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A randomised controlled trial (MindChamp) of a mindfulness-based intervention for children with ADHD and their parents

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Background: Family mindfulness-based intervention (MBI) for child attention-deficit/hyperactivity disorder (ADHD) targets child self-control, parenting and parental mental health, but its effectiveness is still unclear. **Methods:** MindChamp is a pre-registered randomised controlled trial comparing an 8-week family MBI (called 'MYmind') in addition to care-as-usual (CAU) ($n = 55$) with CAU-only ($n = 48$). Children aged 8–16 years with remaining ADHD symptoms after CAU were enrolled together with a parent. Primary outcome was post-treatment parent-rated child self-control deficits (BRIEF); post hoc, Reliable Change Indexes were explored. Secondary child outcomes included ADHD symptoms (parent/teacher-rated Conners' and SWAN; teacher-rated BRIEF), other psychological symptoms (parent/teacher-rated), well-being (parent-rated) and mindfulness (self-rated). Secondary parent outcomes included self-ratings of ADHD symptoms, other psychological symptoms, well-being, self-compassion and mindful parenting. Assessments were conducted at post-treatment, 2- and 6-month follow-up. **Results:** Relative to CAU-only, MBI+CAU resulted in a small, statistically non-significant post-treatment improvement on the BRIEF (intention-to-treat: $d = 0.27$, $p = .18$; per protocol: $d = 0.33$, $p = .11$). Significantly more children showed reliable post-treatment improvement following MBI+CAU versus CAU-only (32% versus 11%, $p < .05$, Number-Needed-to-Treat = 4.7). ADHD symptoms significantly reduced post-treatment according to parent (Conners' and SWAN) and teacher ratings (BRIEF) per protocol. Only parent-rated hyperactivity impulsivity (SWAN) remained significantly reduced at 6-month follow-up. Post-treatment group differences on other secondary child outcomes were consistently favour of MBI+CAU, but mostly non-significant; no significant differences were found at follow-ups. Regarding parent outcomes, significant post-treatment improvements were found for their own ADHD symptoms, well-being and mindful parenting. At follow-ups, some significant effects remained (ADHD symptoms, mindful parenting), some additional significant effects appeared (other psychological symptoms, self-compassion) and others disappeared/remained non-significant. **Conclusions:** Family MBI+CAU did not outperform CAU-only in reducing child self-control deficits on a group level but more children reliably improved. Effects on parents were larger and more durable. When CAU for ADHD is insufficient, family MBI could be a valuable addition. **Keywords:** ADHD; mindfulness; executive functions; parenting.

Introduction

Attention-deficit/hyperactivity disorder (ADHD) is a common neurodevelopmental disorder with a worldwide prevalence of about 5% in children (Polanczyk, de Lima, Horta, Biederman, & Rohde, 2007). Its multi-factorial aetiology, diverse neurocognitive impairments and co-occurring problems make ADHD a complex and heterogeneous disorder (Luo, Weibman, Halperin, & Li, 2019). Self-control deficits in everyday life, such as problems with controlling impulses, switching attention, regulating emotional responses, initiating and organising tasks, impact functioning of children with ADHD (Toplak, Bucciarelli, Jain, & Tannock, 2008). Ratings of child self-control are an important predictor for health, wealth, academic, occupational and crime outcomes years later (Barkley & Fischer, 2011; Daly, Delaney, Egan, & Baumeister, 2015; Langberg, Dvorsky, & Evans, 2013; Moffitt et al., 2011). Therefore, improving self-control is an essential treatment target for ADHD.

Current best practices for child ADHD treatment comprise psychoeducation, pharmacotherapy and/or (cognitive-) behavioural treatments (NICE, 2018). Pharmacotherapy can reduce ADHD symptoms, improve quality of life and adaptive functioning (Coghill, Banaschewski, Soutullo, Cottingham, & Zuddas, 2017), and increase executive function (Isquith, Roth, Kenworthy, & Gioia, 2014; Tamminga, Reneman, Huizenga, & Geurts, 2016).

†Shared second authorship.

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However, pharmacotherapy is ineffective for 20%-35% of children with ADHD (Childress & Sallee, 2014). Further disadvantages include low adherence (around 25% (Brinkman, Simon, & Epstein, 2018)), adverse effects (Storebo et al., 2015) and uncertainty about long-term effect (Swanson, 2019). Meta-analytic evidence of non-pharmacological treatments shows small reductions in core ADHD symptoms which turn non-significant when using probably-blinded raters such as teachers (Sonuga-Barke et al., 2013).

