HOW HAVE HEALTH SYSTEMS MADE DECISIONS BASED ON EVIDENCE COLLECTED IN PCTS? THE TSOS & ACS/COT POLICY COLLABORATION CASE EXAMPLE

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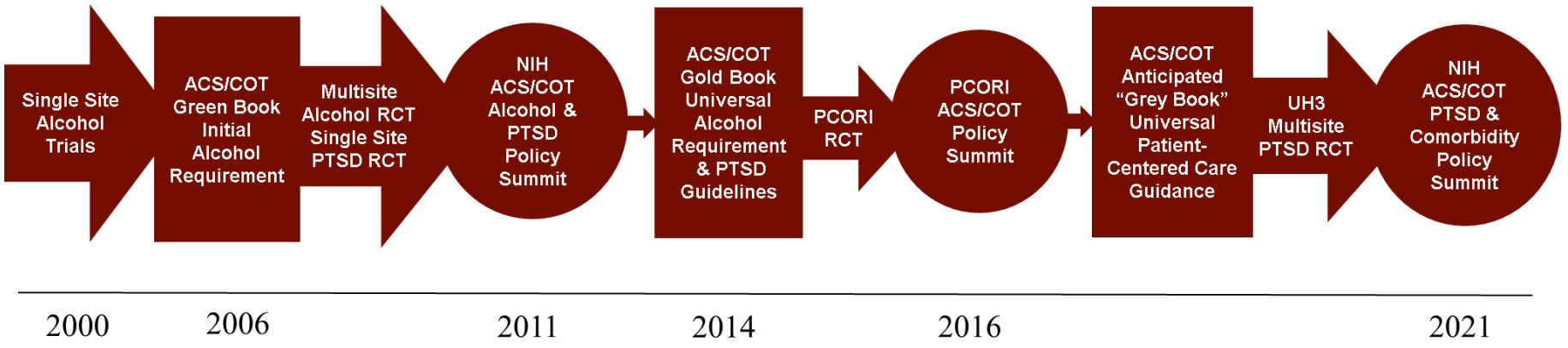
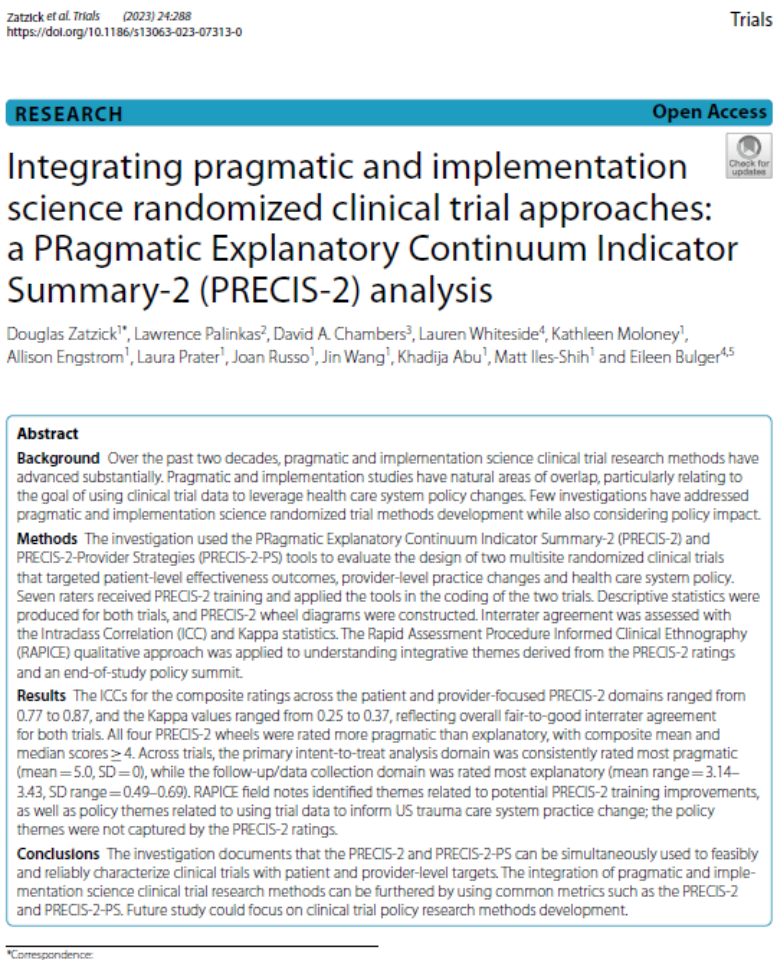
TSOS Pragmatic Clinical Trial & American College of Surgeons Committee on Trauma (ACS/COT) Policy Collaboration



TSOS & ACS/COT Policy Collaboration



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Trials

RESEARCH Open Access

Integrating pragmatic and implementation science randomized clinical trial approaches: a PRagmatic Explanatory Continuum Indicator Summary-2 (PRECIS-2) analysis

Douglas Zatzick[1*], Lawrence Palinkas[2], David A. Chambers[3], Lauren Whiteside[4], Kathleen Moloney[1], Allison Engstrom[1], Laura Prater[1], Joan Russo[1], Jin Wang[1], Khadija Abu[1], Matt Iles-Shih[1] and Eileen Bulger[4,5]

Abstract

Background Over the past two decades, pragmatic and implementation science clinical trial research methods have advanced substantially. Pragmatic and implementation studies have natural areas of overlap, particularly relating to the goal of using clinical trial data to leverage health care system policy changes. Few investigations have addressed pragmatic and implementation science randomized trial methods development while also considering policy impact.

