Effectiveness of the Brains Ahead! Intervention

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Effectiveness of the Brains Ahead! Intervention: 6 Months Results of a Randomized Controlled Trial in School-Aged Children With Mild Traumatic Brain Injury

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Objective: To examine the effectiveness of Brains Ahead!, a psychoeducational intervention aimed to prevent long-term problems with activities and participation in children after mild traumatic brain injury (mTBI). **Participants:** In total, 124 children, aged 6 to 18 years, diagnosed with mTBI and their caregivers. *Method*: After randomization, participants in the intervention group received a face-to-face psychoeducational session with written take-home information and follow-up telephone call(s). Participants in the control group received usual care, consisting of a concise information brochure. **Primary Outcome Measures:** Activities and participation (Child and Adolescent Scale of Participation [CASP]). *Secondary outcomes*: fatigue, postconcussive symptoms (PCSs), posttraumatic stress symptoms (PTSSs), and quality of life (QOL). **Results:** Generalized Estimated Equation analyses showed that both groups improved over the first 6 months post-mTBI, but the intervention group did not differ significantly on the CASP. Mann-Whitney *U* tests showed that the intervention group reported significantly less fatigue, PCSs, and PTSSs and better QOL compared with the control group at 6 months post-MTBI. **Conclusions:** The Brains Ahead! intervention resulted in significant improvements compared with usual care in reducing fatigue, PCSs, and PTSSs and improving QOL. Lack of an effect on activities and participation may be due to the ceiling effect of the CASP.
Key words: *activities and participation*, *children*, *intervention*, *mild traumatic brain injury*, *RCT*

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THE WORLDWIDE INCIDENCE of traumatic brain injury (TBI) in children is high, with 280 to 1373 cases per 100 000 person-years in children aged 0 to 18 years.[1–4] Follow-up care is usually only offered to children after moderate and severe TBI, typically not after mild TBI (mTBI), because complete recovery is expected.[5,6] However, in 6% to 43% of the children, mTBI may lead to long-term postconcussive symptoms (PCSs),[7–9] and these may cause limitations in activities and participation in different settings (eg, at home, in school, and in the community).[10] For these children, adequate treatment at an early stage is essential, but research on this topic is scarce.[11]

To our knowledge, only 2 intervention studies have been conducted to try to improve the level of activities and participation after childhood mTBI.[12,13] Both

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studies used a discharge take-home information booklet describing symptoms and coping strategies for children and their parents.[12,13] The first study combined this booklet with a discharge interview and a follow-up telephone call 24 hours after discharge.[12] Results suggested that activity limitations may be due to overreporting by anxious parents; therefore, reassurance and education for parents about the symptoms of mTBI should be emphasized, as these may aid children in returning to daily activities.[12] The other study implemented reassurance and education in the information booklet and found fewer PCSs at 3 months post-mTBI in the intervention group.[13] Both studies found no effect on daily activities and participation compared with the control group.[12,13] In these studies, only the parent's perspective for outcome on activities and participation was examined.[12,13] Research, however, shows that outcome based on the parent's perspective may differ from that of the child.[14] Studies of adult mTBI[15,16] show the beneficial effects of early, reassuring educational interventions; professionals should carefully monitor progress, offer early symptom-specific treatment when needed, and enable ready access to such a treatment during the first weeks of recovery.[17]

We developed "the Brains Ahead! intervention," which combines an inventory of symptoms, reassurance, and standardized and individualized psychoeducation and follow-up, to prevent or minimize long-term problems with activities and participation.[11,18,19] The present study investigated the effectiveness of the mTBI Brains Ahead! intervention on activities and participation compared with usual care over the first 6 months post-mTBI, assessing the perspectives of both parents and children. We hypothesized that the intervention would be more effective than usual care in preventing problems with activities and participation in the first 6 months post-mTBI. Furthermore, we expected the intervention to be superior to usual care in reducing fatigue, PCSs, posttraumatic stress symptoms (PTSSs), and increasing quality of life (QOL).

METHODS

Design

This multicenter randomized controlled trial (RCT) was nested in the larger Brains Ahead! multicenter prospective cohort study of activities and participation of children after mTBI. The study was approved by the medical ethics committee of Erasmus University Hospital in Rotterdam and by the local committees of the participating hospitals (MEC-2015-047, NL51968.078.14). All caregivers and children 12 years and older provided written informed consent. The study was registered in the Dutch Trial Register as NTR5153. Study details are described elsewhere.[18,19] The trial was designed to conform to CONSORT guidelines.

