

**Early Effects of the Trauma Collaborative Care Intervention:
Results from a Prospective Multicenter Cluster Clinical Trial**

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Purpose: The Trauma Collaborative Care (TCC) program was developed to improve the psychosocial sequelae postinjury. TCC includes the Trauma Survivors Network (TSN) services and TSN coordinator activities to support collaborative care. The impact of the TCC early intervention components (education, peer visits, and coaching calls) on 6-week outcomes was evaluated in a prospective, multicenter, cluster clinical trial.

Methods: Outcomes of 481 patients at 6 trauma centers implementing the TCC program were compared with those of 419 patients at 6 trauma centers receiving usual care. Eligible patients had high-energy orthopaedic trauma injuries requiring surgery and hospital admission. Binary outcomes (pain [0-10] ≥ 5 , Patient Health Questionnaire [PHQ]-9 depression ≥ 10 , Posttraumatic Stress Disorder Checklist [PTSD PCL] ≥ 30 and self-efficacy [0-10] for return to work ≥ 7) were analyzed using a Bayesian hierarchical modeling approach to estimate the intention-to-treat effect. We also estimated the effect had all patients received all components of the intervention. Using the Bayesian formalism, 95% credible intervals and posterior probabilities of a favorable treatment effect are reported.

Results: Of the 481 intervention patients, 371 (77%) received a TSN Handbook, 279 (58%) received a peer visit, and 308 (64%) received ≥ 1 coaching call prior to 6-week assessment. There was substantial variation across the 6 sites in receipt of intervention components. Only 36% of intervention patients received all 3 components (range, 18% to 77%). The posterior estimates of the intention-to-treat effect (odds ratio scale) for all end points favor TCC; however, the credible intervals all include one. For pain and depression, there is 93.3% and 96.4% posterior probability that the TCC program has a favorable effect, respectively. Had all patients received all components of the intervention the estimated effect more strongly favors positive effects of the TCC program. For depression and self-efficacy, the 95% credible intervals exclude one with posterior probabilities of 98.7% and 98%. For pain and PTSD, the 95% credible intervals include one, but the posterior probabilities of a favorable effect are high (97.1% and 95.8%, respectively).

Conclusion: Use of the services offered through the TCC program was highly variable across sites. While there is a suggestion of an intention-to-treat effect on pain, depression, PTSD, and self-efficacy, the results are not statistically significant. Had early components been fully implemented, analysis suggests that the TCC program may lead to significantly lower levels of clinical depression and higher levels of self-efficacy at 6 weeks after injury; there is also a promising effect on pain and PTSD.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.