Methods The investigation used the PRagmatic Explanatory Continuum Indicator Summary-2 (PRECIS-2) and PRECIS-2-Provider Strategies (PRECIS-2-PS) tools to evaluate the design of two multisite randomized clinical trials that targeted patient-level effectiveness outcomes, provider-level practice changes and health care system policy. Seven raters received PRECIS-2 training and applied the tools in the coding of the two trials. Descriptive statistics were produced for both trials, and PRECIS-2 wheel diagrams were constructed. Interrater agreement was assessed with the Intraclass Correlation (ICC) and Kappa statistics. The Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE) qualitative approach was applied to understanding integrative themes derived from the PRECIS-2 ratings and an end-of-study policy summit.

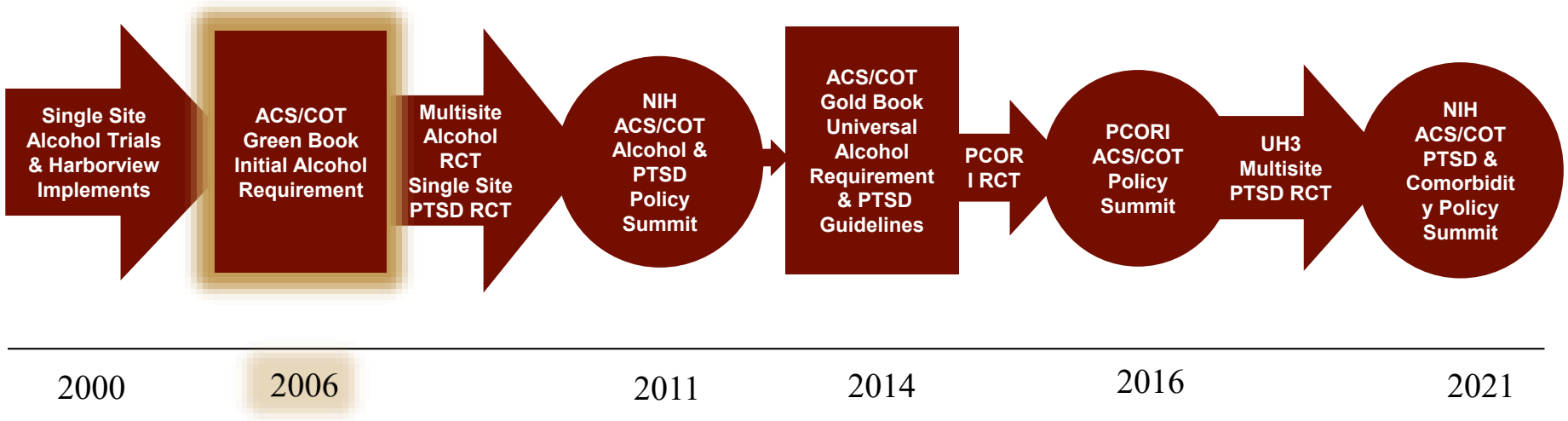
Results The ICCs for the composite ratings across the patient and provider-focused PRECIS-2 domains ranged from 0.77 to 0.87, and the Kappa values ranged from 0.25 to 0.37, reflecting overall fair-to-good interrater agreement for both trials. All four PRECIS-2 wheels were rated more pragmatic than explanatory, with composite mean and median scores ≥ 4. Across trials, the primary intent-to-treat analysis domain was consistently rated most pragmatic (mean = 5.0, SD = 0), while the follow-up/data collection domain was rated most explanatory (mean range = 3.14–3.43, SD range = 0.49–0.69). RAPICE field notes identified themes related to potential PRECIS-2 training improvements, as well as policy themes related to using trial data to inform US trauma care system practice change; the policy themes were not captured by the PRECIS-2 ratings.

Conclusions The investigation documents that the PRECIS-2 and PRECIS-2-PS can be simultaneously used to feasibly and reliably characterize clinical trials with patient and provider-level targets. The integration of pragmatic and implementation science clinical trial research methods can be furthered by using common metrics such as the PRECIS-2 and PRECIS-2-PS. Future study could focus on clinical trial policy research methods development.

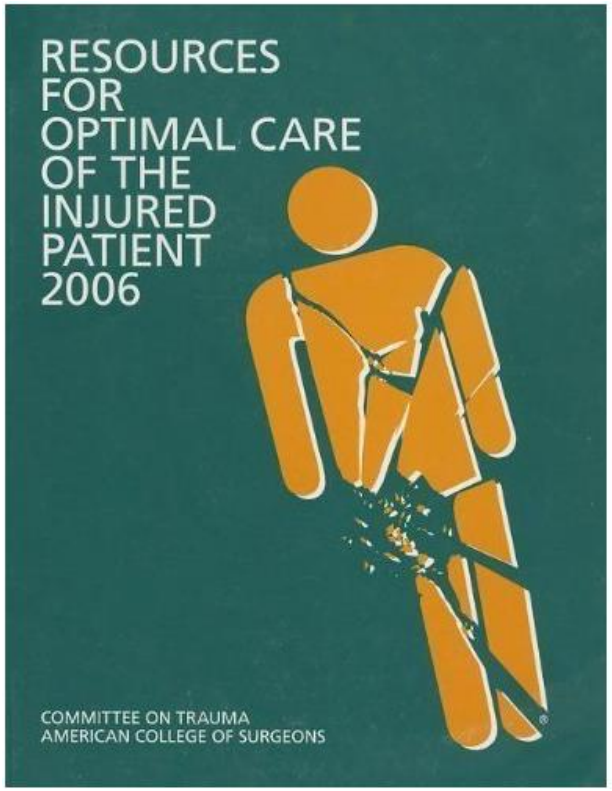
*Correspondence:

