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The Effects of Mindfulness for Youth (MYmind) versus Group Cognitive Behavioral Therapy in Improving Attention and Reducing Behavioral Problems among Children with Attention-Deficit Hyperactivity Disorder and Their Parents: A Randomized Controlled Trial

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Keywords
Attention-deficit hyperactivity disorder · Mindfulness · Child · Family · Randomized controlled trial

Abstract

Introduction: There is a lack of studies evaluating mindfulness-based interventions for children with attention-deficit hyperactivity disorder (ADHD) compared with an evidence-based control. This randomized controlled trial (RCT) evaluated the effects of mindfulness for youth (MYmind) in improving children's attention, behavior, and parent-related outcomes versus cognitive behavioral therapy (CBT). ***Methods:*** A total of 138 families of children with ADHD aged 8–12 years were recruited from the community with 69 randomized to MYmind and 69 to CBT. Participants were assessed at baseline, immediately after intervention, at 3 months and 6 months. The primary outcome was the attention score of the Sky Search subtest of the Test of Everyday Attention for Children (TEA-Ch). Secondary outcomes were child behavior and parent-related assessments. Linear mixed models were used to assess the efficacy of MYmind compared with CBT. ***Results:*** Both MYmind and CBT significantly improved children's attention score at 6 months (MYmind: $\beta = 1.48$, $p = 0.013$, Cohen's $d = 0.32$; CBT: $\beta = 1.46$, $p = 0.008$, $d = 0.27$). There were significant within-group improvements in most secondary outcomes. No significant difference was shown for both primary or secondary outcomes between the two arms at any time point. ***Conclusions:*** Both MYmind and CBT appeared to improve children's attention and behavior outcomes, although no difference was found between these two interventions. This is the largest RCT so far comparing MYmind and CBT

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although there was loss of follow-up assessments during the pandemic. Further RCTs adopting a non-inferiority design are needed to validate the results.

Introduction

Attention-deficit hyperactivity disorder (ADHD) affects a substantial number of children worldwide and is among the top 3 neuropsychiatric disorders among children with a global prevalence of 5% [1]. Children affected with ADHD show symptoms of inattention, hyperactivity, and impulsive behavior which are inappropriate for their age. In addition, people with ADHD perform less well in neuro-psychological tasks that require executive functions including response inhibition, attention, and working memory [2] and they have a three times increased risk of suicide when compared to that of the general population [3]. As a result, children with ADHD experience social, academic, and mental health problems. ADHD is increasingly recognized as a lifelong condition with the majority of people affected having symptoms which persist into adulthood [4].

Although medication is widely adopted as the first-line treatment of choice for ADHD [5], side effects, low compliance, and negative perceptions toward medications [6] are barriers to effective treatment [7, 8]. Moreover, medications may not work for all children and non-biological factors that exacerbate predisposing biological risk call for alternative interventions. In addition, many parents of children with ADHD are also affected by ADHD themselves with these symptoms having a negative impact on their parenting. Therefore, interventions that address both children's and parent's ADHD symptoms concurrently have the potential to work synergistically on both children and parents.

Cognitive behavioral therapy (CBT) is often recommended as the primary evidence-based treatment for ADHD. Meta-analyses demonstrated small to medium effects of behavioral therapy, e.g., on ADHD symptoms and parenting. However, differences in behavioral intervention components can have different effects on children with various demographic and clinical characteristics. Therefore, not all children and their families can benefit from behavioral therapy or CBT [9, 10].

Mindfulness-based interventions are becoming popular with emerging findings supporting its role in improving ADHD outcomes, reducing parenting stress and improving youth emotional functioning [1, 11–13]. Although a number of randomized controlled trials (RCTs) have been conducted [11, 14–16], all have limited sample size with the largest one consisting of 103 participants. Moreover, few have employed an active control or an evidence-based intervention as the active comparison control and therefore difficult to account for non-specific effects. For follow-up time, only one study [16] has a follow-up time up to 6 months post-intervention. Therefore, more research with larger sample size and better comparison control and an appropriate follow-up time is needed. Meta-analyses showed that the effect sizes of MBI among children with ADHD (e.g., Cohen's d = 0.66) [17] were generally larger than those of behavioral therapies (d = 0.26–0.56) [18].

MYmind (mindfulness for youth) is a mindfulness-based 8-week intervention that is run concurrently for children with ADHD and their parents [19]. To our knowledge, only two RCTs were reported using MYmind in improving ADHD symptoms and associated problems among children aged 8–16 years and their parents. Valero et al. [14] randomized 30 adolescents aged 9–14 years into MYmind and wait-list control and showed improvement in children's attention, executive functions, parenting styles, and parenting stress. On the other hand, Siebelink et al. [16] randomized 103 children aged 8–16 years into MYmind and care-as-usual control but failed to show significant difference in reducing child self-control deficits between the two groups although more children improved in the MYmind group. Significant improvement was also seen in parenting stress and ADHD symptoms in parents. We have previously conducted a pilot study using MYmind for children with ADHD together with their parents and showed that MYmind is feasible for children with ADHD and their parents in Hong Kong [20].

