Long-term Benefits of an Early Online Problem-Solving Intervention for Executive Dysfunction After Traumatic Brain Injury in Children
A Randomized Clinical Trial

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IMPORTANCE Executive dysfunction after traumatic brain injury (TBI) in children is common and leads to significant short- and long-term problems in functioning across multiple settings. We hypothesized that improvements in short-term executive function would be maintained to 24 months after injury and that improvements would increase over time in a counselor-assisted problem-solving (CAPS) intervention.

OBJECTIVE To evaluate the efficacy of a CAPS intervention administered within 7 months of complicated mild to severe TBI compared with an Internet resource condition in improving long-term executive dysfunction.

DESIGN, SETTING, AND PARTICIPANTS Multisite, assessor-blinded, randomized clinical trial at 3 tertiary pediatric hospitals and 2 tertiary general medical centers. Participants included 132 adolescents aged 12 to 17 years who sustained a moderate to severe TBI 1 to 7 months before study enrollment.

INTERVENTION Web-based CAPS intervention.

MAIN OUTCOMES AND MEASURES The primary outcome was the parent-reported Global Executive Composite (GEC) of the Behavior Rating Inventory of Executive Function. Secondary outcomes included the Behavioral Regulation Index (BRI) and Metacognition Index (MI) of the GEC.

RESULTS In older (>14 to 17 years) adolescents, the CAPS intervention was associated with lower GEC ratings at 12 (β = −0.46; P = .03) and 18 (β = −0.52; P = .02) months after enrollment. Trends were also observed for older adolescents toward lower GEC ratings at 6 months (β = −0.40; P = .05), lower BRI ratings at 12 (β = −0.40; P = .06) and 18 (β = −0.47; P = .04) months, and lower MI ratings at 6 (β = −0.41; P = .05), 12 (β = −0.46; P = .03), and 18 (β = −0.50; P = .03) months. In younger (12-14 years) adolescents, no group differences were found on the GEC, BRI, or MI ratings.

CONCLUSIONS AND RELEVANCE Delivery of the CAPS intervention early after TBI in older adolescents improves long-term executive function. This trial is, to our knowledge, one of the few large, randomized clinical treatment trials performed in pediatric TBI to demonstrate the efficacy of an intervention for management of executive dysfunction and long-term benefits of an intervention delivered soon after injury. Use of the CAPS intervention clinically should be considered; however, further research should explore ways to optimize delivery.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT00409448
Pediatric traumatic brain injury (TBI) is a global health problem. Neurocognitive and behavioral problems are common after pediatric TBI. Executive dysfunction is associated with short- and long-term functional problems in the home, school, and community. Better treatment of executive dysfunction may lead to improved functioning in everyday settings.

After TBI, many children and families have unmet behavioral, psychosocial, and emotional needs, in part due to environmental barriers. The use of electronic information and telecommunications (telehealth) to deliver interventions is a potential approach to improve access to health care and outcomes. Research has demonstrated the feasibility, accessibility, and benefits of online family problem-solving therapy (OFPST) in this population.

In a randomized clinical trial (RCT) of children and adolescents aged 5 to 16 years with TBI (n = 40), OFPST was associated with significant reductions in behavior problems, particularly among older participants. In an RCT of children and adolescents aged 11 to 18 years (n = 35), OFPST improved parent- and self-reported behavioral problems, but only improved self-ratings, not parent ratings, of executive dysfunction. Subsequently, a large RCT (n = 132) evaluated the efficacy of an online counselor-assisted problem-solving (CAPS) intervention in adolescents 1 and 7 months after TBI. The CAPS intervention was associated with improved externalizing behavior and parent ratings of executive function in older adolescents after treatment compared with an Internet resource control (IRC) group.

We sought to extend this previous work and determine whether improvements in parent-rated executive function previously seen in older adolescents were maintained 12 months after completion of the CAPS intervention. We hypothesized that improvements in executive function seen previously in older adolescents would be maintained. Because the CAPS intervention was designed to prevent the emergence of new problems, we further anticipated that the advantage of the CAPS intervention relative to the IRC would become more prominent over time. We also sought to investigate whether improvements in executive function in the CAPS intervention (vs the IRC) would become more evident over time and with increasing age in younger adolescents. This study extends previous work by evaluating the maintenance of treatment effects of an OFPST in a large (n = 132) sample of adolescents after TBI.

