalization for traumatic injury. Ann Surg. 2008 Sep; 248(3):429-37.

12. Zatzick DF, Rivara FP, Jurkovich GJ, Hoge CW, Wang J, Fan MY, Russo J, Trusz SG, Nathens A, Mackenzie EJ. Multisite investigation of traumatic brain injuries, posttraumatic stress disorder, and self-reported health and cognitive impairments. Arch Gen Psychiatry. 2010 Dec;67(12):1291-300.

13. Archer KR, Heins SE, Abraham CM, Obremskey WT, Wegener ST, Castillo RC. Clinical significance of pain at hospital discharge following traumatic orthopedic injury: general health, depression, and PTSD outcomes at 1 year. Clin J Pain. 2016 Mar;32(3):196-202.

14. Wegener ST, Castillo RC, Haythornthwaite J, MacKenzie EJ, Bosse MJ; LEAP Study Group. Psychological distress mediates the effect of pain on function. Pain. 2011 Jun;152(6):1349-57.

15. Castillo RC, Wegener ST, Heins SE, Haythornthwaite JA, MacKenzie EJ, Bosse MJ; LEAP Study Group. Longitudinal relationships between anxiety, depression, and pain: results from a two-year cohort study of lower extremity trauma patients. Pain. 2013 Dec;154(12):2860-6.

16. McCarthy ML, MacKenzie EJ, Edwin D, Bosse MJ, Castillo RC, Starr A; LEAP study group. Psychological distress associated with severe lower-limb injury. J Bone Joint Surg Am. 2003 Sep;85(9):1689-97.

17. Castillo RC, Huang Y, Scharfstein D, Frey K, Bosse MJ, Pollak AN, Vallier HA, Archer KR, Hymes RA, Newcomb AB, MacKenzie EJ, Wegener S, Hsu JR, Karunakar MA, Seymour RB, Sims SH, Flores E, Churchill C, Hak DJ, Henderson CE, Mir HR, Chan DS, Shah AR, Steverson B, Westberg J, Gary JL, Achor TS, Choo A, Munz JW, Porrey M, Hendrickson S, Breslin MA, McKinley TO, Gaski GE, Kempton LB, Sorkin AT, Virkus WW, Hill LC, Jones CB, Sietsema DL, O'Toole RV, Ordonio K, Howe AL, Zerhusen TJ Jr, Obremskey W, Boyce RH, Jahangir AA, Molina CS, Sethi MK, Vanston SW, Carroll EA, Drye DY, Holden MB, Collins SC, Wysocki E; Major Extremity Trauma Research Consortium (METRC). Association between 6-week postdischarge risk classification and 12-month outcomes after orthopedic trauma. JAMA Surg. 2019 Feb 1;154(2):e184824.

18. Bradford AN, Castillo RC, Carlini AR, Wegener ST, Teter H Jr, Mackenzie EJ. The trauma survivors network: Survive. Connect. Rebuild. J Trauma. 2011 Jun;70(6): 1557-60.

19. Scheuer H, Engstrom A, Thomas P, Moodliar R, Moloney K, Walen ML, Johnson P, Seo S, Vaziri N, Martinez A, Maier R, Russo J, Sieber S, Anziano P, Anderson K, Bulger E, Whiteside L, Heagerty P, Palinkas L, Zatzick D. A comparative effectiveness trial of an information technology enhanced peer-integrated collaborative care intervention versus enhanced usual care for US trauma care systems: clinical study protocol. Contemp Clin Trials. 2020 Apr;91:105970.

20. Zatzick D, Jurkovich G, Rivara FP, Russo J, Wagner A, Wang J, Dunn C, Lord SP, Petrie M, O'Connor SS, Katon W. A randomized stepped care intervention trial targeting posttraumatic stress disorder for surgically hospitalized injury survivors. Ann Surg. 2013 Mar;257(3):390-9.

21. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. JAMA. 2002 Oct 9;288(14):1775-9.

22. Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the chronic care model in the new millennium. Health Aff (Millwood). 2009 Jan-Feb;28(1):75-85.

23. Wegener ST, Pollak AN, Frey KP, Hymes RA, Archer KR, Jones CB, Seymour RB, O'Toole RV, Castillo RC, Huang Y, Scharfstein DO, MacKenzie EJ; METRC. The Trauma Collaborative Care Study (TCCS). J Orthop Trauma. 2017 Apr;31(Suppl 1):S78-87.

24. Swiontkowski MF, Engelberg R, Martin DP, Agel J. Short Musculoskeletal Function Assessment Questionnaire: validity, reliability, and responsiveness. J Bone Joint Surg Am. 1999 Sep;81(9):1245-60.

25. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001 Sep;16(9):606-13.

26. Manea L, Gilbody S, McMillan D. Optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9): a meta-analysis. CMAJ. 2012 Feb 21;184(3):E191-6.

27. Blanchard EB, Jones-Alexander J, Buckley TC, Forneris CA. Psychometric properties of the PTSD Checklist (PCL). Behav Res Ther. 1996 Aug;34(8):669-73.

28. Major Extremity Trauma Rehabilitation Consortium (METRC). Early effects of the trauma collaborative care intervention: results from a prospective multicenter cluster clinical trial. J Orthop Trauma. 2019 Nov;33(11):538-46.

29. Castillo RC, Wegener ST, Newell MZ, Carlini AR, Bradford AN, Heins SE, Wysocki E, Pollak AN, Teter H, Mackenzie EJ. Improving outcomes at Level I trauma centers: an early evaluation of the Trauma Survivors Network. J Trauma Acute Care Surg. 2013 Jun;74(6):1534-40.

30. Reynolds R, Dennis S, Hasan I, Slewa J, Chen W, Tian D, Bobba S, Zwar N. A systematic review of chronic disease management interventions in primary care. BMC Fam Pract. 2018 Jan 9;19(1):11.

31. Katon WJ, Lin EH, Von Korff M, Ciechanowski P, Ludman EJ, Young B, Peterson D, Rutter CM, McGregor M, McCulloch D. Collaborative care for patients with depression and chronic illnesses. N Engl J Med. 2010 Dec 30;363(27):2611-20.

32. Zatzick D, Roy-Byrne P, Russo J, Rivara F, Droesch R, Wagner A, Dunn C, Jurkovich G, Uehara E, Katon W. A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors. Arch Gen Psychiatry. 2004 May;61(5):498-506.

33. Dilworth S, Higgins I, Parker V, Kelly B, Turner J. Patient and health professional's perceived barriers to the delivery of psychosocial care to adults with cancer: a systematic review. Psychooncology. 2014 Jun;23(6):601-12.

34. Kantor V, Knefel M, Lueger-Schuster B. Perceived barriers and facilitators of mental health service utilization in adult trauma survivors: a systematic review. Clin Psychol Rev. 2017 Mar;52:52-68.

35. Scanlon JW, Horst P, Nay JN, Schmidt RE, Waller AE. Evaluability assessment: avoiding type III or IV errors. In Gilbert GR, Conklin PJ, editors. Evaluation management: a source book of readings. Charlottesville: US Civil Service Commission; 1977. p 71-90.