

Comparative effectiveness of family problem-solving therapy (F-PST) for adolescents after traumatic brain injury: Protocol for a randomized, multicenter, clinical trial

Brad G. Kurowski^{a,g,*}, Terry Stancin^b, H. Gerry Taylor^{c,d}, Kelly A. McNally^e, Michael W. Kirkwood^f, Amy Cassidy^a, Eileen King^a, McKenna Sklut^a, Megan E. Narad^a, Shari L. Wade^a

^a Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA

^b Case Western Reserve University and MetroHealth Medical Center, Cleveland Medical Center, Cleveland, OH, USA

^c Biobehavioral Health Center, Nationwide Children's Hospital Research Institute, The Ohio State University, Columbus, OH, USA

^d Case Western Reserve University, Rainbow Babies & Children's Hospital, University Hospitals Cleveland Medical Center, Cleveland, OH, USA

^e Nationwide Children's Hospital, The Ohio State University, Columbus, OH, USA

^f Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, CO, USA

^g Department of Pediatrics and Neurology and Rehabilitation Medicine, University of Cincinnati College of Medicine, Cincinnati, OH, USA

ARTICLE INFO

Clinical Trials Registration:

NCT:02368366

Keywords:

Pediatric traumatic brain injury

Telehealth

Problem solving

Behavior

Executive function

ABSTRACT

Introduction: The objective of this manuscript is to describe the methodology that will be used to test the comparative effectiveness, feasibility, and acceptability of three formats of family problem solving therapy (F-PST) for improving functional outcomes of complicated mild to severe adolescent TBI.

Methods: Three-arm comparative effectiveness, randomized clinical trial (RCT) design. We describe the protocol of a three-arm RCT comparing the effectiveness of three modalities of F-PST to reduce executive dysfunction and behavior problems following TBI in adolescence. The RCT will compare the relative effectiveness among face-to-face; online and self-directed; and therapist-supported online modes of treatment.

Ethics and dissemination: It is anticipated that findings from this work will inform future clinical care practices, with implications for treatment of other patient populations of youth with psychological symptoms arising from neurological conditions. Institutional review board approval will be obtained from all sites prior to commencement of the study.

1. Introduction

Traumatic brain injury (TBI) is a world-wide health problem, one of the most common causes of acquired disability in youth and a source of significant morbidity and family burden [1–6]. TBI results in 7843 deaths, 46,260 hospitalizations, and 1,083,122 emergency department visits in children and young adults yearly in the United States [6]. Early injuries can have a life-long impact [7]. TBI often results in deficits in cognition, behavior, and social development [8–10]. Novel behavior problems are among the most common and problematic consequences [11–13], yet many youth fail to receive needed psychological services due to lack of identification and access [14]. Linking youth with TBI to effective treatments could improve functional outcomes, reduce family burden, and increase treatment satisfaction.

There is also a bidirectional influence of the TBI and family

functioning on outcomes [15]. Parent and family functioning are adversely affected by TBI [16–18] and parental distress and poor parent-child interactions are associated with poorer recovery over time after childhood TBI [12,19–24]. The adverse effects of TBI on parents/families and the central role of family functioning in child recovery highlight the need for interventions designed to facilitate positive family and parental functioning following pediatric TBI.

A number of barriers could prevent families from seeking or receiving services for children's behavioral problems after TBI [25]. Outpatient services may be unavailable altogether or families may have to travel significant distances to obtain appropriate care. Access to professionals with experience in treating patients with pediatric TBI and their families is even more limited, with only a small subset of providers having sufficient training in both TBI and behavioral intervention programs. The use of internet technology makes it possible to

* Corresponding author. Cincinnati Children's Hospital Medical Center, 3333 Burnet Ave. MLC 4009, Cincinnati, OH, 45229-3039, USA.

E-mail address: brad.kurowski@cchmc.org (B.G. Kurowski).

<https://doi.org/10.1016/j.conctc.2018.04.001>

Received 1 December 2017; Received in revised form 30 March 2018; Accepted 3 April 2018

Available online 05 April 2018

2451-8654/ © 2018 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

deliver interventions online without a negative impact on adherence to or satisfaction with treatment [26,27].

In pediatric TBI, several studies demonstrated the potential effectiveness of web-based family problem-solving focused interventions on improving behavioral and social outcomes after pediatric brain injury by working with both the injured child and family [28–30]. The overarching aim of this paper is to describe a protocol for comparing the effectiveness, feasibility, and acceptability of three formats of family problem solving therapy (F-PST) to improve functional outcomes after complicated mild to severe adolescent TBI: Face-to-face F-PST; therapist-guided online F-PST; self-guided online F-PST. Therapist-guided, online F-PST has shown promise in reducing behavior problems in older adolescence following TBI when delivered to the right individuals, youth having existing problems and environmental adversity [31,32]. The comparative acceptability and effectiveness relative to traditional face-to-face treatment is unknown, and it is unclear if families could also benefit from online F-PST without therapist support. We describe the methodology that will be used to test the comparative effectiveness of these modalities for delivering F-PST interventions in anticipation that findings from this work will inform future clinical care practices. Overall, it was hypothesized that participants in the therapist-guided online F-PST group compared to the face-to-face and self-guided conditions will report the greatest improvements in teen-, parent-, and family-level outcomes.