Methods

Subjects
Adolescents aged 12 to 17 years were enrolled 1 to 7 months after hospitalization for TBI. Complicated mild TBI was defined as a Glasgow Coma Scale (GCS) score of greater than 12 with evidence of a neurologic insult on magnetic resonance imaging or computed tomography; moderate TBI, a GCS score of 9 to 12; and severe TBI, a GCS score of less than 9. Participants with complicated mild or moderate TBI were considered to have moderate-type injuries. The GCS was used to characterize injury severity because it was the most consistently obtained clinical variable across study sites. Sites included 3 tertiary pediatric hospitals and 2 tertiary general medical centers in Cincinnati, Denver, Cleveland, and Rochester. Institutional review board approval was obtained from all participating institutions. Written informed consent was obtained from the parents and adolescents. Recruitment proceeded from March 1, 2007, through January 31, 2011. Exclusion criteria consisted of nonblunt trauma, a primary language other than English, significant intellectual disability before the injury, a history of child abuse, insufficient recovery to participate, a history of parental or child psychiatric hospitalization within 1 year before enrollment, residence in an area without high-speed Internet access, or child residence outside the home (eg, a detention facility). Potential participants residing more than 3 hours from the study site were excluded because assessments included computer installation and face-to-face orientation in participants’ homes. Three-hundred eight participants underwent assessment for eligibility. Of these, 52 did not meet inclusion criteria, 52 declined to participate, 67 were ineligible because more than 7 months had intervened since the injury, and 5 could not be contacted. No differences were observed between participants and nonparticipants in age. Nonparticipants were more likely to be nonwhite (24.4% vs 19.7%) and to have less severe TBI as measured by the GCS (mean [SD] score, 10.03 [4.56] vs 11.90 [3.89]).

Design
The study was a multisite, evaluator-blinded RCT conducted according to CONSORT criteria (Figure 1). Participants were randomly assigned to the CAPS or the IRC group. A priori sample size calculations using a repeated-measures analysis of variance method determined that 60 participants per group were required to find an effect size of 0.30 with 84% power at a significance level of 0.05. Randomization was performed by stratifying by sex and race to ensure that these 2 factors were balanced within the sites. We created a program with commercially available software (SAS; SAS Institute) using permuted block sizes for each of the randomizations. An envelope containing group assignment was provided at completion of the baseline visit. Research coordinators were masked to group assignment. A new computer, a web camera, and high-speed Internet access were provided to all families, and they were taught to log on to the website and access online links to TBI resources. Provision of the camera to all participants maintained interviewer naiveté.

CAPS Intervention
The CAPS intervention involved a 6-month web-based, family-centered intervention focused on problem solving, communication, and self-regulation. Session content included the following:
1. Getting started: implementation, monitoring, and goals
2. Staying positive
3. Problem solving
4. Getting organized and working with the school
5. Self-management
6. Verbal and nonverbal communication
7. Controlling behavior/handling crises
8. Self-assessment of skills and identification of supplemental sessions; planning for the future with the following supplemental sessions:
   - Talking with your teenager
   - Taking care of you/marital communication/guilt, grief, and caregiver
   - Social skills
   - After high school
   - Sibling issues
   - Pain management
   - Sleep session
   - Memory session

The 8 core sessions and as many as 4 supplemental sessions per family were provided throughout the 6-month intervention period.

**IRC Intervention**

The IRC participants received a home page with links to online TBI resources, including local, state, and national brain-injury associations.35,36 Families were asked to spend 1 or more hours online per week accessing information on pediatric brain injury throughout the 6-month intervention period. The IRC participants could not access CAPS content.

