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Training Executive, Attention, and Motor Skills (TEAMS): a Preliminary Randomized Clinical Trial of Preschool Youth with ADHD

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Abstract

This preliminary randomized controlled trial compared Training Executive, Attention and Motor Skills (TEAMS), a played-based intervention for preschool children with attention-deficit/hyperactivity disorder (ADHD), to an active comparison intervention consisting of parent education and support (ClinicalTrials.gov Identifier: NCT01462032). The primary aims were to gauge preliminary efficacy and assist in further development of TEAMS. Four- and 5-year-old children with ADHD were randomly assigned to receive TEAMS ($N = 26$) or the comparison intervention (N = 26) with blinded assessments by parents, teachers and clinicians ascertained pretreatment, post-treatment, and 1- and 3-months post-treatment. Changes in ADHD severity, impairment, parenting factors, and neuropsychological functioning over time as a function of treatment condition were assessed using the PROC MIXED procedure in SAS. Across most measures, significant main effects for Time emerged; both treatments were associated with reduced ADHD symptoms that persisted for three months post-treatment. There were no significant Treatment effects or Time x Treatment interactions on symptom and impairment measures, suggesting that the magnitude of improvement did not differ between the two interventions. However, significant correlations emerged between the magnitude of behavioral change, as assessed by parents and clinicians, and the amount of time families engaged in TEAMS-related activities during treatment. Across a wide array of parenting and neuropsychological measures, there were few significant group differences over time. TEAMS and other psychosocial interventions appear to provide similar levels of benefit. Play-based interventions like TEAMS represent a potentially viable alternative/addition to current ADHD treatments, particularly for young children, but more research and further development of techniques are necessary.

Keywords ADHD · Preschool children · Early Intervention · Treatment · RCT · Prevention

Pharmacological and psychosocial (e.g., behavioral parent training, classroom contingency management) interventions have a long history as evidence-based treatments for attention-deficit/hyperactivity disorder (ADHD; for reviews, see Cortese et al. 2015; Fabiano et al. 2009). While efficacious, these interventions have notable limitations, including

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adverse side effects of medications, lack of normalization of functioning for many, and limited evidence that they alter the frequent poor long-term trajectories of these youth (for review see Allan and Chacko 2018; Chacko et al. 2014). These limitations likely reflect, at least in part, the fact that these interventions do not target putative causes and/or mechanisms that maintain/exacerbate ADHD (Chacko et al. 2014). As such, novel treatments that specifically and robustly target these determinants and mechanisms may provide more enduring benefits.

Neuroimaging research suggests that ADHD is likely related to delayed or stunted brain development (for reviews see Hoogman et al. 2017, 2019). Providing potential clues for treatment development, both neuroimaging (Clerkin et al. 2013; Luo et al. 2018; Schulz et al. 2017; Shaw et al. 2015; Szekely et al. 2017) and neuropsychological (Halperin et al. 2008; Miller et al. 2013; Rajendran et al. 2013) data from longitudinal samples suggest that the diminution of ADHD symptoms over development is linked to improved neural functioning. Moreover, an array of neurodevelopmental processes, including neurogenesis, cortical thickening, synaptogenesis, dendritic spine growth and branching, and production of neurotrophic factors are facilitated by environmental enrichment (see reviews by Alwis and Rajan 2014; Redolat and Mesa-Gresa 2012) and/or physical exercise (see reviews by Lin and Kuo 2013; Voss et al. 2013). Together, these data provide compelling evidence that an ADHD trajectory characterized by better outcomes is associated with a normalization of neural and possibly cognitive dysfunction, and that environmental enrichment and physical exercise can promote neural and cognitive growth. As such, it has been hypothesized that enhancement of experience-dependent neurodevelopment can be used to facilitate ADHD symptom reduction over the lifespan (Halperin and Healey 2011; Halperin and Schulz 2006).

Based on data-supported models positing key roles for working memory (Rapport et al. 2001, 2009), inhibitory control (Barkley 1997), attention (Berger and Posner 2000) and executive functions (Pennington and Ozonoff 1996) in the manifestation of ADHD symptoms, several investigators have developed interventions targeting cognitive functioning to improve ADHD symptoms and impairment in children. Some have been designed to enhance attention (Rabiner et al. 2010; Shalev et al. 2007; Stern et al. 2016; Tamm et al. 2010; Toplak et al. 2008) or working memory (Beck et al. 2010; Chacko et al. 2013; Klingberg et al. 2005; van der Donk et al. 2015), while others have targeted multiple domains (Dovis et al. 2015; Hahn-Markowitz et al. 2018; Halperin et al. 2013; Healey and Halperin 2015; Shuai et al. 2017; Smith et al. 2016; Tamm et al. 2019; Tamm and Nakonezny 2015; van der Oord et al. 2012). Some have employed computerized training (e.g., Klingberg et al. 2005; Rabiner et al. 2010; Stern et al. 2016; van der Donk et al. 2015) while others use play-based approaches (Hahn-Markowitz et al. 2018; Halperin et al. 2013; Healey and Halperin 2015; Tamm et al. 2019; Tamm and Nakonezny 2015). Several interventions have been shown to improve attention (Rabiner et al. 2010; Shalev et al. 2007), working memory (Klingberg et al. 2005; Healey and Halperin 2015; van der Donk et al. 2015), and inhibitory control/self-regulation (Diamond et al. 2007). Further, several pilot studies and one randomized controlled trial (RCT; Cerrillo-Urbina et al. 2015; Hoza et al. 2014; Vysniauske et al. 2016) have shown a positive albeit modest impact of physical activity on cognitive functioning and behavior of youth with ADHD (for a review see Halperin et al. 2014). These interventions have been hypothesized to strengthen underlying neural circuits with the aim of eliciting lasting behavioral improvements in children with ADHD.

Several reviews (Chacko et al. 2013, 2014; Halperin et al. 2014) and meta-analyses (Cortese et al. 2015; Rapport et al. 2013; Sonuga-Barke et al. 2013) have identified conceptual and methodological limitations of the neurocognitive training and exercise literature, including the narrow/proximal impact of such interventions (i.e., short term memory; Rapport et al. 2013) and setting-specific behavioral effects reported by informants not blind to treatment (Minder et al. 2018). Most studies have failed to document an appreciable impact on functional impairment, as distinct from core symptoms.