We aimed to evaluate the effects of MYmind in improving children's attention, behavior and executive function, mindfulness, and well-being in children diagnosed with ADHD in Hong Kong. The secondary aims were to evaluate the effects of MYmind in reducing parenting stress, ADHD symptoms, rumination level and improving well-being among parents of children with ADHD. We hypothesized that children randomized to MYmind would have better attention and fewer behavioral problems, higher mindfulness, and better well-being when compared to participants in CBT group at 6 months post-intervention. We also hypothesized that parents randomized to the MYmind will have lower self-reported parental stress, ADHD symptoms, rumination level, and better well-being when compared to the parents in the CBT group.

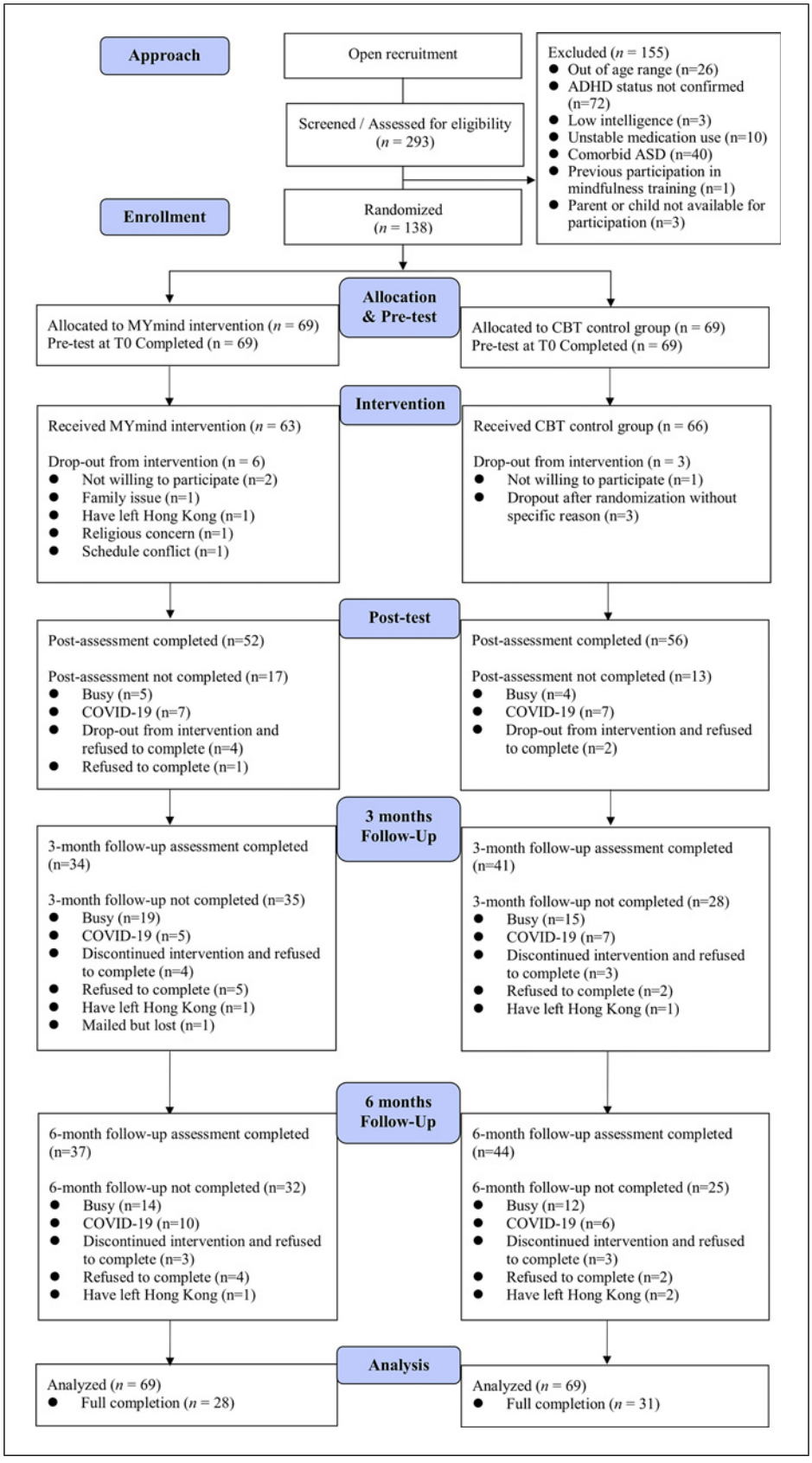

Fig. 1. CONSORT diagram for participant flow.

Materials and Methods

Participants and Procedure

The protocol of this RCT was published previously [21]. Figure 1 presents the CONSORT diagram for the flow of participants. In this study, children aged 8–12 years diagnosed with ADHD and one parent of each child, as decided by each participating family, were recruited from the community. We focused on children in this age group so as to offer early intervention for diagnosed children. There were three reasons: (1) children with ADHD are usually being diagnosed in middle childhood in view of the increased demands for attentional control and self-regulation in primary school [22], (2) a coercive interactional pattern with family members is often developed in this period of time [23], and (3) parents of newly diagnosed children are usually more motivated to receive intervention. We also focused on this age group in our pilot study [20]. Participants were screened for eligibility, and eligible families were randomly allocated to MYmind or CBT group. One child and one of their parents participated in either MYmind or CBT group over 8 weeks with outcome measures collected at baseline (T0), immediate post-intervention (T1), 3 months (T2) and 6 months post-intervention (T3) by a trained research assistant blinded to group allocation.