**Follow-up Assessments**

Masked follow-up assessments were completed a mean of 6, 12, and 18 months after baseline at participants’ homes for both groups. Figure 2 shows the timeline for the study. The
Table 1. Baseline Demographic, Injury Characteristics, and Outcome Measures by Treatment Group and Age

<table>
<thead>
<tr>
<th></th>
<th>CAPS Participants</th>
<th>IRC Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (n = 65)</td>
<td>Younger (n = 32)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at injury, y</td>
<td>14.4 (1.7)</td>
<td>13.0 (0.6)</td>
</tr>
<tr>
<td>Time since injury, y</td>
<td>0.3 (0.2)</td>
<td>0.3 (0.2)</td>
</tr>
<tr>
<td>Medium income ×$1000</td>
<td>71.31 (32.19)</td>
<td>70.60 (32.01)</td>
</tr>
<tr>
<td>SES combined z scoreb</td>
<td>0.10 (1.16)</td>
<td>0.07 (1.15)</td>
</tr>
<tr>
<td>GCS</td>
<td>10.08 (4.85)</td>
<td>10.27 (5.23)</td>
</tr>
<tr>
<td>Severe TBI, No. (%)</td>
<td>25 (39)</td>
<td>12 (38)</td>
</tr>
<tr>
<td>Nonwhite, No. (%)</td>
<td>13 (20)</td>
<td>8 (25)</td>
</tr>
<tr>
<td>Male sex, No. (%)</td>
<td>44 (68)</td>
<td>27 (84)</td>
</tr>
<tr>
<td>GEC</td>
<td>58.61 (10.10)</td>
<td>58.22 (9.21)</td>
</tr>
<tr>
<td>BRI</td>
<td>57.78 (11.11)</td>
<td>57.91 (10.91)</td>
</tr>
<tr>
<td>MI</td>
<td>58.03 (9.54)</td>
<td>57.03 (7.83)</td>
</tr>
<tr>
<td>Treatment Groupa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (n = 66)</td>
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<td></td>
</tr>
<tr>
<td>Younger (n = 24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Older (n = 42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at injury, y</td>
<td>14.7 (1.8)</td>
<td>12.8 (0.8)</td>
</tr>
<tr>
<td>Time since injury, y</td>
<td>0.3 (0.1)</td>
<td>0.3 (0.1)</td>
</tr>
<tr>
<td>Medium income ×$1000</td>
<td>66.25 (22.84)</td>
<td>67.72 (25.67)</td>
</tr>
<tr>
<td>SES combined z scoreb</td>
<td>-0.08 (0.82)</td>
<td>-0.03 (0.92)</td>
</tr>
<tr>
<td>GCS</td>
<td>10.02 (4.36)</td>
<td>8.95 (3.92)</td>
</tr>
<tr>
<td>Severe TBI, No. (%)</td>
<td>26 (39)</td>
<td>11 (46)</td>
</tr>
<tr>
<td>Nonwhite, No. (%)</td>
<td>12 (18)</td>
<td>5 (21)</td>
</tr>
<tr>
<td>Male sex, No. (%)</td>
<td>42 (64)</td>
<td>17 (71)</td>
</tr>
</tbody>
</table>

Abbreviations: BRI, Behavioral Regulation Index; CAPS, counselor-assisted problem-solving; GCS, Glasgow Coma Scale; GEC, Global Executive Composite; GED, General Education Development test; IRC, Internet resource condition; MI, Metacognition Index; SES, socioeconomic status; TBI, traumatic brain injury. 

6-month assessment occurred immediately after the intervention. The 12- and 18-month assessments measured the maintenance of effects over time.

Background Questionnaire
Injury severity was abstracted from hospital records. A combined estimate of socioeconomic status was constructed by calculating the mean z scores for estimated family income using the median income of the census tract for the zip code of the participant’s primary residence and primary caregiver educational level (combined z score).

Outcome Measures
Baseline measures were completed before randomization. To assess executive function, the Behavior Rating Inventory of Executive Function was completed by the family-identified primary caregiver. The Behavior Rating Inventory of Executive Function provides an ecologically valid assessment of executive function in everyday settings, is adversely affected by pediatric TBI, and has good internal consistency and interrater and test-retest reliability. The Global Executive Composite (GEC) of the Behavior Rating Inventory of Executive Function was used as the primary outcome to assess overall executive function. The Behavioral Regulation Index (BRI) and the Metacognition Index (MI), subscales of the GEC, were used as secondary outcomes. Higher scores indicate greater problems. We used t scores for interpretation, with a mean score of 50 (SD, 10).