A meta-analysis by Cortese et al. (2015) found that interventions targeting multiple, rather than single, neurocognitive functions appeared to be most effective. This is not surprising as ADHD is associated with an array of neurocognitive functions (Frazier et al. 2004; Willcutt et al. 2005). Further, interventions that focus on skill transfer to the natural environment may be necessary to fully realize the benefits of treatment (Chacko et al. 2014). Many neurocognitive treatments do not integrate training into "real-world" settings. Finally, while most neurocognitive and exercise training studies have focused on school-age youth and adolescents, interventions during the preschool period may offer greater benefits given the malleability of these factors in early childhood and the potential benefits of treating ADHD before impairments become more intractable (Chacko et al. 2014; Halperin et al. 2012; Halperin and Healey 2011; Sonuga-Barke and Halperin 2010).

With these factors in mind, recent research has focused on the development of play-based interventions for preschool children that target a range of neurocognitive and behavioral domains in real-world settings. Three open clinical trials of these early interventions have yielded encouraging results (Halperin et al. 2013; Healey and Halperin 2015; Tamm and Nakonezny 2015). Halperin et al. (2013) found significant reductions in ADHD symptoms, as assessed by parents and teachers, that were still evident 3 months post-treatment, while Healey and Halperin (2015) reported improvements as assessed by parent report one year after the end of treatment.

Beyond the open clinical trials, we identified three preliminary RCTs that have evaluated the efficacy of play-based interventions in preschool children. Tamm et al. (2019) examined an intervention called Generating Attention, Inhibition and Memory (GAIM) in a sample of 3- to 4-year-old children referred for "self-control" difficulties and randomized to either GAIM or an active control intervention (largely parent education). While both groups evidenced behavioral improvement across a range of measures, significant group differences in favor of GAIM emerged for number and severity of problems at home at 3- and 6-months post-treatment, and clinician-rated ADHD severity at 3 months post-treatment. The groups did not differ significantly on parent ratings of inattention, hyperactivity and impairment; teacher ratings of behavior, or executive function measures (both rated and tested).

Healey and Healey (2019) compared "Enhancing Neurobehavioral Gains with the Aid of Games and Exercise" (ENGAGE) to Triple P – Positive Parenting Program (Triple P; Sanders 1999) in 3- and 4-year-old children with elevated parent ratings of hyperactivity. Triple P is an evidence based parenting program that applies social learning, cognitive behavioral and developmental approaches to the prevention and treatment of social and behavioral problems in children. Initially, half of the sample was randomized to ENGAGE or Triple P and the other half to a waitlist control condition for 8 weeks. After 8 weeks, those in the waitlist group were randomized to either ENGAGE or Triple P. ENGAGE was found to be as effective as Triple P in reducing parent-rated hyperactivity, attention problems and aggression, with gains maintained over a 12-month follow-up period, for both interventions. Children in the waitlist condition showed minimal behavioral change. Teacher rating changes were difficult to interpret because mean scores prior to treatment were within the normal range.

Finally, Vibholm et al. (2018) compared "Training Executive, Attention and Motor Skills" (TEAMS) to an active treatment based on Danish National Clinical Guidelines for preschool children with ADHD (consisting of psychoeducational, psychosocial, and behavioral procedures targeting children and parents) in a sample of children diagnosed with ADHD. Significant improvements over time of similar magnitude were noted for both groups. However, these findings are difficult to interpret because there was 73% attrition in the active control group, with most drop-outs wanting to receive pharmacological treatment. In contrast, only one child (3%) dropped-out of the TEAMS group, with parents' seldomly requesting medication.

Together, these findings suggest that play-based interventions for preschool children with ADHD that target neural/neurocognitive development may be beneficial to these dysregulated youngsters. However, only one of three RCTs studied children diagnosed with ADHD, and that study of TEAMS had high attrition making findings difficult to interpret, although notably, drop-outs were almost exclusively in the active control group. Therefore, a more rigorous double-blind randomized controlled study of preschool children with ADHD is warranted.

Based on the notion that novel treatment development requires an iterative process of treatment modifications and small-scale testing, the present study used rigorous methodology but a modest sample size to compare TEAMS to an active control intervention. Our primary aims were to evaluate preliminary efficacy of this play-based intervention for preschool children with ADHD and to assist in further development of TEAMS by identifying aspects of the program that require modification and further testing.

Method

Participants

Four- and 5-year-old children with hyperactivity and attention problems were recruited through local advertisements and contacts at preschools (ClinicalTrials.gov Identifier: NCT01462032). Prospective participants were initially screened by telephone and excluded if the child: (a) had a chronic medical illness or was taking systemic medication to treat a behavioral, psychiatric, neurological or medical condition (e.g., stimulant or non-stimulant ADHD medications, anti-depressants, neuroleptics, anti-seizure medications, and systemically administered steroids for asthma or another condition); (b) had a diagnosed neurological disorder; (c) had a diagnosis of autism spectrum disorder (ASD); (d) was not attending day care or school; (e) was not English-speaking; or (f) had a parent enrolled in a parent management training program for behavioral problems.

Parents of children not excluded during the telephone screen were sent parent and teacher versions of the ADHD Rating Scale–IV (ADHD-RS-IV; DuPaul et al. 1998), the Behavior Assessment System for Children–Second Edition (BASC-2; Reynolds and Kamphaus 2004), and the Children's Problems Checklist (CPC; Healey et al. 2008). Eighty-one children who showed evidence of elevated ADHD symptoms and impairment, defined as a T-score on the Hyperactivity scale of the BASC-2 of at least 65 by either teacher or parent rating, and a score of at least 60 by the other rater, as well as evidence of at least some impairment on the CPC, were invited for a more in-depth evaluation.

Parents were administered the Kiddie-Schedule for Affective Disorders and Schizophrenia Present and Lifetime Version (K-SADS-PL; Kaufman et al. 1997) and a demographics and developmental interview. Children were administered the Stanford–Binet Fifth Edition Abbreviated Battery (SB-5 ABIQ; Roid 2003) to generate an estimated IQ score (ABIQ), and the clinician completed the Child Autism Rating