- Pragmatic trials directly target ACS/COT policy requirements
- Policy requirement combined with ACS/COT verification site visit constitutes a health care system level implementation strategy
- All TSOS PCT grant applications include an up-front ACS/COT commitment to an end-of-study policy summit

TSOS Pragmatic Clinical Trial & ACS/COT Policy Collaboration



ACS/COT 2006 Alcohol Requirement



- Alcohol screening and intervention required for Level I trauma centers
- Alcohol screening required for Level II trauma centers
- Verification site visit every 3 years

Decisional Uncertainty Regarding the Strength of the Evidence-Base Supporting the ACS/COT Alcohol Requirement

SBIRT in Emergency Care Settings: Are We Ready to Take it to Scale?

Edward Bernstein, MD, Judith A. Bernstein, RNC, PhD, Jack B. Stein, PhD, and Richard Saitz, MD, MPH

Abstract

This article summarizes a panel discussion on "SBIRT in the emergency care setting: are we ready to take it to scale?" Dr. Edward Bernstein commented on the historical developments of emergency department (ED) screening, brief intervention (BI), and referral to treatment (SBIRT) research, practice, and knowledge translation. Dr. Jack Stein addressed SBIRT grant program progress to date, the reimbursement stream, SBIRT lessons learned, and unanswered questions. Dr. Richard Saitz reviewed the limitations of the evidence for alcohol and drug ED screening and BI and cautioned on the danger of proceeding to practice and broad dissemination without evidenced based on randomized controlled trials with sufficient sample size and clinically important outcomes.

ACADEMIC EMERGENCY MEDICINE 2009; 16:1072–1077 © 2009 by the Society for Academic Emergency Medicine

Prospective Cohort Study: Dip and Recurrence in Alcohol use after Injury (Dunn et al 2003)

The Journal of TRAUMA® Injury, Infection, and Critical Care

Hazardous Drinking by Trauma Patients during the Year after Injury

Chris Dunn, PhD, Douglas Zatzick, MD, Joan Russo, PhD, Frederick Rivara, MD, MPH, Peter Roy-Byrne, MD, Rick Ries, MD, Dave Wisner, and Larry Gentilello, MD

Background: To improve reinjury prevention strategies targeting hazardous drinking, we determined its predictors and longitudinal course in the year after injury.

Methods: This was a prospective study of 101 randomly selected hospitalized trauma patients who before injury represented the full range of substance abuse, from severe to none. We hypothesized that clinical data obtained routinely by trauma centers would predict hazardous drinking during the postinjury year.

Results: Drug and alcohol use dropped markedly 1 month after injury but returned to preinjury levels by 4 months. Forty-one percent of the sample drank hazardously before injury, and 55% drank hazardously after. From before to after injury, 20% of patients worsened their hazardous drinking status, and only 6% of patients improved it. Three clinical predictors of hazardous drinking during the year were identified: any positive blood alcohol concentration > 0 at admission (odds ratio [OR], 9.18; 95% confidence interval [CI], 2.51–33.56), any days > 0 of using nonprescription drugs of abuse in the month before injury (OR, 6.63; 95% CI, 1.76–25.04), and suffering an intentional injury (OR, 5.1; 95% CI, 1.38–18.77).

Conclusion: Efforts to reduce hazardous drinking after injury should target patients with this risk profile and focus on the 1- to 4-month period after injury hospitalization.

J Trauma. 2003;54:707–712.

Hazardous drinking is defined by the World Health Organization as any pattern of drinking alcohol that confers the risk of harm.[1] A common drinking pattern by trauma patients that creates a high injury or reinjury risk is infrequent but heavy consumption on single occasions by individuals with little experience functioning while intoxicated.[2] Patients admitted to trauma centers with positive toxicology tests for any drugs of abuse or any blood

talization, trauma centers need rapid, cost-effective ways to initially identify patients at risk for hazardous drinking.

Previous studies report that substance abuse first decreases after injury, but eventually returns to preinjury levels during the postinjury months. The exact timing of these changes is unclear. Gentilello et al. found that patients receiving no intervention in the hospital reduced their drinking at 6 months but returned to preinjury levels by 12 months.[6] In

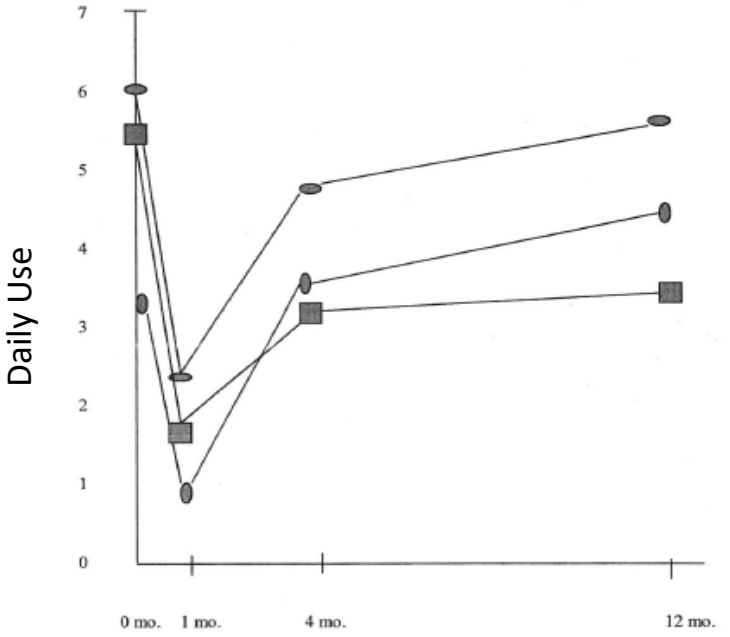


Fig. 1. *Longitudinal course of alcohol and drug use from the month before injury through the year after injury.* Vertical axis *indicates days per month; on the* horizontal axis, *0 months indicates the month*