Statistical Analysis
We used χ² and 2-tailed unpaired t tests to compare demographic variables between treatment groups. Mixed-model analysis (Proc Mix procedure in SAS; SAS Institute) was used to evaluate group differences in executive function at follow-up as assessed by the GEC. The primary independent variable was the interaction term of age at injury (younger vs older) by group (CAPS vs IRC) by time since baseline (TSB). Because the CAPS intervention is more beneficial in older adolescents, the age at injury variable was dichotomized into adolescents aged 12 to 14 years; the older group, older than 14 to 17 years. Unless otherwise indicated, data are expressed as mean (SD). Percentages have been rounded and might not total 100.

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Mixed-Model Analysis and Contrast Between CAPS and IRC Groups for Younger and Older Adolescents at Different Points After the Intervention

<table>
<thead>
<tr>
<th></th>
<th>Unstandardized Estimate</th>
<th>Standardized Estimate</th>
<th>t Value (df)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Global Executive Composite</strong></td>
<td></td>
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<tr>
<td>Age at injury</td>
<td>-0.83 (2.81)</td>
<td>-0.24 (0.07)</td>
<td>-0.29 (170)</td>
<td>.77</td>
</tr>
<tr>
<td>TSB</td>
<td>-2.81 (0.83)</td>
<td>-0.33 (0.22)</td>
<td>-3.40 (321)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Group, CAPS vs IRC</td>
<td>-3.95 (2.56)</td>
<td>-0.12 (0.11)</td>
<td>-1.54 (172)</td>
<td>.13</td>
</tr>
<tr>
<td>TSB × group</td>
<td>-1.40 (1.29)</td>
<td>0.16 (0.33)</td>
<td>-1.09 (323)</td>
<td>.28</td>
</tr>
<tr>
<td>Group × age at injury</td>
<td>1.89 (3.93)</td>
<td>0.07 (0.12)</td>
<td>0.48 (171)</td>
<td>.63</td>
</tr>
<tr>
<td>TSB × age at injury</td>
<td>0.82 (1.45)</td>
<td>0.31 (0.17)</td>
<td>0.57 (320)</td>
<td>.57</td>
</tr>
<tr>
<td>Group × TSB × age at injury</td>
<td>3.67 (2.02)</td>
<td>0.35 (0.21)</td>
<td>1.82 (321)</td>
<td>.07</td>
</tr>
<tr>
<td><strong>Behavioral Regulation Index</strong></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Age at injury</td>
<td>-0.99 (3.05)</td>
<td>-0.08 (0.24)</td>
<td>-0.32 (169)</td>
<td>.75</td>
</tr>
<tr>
<td>TSB</td>
<td>-2.08 (0.88)</td>
<td>-0.16 (0.07)</td>
<td>-2.36 (320)</td>
<td>.02</td>
</tr>
<tr>
<td>Group, CAPS vs IRC</td>
<td>-3.00 (2.78)</td>
<td>-0.23 (0.22)</td>
<td>-1.08 (171)</td>
<td>.28</td>
</tr>
<tr>
<td>TSB × group</td>
<td>-1.95 (1.37)</td>
<td>-0.15 (0.11)</td>
<td>-1.42 (322)</td>
<td>.16</td>
</tr>
<tr>
<td>Group × age at injury</td>
<td>3.12 (4.26)</td>
<td>0.24 (0.33)</td>
<td>0.73 (169)</td>
<td>.47</td>
</tr>
<tr>
<td>TSB × age at injury</td>
<td>0.11 (1.54)</td>
<td>0.01 (0.12)</td>
<td>0.07 (319)</td>
<td>.95</td>
</tr>
<tr>
<td>Group × TSB × age at injury</td>
<td>4.18 (2.15)</td>
<td>0.33 (0.17)</td>
<td>1.94 (320)</td>
<td>.05</td>
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<tr>
<td><strong>Metacognition Index</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age at injury</td>
<td>-0.94 (2.65)</td>
<td>-0.08 (0.24)</td>
<td>-0.36 (169)</td>
<td>.72</td>
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<tr>
<td>TSB</td>
<td>-2.87 (0.77)</td>
<td>-0.26 (0.07)</td>
<td>-3.71 (322)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Group, CAPS vs IRC</td>
<td>-3.96 (2.41)</td>
<td>-0.36 (0.22)</td>
<td>-1.64 (171)</td>
<td>.10</td>
</tr>
<tr>
<td>TSB × group</td>
<td>-1.03 (1.21)</td>
<td>-0.09 (0.11)</td>
<td>-0.85 (323)</td>
<td>.39</td>
</tr>
<tr>
<td>Group × age at injury</td>
<td>0.64 (3.70)</td>
<td>0.06 (0.33)</td>
<td>0.17 (171)</td>
<td>.86</td>
</tr>
<tr>
<td>TSB × age at injury</td>
<td>0.98 (1.36)</td>
<td>0.09 (0.12)</td>
<td>0.72 (321)</td>
<td>.47</td>
</tr>
<tr>
<td>Group × TSB × age at injury</td>
<td>3.57 (1.90)</td>
<td>0.32 (0.17)</td>
<td>1.88 (322)</td>
<td>.06</td>
</tr>
</tbody>
</table>