Participants

All children aged 6 to 18 years who presented with mTBI at the emergency departments of 2 Dutch hospitals (Erasmus University Hospital, Rotterdam; Amphia Hospital, Breda) between May 2015 and April 2018 and their caregiver(s) (ie, parents or legal guardians) were eligible for participation.[18,19] Mild TBI was defined according to the criteria of the American Congress of Rehabilitation Medicine and the World Health Organization Collaborating Centre for Neurotrauma Task Force on Mild Traumatic Brain Injury.[20] The treating physician confirmed the diagnosis of mTBI if the following criteria were met: (1) Glasgow Coma Scale (GCS) score of 13 to 15 at 30 minutes after the incident or as soon as the child entered the emergency department of the participating hospital; and (2) one of the following criteria: change in mental functioning immediately after the incident (ie, disoriented); loss of consciousness (LOC) of, at most, 30 minutes; posttraumatic amnesia (PTA) of a maximum of 24 hours; and other transient neurological signs such as seizures. These symptoms must not have been caused by other etiologies or intoxications. Exclusion criteria were as follows: (1) a previous head trauma confirmed by a neurologist; (2) progressive neurological problems or disease; (3) attending a day care center or school for cognitively impaired children; and (4) insufficient knowledge of the Dutch language (child or caregivers).

Procedure

Eligible children with mTBI and their caregivers were registered at the participating hospitals and their identities communicated to the researcher. Within the first week after mTBI, the researcher contacted caregivers by phone to assess their willingness to participate in the study. Interested caregivers and children received written study information. The baseline measurement (T_0) was scheduled 2 weeks post-mTBI, after written informed consent was obtained from caregivers and children older than 12 years. After baseline measurements, participants were randomized into the intervention group or the control group (allocation ratio 1:1). Subsequently, the intervention group received the Brains Ahead! intervention and the control group received usual care. Further measurements in both groups took place at 3 (T_1) and at 6 (T_2) months post-mTBI. All measurements took place at the participants' home.

Randomization and blinding

All measurements were obtained by a researcher who was unaware of the group assignment (single-masking).

The success of masking was checked by asking the researcher about group allocation for all participants after study completion. Randomization was performed by an independent person, using computerized block randomization (block size $n = 8$). The randomization scheme included stratification by age (6-12 or 12-18 years), gender (male or female), and hospital (Erasmus University Hospital, Rotterdam, or Amphia Hospital, Breda). Caregivers were assigned to the same group as their child.

Interventions

The usual care consisted of a concise information brochure offered at discharge from the emergency department that contained recommendations to return to the general practitioner or hospital in case of increased symptoms during the first days after the injury.[18,19]

The Brains Ahead! intervention consisted of 2 sessions administered by a health professional, experienced and educated in child rehabilitation after mTBI. The first session was offered within 2 to 4 weeks and the second session 6 to 8 weeks post-mTBI. The first session consisted of an inventory of symptoms and psychoeducation, both presented face-to-face at the hospital. The inventory contains a list of known consequences of mTBI. The child and the caregiver indicated whether or not the child experienced each symptom; this information would enable focused psychoeducation. The psychoeducation contained standardized information about the causes, incidence, possible consequences of mTBI, and information and advice about returning to activities and participation, sensory sensitivity, and stress tolerance after mTBI. Furthermore, it contained individualized information on the symptoms endorsed by the child and advice directed to the child's specific situation regarding activities and participation. The psychoeducation was provided both verbally via a PowerPoint presentation on a laptop and in a booklet with the standardized information for each child and a booklet with the standardized information for each caregiver. Additional information about individual symptoms endorsed by the child was provided to that specific child and the caregiver in single items for each indicated symptom; for example, additional information on fatigue when the child experienced fatigue. The second session consisted of a follow-up contact by telephone during which the interventionist answered questions about the provided psychoeducation, if any, and inquiries about specific symptoms experienced after the mTBI. In case new PCSs had emerged (eg, concentration problems or fatigue emerging when returning to school after the summer holidays), participants received a short explanation about these symptoms by telephone and were sent extra standardized information about these symptoms. Extra telephone consultations were offered but were used only once. A more detailed description of the rationale and description of the intervention, including a case example, can be found elsewhere.[19] A separate process evaluation was performed to investigate whether the intervention adhered to protocol. The results of the process evaluation will be reported elsewhere.