Single Site Trauma Center-Based Motivational Interviewing Randomized Efficacy Trial Targeting Alcohol: Reductions in Alcohol Consumption & Recurrent Injury Admission (Harborview 1999)

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Alcohol Interventions in a Trauma Center as a Means of Reducing the Risk of Injury Recurrence

Larry M. Gentilello, MD,*|| Frederick P. Rivara, MD, MPH,†|| Dennis M. Donovan, PhD,¶ Gregory J. Jurkovich, MD,*|| Elizabeth Daranciang, MPH,|| Christopher W. Dunn, PhD,|| Andres Villaveces, MD, MPH,|| Michael Copass, MD,§ and Richard R. Ries, MD‡

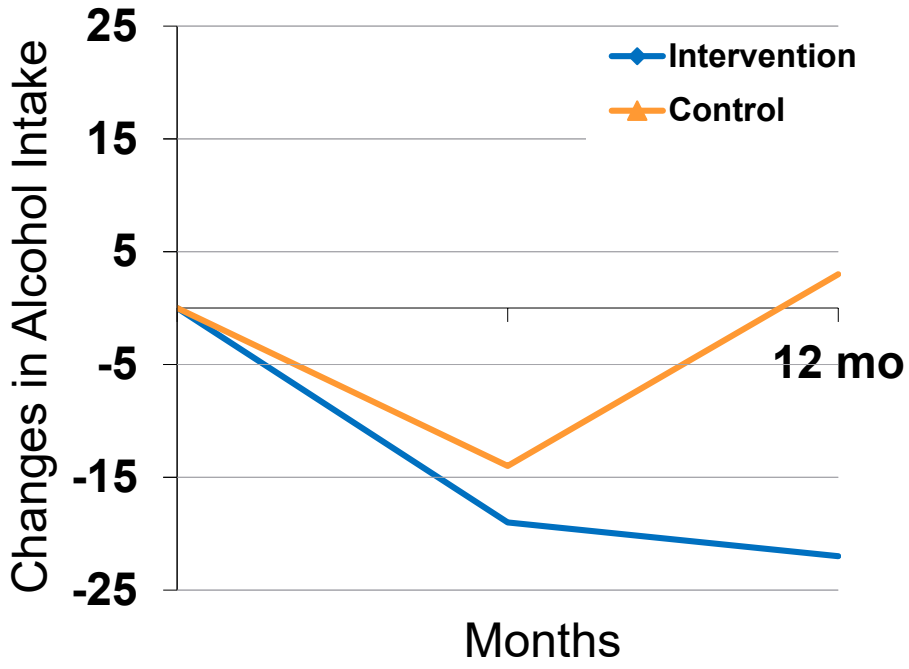
*From the Departments of *Surgery, †Pediatrics, ‡Psychiatry, and §Medicine, University of Washington School of Medicine, the ||Harborview Injury Prevention and Research Center, and the ¶University of Washington Alcohol and Drug Abuse Institute, Seattle, Washington*

Objective
Alcoholism is the leading risk factor for injury. The authors hypothesized that providing brief alcohol interventions as a routine component of trauma care would significantly reduce alcohol consumption and would decrease the rate of trauma recidivism.

Methods
This study was a randomized, prospective controlled trial in a level 1 trauma center. Patients were screened using a blood alcohol concentration, gamma glutamyl transpeptidase level, and short Michigan Alcoholism Screening Test (SMAST). Those with positive results were randomized to a brief intervention or control group. Reinjury was detected by a computerized search of emergency department and statewide hospital discharge records, and 6- and 12-month interviews were conducted to assess alcohol use.

Results
A total of 2524 patients were screened; 1153 screened positive (46%). Three hundred sixty-six were randomized to the intervention group, and 396 to controls. At 12 months, the intervention group decreased alcohol consumption by 21.8 ± 3.7 drinks per week; in the control group, the decrease was 6.7 ± 5.8 ($p = 0.03$). The reduction was most apparent in patients with mild to moderate alcohol problems (SMAST score 3 to 8); they had 21.6 ± 4.2 fewer drinks per week, compared to an increase of 2.3 ± 8.3 drinks per week in controls ($p < 0.01$). There was a 47% reduction in injuries requiring either emergency department or trauma center admission (hazard ratio 0.53, 95% confidence interval 0.26 to 1.07, $p = 0.07$) and a 48% reduction in injuries requiring hospital admission (3 years follow-up).

Conclusion
Alcohol interventions are associated with a reduction in alcohol intake and a reduced risk of trauma recidivism. Given the prevalence of alcohol problems in trauma centers, screening, intervention, and counseling for alcohol problems should be routine.