Abbreviations: CAPS, counselor-assisted problem-solving; IRC, Internet resource condition; NA, not applicable; TSB, time since baseline.

Results

Participants and Demographics

No adverse events were reported in the IRC or the CAPS groups. The groups did not differ significantly on baseline demographic characteristics (Table 1). Baseline BRI scores did not differ between groups, but MI scores were higher in the IRC group (Table 2). One hundred thirty-two participants...
were randomized to the CAPS (n = 65) or the IRC (n = 67) groups (Figure 1). The CONSORT diagram (Figure 1) shows the number unavailable for follow-up in each group at the 6-, 12-, and 18-month assessments. The final analysis included 65 CAPS and 66 IRC participants. Regardless of group, adolescents who did not complete the intervention were disproportionately nonwhite (13 [23%] for those who dropped out vs 13 [14%] for those who completed) and had a lower median income ($52,800 [Q1 $21,740] vs $73,400 [Q3 $26,000] for completers). Injury severity, age, and sex did not differ between those who did and did not complete the study. The mean number of sessions completed in the CAPS group was 7.23 (2.99; range, 0–13). Parent- and self-reported time spent viewing information on the web did not differ between the CAPS and IRC groups.26

**Primary Outcome**

The interaction term of group by TSB by age at injury fell just short of significance, suggesting a trend for differential improvements on the GEC (Table 2). Because different findings for younger vs older adolescents were anticipated, the interaction of group by time since injury was examined for older and younger participants. In older adolescents, the CAPS group had lower GEC ratings than the IRC group, indicative of better functioning, at 12 and 18 months after assessment, with a trend toward a lower GEC rating at 6 months (Figure 3). In younger adolescents, no group differences were found at any point.

**Secondary Analyses**

The interaction term of group by TSB by age at injury showed a trend for improvements over time on the BRI and MI (Table 2). In older adolescents, the CAPS group demonstrated a trend toward lower BRI ratings 12 and 18 months after assessment (Figure 4A) and lower MI ratings 6, 12, and 18 months after assessment relative to the IRC (Figure 4B). In younger adolescents, no significant group differences were found.

**Exploratory Analyses**

The interaction of severity by age at injury by group by TSB did not meet the threshold for inclusion in the model (P = .59). Subsequent model trimming eliminated all terms that included severity, indicating that severity did not have main or moderation effects on the maintenance of treatment effects.