Measurements

All instruments have sound psychometric properties and are recommended as instruments for evaluating outcomes in children after brain injury.[21–29]

Baseline characteristics

The electronic patient hospital file was used to collect the child's and caregiver's clinical and demographic characteristics at baseline such as injury-related factors (eg, GCS score, LOC, PTA, cause of injury), personal factors (eg, age at injury, gender), and environmental (eg, socioeconomic status [SES]) factors. The SES was determined by using a list of occupations on which each was linked to a given SES level (Centraal Bureau voor de Statistiek, 2010). Baseline information on the child's preinjury functioning was collected by using the Child Behavior Checklist (CBCL)[21] and the Family Assessment Device–General Functioning (FAD-GF).[22]

Primary outcome

Activities and participation were assessed with the Child and Adolescent Scale of Participation–Dutch language version (CASP-DLV).[23,24] The 20 items of the CASP-DLV are categorized according to the following settings: at home, in the community, at school, and in the environment, and can be scored on a 4-point scale: 1, age-appropriate; 2, slightly impaired; 3, heavily impaired; and 4, not capable. Summary scores are created by adding the item responses, dividing by the maximum possible score, and multiplying this number by 100 to conform to a 100-point scale. A higher score represents better outcome. In cases of missing and not applicable scores, the sum of the item responses is divided by the by the maximum possible score on the answered items. Since the CASP is well known for its ceiling effect,[30,31] we dichotomized the scores as follows: 0, deviant functioning/any score less than 100; and 1, full functioning/a score of 100, in comparison with their healthy/noninjured age-related peers. The CASP-DLV as filled out by the caregiver for children aged 6 to 18 years was the primary outcome measure. Furthermore, children aged 10 to 18 years filled out the CASP self-report.

Secondary outcome

Fatigue, CPSs, PTSSs, and QOL were measured with several questionnaires completed by both the child and

the caregiver. Fatigue was measured with the Paediatric Quality of Life Inventory–Multidimensional Fatigue Scale (PedsQL-Fatigue). The PedsQL-Fatigue is an 18-item questionnaire that measures fatigue on a 5-point scale: 0, *never*; 1, *rarely*; 2, *sometimes*; 3, *often*, and 4, *almost always*.[25] The items are hereafter reverse-scored on a 0 to 100 scale, with a higher score indicating fewer symptoms of fatigue.

PCS was measured with the Health and Behaviour Inventory (HBI), a 50-item questionnaire that measures the experience of PCSs on a 4-point scale: 1, *never*; 2, *seldom*; 3, *sometimes*, and 4, *often*.[26] Total scores, ranging between 50 and 200, are calculated by adding the item scores, with a lower total score representing fewer PCSs.

PTSS was measured with the Impact of Event Scale (IES), a 34-item questionnaire measuring possible post-traumatic stress responses on a 5-point scale: 1, *never*; 2, *rarely*; 3, *sometimes*; 4, *often*; and 5, *always*.[27] The total score range is 34 to 170, with a lower score representing fewer symptoms.

QOL was measured with the Paediatric Quality of Life inventory–Quality of Life Scale (PedsQL-QoL), a 23-item questionnaire that measures problems related to QOL on a 5-point scale: 0, *never*; 1, *rarely*; 2, *sometimes*; 3 *often*, and 4, *almost always*.[28] The items are hereafter reverse-scored on a 0 to 100 scale, with a higher score indicating better QOL.

Sample size

Sample size calculations were based on previous studies of pediatric TBI patients' participation that relied on parent reports of the CASP-DLV. For the CASP-DLV, a standardized difference of 0.5 was expected.[24] Based on an α of .05 and a power of 0.8, a minimum of 63 children per group were required (total 126). A dropout rate of 10% was expected; therefore, the number of participants was set at 140.

Statistical analyses

Possible differences between groups at baseline were tested with independent-samples *t* tests, Mann-Whitney *U* tests, and χ^2 tests, where appropriate. Skewness between −1 and +1 was accepted to meet the assumption for normality.

The effectiveness of the intervention on the dichotomous CASP-DLV parent report was assessed using Generalized Estimating Equations (GEE), an extension of general linear models for repeated-measures analysis. To model associations with the binary dependent variable, GEE analyses included a logit-link for the binomial family and an exchangeable working correlation matrix (also known as population-averaged or marginal logistic regression analysis). The analyses provide odds ratios and their 95% confidence intervals. The CASP DLV was included as dependent variable. Time of measurement, group assignment, and the interaction between time of measurement and group (to model change over time) were included as independent variables. Analyses were primarily performed for the dichotomized CASP-DLV parent report total scores and scores for different settings. In addition, we performed GEE analyses for the CASP self-report dichotomized total scores and dichotomized scores for different settings for children aged 10 to 18 years for both self-report and parent report data. Course of functioning has been shown to differ for the 2 perspectives. The intention-to-treat principle was used. Data were analyzed with IBM SPSS Statistics 25. The level of significance was set at $P < .05$ in 2-sided tests. The effectiveness of the intervention on the secondary outcome measures at 6 months post-mTBI was assessed using Mann-Whitney *U* tests, since assumptions for normality were not met.