Single Site Stepped Collaborative Care with Motivational Interviewing Element Targeting Alcohol Consumption (Harborview 2004)

ORIGINAL ARTICLE

A Randomized Effectiveness Trial of Stepped Collaborative Care for Acutely Injured Trauma Survivors

Douglas Zatzick, MD; Peter Roy-Byrne, MD; Joan Russo, PhD; Frederick Rivara, MD, MPH; RoseAnne Droesch, MSW; Amy Wagner, PhD; Chris Dunn, PhD; Gregory Jurkovich, MD; Edwina Uehara, PhD; Wayne Katon, MD

Context: Although posttraumatic stress disorder (PTSD) and alcohol abuse frequently occur among acutely injured trauma survivors, few real-world interventions have targeted these disorders.

Objective: We tested the effectiveness of a multifaceted collaborative care (CC) intervention for PTSD and alcohol abuse.

Design: Randomized effectiveness trial.

Participants: We recruited a population-based sample of 120 male and female injured surgical inpatients 18 or older at a level 1 trauma center.

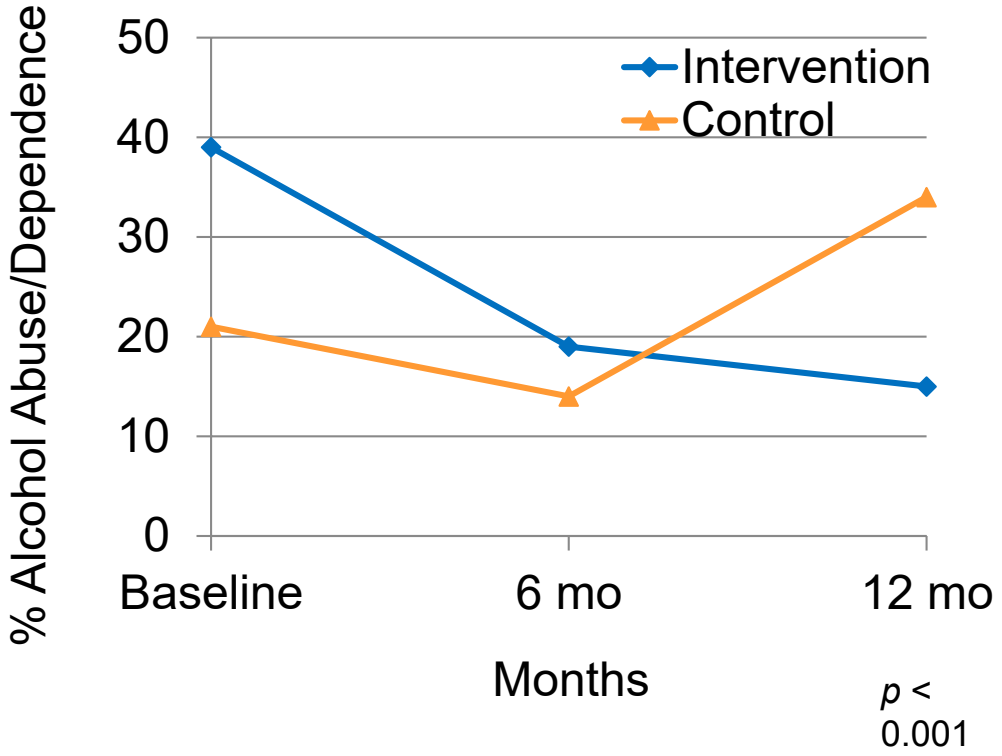
Intervention: Patients were randomly assigned to the CC intervention (n = 59) or the usual care (UC) control condition (n = 61). The CC patients received stepped care that consisted of (1) continuous postinjury case management, (2) motivational interviews targeting alcohol abuse/dependence, and (3) evidence-based pharmacotherapy and/or cognitive behavioral therapy for patients with persistent PTSD at 3 months after injury.

Main Outcome Measures: We used the PTSD symptomatic criteria (PTSD Checklist) at baseline and 1, 3, 6, and 12 months after injury, and alcohol abuse/dependence (Composite International Diagnostic Interview) at baseline and 6 and 12 months after injury.

Results: Random-coefficient regression analyses demonstrated that over time, CC patients were significantly less symptomatic compared with UC patients with regard to PTSD ($P = .01$) and alcohol abuse/dependence ($P = .048$). The CC group demonstrated no difference (−0.07%; 95% confidence interval [CI], −4.2% to 4.3%) in the adjusted rates of change in PTSD from baseline to 12 months, whereas the UC group had a 6% increase (95% CI, 3.1%-9.3%) during the year. The CC group showed on average a decrease in the rate of alcohol abuse/dependence of −24.2% (95% CI, −19.9% to −28.6%), whereas the UC group had on average a 12.9% increase (95% CI, 8.2%-17.7%) during the year.

Conclusions: Early mental health care interventions can be feasibly and effectively delivered from trauma centers. Future investigations that refine routine acute care treatment procedures may improve the quality of mental health care for Americans injured in the wake of individual and mass trauma.