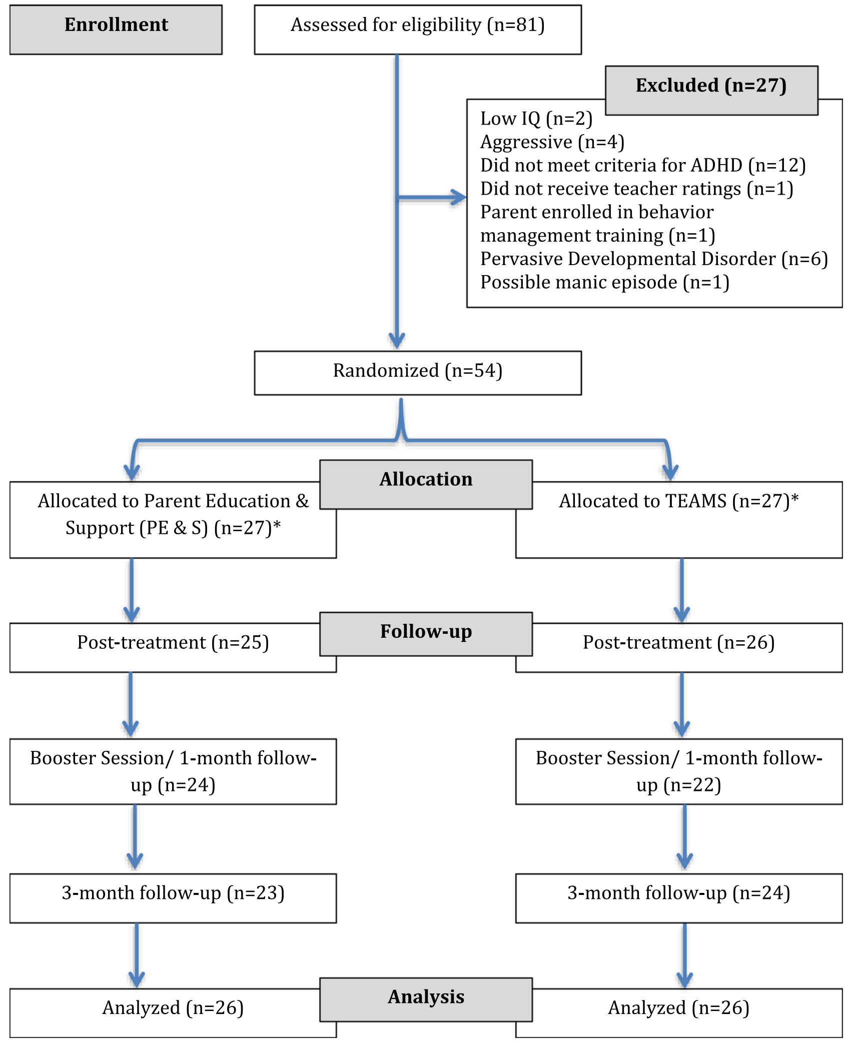

Fig. 1 CONSORT flow diagram. *1 child randomized to the each of the groups attended no sessions. The child randomized to the PE&S group was withdrawn by the parent who wished to trial medication. The parent of the child in the TEAMS group was unable to be contacted after randomization had taken place

Scale (CARS; Schopler et al. 1986) to rule out ASD. Children were included if they met DSM-IV (American Psychiatric Association 1994)[1] diagnostic criteria for ADHD and had an ABIQ of at least 80. Children who showed evidence of severe and persistent physical aggression ($n = 4$) were excluded out of concern for the safety of other children in the group.

Based on this evaluation, 54 children completed a pre-treatment evaluation and were randomized to treatment groups. One participant from each TEAMS and Parent Education and Support (PE&S) active comparison group withdrew before completing any treatment sessions. These two individuals were excluded from subsequent analyses, and all data reported are based on a sample size of 26 for each group (see Fig. 1 for a detailed consort diagram).

As shown in Table 1, most participants were male, the sample was ethnically diverse, and of mostly middle-class background. On average, participants' intellectual functioning fell in the average range. The majority of children met criteria for ADHD Combined Type, and a substantial proportion had comorbid Oppositional Defiant Disorder (ODD). No differences in baseline demographic and descriptive variables were observed as a function of treatment group.

This study was approved by the City University of New York Institutional Review Board. Following a full description of the study, parents signed informed consent forms.

Measures

Behavioral Measures

K-SADS-PL **(K-SADS-PL; Kaufman et al. 1997)** The K-SADS-PL was administered by well-trained graduate students or Ph.D.-level psychologists. The full K-SADS-PL was administered at pre-treatment, but follow-up assessments (post-treatment and 1- and 3-month follow-up) were restricted to the complete ADHD and ODD modules. Follow-up interviews were conducted by individuals

[1] All children would have met criteria for ADHD according to DSM-5 (American Psychiatric Association 2013) criteria.

Table 1 Demographic variables as a function of treatment group

Variable	PE & S (n = 26) N (%)	TEAMS (n = 26) N (%)	χ^2 (df)	P	φ/V
Sex, male	19 (73.1)	20 (76.9)	.10 (1)	.75	.04
Ethnicity, Latinx	9 (34.6)	15 (57.7)	2.77 (1)	.095	.23
Race			1.67 (3)	.64	.18
Asian	2 (7.7)	1 (3.8)			
Black/African American	1 (3.8)	0 (0)			
White	18 (69.2)	18 (69.2)			
Biracial/ Multiracial	5 (19.2)	7 (26.9)			
Annual household income (USD)			1.35 (5)	.93	.17
<10,000	1 (4.2)	1 (4.0)			
10,000-24,999	2 (8.3)	2 (8.0)			
25,000-39,999	2 (8.3)	3 (12.0)			
40,000-69,999	3 (12.5)	5 (20.0)			
70,000-99,999	7 (29.2)	8 (32.0)			
≥100,000	9 (37.5)	6 (24.0)			
ADHD presentation			2.50 (3)	.48	.22
Inattentive	4 (15.4)	1 (3.8)			
Hyperactive/Impulsive	5 (19.2)	6 (23.1)			
Combined	15 (57.7)	18 (69.2)			
Not otherwise specified	2 (7.7)	1 (3.8)			
ODD, present	13 (50)	11 (42.3)	.31 (1)	.58	.08
	Mean (SD)	Mean (SD)	t (df)	P	d
Age, years	4.88 (.60)	4.95 (.46)	−.46 (50)	.65	.13
SES	61.48 (17.82)	65.60 (18.31)	−.81 (48)	.42	.23
Full scale IQ	107.50 (10.26)	107.50 (13.07)	0.0 (50)	1.00	0

SES, Socioeconomic status as measured using the Nakao-Treas Socioeconomic Index; Full scale IQ; Stanford Binet V Abbreviated Intelligence Quotient

who were not involved in the treatment and were blind to group placement. For each child, the same interviewer conducted the pre-treatment, post-treatment, 1-month and 3-month follow-up evaluations. Dimensionalized ADHD symptom scores served as outcome measures. Test-retest stability of the K-SADS-PL total ADHD score in our longitudinal sample (Rajendran et al. 2013) of 3–4 year olds reassessed 12-months later was .82.

ADHD-RS-IV **(DuPaul et al. 1998; McGoey et al. 2007)** Home and school versions were collected at screening and were re-administered at pre-treatment, post-treatment, 1-month, and 3-month follow-up. Cronbach's alphas for the current sample were .89 (1- and 3-month follow-up) and .91 (pre- and post-treatment) for parent severity ratings, and .93 (pre- and post-treatment) to .95 (1- and 3-month follow-up) for teacher-rated ADHD severity. Four-week test-retest reliability for the parent and teacher total ADHD score in preschoolers was .87 and .94, respectively (McGoey et al. 2007).