RESULTS

Participant characteristics

The flow of participants is presented in Figure 1. Between May 2015 and April 2018, a total of 124 participants were included in the study of which 123 completed the trial. After randomization, 1 participant dropped out of the intervention group because the parents believed it was better for their child not to be reminded about the mTBI.

Baseline characteristics are presented in Table 1. No significant group differences were found on demographic characteristics, premorbid functioning, and mTBI symptom characteristics at 2 weeks post-mTBI. Furthermore, tests showed no significant baseline differences on the primary and secondary outcome measures (see Tables 2 and 3), except for PCSs as reported by the caregivers, with lower levels of baseline PCSs in the intervention group ($P = .048$).

Effects of the intervention

The total CASP-DLV score improved significantly in both groups over time between 2 weeks and 6 months post-mTBI, as did the CASP-DLV scores in all settings (at home, in the community, in school, and in the environment) (see Table 2). This applies for both parent reports and the child self-report.

The CASP-DLV parent report for children aged 6 to 18 years during the first 6 months post-mTBI is presented in Table 4. For children aged 10 to 18 years from both the parents' and child's perspectives (see Table 5), a significant difference was found only in the community setting based on the caregivers' perspective. Since no children reported full functioning on the total level of activities and participation at baseline (see Table 2), a

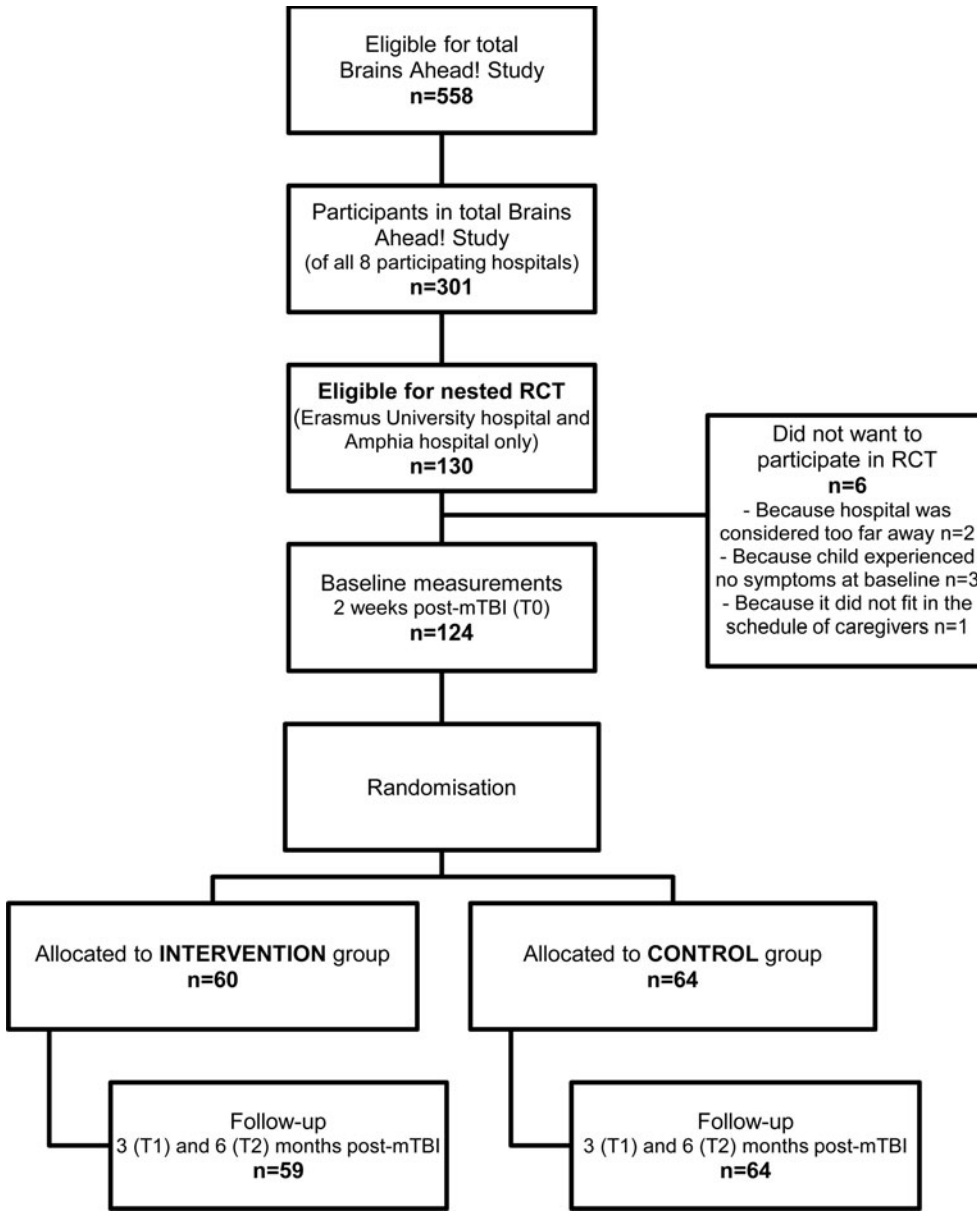

Figure 1. Flow of participants. mTBI indicates mild traumatic brain injury; RCT, randomized controlled trial; T_1, 3 months post-mTBI; T_2, 6 months post-mTBI.