Arch Gen Psychiatry. 2004;61:498-506



Disseminating Organizational Screening & Brief Intervention Services (DO-SBIS, 2007-2012) Multisite Pragmatic Trial Targeting Alcohol: 20 Sites, Patient N = 878

Addiction
RESEARCH REPORT
doi:10.1111/add.12492

Disseminating alcohol screening and brief intervention at trauma centers: a policy-relevant cluster randomized effectiveness trial*

Douglas Zatzick[1], Dennis M. Donovan[2], Gregory Jurkovich[3], Larry Gentilello[1], Chris Dunn[4], Joan Russo[4], Jin Wang[1], Christopher D. Zatzick[5], Jeff Love[4], Collin McFadden[4] & Frederick P. Rivara[6]

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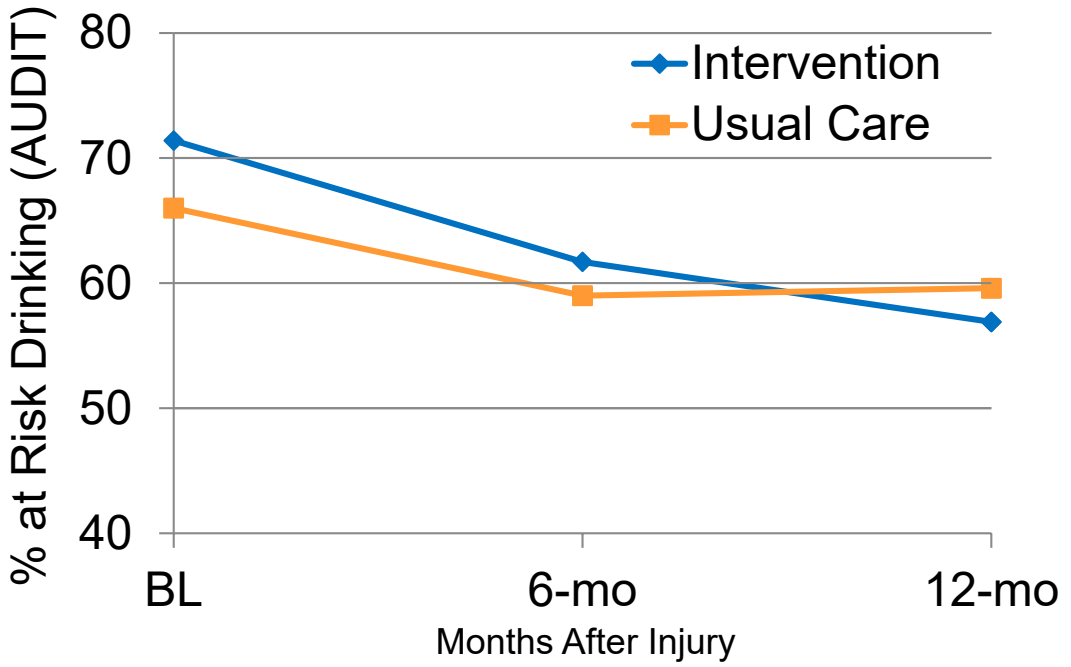
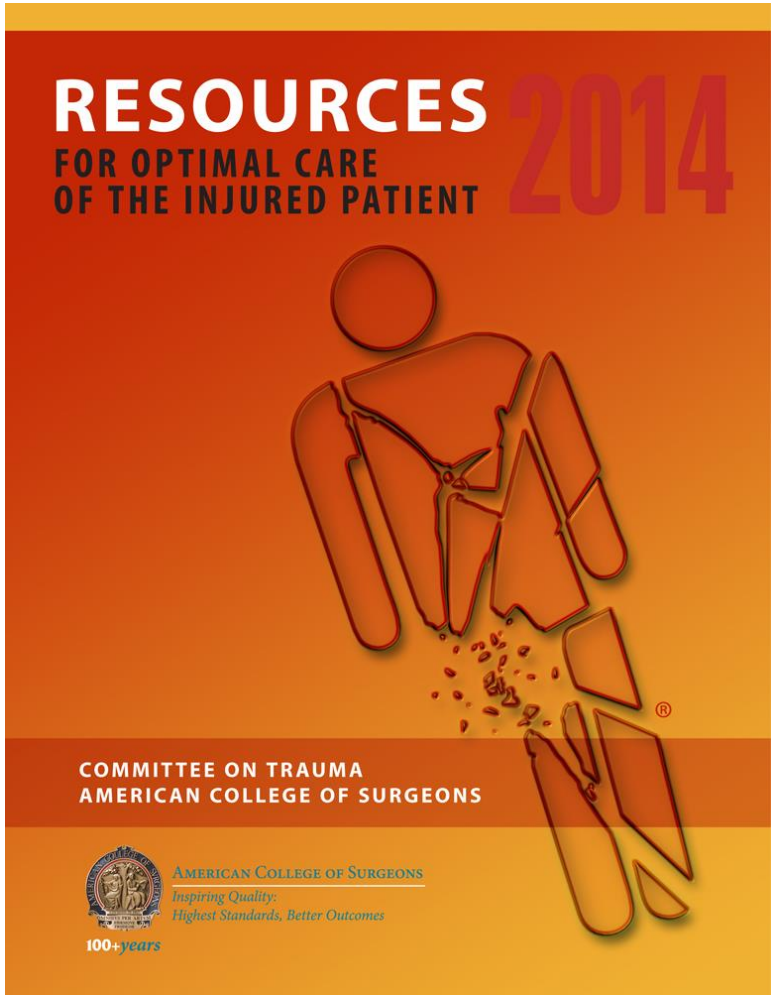