Clinical Global Impression – Severity (CGI-S) and Improvement (CGI-I) Scales **(CGI-S; National Institue of Mental Health 1985)** The CGI-S was completed by blinded clinicians at pre-treatment, post-treatment, and 1- and 3-months follow-up to assess symptom severity and treatment response. A child was assessed by a clinician on severity of mental illness from 1 = Normal to 7 = Extremely Ill. The CGI-I was completed at each post-treatment assessment point by blinded clinicians who rated how much the child's illness had improved or worsened relative to baseline, from 1 = Very Much Improved to 7 = Very Much Worse.

Children's Problem Checklist **(CPC; Healey et al. 2008)** Parents and teachers rated impairment on a 4-point scale (none to severe). Cronbach's alpha for the current sample ranged from .74 (pre-treatment) to .78 (3-month follow-up) for parent ratings and .73 (post-treatment) to .77 (3-month follow-up) for teacher ratings. Six-month test-retest reliability for parent and teacher impairment reports in preschoolers was .69 and .70, respectively (Healey et al. 2008).

Social-Emotional Measures

***Parenting Stress Index – Third Edition* (PSI; Abidin 1995)** The 36-item Short Form was administered at all four time points to assess stress in the parent-child relationship. Test-retest reliability for the total stress score across a 6-month period is .84 (Abidin 1995).

***Parent Behavior Inventory* (PBI; Weis and Toolis 2010)** Parents completed this 30-item questionnaire at all four time points, generating three scores: Warmth, Control and Hostility. For our sample, alphas ranged from .66 (Warmth, post-treatment) to .86 (Control, post-treatment).

Intellectual and Neuropsychological Testing

***The Stanford Binet-5* (SB5; Roid 2003)** Children completed a 2-subtest abbreviated battery (Object Series/Matrices and Vocabulary), to provide an ABIQ score prior to treatment.

NEPSY-II (Korkman et al. 2007) Selected NEPSY-II subtests appropriate for use with 4- to 5-year-old children were administered prior to and following treatment to examine the impact of TEAMS on neurocognitive functioning. The following subtests were selected: Statue (motor persistence and inhibition), Speeded Naming (rapid semantic access to and production of names of colors, shapes, and sizes), Word Generation (semantic verbal fluency), Memory for Designs (spatial memory for novel visual material), Sentence Repetition (attention and verbal memory), Manual Motor Sequences (the ability to imitate a series of rhythmic movement sequences) and Block Construction (visuomotor ability). Korkman et al. (2007) examined test-retest reliability in preschool children by administering most of these subtests twice, on average, 21 days apart. Reliability ranged from .64–.88.

Day-Night Stroop* (DNST; Berwid et al. 2005*) The DNST assessed inhibitory control at all four time periods. Comprising two 16-trial blocks – a control condition followed by a conflict condition – children were shown cards with either a sun on a blue background or a moon and stars on a black background in randomized order. During the control condition, children had to answer "day" when they were shown the sun and "night" when they saw the moon/stars. During the conflict condition, they had to respond "night" when they saw the sun and "day" when they saw the moon/stars. Correct, self-corrected, and incorrect responses were recorded.

Treatment Interventions

Both the TEAMS and PE&S interventions consisted of groups of 4–6 children and their parents. For children from two-parent homes, both parents were encouraged to attend. Parent groups were run by a PhD-level psychologist with a co-leader who was a doctoral student or postdoctoral fellow. Child groups were led by a team of three staff; typically two undergraduate students and one psychologist or clinical psychology PhD student. Parent and child groups were held in adjacent rooms to facilitate management of separation issues. To assess treatment fidelity, the child room had digital cameras and all parent sessions were audio-recorded.

TEAMS Participants randomized to TEAMS attended weekly 90-min sessions for 5 weeks, with a booster session 1 month later. During each session children were introduced to a set of games targeting an array of neurocognitive domains including: inhibitory control (e.g., variations of "Simon Says," freeze dance); working memory (recalling shopping lists or finding "hidden treasures" under cups); motor control (games with balls; hopping, jump rope); attention/ tracking (e.g., "3-card Monte"); visuospatial abilities (e.g., puzzles); and planning (e.g., packing for a picnic). New games were introduced during each session. In addition, aerobic exercises such as jumping jacks and burpees, as well as relaxation techniques (e.g., deep breathing, guided imagery), were introduced in separate 5-min blocks. A group-based behavioral plan was used to maintain an acceptable level of behavioral control and engagement of the children.

Parent sessions consisted of 20 min of psychoeducation on topics related to ADHD (e.g., etiology, assessment, longitudinal course, evidence-based treatments), coupled with group-level support. However, sessions focused primarily on: (a) barriers and difficulties experienced during the preceding week related to playing TEAMS games with their child; (b) brainstorming to address identified barriers; and (c) descriptions and demonstrations of the new games being taught to their children, the skills supported by each game, and methods for scaffolding difficulty level. To increase intensity of the intervention, parents were directed to spend at least 30 min per day playing the games and engaging in aerobic exercise with their children.

Family engagement to maintain intensity was a necessary component of TEAMS. To measure engagement/intensity, Daily Diaries were emailed to parents each day at 5:00 pm. These short questionnaires queried about which games were played and for how long. To encourage parents to complete the reports on a daily basis, they were compensated $2 if the diary was submitted by 10:00 AM the following day and $1 if submitted by 3:00 pm. If diaries were not received by 5:00 pm (i.e., 24 h later), the parent(s) received a telephone reminder.

Parent education and support (PE&S) A series of parent sessions and concurrent child play groups served as the active control intervention. The frequency and duration of sessions, as well as the composition of the groups, were matched to those employed for the TEAMS intervention. The child sessions were identical to those in the TEAMS intervention. The parent sessions were nearly identical, except that parents were not introduced to the games during their sessions and were not encouraged to play the games with their children at home. However, relative to TEAMS, the psychoeducation and parent support components assumed greater primacy (and were of longer duration) since new games and strategies were not introduced. A recent review (Dahl et al. 2019) reported moderate to large effects of psychoeducation on ADHD symptom improvement as reported by parents and teachers (Hedges' g = . 787).