GEE for this measure could not be determined. Therefore, we performed a logistic regression analysis with the CASP-DLV as dependent variable and group allocation as the independent binary variable. The regression analysis showed a significant result at 3 months (T_1) post-mTBI ($\beta = -.99$, $P = .036$) and at 6 months (T_2) post-mTBI ($\beta = -1.11$, $P = .020$), indicating a higher self-reported total level of activities and participation in the intervention group than in the control group.

We found significant group differences in favor of the intervention group at T_2 (6 months) post-mTBI on the PedsQL-Fatigue, IES, PedsQL-QoL, and HBI, except for the HBI scores, which were based on the parent reports (see Table 6).

Success of blinding

The researcher selected the correct group allocation in 73 (59%) of the cases.

DISCUSSION

Children with mTBI and their caregivers reported increasing levels of activities and participation of the child during the first 6 months post-mTBI, irrespective of group allocation. Caregivers in the intervention group rated children aged 10 to 18 years to be more active and to participate more in the community than those in the control group. Although not significantly different, more children in the intervention group

TABLE 1 *Baseline characteristics at* T_0

Characteristics	Control group ($N = 64$), *n* (%)	Intervention group ($N = 60$), *n* (%)
Personal		
Child gender (male)	39 (60.9)	32 (53.3)
Child age at injury in years, mean (SD)	11.7 (3.5)	11.5 (3.3)
Range (Min-Max)	6-17	6-17
Injury-related		
GCS score		
13	5 (7.8)	5 (8.3)
14	16 (25.0)	11 (18.3)
15	43 (67.2)	44 (73.3)
LOC duration		
None	31 (48.4)	27 (45.0)
<2 min	19 (29.7)	21 (35.0)
2-5 min	11 (17.2)	8 (13.3)
>5 min	3 (4.7)	4 (6.7)
PTA duration		
None	13 (20.3)	14 (23.3)
<1 h	33 (51.6)	35 (58.3)
1-2 h	5 (7.8)	2 (3.3)
2-6 h	10 (15.6)	6 (10.0)
6-12 h	2 (3.1)	2 (3.3)
12-18 h	0 (. . .)	0 (. . .)
18-24 h	1 (1.6)	1 (1.7)
Cause of injury		
Traffic crashes	20 (31.3)	23 (38.3)
Sports injuries	21 (32.8)	14 (23.3)
Outdoor play injuries	15 (23.4)	14 (23.3)
Injuries at school/work	3 (4.7)	5 (8.3)
Injuries at home	2 (3.1)	3 (5.0)
Physical abuse	2 (3.1)	0 (0.0)
Other	1 (1.6)	1 (1.7)
Environmental		
SES		
Low	16 (25.0)	17 (28.3)
Average	14 (21.9)	15 (25.0)
High	34 (53.1)	28 (46.7)
Preinjury functioning		
Preinjury behavioral functioning (CBCL T-scores)		
Normal score	55 (85.6)	53 (90.1)
Mild impaired	5 (8.0)	5 (8.5)
Severe impaired	4 (6.4)	2 (3.4)
Preinjury family functioning (FAD-GF)		
Healthy score	50 (78.1)	51 (85.0)
Unhealthy score	14 (21.9)	9 (15.0)

Abbreviations: CBCL, Child Behavior Checklist; FAD-GF, Family Assessment Device–General Functioning; GCS, Glasgow Coma Scale; LOC, loss of consciousness; PTA, posttraumatic amnesia; SES, caregiver's socioeconomic status.

self-reported full functioning on the level of activities and participation in all settings than those in the control group at 3 and 6 months post-mTBI. In addition, children with mTBI and caregivers who received the Brains Ahead! intervention reported significantly fewer functional (fatigue and PCSs) and PTSSs and an improved QOL at 6 months post-mTBI than those who received usual care. Caregivers in the intervention group reported fewer PCSs at baseline than those in the control group, which could explain why—in contrast to the other outcome measures—a nonsignificant improvement on PCSs by caregivers was found. These findings indicate that the Brains Ahead! intervention has the potential to decrease functional and PTSSs and increase QOL after mTBI in children.