$p < 0.05$

ACS/COT Alcohol Requirement in the Wake of the DO-SBIS Trial

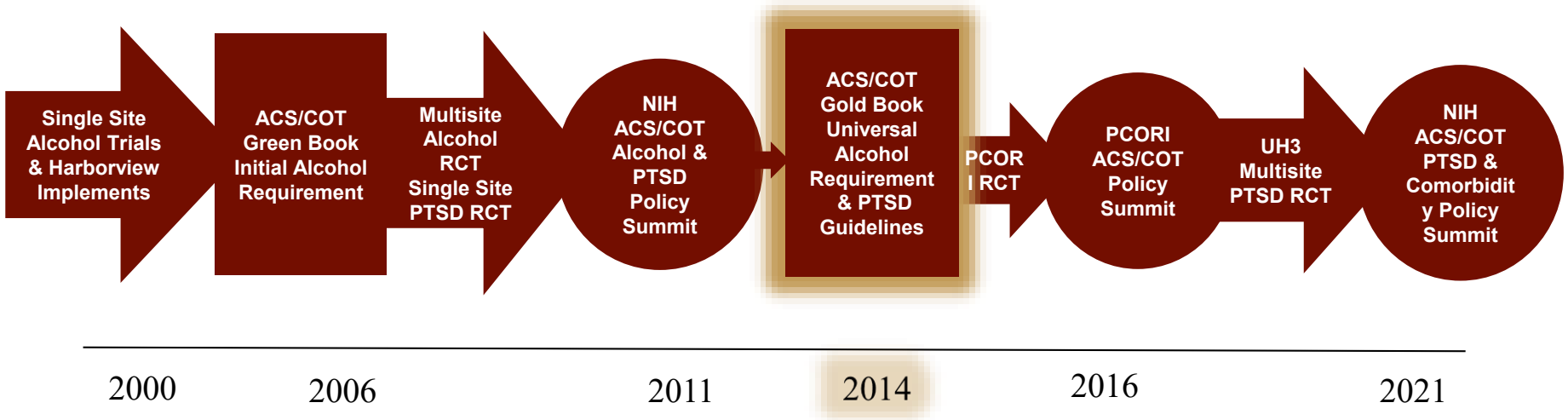


2014 Alcohol Requirement

Universal Screening & Intervention Mandate at Level I & II trauma centers

Verification Site Visit Every 3 Years

TSOS Pragmatic Clinical Trial & ACS/COT Policy Collaboration



TSOS NIH Collaboratory UH3 Trial (25 sites, N = 635)

JAMA Surgery | Original Investigation

Stepped Collaborative Care Targeting Posttraumatic Stress Disorder Symptoms and Comorbidity for US Trauma Care Systems
A Randomized Clinical Trial

Douglas Zatzick, MD; Gregory Jurkovich, MD; Patrick Heagerty, PhD; Joan Russo, PhD; Doyanne Darnell, PhD; Lea Parker, BA; Michelle K. Roberts, MPH; Rddhi Moodliar, BA; Allison Engstrom, MSW; Jin Wang, PhD; Eileen Bulger, MD; Lauren Whiteside, MD; Deepika Nehra, MD; Lawrence A. Palinkas, PhD; Kathleen Moloney, BA; Ronald Maier, MD

IMPORTANCE To date, few multisite investigations have evaluated early interventions for injured patients with posttraumatic stress disorder (PTSD) symptoms.

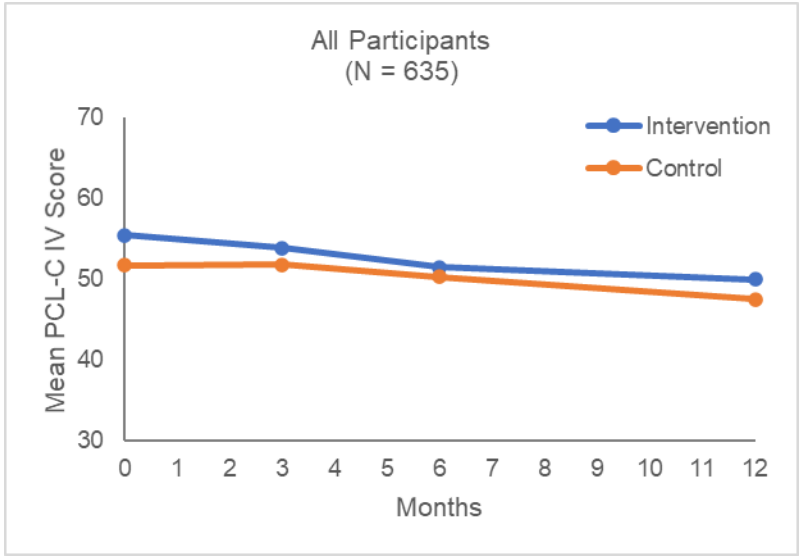
OBJECTIVE To simultaneously assess the effectiveness and implementation of a brief stepped collaborative care intervention targeting PTSD and comorbidity.

DESIGN, SETTING, AND PARTICIPANTS A stepped-wedge cluster randomized clinical trial was conducted at 25 US level I trauma centers. Participants included hospitalized survivors of physical injury who underwent a 2-step evaluation for PTSD symptoms. Patients reporting high levels of distress on the PTSD Checklist (PCL-C) were randomized (N = 635) per the stepped-wedge protocol to enhanced usual care control (n = 370) or intervention (n = 265) conditions. The study was conducted from January 4, 2016, through November 2018. Data analysis was performed from November 4, 2019, to December 8, 2020.