The inclusion criteria included children: (1) aged 8–12 years; (2) having a psychiatrist's or psychologist's diagnosis of ADHD according to the Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) [24] with the diagnosis validated by the presence of clinically relevant inattentive and/or hyperactive-impulsive symptoms using T-scores of parent or teacher version of Strengths and Weaknesses of ADHD Symptoms and Normal Behavior (SWAN; Chinese version) [25] at or above 95th percentile, or both parent and teacher versions at or above 85th percentile; (3) with a normal range of cognitive functioning and the ability to comprehend the materials distributed for weekly home practice; and (4) either not on medication for ADHD or taking a stable dosage of the same medication for ADHD with at least of 3 months prior to joining the study with no intention to change medication during the study period. The exclusion criteria of children and parents were (1) inability to communicate and apprehend Cantonese, the language adopted in the groups; (2) severe comorbid conduct/behavior problems exhibited by the child within 2 min during intake that interrupted the interaction between parent and assessor and would hamper the learning process in the group trainings (modified from a subtest in the Autism Diagnostic Observation Schedule) [26]; (3) being unable to join the study due to either medical or psychological condition; and (4) history of participating in mindfulness-based training for participating child and/or parent.

An individual interview was scheduled with one of the investigators for confirmation of inclusion and exclusion criteria, explanation of study objectives and procedures, and obtaining informed consent. Trained research staff conducted all baseline assessments and outcome measures. Among the 293 recruited families, 155 were excluded due to not fulfilling the inclusion criteria with a final total number of 138 families enrolled in the study. One hundred and thirty-eight families (one child and one parent in each family) were randomly allocated to either the MYmind or CBT group. The randomization, blinding, concealment, and the research design of this study were fully described in the published protocol [21]. The study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (the Joint CUHK-NTEC CREC 2015.193) and was registered in the Chinese Clinical Trial Registry (ChiCTR1800014741). The current study followed the methodological recommendations for psychotherapy trials by Guidi et al. [27] related to treatment and medication use, type of control group, therapeutic components, blinding, selection of outcome measures, and possible side effects.

Intervention: Mindfulness for Youth (MYmind)

We used the locally translated and adapted MYmind treatment protocol described in our previous study [20]. In brief, MYmind consisted of 8 weekly 90-min group interventions for both children and one of their parents that was run as concurrent groups. The child group consisted of 5–6 children and the parent group of 5–12 parents. Handouts describing homework practices, theme of each session, homework daily diaries, and recordings of mindfulness exercises were provided to each family. The mindfulness training was led by trained healthcare professional instructors who have completed an 8-week mindfulness training program (either mindfulness-based stress reduction or mindfulness-based cognitive therapy) and the MYmind intensive training program led by the originator of MYmind (S.B.).

Active Control: Cognitive Behavioral Group for Children and Psychoeducation for Parents (CBT)

Children and parents in the active control group received CBT training and psychoeducation based on CBT principles, respectively, over 8 weekly 90-min sessions (online suppl. Tables S1, S2; for all online suppl. material, see https://doi.org/10.1159/000534962). The intervention content was designed by one of the investigators (S.K.C.C.) who is an educational psychologist together with experienced healthcare professionals in family medicine and psychology using current CBT treatment and training guide for children with ADHD and their families [28, 29]. CBT for children included academic problem handling, self-control, problem-solving, understanding and response to emotions, listening and conversational skills, perspective taking in social situations, and social problem handling. Engaging activities, analysis of common scenarios related to the topics, group discussions on daily applications, and home practices were included to improve children's understanding and their use in daily applications. In the concurrent parent psychoeducation group, skills covered in the children's group were reinforced with description of the rationale of the training. Parents were invited to identify children's related problems through group discussion with the aim to understand and support children's learning through role-play and to facilitate daily applications of skills learned in home settings. Simple self-care and relaxation skills were also taught to reduce parents' stress.

Both MYmind and CBT were led by experienced instructors consisting of psychologists (clinical, educational, and counseling), social workers, teachers, and counselors. The average post-qualification clinical experiences of instructors were 12.10 years (standard deviation [SD] = 6.05) in the MYmind child group, 17.38 years (SD = 10.64) in the MYmind parent group, 8.56 years (SD = 7.32) in the CBT child group, and 7.83 years (SD = 5.00) in the CBT parent group.

Due to social restriction measures implemented during the COVID-19 pandemic within the study period, one group of

MYmind and one group of CBT were postponed after the 2nd session with subsequent sessions conducted using Zoom. A total of four (5.8%) participating families received MYmind intervention and four (5.8%) CBT intervention with the online format in this study. To assess intervention fidelity, all group sessions were audio-taped and a random sample was rated by independent reviewers, using a 4-point Likert scale (0–3) fidelity checklist.

Measures

Basic demographic data of children were collected at baseline including their age, sex, birth order, medication use, and presence of any previous diagnosis of psychiatric comorbidities. Demographics of the participating parent collected included age, sex, relationship with the participating child, education level, family income, occupation, number of children in the family, and current marital status.

