

ORIGINAL ARTICLE

Evaluation of the Short-Term Executive Plus Intervention for Executive Dysfunction After Traumatic Brain Injury: A Randomized Controlled Trial With Minimization



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Abstract

Objective: To determine whether the Short-Term Executive Plus (STEP) cognitive rehabilitation program improves executive dysfunction after traumatic brain injury (TBI).

Design: Randomized, waitlist controlled trial with minimization and blinded outcome assessment.

Setting: Community.

Participants: Participants with TBI and executive dysfunction (N=98; TBI severity 50% moderate/severe; mean time since injury \pm SD, 12 \pm 14y; mean age \pm SD, 45 \pm 14y; 62% women; 76% white).

Intervention: STEP program: 12 weeks (9h/wk) of group training in problem solving and emotional regulation and individual sessions of attention and compensatory strategies training.

Main Outcome Measures: Factor analysis was used to create a composite executive function measure using the Problem Solving Inventory, Frontal Systems Behavior Scale, Behavioral Assessment of the Dysexecutive Syndrome, and Self-Awareness of Deficits Interview. Emotional regulation was assessed with the Difficulties in Emotion Regulation Scale. The primary attention measure was the Attention Rating and Monitoring Scale. Secondary measures included neuropsychological measures of executive function, attention, and memory and measures of affective distress, self-efficacy, social participation, and quality of life.

Results: Intention-to-treat mixed-effects analyses revealed significant treatment effects for the composite executive function measure ($P=.008$) and the Frontal Systems Behavior Scale ($P=.049$) and Problem Solving Inventory ($P=.016$). We found no between-group differences on the neuropsychological measures or on measures of attention, emotional regulation, self-awareness, affective distress, self-efficacy, participation, or quality of life.

Conclusions: The STEP program is efficacious in improving self-reported post-TBI executive function and problem solving. Further research is needed to identify the roles of the different components of the intervention and its effectiveness with different TBI populations.

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Executive dysfunction is one of the hallmarks of traumatic brain injury (TBI) and is associated with significant morbidity.^{1,2} Executive functions are essential for goal-directed behavior,

and their disruption can have deleterious effects on all areas of life, including independent living and vocational, academic, and social functioning.^{1,2} Executive dysfunction after TBI is, in some cases, linked to impulsivity, emotional dysregulation, and violent behavior, particularly in injuries affecting the prefrontal cortex and the medial temporal regions of the brain.³ Behavioral interventions, including a focus on metacognitive strategies, have been used to treat executive dysfunction with some success.⁴⁻¹² A meta-analysis by Kennedy et al⁵ examining the

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efficacy of metacognitive strategy instruction revealed that effect sizes were comparable with or larger than those in control interventions and significantly better than chance. They concluded that there is sufficient evidence to recommend the clinical use of these approaches with young to middle-aged adults with TBI.⁵

The present study evaluates Short-Term Executive Plus (STEP), a novel intervention that integrates several theoretically and empirically supported treatments for post-TBI executive dysfunction. The goal of STEP is to teach a core set of metacognitive skills that can be applied across a wide range of real life activities. The treatments included in STEP are problem solving training,⁴⁻¹² emotional regulation training,^{6,13-15} attention training,^{4,16,17} and use of cognitive supports.^{4,17}

STEP was designed to provide an intensive but time-limited intervention for individuals whose family, school, or work responsibilities preclude participation in longer intervention programs. STEP is rooted in a theoretical model, explicated in detail elsewhere,¹⁸ that integrates theories of cerebral function and organization,^{2,19-23} cognitive behavioral theories of problem solving,^{24,25} and principles of learning theory.²⁶ The model assumes that executive dysfunction is rooted in deficits in problem solving; that emotional regulation facilitates problem solving, whereas dysregulation undermines it; and that attention training facilitates the building of problem solving and emotional regulation skills. Thus, problem solving, emotional regulation, and attention are the primary targets of STEP. To maximize skill learning and promote generalization, the STEP intervention is structured, provides sufficient repetition of content, and is contextualized (ie, based on real-life problems facing the individual with TBI), and skills are applied in vivo throughout all aspects of the treatment program. External memory and organizational aids are also used to promote learning.