Procedures

At study intake, parents and children were informed of randomization to one of the two interventions (TEAMS or PE&S). No information was provided regarding the relative benefits of the two programs. As part of the study description, parents were told that two different interventions were being compared, both of which had the potential to be helpful, but that it was not known whether either would help their child or would emerge as therapeutically superior. Following parent consent, the KSADS-PL was completed by a clinician with the parents to ascertain psychiatric diagnoses, including ADHD. During this assessment, parent and teacher rating scales, neurocognitive testing, and the child's initial evaluation were completed (see above). All assessments were conducted by research staff who were blind to participant treatment randomization. Participants were randomly assigned to treatment condition via a coin toss (TEAMS = 26; PS&E = 26; see Fig. 1 for CONSORT Diagram).

Data Analysis

Of 208 possible observations for each measure (52 participants across 4 time points), seven participants missed one or more in-person evaluations, for a total of 12 (5.8%) missing assessments. Attempts were made to obtain rating scales from these participants with reasonable success. Four (1.9%) data points are missing for the PBI and 8 (3.8%) for the PSI. Twelve (5.8%) of DNST data points are missing, but for all other variables where there was missing data, the last observation was carried forward.

Change in ADHD severity and impairment, parenting stress and parenting style, and neuropsychological functioning from baseline through 3-month follow-up as a function of treatment condition was assessed using the PROC MIXED procedure in SAS. Maximum likelihood estimation with an unstructured covariance matrix was used, and the intercept set to random. Treatment condition was coded PE&S (0) and TEAMS (1), while follow-up time period was coded in a stepwise manner so change in outcome is relative to the most recent time point. That is, T1 = change from pre- to post-treatment; T2 = change from post-treatment to 1-month follow-up; and T3 = change from 1-month to 3-month follow-up. Change in ADHD severity was measured by dimensionalized semi-structured clinical interview responses (K-SADS-PL), teacher and parent ADHD rating scales (ADHD-RS-IV), and clinician-rated CGI-S. The CPC was used to index the severity of children's impairment in home and school. Effect sizes for each parameter of the mixed models were calculated by dividing the parameter for the fixed effect by the standard deviation of the random effect parameter (square root of UN(1,1)). Given that the random effect parameter reflects the subject to subject variability, our effect size estimate is analogous to Cohen's d and can interpreted the same way (small = .2, medium = .5, large = .8).

Change in functioning at each follow-up period compared to pre-treatment was assessed via clinician judgment using the CGI–I. The scale was dichotomized so at each follow-up period, children were grouped into those who showed (any) improvement from pre-treatment and those who showed no change or whose behavior had deteriorated. Chi-square analyses were carried out at each time point to determine whether there was a difference in proportion of individuals who improved as a function of treatment condition.

As noted above, parents of children in the TEAMS group completed daily diaries, indicating how many minutes they spent playing TEAMS games. To carry out a preliminary assessment of whether the amount of time spent playing games during the treatment period was related to degree of improvement across time, the average daily number of minutes spent playing games was correlated with parent-, teacher- and clinician-rated behavioral change from pre-treatment to each follow-up period (i.e., post-treatment, 1-month and 3-month follow-ups).

Finally, exploratory analyses investigated whether change in neuropsychological functioning was observed from pre-treatment through 3-month follow-up using the PROC MIXED procedure described above. Raw scores on neuropsychological tests served as outcome variables. All analyses controlled for baseline age (in years), which was grand mean centered.

Results

Retention, Compliance and Treatment Fidelity

Overall, 88.1% and 96.2% attendance was observed for the TEAMS and PE&S groups, respectively. The overall completion rate for Daily Diaries was 97.7%; the completion rates for the TEAMS and active control groups were 97.4% and 97.9%, respectively. Within the TEAMS group, treatment compliance, as measured using the Daily Diaries, was variable across families. Parents reported engaging in TEAMS games with their child on average 46.4% (range = 3.3% - 100%) of eligible days (excluding days with sessions) during the treatment period. On days when games were played at home, children played for a mean (SD) of 41.22 (22.87) minutes, but again there was high variability (range = 14.33–107.36 min).

Twenty-seven (45%) child sessions were analyzed to assess treatment fidelity. Video-recordings of children's groups were analyzed to assess adherence to four elements: establishing group rules; implementing the behavioral plan, administering prizes, and spending time on all five games. Adherence to the protocol was 97.2%. Audio-recordings of 10 (30%) PE&S parent sessions (including boosters) were analyzed to ensure they included a discussion of behavioral concerns for the previous week, psychoeducation about ADHD, and breakout questions, but refrained from discussions of behavioral management strategies, the TEAMS intervention, or other ways to enhance cognition. Treatment fidelity was 98.1%. Finally, audio-recordings of 14 (46.7%) TEAMS parent sessions were analyzed to determine whether leaders discussed with parents their children's behavior over the previous week, and specifically checked in with each parent; success/difficulties with playing games at home; psychoeducation about ADHD; breakout questions; introduction of new games; and instructions on how to scaffold the games, while avoiding detailed discussion of behavioral management strategies. Fidelity was 92.6%.

Behavioral Outcomes

(See Table 2 for means/SDs and Table 3 for path coefficients and effect sizes).

ADHD Severity Irrespective of treatment, at 5-weeks post-treatment, teachers reported a significant decrease in children's ADHD severity. Likewise, clinicians' evaluated children's ADHD severity as decreasing from pre- to post-treatment on both the K-SADS-PL and the CGI-S. The decrease in severity did not reach significance according to parent ratings. No further change in ADHD severity was observed between post-treatment and 1-month follow-up, or between 1-month and 3-month follow-up periods, with the exception of clinicians, for whom mean severity increased from 1-month to 3-month follow-up. No significant Time x Treatment interactions were observed, indicating that improvement did not differ across treatment groups.

There was no significant difference in the number of children whose symptoms improved from pre-treatment to follow-up versus those whose severity was unchanged or worsened as a function of treatment condition (pre- to post-treatment, $\chi2 = .49$ (1), $p = .48$; pre-treatment to 1-month follow-up, $\chi2 = 2.01$ (1), $p = .16$; pre-treatment to 3-month follow-up, $\chi2 = .21$ (1), $p = .65$).

ADHD-related Impairment There was no change in impairment over the course of treatment or the follow-up period according to parents' ratings. Teachers reported a decrease in school-related impairment from pre- to post-treatment, and no change from post-treatment to 1-month follow-up, or from 1-month to 3-month follow up. For parents and teachers, there was no significant effect of treatment condition, and no significant Time x Treatment interactions.

Games Practice and Treatment Outcomes

To evaluate whether outcomes were in part related to how often children played games, Pearson correlations were carried out between the average number of minutes each day children in the TEAMS group spent playing games and ratings of behavioral change across time.