Primary Outcome

Children's selective attention measured by the attention score of Sky Search subtest of the Test of Everyday Attention for Children (TEA-Ch) [30] at 6 months served as the primary outcome. The TEA-Ch is a game-like test and is widely used by healthcare professionals in Hong Kong to test for attention of local children. We used this test as the primary outcome as it was more objective than the parent-rated child behavior outcomes as both child and parent jointed the intervention in this study.

Secondary Outcomes

Secondary outcomes of children included attention skills measured by other subtests of TEA-Ch (creature counting, opposite worlds, and code transmission) [30], attention measured by the Attention Network Test – Child version (ANT) [31], ADHD symptoms measured by the SWAN Rating Scale (parent version) [32], disruptive behavior measured by the Eyberg Child Behavior Inventory (ECBI) [33], executive function measured by the Behavior Rating Inventory of Executive Function (BRIEF) [34], levels of mindfulness measured by the Child and Adolescent Mindfulness Measure (CAMM) [35], and well-being measured by the World Health Organization Well-being Index (WHO-5 Child) [36]. Secondary outcomes of parents included parental stress measured by the Parenting Stress Index–Short Form (PSI) [37], ADHD symptoms of parents measured by the Adult ADHD Self-Report Scale (ASRS) [38], well-being measured by the WHO-5 (i.e., WHO-5 Parent) [36], and levels of rumination measured by the Rumination Response Scale (RRS) [39]. For further details and motivation to include these secondary outcomes, please see the trial protocol [21].

Data and Statistical Analysis

Intention-to-treat principle (ITT) was adopted for all the analyses on primary and secondary outcomes. Per-protocol analyses were only conducted on the primary outcome as an additional information in the confirmatory analysis. Linear mixed models (LMMs) were used to compare the relative change between the two arms (MYmind vs. CBT) on selective attention assessed with TEA-Ch (primary outcome) and other results of TEA-Ch, ANT, SWAN, BRIEF, ECBI, PSI, ASRS, RRS, WHO-5 Child, and WHO-5 Parent (secondary outcomes) with the score of various outcome measures as the dependent variable and the assigned group and time as well as their interaction term as the predictors in the LMM. For within-group comparison, LMMs were adopted for each of the two arms, with the score of different outcome measures as the dependent variable and with time as the predictors in the LMM. Maximum likelihood estimation was used to handle missing data in the analyses with LMMs. Given that statistically significant group differences were found for WHO-5 Child and RRS at baseline, the adjustment method suggested by Twisk et al. [40] was used in the corresponding analyses: $y_t \sim \alpha + \beta_1 dummytime_1 + \beta_2 dummytime_2 + \beta_3 dummytime_1 \times treatment + \beta_4 dummytime_2 \times treatment$, where y_t was the measure of WHO-5 Child or RRS at the two follow-up measurements, α was the average outcome measure of all samples at baseline, $\beta 1$ and $\beta 2$ were the average effects of the control group (CBT) at the two follow-ups, and $\beta 3$ and $\beta 4$ were the treatment effects (MYmind vs. CBT) at the two follow-ups.

Effect size estimates were obtained for results of TEA-Ch, ANT, SWAN, BRIEF, ECBI, PSI, ASRS, RRS, WHO-5 Child, and WHO-5 Parent, with the between-group effect sizes (Cohen's *d*) being calculated using the mean differences from baseline and the SDs of the two groups at each time point, and the within-group *d* being calculated with the means, their SDs, and correlation at each time point of each of the two groups separately. For the effect sizes (*d*'s) generated by Cohen's method, the cutoff points of 0.2, 0.5, and 0.8 to indicate small, medium, and large effect sizes were adopted [41].

The CONSORT 10 standards were adopted for reporting the study results. Mean (SD), frequency and percentage, and 95% confidence interval (95% CI) were used for data description. A series of χ^2, Fisher's exact test, and *t* test were conducted to examine whether there were any demographic differences between the intervention and control arms, such as gender or medication use, as well as to examine if there were any group differences in the pre-intervention data. An additional analysis on the primary outcome measures was conducted with the pre-intervention data having statistically significant group difference, if any, added as covariates. Interaction effect model was performed as sensitivity analysis to investigate moderating effect of age, gender, and ADHD medication use on the relationship between intervention and primary outcome. Subgroup analysis of ADHD medication use was performed to assess the robustness of the primary analysis. To better understand the pattern of within-subject change, the Reliable Change Index (RCI) analyses [42] were conducted on the change scores in the primary outcome in the ITT sample as exploratory analyses. Bonferroni correction was applied for secondary outcomes to take into account the multiple testing issue, where significance level of 0.05 was adjusted by the number of multiple comparisons. *p* values greater than Bonferroni-corrected *p* value but less than 0.05 were considered suggestive of an association.

Sample Size Calculation

As reported in our protocol paper, referring to the effect sizes of previous studies on MYmind and the assumed small effect size in the active control group, a medium effect size between the two groups on the attention score of the Sky Search subtest of TEA-Ch was conservatively expected. With a two-tailed α error of 5%, an 80% power, and a test of two independent groups, the required sample size was estimated to be 64 families for each arm. With a conservative estimate of 10% dropout rate based on the pilot study on MYmind in Hong Kong, the present study intended to include 70 families for each arm, therefore 140 families (140 children and 140 parents) in total.