The results of our study correspond to those of earlier intervention studies in children after mTBI, showing an intervention effect on PCSs and stress symptoms[13] but

TABLE 2 *Dichotomized descriptive outcome for primary outcome measure (CASP) over time*[a]

	T_0		T_1		T_2	
CASP Setting	**Control group, *n* (%)**	**Intervention group, *n* (%)**	**Control group, *n* (%)**	**Intervention group, *n* (%)**	**Control group, *n* (%)**	**Intervention group, *n* (%)**
Caregiver report (6-18)						
Total	9 (14.1)	17 (28.3)	34 (53.1)	33 (55.0)	39 (60.9)	36 (60.0)
At home	26 (40.6)	27 (45.0)	46 (71.9)	47 (78.3)	55 (85.9)	49 (81.7)
In the community	25 (39.1)	20 (33.3)	43 (67.2)	42 (70.0)	51 (79.7)	44 (73.3)
At school	24 (37.5)	26 (43.3)	50 (78.1)	45 (75.0)	55 (85.9)	53 (88.3)
In the environment	21 (32.8)	26 (43.3)	44 (68.8)	38 (63.3)	45 (70.3)	45 (75.0)
Caregiver report (10-18)						
Total	7 (16.7)	7 (17.1)	20 (47.6)	23 (56.1)	24 (57.1)	26 (63.4)
At home	16 (38.1)	14 (34.1)	29 (69.0)	32 (78.0)	35 (83.3)	36 (87.8)
In the community	19 (45.2)	8 (19.5)	27 (64.3)	28 (68.3)	30 (71.4)	31 (75.6)
At school	16 (38.1)	13 (31.7)	33 (78.6)	30 (73.2)	35 (83.3)	37 (90.2)
In the environment	14 (33.3)	13 (31.7)	27 (64.3)	26 (63.4)	29 (69.0)	31 (75.6)
Self-report (10-18)						
Total	0 (0.00)	3 (7.3)	11 (26.2)	20 (48.8)	10 (23.8)	20 (48.8)
At home	4 (9.5)	6 (14.6)	21 (50.0)	27 (65.9)	22 (52.4)	30 (73.2)
In the community	4 (9.5)	5 (12.2)	22 (52.4)	26 (63.4)	24 (57.1)	30 (73.2)
At school	10 (23.8)	8 (19.5)	27 (64.3)	30 (73.2)	30 (71.4)	33 (80.5)
In the environment	5 (11.9)	4 (9.8)	17 (40.5)	24 (58.5)	14 (33.3)	23 (56.1)

Abbreviations: CASP, Child and Adolescent Scale of Participation; T_0, 2 weeks post-mTBI; T_1, 3 months post-mTBI; T_2, 6 months post-mTBI.
[a]Numbers represent the count of children with dichotomized full functioning scores on the CASP at T_0, T_1, and T_2.

not on the daily level of activities.[12,13] To the best of our knowledge, this is the first study to report positive results on QOL after mTBI in children who received an early psychoeducational intervention. Furthermore, our study adds to the literature showing that perspectives of children and caregivers concerning activities and participation differ. In addition, decisions of caregivers about letting their child return to daily activities or not (eg, based on anxiety of the caregiver) affect the level of activities and participation as reported by the child. Therefore, we emphasize the importance of assessing both perspectives in future studies and in clinical settings.

What distinguishes the Brains Ahead! intervention from existing interventions is the individualized approach, in particular, the specific attention to those symptoms the individual child experiences and to the unique situation of each child and family in planning to return to activities and participation. Although not all children suffer from all possible symptoms after mTBI,

TABLE 3 *Baseline descriptive outcome for secondary outcome measures* (T_0)

	n	**Control, mean (SD)**	**Intervention, mean (SD)**
PedsQL-Fatigue—Parents	124	62.39 (2.45)	65.32 (2.33)
PedsQL-Fatigue—Children	124	62.74 (2.01)	63.18 (2.14)
PCS HBI—Parents	124	98.31 (2.89)[a]	90.70 (2.86)[a]
PCS HBI—Children	106	99.67 (2.60)	99.40 (2.94)
PedsQL-QoL—Parents	124	69.94 (2.43)	72.33 (2.46)
PedsQL-QoL—Children	124	71.77 (2.02)	75.21 (1.79)
PTSS IES—Parents	124	62.30 (2.18)	60.42 (1.97)
PTSS IES—Children	106	65.02 (2.26)	61.06 (1.78)

Abbreviations: HBI, Health and Behavior Inventory; IES, Impact of Event Scale; PCS, postconcussive symptoms; PedsQL-Fatigue, Paediatric Quality of Life Inventory—Fatigue scale; PedsQL-QoL, Paediatric Quality of Life Inventory—Quality of Life scale; PTSS, posttraumatic stress symptoms; T_0, 2 weeks post-mTBI.
[a]Significant difference at baseline between groups.