For parent ratings on the ADHD-RS-IV, significant correlations were obtained between time spent playing games and positive behavioral change pre-treatment to 1-month follow-up, $r = .51$, $p = 0.01$, and pre-treatment to 3-month follow-up, $r = .61$, $p = .001$. For teacher ratings, no significant associations were obtained between time spent playing games during the 5-week intervention and change from pre-treatment to any follow-up, rs = −.22–.30, ps ≥ .14. A significant correlation was obtained between time spent playing games and clinician-rated improvement from pre-treatment to post-treatment, $r = -.49$, $p = .01$, but not pre-treatment to 1-month, $r = -.04$, $p = .85$, or pre-treatment to 3-month follow-ups, $r = -.17$, $p = .41$.

Social-Emotional Outcomes

(See Table S1 for means/SDs and Table S2 for path coefficients and effect sizes).

Parenting Stress (PSI) A significant effect of Time emerged for Parental Distress, such that there was a decline in Parental Distress from pre-treatment to post-treatment, irrespective of treatment condition. A significant Time x Treatment interaction was observed for the Difficult Child scale, such that a greater decline in stress was observed from pre- to post-treatment for parents of children in the TEAMS condition than parents of children in the PE&S condition. No significant effects were found for the Parent-Child Interaction and Total Stress scales.

Parental Behavior (PBI) Parents' reports of parenting style were stable across the intervention and follow-up period, with no significant effects of Time. Parents' reports of their Warmth and Control were not significantly different across the two groups, and no Time x Treatment interactions were observed. Parents of children in TEAMS rated their parenting as more hostile than parents of children in PE&S, irrespective of time.

Table 2 Mean (SD) scores for symptoms and impairment as a function of treatment group and time

	Pre-treatment		Post-treatment		1-month follow-up		3-month follow-up	
	PE&S Mean (SD)	TEAMS Mean (SD)	PE&S Mean (SD)	TEAMS Mean (SD)	PE&S Mean (SD)	TEAMS Mean (SD)	PE&S Mean (SD)	TEAMS Mean (SD)
ADHD Severity - KSADS	29.54 (5.81)	32.12 (3.44)	27.35 (6.58)	30.27 (4.51)	26.77 (7.79)	29.00 (4.19)	27.81 (6.71)	30.12 (3.71)
ADHD Severity-P	31.92 (11.49)	34.54 (9.00)	28.69 (10.69)	28.50 (9.61)	27.54 (8.87)	30.27 (9.26)	27.04 (9.37)	29.92 (9.59)
ADHD Severity–T	29.81 (11.78)	33.12 (11.04)	26.35 (11.38)	29.65 (11.11)	24.62 (14.09)	27.35 (10.94)	27.89 (13.31)	28.65 (11.75)
ADHD Severity - Clinical Global Impression	5.88 (0.93)	6.19 (0.69)	5.24 (1.13)	5.77 (0.76)	5.00 (1.22)	5.64 (0.91)	5.42 (1.35)	5.76 (0.93)
Impairment at home-P	7.23 (4.33)	7.73 (3.26)	6.73 (4.03)	6.58 (3.80)	6.58 (3.83)	6.69 (4.00)	6.27 (3.75)	6.54 (3.65)
Impairment at School-T	6.85 (3.53)	7.12 (3.39)	5.31 (3.34)	6.23 (3.29)	4.92 (3.71)	5.92 (3.39)	5.65 (4.14)	6.54 (3.51)

Notes: Mean (SD) for study outcome measures from pre-treatment through 3-month follow-up (FU) as a function of treatment group (Parent Education & Support, PE&S vs. TEAMS). ADHD Severity measured using: Kiddie SADS; parent (P)- and teacher (T)-rated Attention Deficit Hyperactivity Disorder Rating Scale; Clinical Global Impression Severity Score. Impairment measured using: parent- and teacher-rated Children's Problems Checklist for home and school respectively

Neuropsychological Outcomes

(See Table S3 for means/SDs and Table S4 for path coefficients and effect sizes).

Age was a significant predictor in all analyses, with older children achieving higher scores than younger children. This was expected as raw scores were used in analyses.

For all analyses, there was no significant effect of condition, suggesting that there were no systematic differences in performance by the children in the two treatment groups. A significant effect of Time was observed for five of the NEPSY-II measures (Word Generation, Speeded Naming – Correct Responses, Sentence Repetition, Memory for Designs, and Manual Motor Sequences), such that improvement in performance was observed between pre- and post-treatment, irrespective of treatment condition. Only one significant interaction was found; a significant Time x Treatment interaction for Word Generation showing greater improvement from pre- to post-treatment for the PE&S group.

Discussion

This preliminary double blind randomized controlled trial (RCT) compared TEAMS to an active comparison intervention with outcomes assessed via parent, teacher and clinician reports immediately following treatment as well as one and three months later. Our aims were to evaluate preliminary efficacy of this play-based intervention for preschoolers with ADHD and to assist in further development of TEAMS by identifying aspects of the program that require modification and further testing. Overall, the trial appeared to be successful in that both attrition and missing data were minimal and did not differ significantly between the groups, allowing for more valid analyses on the effects of TEAMS relative to an alternative treatment condition.

Across most measures, significant main effects for time emerged, with primarily medium to large effect sizes, indicating that both treatments were associated with a reduction in ADHD symptoms and that behavioral improvements persisted for up to three months post treatment. There were small differences across informants such that teachers and clinicians (both blind reporters) indicated significant reductions in ADHD symptoms from pre- to post-treatment, with no subsequent changes for teacher reports but some increase in symptoms reported by clinicians at the 3-month follow-up. Teachers also reported reductions in impairment across the entire 3-month follow-up period. Nevertheless, there were no significant treatment effects or Time x Treatment interactions on symptom and impairment measures, suggesting that the magnitude of improvement did not differ between the two interventions. Further, across a wide array of parenting style, parent stress and neuropsychological measures, there were few significant differential group differences over time and those that emerged may represent Type 1 error given the number of analyses conducted.