Table 1. Baseline information of participating children with ADHD and their parents

	MYmind (n = 69)	CBT (n = 69)	t/χ^2 value	p value
Child age at enrolment, mean (SD), years	8.9 (1.0)	9.2 (1.1)	−1.681	0.095[1]
Male, n (%)	52 (75.4)	47 (68.1)	0.894	0.345[2]
Comorbidity of participating child, n (%)				
Oppositional defiant disorder	6 (8.7)	5 (7.2)	0.099	0.753[2]
Conduct disorder	1 (1.4)	1 (1.4)	–	1.000[3]
Disruptive mood dysregulation	0 (0)	2 (2.9)	–	0.496[3]
Specific learning disorder	6 (8.7)	14 (20.3)	3.742	0.053[2]
Anxiety disorder	2 (2.9)	5 (7.2)	–	0.441[3]
Major depressive disorder	0 (0)	2 (2.9)	–	0.496[3]
Obsessive-compulsive disorder	0 (0)	2 (2.9)	–	0.496[3]
Tic disorder	0 (0)	4 (5.8)	–	0.120[3]
Others	18 (26.1)	24 (34.8)	1.232	0.267[2]
Child's medication status, n (%)				
On prescribed ADHD medication	35 (50.7)	29 (42.0)	1.049	0.306[2]
Methylphenidate	30 (85.7)	25 (86.2)		
Atomoxetine	1 (2.9)	1 (3.4)		
Methylphenidate and atomoxetine	1 (2.9)	1 (3.4)		
Unspecified	3 (8.6)	2 (6.9)		
Child's treatment history in the past 2 months, n (%)				
Used any healthcare services	42 (60.9)	38 (55.1)	0.476	0.490[2]
Public healthcare services	26 (61.9)	22 (57.9)		
Private healthcare services	8 (19.0)	10 (26.3)		
Community healthcare services	2 (4.8)	2 (5.3)		
≥2 types of healthcare services	6 (14.3)	4 (10.5)		
Children in family, n (%)			0.021	0.885[2]
1 child	27 (39.1)	27 (39.1)		
>1 child	38 (55.1)	40 (58.0)		
Birth order of participating child, n (%)			0.009	0.925[2]
First born	50 (72.5)	52 (75.4)		
Not first born	15 (21.7)	15 (21.7)		
Participating parent's relationship to child, n (%)			0.036	0.849[2]
Mother	57 (82.6)	57 (82.6)		
Mean age of participating parent, mean (SD), years	42.5 (5.0)	41.6 (5.1)	0.950	0.344[1]
Parent's marital status, n (%)			0.031	0.860[2]
Single/divorced/spouse diseased	9 (13.0)	10 (14.5)		
Married/cohabitation/remarried	56 (81.2)	57 (82.6)		
Participating parent's employment, n (%)			1.390	0.238[2]
Employed/self-employed	47 (68.1)	42 (60.9)		
Full-time parent/retired/unemployed/student	18 (26.1)	25 (36.2)		
Participating parent's education, n (%)			1.464	0.226[2]
Secondary or below	20 (29.0)	27 (39.1)		
Diploma or above	45 (65.2)	39 (56.5)		
Monthly household income, n (%)			0.745	0.388[2]
≤ HKD 29,999	31 (44.9)	27 (39.1)		
≥ HKD 30,000	33 (47.8)	39 (56.5)		

MYmind, mindfulness-based intervention program for children with ADHD; CBT, cognitive behavioral therapy. [1]By two-sample t test. [2]By χ^2 test. [3]By Fisher's exact test.

Results

A total of 138 eligible participating families were randomly assigned into intervention condition (MYmind; n = 69) and active control condition (CBT; n = 69). The demographic information is presented in the summary table (Table 1). The average age of children in the MYmind and CBT groups was 8.9 years (SD = 1.0) and 9.2 years (SD = 1.1), respectively (percentage of boys: 75.4% and 68.1%). There was no significant difference between the two conditions in any of the demographic variables, use of ADHD medications, or healthcare services.

Table 2. Within-group comparison of primary outcome (TEA-Ch Sky Search attention score) at different time points of study

	MYmind				CBT			
	Mean (SD)	Change from baseline, mean (SD)	Treatment effect (95% CI)[a]	*p* value	Mean (SD)	Change from baseline, mean (SD)	Treatment effect (95% CI)[a]	*p* value
TEA-Ch: Sky Search – attention score								
Baseline	8.7 (3.0)				9.1 (2.9)			
Post-intervention	9.4 (3.0)	0.9 (3.9)	0.71 (−0.32, 1.73)	0.174	10.1 (3.5)	0.8 (3.1)	0.86 (0.06, 1.66)	0.035
3 months	9.5 (3.0)	0.9 (3.4)	0.74 (−0.30, 1.78)	0.158	10.6 (3.7)	1.5 (3.4)	1.21 (0.17, 2.24)	0.024
6 months	10.0 (3.8)	1.2 (3.7)	1.48 (0.32, 2.64)	0.013	10.5 (3.3)	1.0 (3.6)	1.46 (0.40, 2.53)	0.008

MYmind, mindfulness-based intervention program for children with ADHD; CBT, cognitive behavioral therapy; TEA-Ch, Test of Everyday Attention for Children. [a]Baseline measures (T0) as referent.