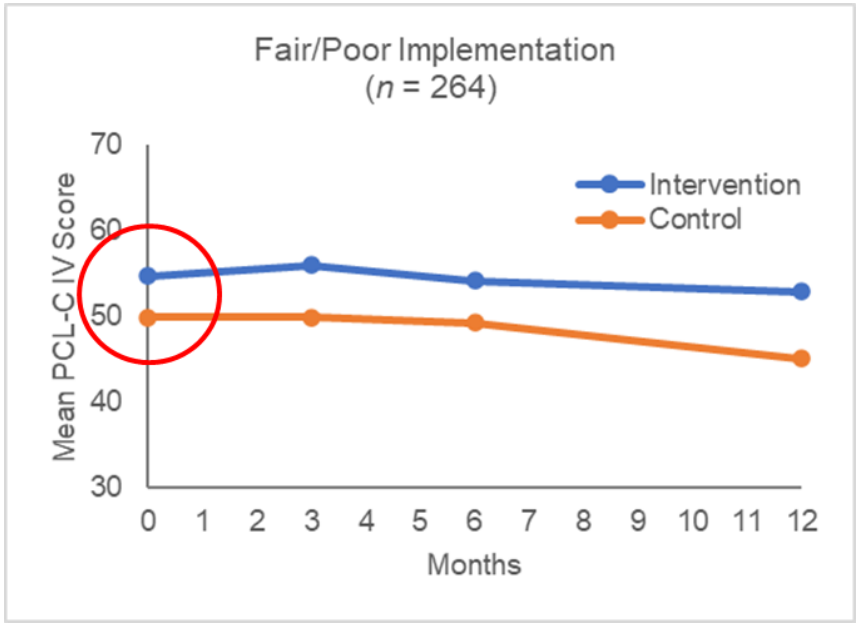
INTERVENTIONS The Trauma Survivors Outcomes and Support collaborative care intervention included proactive injury case management that assisted patients transitioning from hospital inpatient to outpatient and community settings. The intervention also integrated evidence-based pharmacotherapy and psychotherapeutic elements targeting PTSD symptoms and comorbidity.

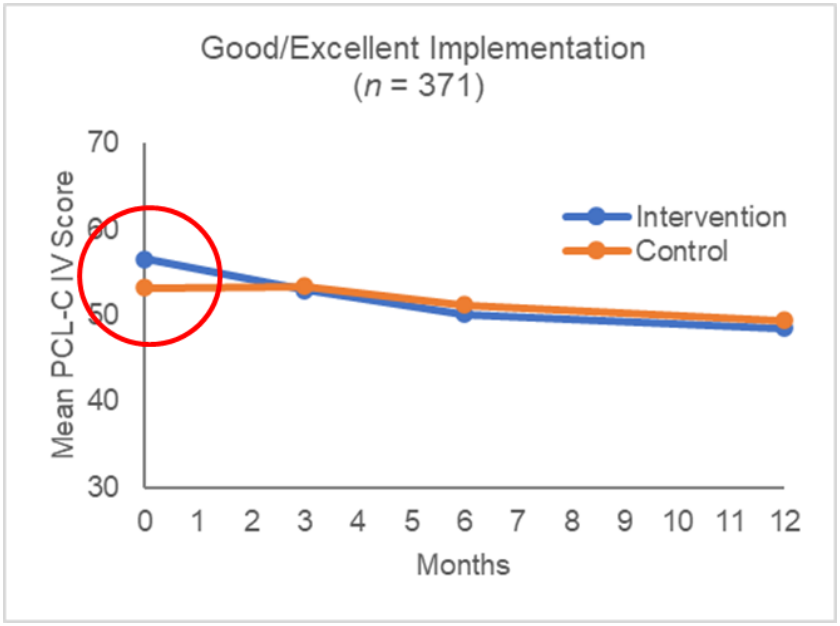
MAIN OUTCOMES AND MEASURES The primary study outcome was PTSD symptoms assessed

Invited Commentary
Supplemental content

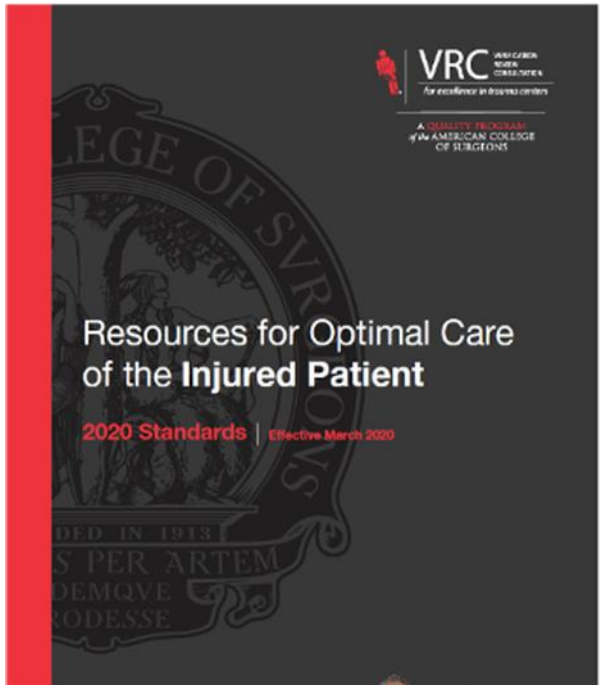


NIH Collaboratory UH3 Trial (N = 635): Stratification by Quality of Trauma Center Implementation





ACS/COT Psychological Sequelae Screening & Referral Requirement in the Wake of the TSOS 25 Site NIH Collaboratory Cluster Randomized Pragmatic Trial (2015-2021)



- Trauma Centers must have the following in place to meet the mental health needs of trauma patients:
  1. Protocols to identify patients at high risk for psychological sequelae
  2. A referral process for patients who have been identified as high risk for psychological sequelae