These largely negative findings are consistent with previously conducted RCTs of TEAMS and similar play-based interventions in that there were no significant differences between TEAMS and an active comparison group. Tamm et al. (2019) reported similar benefits following treatment with their GAIM intervention and an active control condition that was made-up largely of parent education. Similarly, Healey and Healey (2019) reported no significant differential improvements from ENGAGE versus Triple P, a manualized parent training program. Finally, an RCT examining TEAMS versus a comparison group that received treatment based on Danish National Clinical Guidelines for preschool children with ADHD, which included a range of psychosocial interventions, reported no differential group differences over time, although both groups improved (Vibholm et al. 2018). However, in this latter study there was 73% attrition in the control group, where authors report that most drop-outs left the study to get

Table 3 Fixed and random effect coefficients for ADHD Severity and Impairment (N = 52)

	Fixed Effects	Estimate	SE	DF	t-value	P	Effect Size	Random Effects	Estimate	SE	z	p
ADHD Severity, KSADS	Intercept	29.54	1.07	50	27.65	<.0001	6.97	Intercept (UN1,1)	17.99	4.11	4.37	<.0001
	T1	−2.19	0.95	150	−2.31	0.02	−0.52					
	T2	−0.58	0.95	150	−0.61	0.54	−0.14					
	T3	1.04	0.95	150	1.10	0.28	0.25					
	Condition	2.54	1.52	150	1.67	.097	0.60					
	T1xCondition	0.49	1.35	150	0.36	0.72	0.12					
	T2xCondition	−0.80	1.34	150	−0.60	0.55	−0.19					
	T3xCondition	0.08	1.34	150	0.06	0.95	0.02					
ADHD Severity-P	Intercept	31.92	1.88	50	16.99	<.0001	4.26	Intercept (UN1,1)	56.14	12.80	4.39	<.0001
	T1	−3.23	1.66	150	−1.95	.053	−0.76					
	T2	−1.15	1.66	150	−0.70	.49	−0.15					
	T3	−0.50	1.66	150	−0.30	.76	−0.07					
	Condition	2.62	2.66	150	0.98	.33	0.35					
	T1xCondition	−2.81	2.34	150	−1.20	.23	−0.38					
	T2xCondition	2.92	2.34	150	1.25	.21	0.39					
	T3xCondition	0.15	2.34	150	0.07	.94	0.02					
ADHD Severity-T	Intercept	29.81	2.31	50	12.93	<.0001	3.00	Intercept (UN1,1)	98.55	21.30	4.63	<.0001
	T1	−3.46	1.75	150	−1.98	.049	−0.35					
	T2	−1.73	1.75	150	−0.99	.32	−0.17					
	T3	3.27	1.75	150	1.87	.06	0.33					
	Condition	3.05	3.27	150	0.93	.35	0.31					
	T1xCondition	0.63	2.48	150	0.25	.80	0.06					
	T2xCondition	−0.95	2.46	150	−0.38	.70	−0.10					
	T3xCondition	−1.96	2.47	150	−0.79	.43	−0.20					
ADHD Severity, CGI Severity	Intercept	5.88	0.20	49	29.86	<.0001	8.77	Intercept (UN1,1)	0.45	0.12	3.90	<.0001
	T1	−0.64	0.20	143	−3.15	.002	−1.00					
	T2	−0.24	0.21	143	−1.17	.24	−0.36					
	T3	0.42	0.21	143	2.01	.046	0.63					
	Condition	0.32	0.28	143	1.15	.25	0.48					
	T1xCondition	0.22	0.29	143	0.77	.44	0.33					
	T2xCondition	0.12	0.29	143	0.40	.69	0.18					
	T3xCondition	−0.30	0.29	143	−1.02	.31	−0.45					
Impairment at home-P	Intercept	7.23	0. 74	50	9.79	<.0001	2.40	Intercept (UN1,1)	9.06	2.03	4.46	<.0001
	T1	−0.50	0.63	150	−0.80	.43	−0.17					
	T2	−0.15	0.63	150	−0.25	.81	−0.05					
	T3	−.31	0.63	150	−0.49	.62	−0.10					
	Condition	0.50	1.04	150	0.48	.63	0.17					
	T1xCondition	−0.65	0.89	150	−0.74	.46	−0.22					
	T2xCondition	0.27	0.89	150	0.30	.76	0.09					
	T3xCondition	0.15	0.89	150	0.17	.86	0.05					
Impairment at school-T	Intercept	6.85	0.68	50	10.04	<.0001	2.73	Intercept (UN1,1)	6.29	1.53	4.12	<.0001
	T1	−1.54	0.67	150	−2.30	.02	−0.61					
	T2	−0.38	0.67	150	−0.58	.57	−0.15					
	T3	0.73	0.67	150	1.09	.28	0.29					
	Condition	0.27	0.96	150	0.28	.78	0.11					
	T1xCondition	0.65	0.94	150	0.69	.49	0.26					
	T2xCondition	0.08	0.94	150	0.08	.94	0.03					
	T3xCondition	−0.12	0.94	150	−0.12	.90	−0.05					

Time: Intercept, pre-treatment; T1, change from pre-treatment to post-treatment; T2, change from post-treatment to 1-month follow up; T3, change from 1-month to 3-month follow-up. Condition, Parent Education & Support (PE & S) (0) vs. TEAMS (1). ADHD Severity measured using: Kiddie SADS; parent (P)- and teacher (T)-rated Attention Deficit Hyperactivity Disorder Rating Scale; Clinical Global Impression Severity Score. Impairment measured using: parent- and teacher-rated Children's Problems Checklist for home and school respectively

pharmacological treatment. In contrast, they reported that parents in the TEAMS group seldom raised this request and there was minimal attrition in the TEAMS group, suggesting that TEAMS either provided greater benefit or was at least more palatable. Together, these findings suggest that either 1) TEAMS has benefits that are similar to other psychosocial interventions typically employed with preschool children with ADHD, or 2) both more traditional and play-based interventions, as implemented, are largely ineffective and that time related improvements are not indicative of a true treatment effect. The only published RCT to shed light on these two possibilities is that of Healey and Healey (2019), who employed an 8-week wait-list control condition prior to the implementation of their two active treatments in half of their sample. No significant behavioral changes were seen over the 8-week wait-list period, but following the onset of both interventions, behavior began to improve. Thus, it seems more likely that TEAMS and other psychosocial interventions provide similar levels of benefit.

Despite these largely non-significant findings, it is notable that significant correlations emerged between the magnitude of behavioral change, as assessed by parents and clinicians, and the amount of time that families engaged in TEAMS-related activities during the active treatment period. Given that engagement with the intervention outside of the treatment sessions was highly variable across families, this suggests that increasing intensity, motivation, and treatment duration might result in greater efficacy, even if relations were largely due to positive attention effects. Given the conceptual bases of TEAMS, that increased engagement in cognitively challenging activities and physical exercise would facilitate brain development and alter ADHD symptom trajectories, it was perhaps naïve or only a manageable starting point to employ a 5-week treatment duration. Five weeks is likely too short a period to engrain the lifestyle changes needed to achieve these clinical goals and dwarfs the duration of most empirically validated psychosocial interventions. Further, increased efforts may be necessary to fully engage and motivate families so that they meet the goal of 30–45 min per day of prescribed activities.