The mean number of classes attended for parent and child was found to be above 6 with the mean attendance rate above 75% for both groups. In the MYmind and CBT conditions, 72.5% and 81.2% of both parent and child attended at or above 75% classes, respectively. The difference in attendance rate between two groups was not significant (parents: $p = 0.300$; children: $p = 0.296$). Examination of 55 audio-taped group sessions (MYmind child group: 16; MYmind parent group: 16; CBT child group: 12; CBT parent group: 11) showed comparable overall adherence ratings for MYmind (child group: 2.58; parent group: 2.74) and CBT (child group: 2.41; parent group: 2.41), suggesting that the facilitators of the reviewed sessions had covered the content adequately. Throughout the trial, there was no report of side effects in either MYmind or CBT.

Analyses on the Primary Outcome

Between-group LMM showed no significant difference in the change of attention score in Sky Search subtest of TEA-Ch between MYmind and CBT at post-intervention ($\beta = -0.16$, 95% CI: −1.44 to 1.13, $p = 0.809$), at 3 months ($\beta = -0.54$, 95% CI: −2.01 to 0.92, $p = 0.464$), or at 6 months ($\beta = 0.20$, 95% CI: −1.33 to 1.74, $p = 0.793$). The effect sizes of group differences were found to be negligible at all time points ($d = -0.20$ to 0.06).

The results of within-group comparison on the attention score at each time point are shown in Table 2. The estimated means and 95% CIs as generated by the LMM procedure were used to produce the trajectories in Figure 2. Within-group comparison showed a significant increase in the attention score of MYmind group at T3 with a small effect size ($\beta = 1.48$, $p = 0.013$, $d = 0.32$). In CBT group, the increase in attention score at all time points was found to be significant with small effect sizes (T1: $\beta = 0.86$, $p = 0.035$, $d = 0.27$; T2: $\beta = 1.21$, $p = 0.024$, $d = 0.45$; T3: $\beta = 1.46$, $p = 0.008$, $d = 0.27$).

Per-protocol analyses were conducted on the primary outcome for the 106 participants with an attendance rate at or higher than 75% (i.e., 6 sessions or more out of 8 sessions) for both participating parents and children. Overall, the per-protocol analysis results were comparable to the results of ITT analyses (online suppl. Table S3). Exploratory RCI analyses indicated no significant difference in the number of children with reliable change between MYmind and CBT at any point (online suppl. Table S4). The dropout rates at T2 were similar across the three different levels of change in attention score observed at post-intervention assessment (T1). Seven children in MYmind group displayed deterioration in attention score at T1. All of them completed follow-up assessment at T3 with the lowest dropout rate (improved: 50%, not changed: 52%, deteriorated: 0%; $p = 0.041$).

Analyses on the Secondary Outcomes

Online supplementary Tables S5 and S6 summarize the results of between-group comparisons on the secondary outcomes. The results of LMM showed non-significant difference in changes of other TEA-Ch subtests, ANT scores, ECBI subscale and total scores, SWAN subscale and total scores, BRIEF GEC, WHO-5 Child, CAMM, PSI subscale and total scores, WHO-5 Parent, RRS, and ASRS subscale and total scores between MYmind and CBT at any time point, as suggested by the non-significant group × time interactions ($p = 0.060$–0.989). For all secondary outcomes, the effect sizes for group

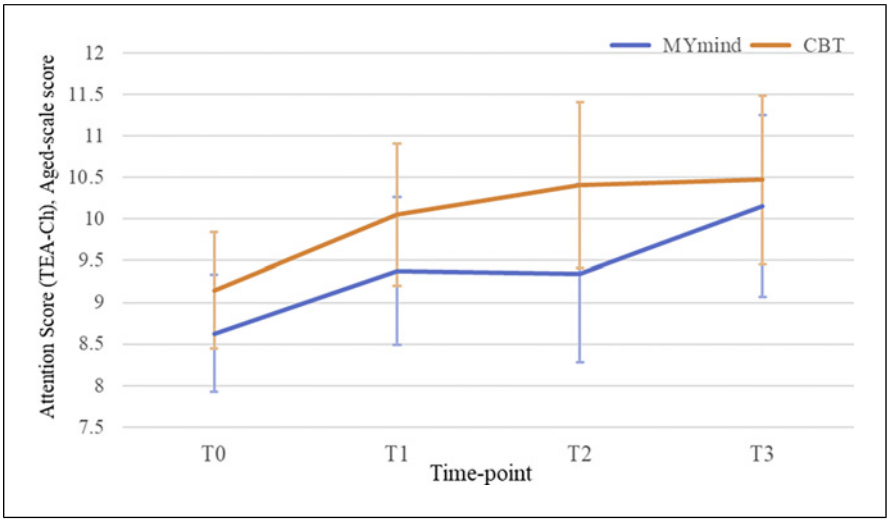

Fig. 2. Estimated mean scores for attention score of both groups over the study period (ITT).

differences were found to be small to moderate at all time points (d = −0.49 to 0.40).