TABLE 4 *Intervention effect on the CASP-DLV (primary outcome measure)[a]—Randomization × Time*

	Wald χ^2 interaction	*df*	*P*	OR	95% CI for OR
Total					
T_0-T_1-T_2	3.739	2	.154		
T_0-T_1	3.657	1	.077	2.692	0.976-7.428
T_0-T_2	2.454	1	.117	2.240	0.817-6.146
Home					
T_0-T_1-T_2	2.497	2	.287		
T_0-T_1	1.194	1	.275	1.827	0.620-5.385
T_0-T_2	0.105	1	.746	0.845	0.305-2.340
Community					
T_0-T_1-T_2	1.500	2	.472		
T_0-T_1	0.122	1	.727	1.210	0.415-3.525
T_0-T_2	0.619	1	.431	0.684	0.266-1.760
School					
T_0-T_1-T_2	0.755	2	.685		
T_0-T_1	0.093	1	.761	1.198	0.374-3.841
T_0-T_2	0.746	1	.388	1.517	0.589-3.908
Environment					
T_0-T_1-T_2	2.119	2	.347		
T_0-T_1	0.355	1	.551	1.349	0.504-3.606
T_0-T_2	2.053	1	.152	1.994	0.776-5.128

Abbreviations: CASP-DLV, Child and Adolescent Scale of Participation—Dutch language version; CI, confidence interval; GEE, Generalized Estimating Equations; mTBI, mild traumatic brain injury; OR, odds ratio; T_0, 2 weeks post-mTBI; T_1, 3 months post-mTBI; T_2, 6 months post-mTBI.

[a]GEE outcome for CASP-DLV parent reports for children aged 6 to 18 years.

ours is the first intervention to first screen for symptoms per child and then integrate the findings of this screening into the provision of information. This ensures that, although partly standardized information is given, the intervention is now more child-specific and an information overload is prevented.

This study has several strengths. First, previous studies used mixed TBI samples, with small groups of children with mTBI included with those who sustained injuries of greater severity, thereby providing little insight into activities and participation for this specific group.[23,24,30] We included children with mTBI only and evaluated children of all school ages (6-18 years) who suffered from mTBI and their caregivers. Second, the study design, a nested RCT in a multicenter longitudinal prospective cohort, enabled us to investigate the effectiveness of the intervention on a relatively short-term basis. We believed this was an efficient way of investigating this group of participants from an ethical perspective as well. And, third, the outcome instruments used in this study are recommended for evaluating outcomes in children after brain injury[29] and based largely on the *International Classification of Functioning, Disability and Health for Children and Youth* (*ICF-CY*).

This study also has some limitations. First, children and adolescents with mTBI were recruited from emergency departments of 2 hospitals and may therefore not be representative of the larger population of children with mTBI (eg, those children who do not receive acute medical care). Second, with regard to data collection, retrospective ratings of preinjury functioning of the child and the family were gathered. This may be a concern for bias, although ratings were collected within 2 weeks post-mTBI, which seems a reasonably practical time frame for gathering such information. Finally, we included a rather high SES group and–as discussed earlier–the intervention group reported lower PCSs at baseline.

The lack of effectiveness of the intervention on activities and participation may be explained by the idea that, although children may suffer from symptoms such as fatigue, PCSs, PTSSs, and a lower perceived QOL, they may still participate fully in all activities despite their symptoms. In the long term, however, untreated symptoms may gradually have more of an impact and the child's tolerance and stamina might start to decline. Therefore, future studies should aim to evaluate children after a longer follow-up time post-mTBI. Another reason for the lack of effectiveness of the intervention on activities and participation may be the ceiling effect on the CASP. The CASP seems a reliable instrument to assess activities and participation in children with

TABLE 5 *Intervention effect for primary outcome measure—Parent and child reports for children aged 10 to 18 years—Randomization × Time*