2. Methods

2.1. Overview and study design

A randomized clinical trial (RCT) design will be used to examine the comparative effectiveness of three versions of F-PST in improving/ameliorating patient- and caregiver-reported behavioral outcomes (See Fig. 1). The three groups (therapist-guided face-to-face F-PST; therapist-guided online F-PST; and self-guided online F-PST) have equivalent content but vary in the mode of delivery (face-to-face versus web-based) and the degree of therapist involvement. We will assess patient treatment modality preferences to assess how preferences influence treatment effectiveness. Although we considered a partially randomized patient preference trial design [33], we opted for a traditional RCT design given the equipoise among the treatment groups and uncertainty regarding the proportion of patients who would decline randomization. The face-to-face arm reflects the current standard of care that families are likely to receive following TBI across the country. If families prove unable to participate in the face-to-face arm, we will have critical new

information about the feasibility of current standards of care. The study is registered on clinicaltrials.gov (NCT: 02368366).

2.2. Sample characteristics

Participants will include families of approximately 160 youth aged 14–19 years with complicated mild to severe TBI as defined below (see Recruitment). Adolescents will need to have persistent behavior symptoms for at least one month post injury. We chose not to impose a maximum time since injury, given that research [13,34–36], and feedback from families suggest that concerns may not become apparent until months or years post injury and many problems tend to persist or worsen over time. Given substantial differences in management and recovery trajectory between mild TBI/concussion (i.e., typical recovery in < 2 weeks) and more severe TBI, we excluded adolescents with uncomplicated mild TBI. Inclusion/exclusion criteria are detailed under Recruitment.

The study will be conducted at five hospitals affiliated with academic institutions in Ohio and Colorado to ensure that the sample size is adequate, ethnically diverse, and representative of children with TBI. Cincinnati Children's maintains a Level I Trauma Center and is one of the few inpatient pediatric rehabilitation programs accredited by the Commission on the Accreditation of Rehabilitation Facilities in the state of Ohio. MetroHealth Medical Center in Cleveland, Ohio includes a Level I trauma center with pediatric commitment. Rainbow Babies & Children's Hospital maintains a Level I Trauma Center and serves as the pediatric hospital for the University Hospital Health System in Cleveland, Ohio. Children's Hospital Colorado (CHCO) is the Rocky Mountain region's only Level 1 Pediatric Trauma Center. Nationwide Children's hospital in Columbus, Ohio is also a level I Trauma Center. We anticipate recruiting 80 children per year in years 1 and 2 across the sites. Males and females will be recruited for participation in the study consistent with the demographics of patients treated for TBI at the participating sites.

3. Procedures

3.1. Recruitment

Potentially eligible children will be identified either during hospitalization or after discharge based on trauma registry information, during an outpatient medical visit, via referral or letter from their physician at participating hospitals, or via ClinicalTrials.gov. Recruitment from multiple access points for families will allow

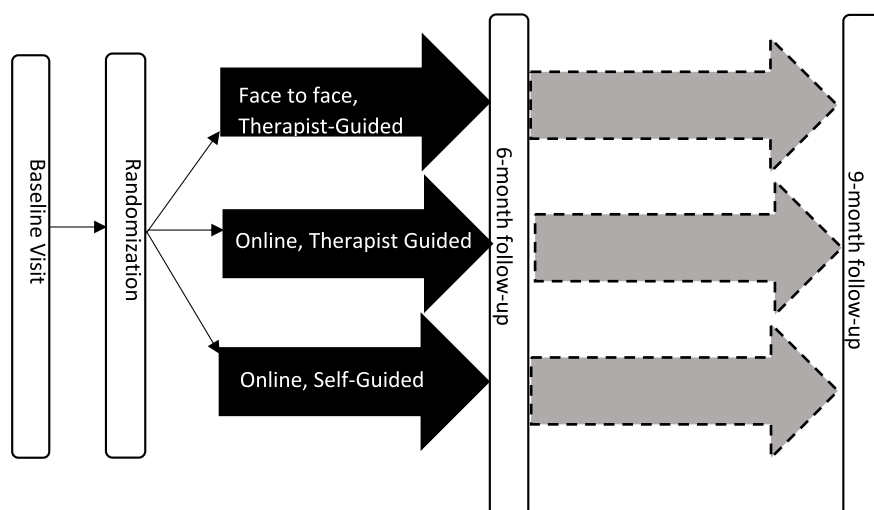


Fig. 1. STUDY DESIGN. Study design is a randomized clinical trial (RCT) that examines the comparative effectiveness of three versions of family problem solving therapy (F-PST): Therapist-guided face-to-face F-PST; therapist-guided online F-PST; and self-guided online F-PST.

Download English Version:

<https://daneshyari.com/en/article/8519268>

Download Persian Version:

<https://daneshyari.com/article/8519268>

[Daneshyari.com](https://daneshyari.com)