The results of within-group LMMs for the secondary outcomes separately conducted for MYmind and CBT appear in the online supplementary Tables S7 and S8. Treatment effects that retained statistical significance after the Bonferroni correction were indicated with an asterisk. Most associations remained significant after correction with the Bonferroni method. At T1, participants in both groups significantly improved opposite world total time, ECBI-IS, and SWAN; only MYmind significantly improved TEA-Ch creature counting timing score and WHO-5 Parent. At T2, both arms significantly improved in TEA-Ch creature counting timing score, same world total time and opposite world total time, ECBI-IS, and SWAN; only MYmind significantly enhanced BRIEF GEC and WHO-5 Parent; only CBT significantly enhanced ANT conflict and ECBI-PS. At T3, both arms significantly improved same world total time and opposite world total time, ANT conflict, ECBI-IS, and SWAN; only MYmind significantly improved creature counting timing score and BRIEF GEC; only CBT significantly improved TEA-Ch creature counting total correct score.

However, some associations were no longer significant after the Bonferroni correction. In MYmind group, p values of TEA-Ch same world total time, ANT orienting and BRIEF GEC at T1, ANT conflict at T2, TEA-Ch creature counting total correct score and WHO-5 Parent at T3 were greater than Bonferroni adjusted significance level. On the other hand, p values of ANT conflict, WHO-5 Child and RRS Parent at T1, BRIEF GEC at T2, creature counting timing score, BRIEF GEC, ANT orienting, ECBI-PS, and RRS Parent at T3 in CBT group were greater than adjusted significance level. For both MYmind and CBT, there were generally small to moderate effect sizes for within-group improvement in the secondary outcomes.

Moderating effects of age, gender, and ADHD medications were non-significant, and the model with no interaction fitted the data no worse than the model with interaction term. Between- and within-group comparisons of primary outcome at different time points in the subgroups with and without ADHD medications were presented in the online supplementary Table S9. No significant between-group difference was found for overall and subgroups at any time point. Similar results using subgroup analyses with ADHD medications were obtained. Significant improvement was observed in the CBT group at immediate post-intervention and with the largest treatment effect at the primary end point of 6 months post-intervention in both arms. Positive treatment effects were sustained in subgroup with ADHD medications in the CBT group at 3 months post-intervention and subgroup without ADHD medications for both arms at all follow-up assessments with non-statistically significant associations. Because of the small number of participants in the subgroups, the statistical power to detect significant difference in subgroup analysis was limited.

Discussion

To our knowledge, this is the largest RCT and one of the very few that compared a mindfulness-based intervention (MYmind) for children with ADHD and their

parents with an evidence-based control (CBT). We showed that there was no difference in children's attention and parent-rated child behavior outcomes between MYmind and CBT although both conditions appeared to have improvements albeit only with small to moderate effect sizes in the primary and secondary outcomes. CBT was used as the active evidence-based comparison as CBT is recommended in current guidelines (e.g., NICE guideline) for children and adolescents with ADHD [43]. This is supported by findings from a recent review demonstrating that CBT has mild to moderate effect size for children and adolescents with ADHD [1]. In addition to comparing MYmind with an evidence-based control, this is also one of the very few studies that were conducted in a non-Caucasian population. Other unique characteristics of this study included both cognitive task-oriented and parent-rated child behavior measures that provide both cognitive and day-to-day functioning outcomes relevant to children with ADHD and their families. Both group interventions were provided by instructors with good post-qualification experience and with good fidelity check results. In contrast to our hypotheses, MYmind was not found to be superior to group CBT in reducing inattention and behavioral symptoms among children with ADHD. It was also not superior to CBT in reducing self-reported parent stress, ADHD symptoms, or rumination levels or improving well-being when compared to CBT.

Although previous studies [1, 11] suggested mindfulness-based interventions are potentially useful strategies to reduce ADHD symptoms in children and adolescents, most were of poor or fair quality. Only a few previous studies have compared mindfulness training with an active control. Results from a recent systematic review and meta-analysis have only cited two studies that compared mindfulness training with active controls. One [44] used mindfulness training as an adjunct to behavior modification when compared to behavior modification alone. However, the study was small with only 29 participants in each arm and was conducted in elementary school children with ADHD. It was also not a family-based mindfulness intervention. Another study [45] compared mindfulness training with emotional education over 8 weeks but with only 2-month follow-up and only consisted of a total of 30 participants. Other studies either used wait-list control or usual care as comparison group with short follow-up time and small sample size than the present one [11]. Another systematic review by Barranco-Ruiz et al. [46] was obtained on 12 studies using mind-body intervention including yoga exercise group. The authors rated 11 out of the 12 studies as poor in methodology. Therefore, the current study is one of the most rigorous in the literature with respect to study design and methodology.

In contrast to previous studies, we were unable to demonstrate significant improvement in parental ADHD symptoms or parental stress in the MYmind arm although parental well-being appears to improve. Moreover, there was no significant reduction in parents' rumination level while there was an increase in rumination in the CBT arm even though the group difference was not statistically significant. In the literature, parent-related improvements were suggested as the most consistent improvement across mindfulness-based intervention studies with results showing more positive changes in the mindfulness group when compared to control. We are unable to conclusively explain the lack of positive effects on parent-related outcomes in the current study although we speculated that the timing of outcome collection during COVID-19 may have contributed to increased stress among parents over time. A recent study by Zhang et al. [47] conducted during the COVID pandemic found similar findings of no significant improvement on mental health outcomes among caregivers of psychosis patients after receiving CBT.