	Wald χ^2 interaction	*df*	*P*	OR	95% CI for OR
CASP-DLV Child Reports 10-18 years old (N = 83)					
Total[a]					
T_0-T_1-T_2					
T_0-T_1					
T_0-T_2					
Home					
T_0-T_1-T_2	0.158	2	.924		
T_0-T_1	0.137	1	.711	0.741	0.152-3.622
T_0-T_2	0.049	1	.826	0.844	0.188-3.798
Community					
T_0-T_1-T_2	0.190	2	.909		
T_0-T_1	0.167	1	.682	0.728	0.159-3.332
T_0-T_2	0.061	1	.805	0.837	0.205-3.425
School					
T_0-T_1-T_2	1.163	2	.559		
T_0-T_1	0.832	1	.362	0.545	0.148-2.007
T_0-T_2	1.048	1	.306	0.512	0.142-1.844
Environment					
T_0-T_1-T_2	1.708	2	.426		
T_0-T_1	1.625	1	.202	0.345	0.067-1.771
T_0-T_2	1.384	1	.239	0.385	0.079-1.887
CASP-DLV Parent Reports 10-18 years old (N = 83)					
Total					
T_0-T_1-T_2	0.251	2	.882		
T_0-T_1	0.040	1	.841	0.878	0.248-3.108
T_0-T_2	0.217	1	.641	0.732	0.198-2.716
Home					
T_0-T_1-T_2	1.008	2	.604		
T_0-T_1	0.223	1	.636	0.722	0.187-2.784
T_0-T_2	0.994	1	.319	0.529	0.151-1.850
Community					
T_0-T_1-T_2	6.081	2	.048		
T_0-T_1	3.932	1	.047	0.269	0.073-0.985
T_0-T_2	5.437	1	.020	0.245	0.075-0.799
School					
T_0-T_1-T_2	1.150	2	.563		
T_0-T_1	0.822	1	.365	0.524	0.130-2.119
T_0-T_2	0.001	1	.982	1.014	0.291-3.486
Environment					
T_0-T_1-T_2	0.253	2	.881		
T_0-T_1	0.200	1	.655	0.760	0.228-2.534
T_0-T_2	0.004	1	.950	0.964	0.306-3.037

Abbreviations: CASP-DLV, Child and Adolescent Scale of Participation—Dutch language version; CI, confidence interval; mTBI, mild traumatic brain injury; OR, odds ratio; T_0, 2 weeks post-mTBI; T_1, 3 months post-mTBI; T_2, 6 months post-mTBI.
[a]Total CASP score results for children's self-report is omitted because it could not be modeled.

more severe head injuries, but it may not be the best measure for children with mTBI. To the best of our knowledge, though, a better instrument to assess activities and participation in children after mTBI does not yet exist. We emphasize the importance of developing an instrument that is more sensitive in distinguishing levels of activities and participation among children with mild brain injuries. The lack of effectiveness on activities and participation of our intervention may also be explained by the fact that most children recover completely after mTBI without intervention. In our study, the intervention was provided to all children with mTBI, while it might be better to provide it only to those who are at risk for long-term problems. For this, prognostic factors for long-term outcomes in activities and participation should be identified. Currently, feasibility of

TABLE 6 *Intervention effect on secondary outcome measures (T_2)*

	T_2 Control, mean (SD)	T_2 Intervention, mean (SD)	*N*	*U*	*P*
PedsQL-Fatigue—Parents	73.81 (2.12)	80.11 (2.10)	123	1468.000	.033
PedsQL-Fatigue—Children	69.86 (2.30)	77.26 (2.28)	123	1438.500	.023
PCS HBI—Parents	83.69 (3.07)	79.51 (3.15)	123	1659.500	.247
PCS HBI—Children	92.05 (3.39)	82.04 (3.26)	105	1043.500	.037
PedsQL-QoL—Parents	76.51 (2.82)	86.42 (1.71)	123	1472.500	.035
PedsQL-QoL—Children	80.81 (1.95)	88.47 (1.36)	123	1299.500	.003
PTSS IES—Parents	49.77 (1.85)	44.22 (1.56)	123	1293.500	.003
PTSS IES—Children	61.70 (3.00)	50.19 (1.91)	105	945.500	.007

Abbreviations: HBI, Health and Behavior Inventory; IES, Impact of Event Scale; PCS, postconcussive symptoms; PedsQL-Fatigue, Paediatric Quality of Life Inventory-Fatigue scale; PedsQL-QoL, Paediatric Quality of Life Inventory-Quality of Life scale; PTSS, posttraumatic stress symptoms; T_0, 2 weeks post-mTBI.

the Brains Ahead! intervention process is being evaluated and prognostic factors for outcome on activities and participation are examined. Findings of these studies may further support implementation of the intervention in clinical practice, especially to those who are at risk for long-term problems. Furthermore, long-term follow-up data in this cohort will be collected at 1.5 and 5 years post-mTBI and may be useful for future trial designs.

CONCLUSION

Superiority for the intervention over usual care was found for fatigue, PCSs, PTSSs, and QOL. Effect on activities and participation should be studied using other more sensitive outcome measures and extend to a longer-term follow up. Despite the lack of effect found on activities and participation, we recommend implementation of the intervention because of the positive effect on functional outcome and QOL.

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