In addition, if TEAMS is conceptualized as a preventive intervention rather than an acute treatment, the lack of short-term effects should not be surprising. Unlike medication or behavioral treatments that target symptoms, the aim of TEAMS is to instill lifestyle changes that might alter neural and behavioral developmental trajectories over time. As such, relatively small changes early-on should have the potential to yield substantially greater benefits over development (Halperin et al. 2012; Sonuga-Barke and Halperin 2010). Clearly, much longer follow-up periods will be necessary to determine whether interventions such as TEAMS alter developmental trajectories, reduce later reliance on medication, and/or improve long-term outcomes. However, the lack of substantial short-term effects also raises the possibility that implementation of TEAMS strategies early on might need to be accompanied by other interventions, such as parent management training or medication, which might have a more rapid impact on symptom attenuation and/or operate synergistically to optimize response to TEAMS.

Given the conceptual basis for TEAMS that the intervention would enhance neural growth and development, it is notable that TEAMS did not provide differentially greater enhancement of neurocognitive function relative to other interventions, although most neuropsychological measures improved over time irrespective of treatment group. This result is similar to findings with other play-based interventions (Healey and Healey 2019; Tamm et al. 2019). One possibility is that the observed behavioral improvement with TEAMS and related interventions is due to improved parent – child relations, as a key strategy is teaching parents to spend more time playing with their children. However, it is equally if not more likely that the follow-up period was too short to detect cognitive enhancements beyond those attributable to practice effects. This is particularly true given that few preschool neuropsychological tests have alternate forms and many, especially at younger ages, have only modest reliability.

Of note, the children in this study were preschool aged, a period with considerable variability in normal development, which might affect the reliability and predictive validity of the ADHD diagnosis. A recent review (Halperin and Marks 2019) concluded that studies indicate both continuity and discontinuity of preschool ADHD into later development. Most children with ADHD during early childhood display persisting symptoms and impairment; only a minority ‘outgrows’ early difficulties. This conclusion is supported by many studies, perhaps most clearly by Lahey et al.’s (2016) study of a preschool sample followed through adolescence, and a 6- year follow-up of the Preschool ADHD Treatment Study, which showed that 89% of the sample continued to meet criteria for ADHD (Riddle et al. 2013). Notably, the majority of hyperactive/inattentive preschool children who do not meet criteria for ADHD during the preschool years go on to meet criteria for the diagnosis just a few years later. This suggests that early preventive interventions such as TEAMS, if found to be effective, should be considered even for young children who may fall short of meeting full diagnostic criteria for ADHD.

This study has several strengths, including an RCT design, rigorously diagnosed children with ADHD, minimal attrition and missing data, the use of multiple informants with parents (who were told that both treatments might work), teachers and clinicians providing blinded assessments, the use of an active comparison group, and a 3-month follow-up period. In addition, TEAMS is unlikely to have untoward effects, which is important for a preventive intervention. However, this preliminary study had several limitations. First is the modest sample size and large number of statistical tests employed. As our mixed model was analogous to a series of independent samples t-tests of Time 1 vs. Time 2 mean of the difference scores (i.e., group differences in pre- to post-treatment, post-treatment to 1-month follow-up, and 1-month to 3-month follow-up), we conducted a post-hoc power analysis using G*Power’s (Faul et al. 2007) t-test for independent groups to determine the sample size required to detect a small effect ($d = .20$) with $\alpha = 0.05$ and power = .80. This power analysis generated a required sample size of $N = 788$. Thus, a much larger sample, perhaps using a multi-center approach, would be necessary to detect what would be expected to be small group differences from an active control group, particularly when considering prevention effects. Second, it would have been advantageous to have included a wait-list control or treatment-as-usual group in addition to the active control group. This would have allowed us to more definitively determine whether behavioral improvements over time were related to the interventions. Limited funding for this trial precluded the inclusion of a third group. Notably, our active control condition was closely matched to TEAMS with identical child groups. However, during each 90-min parent session, parents in the control group received approximately an hour more parent education and support as compared to the TEAMS parent group. Although parents in the TEAMS group also received education and support, a larger portion of their 90-min session focused on teaching parents the games, encouraging them to play the prescribed games with their children, and discussing barriers to playing the games at home. Several studies have found evidence that parent education and support yields benefits for children with ADHD, with a recent review (Dahl et al. 2019) reporting moderate to large effects of psychoeducation on ADHD symptom improvement.

Beyond study limitations, we believe that experience from this trial highlighted for us certain limitations of TEAMS as it was administered in this trial and points to changes that are likely to improve outcomes. First, and perhaps most importantly, the duration of treatment needs to be extended well-beyond 5 weeks. Although it is difficult to specify how long treatment duration should be, it is likely to be months rather than weeks, with perhaps a tapering from weekly to bi-weekly and eventually monthly sessions. Alternatively, intensity could be increased to twice or three times per week. Our initial open clinical trial of TEAMS (Halperin et al. 2013), included one group (out of seven) that met twice a week. We were limited to that one group because parents were generally unable (or unwilling) to attend sessions more than once per week. Whether increasing duration or intensity, perhaps some sessions could be completed remotely (e.g., video-conferencing). Further testing will be needed to evaluate which approach most successfully creates lifestyle changes for the children and families that incorporate cognitively enhancing activities and physical exercise into their daily routines. Second, it might be advantageous to provide parents with behavior management techniques either prior to the initiation of TEAMS or to incorporate such techniques into the parent sessions. This change could provide greater short-term behavioral improvements in children and provide skills to parents so that they can better engage their children in the prescribed play. Approaches should be utilized that help support parents' ability to implement games at home. As an example, methods that utilize mobile health approaches to behavioral skills implementation have been utilized in parenting-based interventions (Chacko et al. 2016) and such approaches may offer benefits for parents in TEAMS. Our data indicate considerable variability across families with regard to the extent to which they engaged in TEAMS activities at home, and suggests that those with greater engagement in games had better outcomes. Thus, increasing home implementation of games will likely enhance benefits.

In summary, play-based interventions that target an array of neurocognitive functions represent a new and viable alternative/addition to current ADHD treatments, particularly for young children. Initial evidence seems promising, but more research and further development of techniques are clearly necessary. While we posit that enhancement of brain development is key to efficacy, more research is necessary to identify mechanisms of action and which children respond best to this intervention. Our hope is that when implemented in early development, TEAMS and similar play-based modalities may function as preventive interventions.

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Compliance with Ethical Standards

Conflict of Interest The authors have no conflicts of interest to disclose.

Ethical approval This research was approved by the Institutional Review Board (IRB) of the City University of New York.

Informed consent Following a full review of the study, parents of all children signed IRB-approved informed consent forms.

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