Although there were no significant differences between the two interventions, both arms appear to improve over time in both primary and secondary outcomes although the improvement was only small to moderate, and for MYmind, the attention score only improved at 6 months post-intervention. Findings from a systematic review suggested the benefits of mindfulness training for improving attention control among children [48] although the effect size is smaller in our present study and the effect was demonstrated only at 6 months. We are unsure about the reasons for only observing significant improvement at 6 months post-intervention but note that previous studies on clinical outcomes also showed mindfulness may show its effects after 5–6 months [49–51]. A pragmatic quasi-experimental wait-list design study on family mindfulness training for childhood ADHD also found parenting stress only improved at 1-year follow-up, while no improvement was observed during wait-list period [52]. The reasons for only noticing results over longer time interval were uncertain and could be that mindfulness is often regarded as a lifestyle behavioral change instead of a treatment that may take time to see the changes. It can also be simply due to survival bias with those being able to complete follow-up assessment being more compliant to interventions. We were also uncertain how the presence of COVID pandemic has affected the outcomes measured in this study, given the possible increased parental stress during the pandemic.

There were several limitations in the current study. First, the rate of incomplete assessment was relatively high despite our efforts in retaining participants. We encountered significant difficulties in participant recruitment, intervention delivery, and performing follow-up assessment since mid-2019 due to social unrest followed by the COVID-19 pandemic in Hong Kong. On the other hand, more than 70% of participants have completed at least 6 out of 8 training sessions with 80% completed the assessment post-intervention. Therefore, the findings could have been affected by the incomplete follow-up data, making the sample size underpowered to show significant effects. Nevertheless, earlier research demonstrated that providing mindfulness training to a parent improved child's compliance. Subsequently, when the children themselves underwent similar training to that provided to their parents, compliance significantly increased and persisted during the follow-up period [53]. Second, the lack of blinding among participants or instructors could have affected the results. However, this is a methodological limitation common to most behavioral intervention studies. In the current study, it is impossible to blind participants or instructors in intervention groups. We have used cognitive task performance as the primary outcome (TEA-Ch) and employed research staff who were blinded to group allocation to conduct the assessments. For the use of cognitive task performance, some may argue that using cognitive task as a primary outcome may not correlate with day-to-day functioning or real-life situations and therefore may not translate into meaningful outcomes. On the other hand, since parents in the study were active participants, using a gold standard parent-rated ADHD symptom measure (usually measured by parent or teacher reports of behavior over time) as primary outcome may have introduced measurement bias [54]. Therefore, we resolved to use cognitive task performance as a more objective measure in this study. Third, since children in both conditions showed significant within-group improvement in their attention and this is only a 2-arm RCT, we cannot exclude the improvement due to regression to the mean or maturation due to our study design. Fourth, due to the COVID-19 pandemic, some of our treatment sessions were conducted using Zoom, despite the small percentage of participants affected (5.8% families in each arm received courses through Zoom). Finally, we did not include an inactive control group for comparison (e.g., usual care, waiting list control), which was, however, suggested to have potential disadvantages such as lack of control for non-specific treatment effects and ethical issues related to delay of treatment [55].

In a recent review on non-pharmacological interventions for ADHD in children and adolescents, Sibley et al. [1] recommended mindfulness training as secondary pediatric ADHD treatments due to its modest efficacy. As the largest trial in evaluating mindfulness training for children and adolescents with ADHD together with their parents, the current study adds further evidence on the potential positive effects, albeit mild to moderate, of mindfulness in improving children's ADHD-associated attentional and behavioral problems and parents' well-being despite several limitations described above. Future studies should validate the present findings by using an RCT with a non-inferiority design, a larger sample size, and a longer follow time and be conducted under the context without the impact of COVID-19 on social restrictions where the follow-up completion of all outcome assessments are less affected. We shall also look into participant's intervention match to assess who may be most suitable to participate in mindfulness-based interventions versus other evidence-based interventions for children and their parents affected by ADHD. For example, the pragmatic quasi-experimental wait-list study conducted in the Netherlands showed that children of fathers who were above but not below the ADHD threshold showed greater improvements than children of fathers below the threshold [52]. In this study, most parents were mothers. Future studies may consider to target fathers with ADHD symptoms and their children. Future studies may also look into different modes of family training; e.g., fathers and/or mothers are pre-trained to guide the mindfulness practices at home or join regular reunion sessions after training to boost the effects after the 8-week course [56]. As this study included children aged 8–12 years, future study may also examine children beyond this age group.

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Statement of Ethics

This study protocol was reviewed and approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CREC), approval number 2015.193. Written informed consent was obtained from all participating children and parents.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

S.Y.S.W., S.K.C.C., and D.Z. contributed to literature review and development of the original study design. S.M.B., S.K.C.C., H.H.M.L., and S.Y.S.W. contributed to intervention design, training, and implementation. W.W. contributed to data cleaning and analyses. S.K.C.C. finalized the statistical analysis and drafted the initial manuscript under S.Y.S.W.'s and B.H.K.Y.'s supervision. S.Y.S.W. finalized the manuscript. All authors have read, revised, and approved the final manuscript.

Data Availability Statement

In order to protect the privacy of participating parents and children, we did not make the data presented in this study publicly available. Access to data may be obtained by contacting the corresponding author.

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