**Discussion**

Findings demonstrated that an OFPST delivered soon after TBI in adolescents had sustained benefits relative to the provision of web-based information only on a measure of everyday executive function. The positive effects of the intervention were observed only in adolescents older than 14 years. This RCT is one of the largest to demonstrate long-term positive effects in reducing problems in executive function after adolescent TBI. To our knowledge, this study is the first to demonstrate that an online problem-solving intervention introduced within the first 7 months after injury has long-term beneficial effects for executive function after adolescent TBI. In the context of the current paucity of evidence-based data on effective interventions for pediatric TBI, these findings provide strong empirical support for 1 approach to treatment, at least for older adolescents.

Our results expand on our previous study35 that evaluated the postintervention efficacy of online problem-solving interventions for management of executive function after pediatric TBI. Consistent with our hypothesis, the advantage of
the CAPS intervention compared with an information-only condition for older adolescents was sustained 12 months after intervention completion. The beneficial effects were observed for global executive function with improvements of comparable magnitude seen in behavioral regulation and metacognitive aspects of executive function. However, these benefits did not extend to younger adolescents, even with increasing time (and age) after intervention. These findings indicate that early intervention after moderate to severe TBI in older adolescents improves long-term everyday executive function skills and that the age at which the intervention is delivered is an important determinant of treatment success.

The finding of positive effects of the CAPS intervention on executive function of older adolescents is similar to previous results.35,36 The preferential benefit in older adolescents may indicate that they are more developmentally capable of benefiting from a problem-solving intervention. Initiation of the intervention later after injury in younger children may lead to greater benefit because they would be developmentally ready for the intervention. In addition, alternative interventions beneficial to younger adolescents need to be identified.

The study did not preselect participants with problems but included all participants regardless of symptom burden. However, because analysis examined maintenance relative to baseline symptom levels, the persisting benefits of the CAPS intervention reflect changes relative to pretreatment status. Demonstration of the sustained benefits on executive function for the CAPS group as a whole makes a strong case for the effectiveness of the CAPS intervention and may reflect a broader subclinical reduction in symptom levels or amelioration of age-related symptom increases that would otherwise have occurred across the follow-up period.

Children with TBI often have unmet health and behavior needs,22–23 and telehealth technology may facilitate access for services after pediatric TBI. Our findings demonstrate that early intervention has long-term benefits. Because telehealth is not a traditional part of standard care, implementation studies that allow access to online problem-solving training soon after injury are needed. Integration of CAPS or other problem-solving interventions into the outpatient management of pediatric TBI should be considered. Future studies will need to evaluate the potential benefit of telehealth interventions introduced longer after injury.

Outcome measures were based on parent report only. Evaluation of teacher report may provide insight into generalization of improvements to school settings. Self-report may provide further insight into the adolescent’s perspective on intervention benefits. Laboratory-based measures of executive function were not used; however, the Behavior Rating Inventory of Executive Function has good ecological validity and correlates with functioning in everyday settings.40–45 Although our findings highlight the potential ecological impact of the CAPS intervention for executive dysfunction after pediatric TBI, we were unable to conceal assignment from families or participants. Therefore, some effects of the intervention may be attributable to participant and family expectations or biases. A further limitation is that the IRC group did not receive an equal amount of therapist contact; therefore, we are unable to definitively determine if the positive effects are related to the problem-solving intervention itself or generalized therapist involvement. However, this study focused on long-term follow-up after completion of the initial therapy sessions, and the CAPS and IRC groups had similar interactions with research staff during this phase of the study. Finally, generalizability is limited by a recruitment bias toward more severely injured youth and by the relatively low percentage of minority participants.

Conclusions

Delivery of the CAPS intervention soon after injury provides long-term improvement of everyday executive function after TBI in older adolescents. This RCT is one of the few large studies performed in pediatric TBI. The findings demonstrate the efficacy of an online problem-solving intervention for management of executive dysfunction. To our knowledge, this study is the first to demonstrate long-term benefits of an intervention delivered soon after injury. Clinical use of the CAPS intervention should be considered; however, further research needs to define the optimal timing after injury for delivery and characteristics of the individuals and families who are most likely to benefit from the CAPS intervention or other online problem-solving interventions. Future studies will need to evaluate whether delivery of the intervention later after injury also has beneficial effects.
Research Original Investigation

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REFERENCES


Early Online Problem-Solving Intervention for TBI

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