The purpose of the study was to evaluate the efficacy of STEP in improving executive dysfunction, attention, and emotional regulation. We hypothesized that individuals receiving STEP would experience significant improvements in executive function, attention, and emotional regulation compared with untreated controls. We also examined the effects of the intervention on learning, memory, affective distress, self-efficacy, participation, and quality of life.

Methods

Overview

This study was a single-center, randomized, waitlist (WL) controlled trial using minimization with blinded outcome assessments that took place at the Mount Sinai Medical Center starting in January 2008. Enrollment ended in March 2012, and collection of primary outcome data concluded in June 2012. The Icahn School of Medicine at Mount Sinai Institutional Review Board approved the study. All participants provided written informed consent.

List of abbreviations:

APT-II	Attention Process Training, Second Edition
FrSBe	Frontal Systems Behavior Scale
STEP	Short-Term Executive Plus
TBI	traumatic brain injury
WCST	Wisconsin Card Sorting Test computer version 4
WL	waitlist

Participants

We recruited participants at the Mount Sinai Medical Center through clinician and service provider referrals, mailings, the research center website, and flyers distributed at Mount Sinai and at conferences and support groups attended by individuals with TBI. After giving informed consent, participants underwent a face-to-face screening involving a clinical interview, neuropsychological assessment, and self-report measures. Participants were required to be adults (≥ 18 y) with a history of TBI that met, at minimum, American Congress of Rehabilitation Medicine criteria²⁷ for mild TBI: a blow to the head followed by 1 of the following: (1) loss of consciousness, (2) period of being dazed and confused, (3) period of posttraumatic amnesia, or (4) clinical signs of altered neurologic function. Participants were required to be at least 3 months postinjury, speak English, have executive dysfunction (Frontal Systems Behavior Scale [FrSBe]²⁸ T score ≥ 64 or Wisconsin Card Sort Test-4 [WCST]²⁹ < 4 categories completed), be oriented to time, place, and person (Galveston Orientation and Amnesia Test³⁰ ≥ 75), have at least a sixth-grade reading level and sufficient intelligence to benefit from treatment (full scale intelligence quotient ≥ 75). Exclusion criteria were lack of mental capacity to give informed consent (measured using the Aid to Capacity Evaluation³¹); active substance abuse, psychosis, or suicidality (assessed using the Structured Clinical Interview for DSM-IV Disorders³²); unsuitability for group participation (eg, offensive behavior, assessed through clinical interview); and concurrent participation in other cognitive rehabilitation.

Randomization

After participants completed the baseline assessment and were qualified for inclusion, the research coordinator randomized them to immediate start or WL. (Although the study used random assignment with minimization and some participants were assigned to groups based on group size, we have used the term randomization throughout because this was the principal mode of group allocation.) Participants randomized to immediate start began treatment on the next available start date (within 4wk of assessment completion). Participants randomized to WL began treatment on the first available start date 12 weeks from the baseline assessment. Because individuals with more severe attention or executive function impairments might respond differently to the intervention than those with milder impairments, we used randomization with complete minimization.³³ Although age, severity, and time postinjury are important prognostic factors in rehabilitation outcomes, we decided to achieve trial arm balance on deficits we wanted to ameliorate or that closely impacted ability to benefit, rather than grosser determinants. Therefore, minimization was based on scores on an attention task (Conners' Continuous Performance Task-II³⁴ index score > 5.99 = low functioning) and on an executive function task (WCST < 4 categories completed = low functioning). In addition, minimization took into account whether participants were self-referred or clinician referred. We entered scores into the Minim program^a to determine treatment allocation (immediate start vs WL). We allocated 18 participants without randomization when this was necessary to keep the size of the treatment group between 3 and 8; these participants were allocated in strict order of qualification. In all instances, the Conners' Continuous Performance Task-II and WCST scores and referral type information for these 18 participants were input into the Minim program to take them into account in future randomizations.

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