Response to child ADHD treatment is also influenced by parental symptoms of ADHD or depression which are more frequent among parents with a child with ADHD (Deault, 2010; Rasmussen et al., 2018). Parental psychopathology is associated with more negative (e.g. harsh, lax, disengaged) and less positive parenting, more severe child psychopathology, persistence of child ADHD symptoms into adulthood and lower child's quality of life (Agha, Zammit, Thapar, & Langley, 2017; Efron, Furley, Gulenc, & Sciberras, 2018; Park, Hudec, & Johnston, 2017; Roy et al., 2016). Positive parenting (i.e. emotional support, intellectual stimulation, and affection) and family climate (i.e. active recreational organisation and cohesion) are protective factors for children with ADHD symptoms (Dvorsky & Langberg, 2016; Wustner et al., 2019). A meta-analysis of RCTs on behavioural interventions for child ADHD, including parent training, found medium positive effects on parenting quality, small improvements in parenting self-concept, but no effect on depression/anxiety or well-being of parents (Daley et al., 2014).

Mindfulness-based intervention (MBI) may reach children that insufficiently respond to current best practices in ADHD treatment. MBIs directly target self-control and can elicit positive effects on psychological symptoms and behaviour of children and parents (e.g. (Burgdorf, Szabo, & Abbott, 2019; Wielgosz, Goldberg, Kral, Dunne, & Davidson, 2019)). Improving neurocognitive functions is considered to be one possible working mechanism of MBIs (Wielgosz et al., 2019), supported by neuroimaging studies (Tang, Holzel, & Posner, 2015).

A meta-analysis on MBIs for ADHD found medium reductions in inattentiveness ($d = -0.66$) and hyperactivity/impulsivity ($d = -0.48$) in youth, but included studies without control-group or randomisation and small sample sizes (Cairncross & Miller, 2020). Another meta-analysis including only randomised controlled trials (RCTs) focussed on both mindfulness and yoga-based interventions and found a medium reduction in inattentiveness ($g = -0.52$) and a small reduction in hyperactivity/impulsivity ($g = -0.40$) in youth (Zhang, Diaz-Roman, & Cortese, 2018). Three subsequent RCTs studying MBIs in the treatment of youth with ADHD found significant reductions in parent-rated ADHD symptoms (Behbahani, Zargar, Assarian, & Akbari, 2018), teacher-rated ADHD symptoms (Muratori et al., 2020), and improvements in emotional self-regulation (Huguet, Izaguirre Eguren, Miguel-Ruiz, Vall Valles, & Alda, 2019) and a sustained attention task (Muratori et al., 2020).

Mindful parenting training is a specific type of MBI in which parents intentionally bring mindful awareness to the parent–child relationship (Bögels & Restifo, 2014). Parents develop qualities such as listening with full attention to the child, self-regulation in the parenting relationship, compassion for self and child, and non-judgmental acceptance and emotional awareness of self and child (Duncan, Coatsworth, & Greenberg, 2009). A review and meta-analysis showed that mindful parenting training can decrease psychological distress (Rayan & Ahmad, 2017) and parenting stress (Burgdorf et al., 2019). However, RCTs on MBI as treatment for children with ADHD that included parental outcomes are scarce. Behbahani et al., (2018) compared the addition of a mindful parenting training with pharmacotherapy for children with pharmacotherapy-only and found significant reductions in parenting stress. Lo et al., (2017) compared a family MBI with waitlist-control for young children and their parents and found small positive effects on parenting stress and parental well-being, but no significant effect on parental ADHD symptoms and mindful parenting.

MindChamp examines the effectiveness of a family MBI (called 'MYmind') as an add-on to care-as-usual (CAU) for ADHD. We addressed limitations of previous RCTs by conducting a pre-registered well-powered RCT, in which the actual treatment received in both groups was documented and probably-blinded raters (teachers) were included. Short- and long-term treatment effects in both youth (8–16 years) and parents were assessed. Further, because the effects of MBI can be heterogeneous, as shown in our qualitative study (Siebelink et al., 2020), we explored response to treatment on both individual and group levels. Our primary outcome was post-treatment parent-rated self-control deficits of the child. Secondary child outcomes include parent- and teacher-rated ADHD and other psychological symptoms, parent-rated well-being and self-rated mindfulness. Secondary parent outcomes include self-rated ADHD and other psychological symptoms, well-being, self-compassion and mindful parenting.

Methods

Trial design

MindChamp (Mindfulness training for Children with ADHD and Mindful Parenting) is a pre-registered parallel group RCT, where a family MBI in addition to CAU (MBI+CAU) is compared with CAU-only (Siebelink et al., 2018). Assessments took place at baseline (T0), post-treatment (T1), two (T2) and six month (T3) follow-up. A selection of outcomes was collected at T2 and all but the teacher-rated outcomes at T3. Medical ethical approval for the protocol was given by the CMO Arnhem-

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Nijmegen, registration: 2015-1938. ClinicalTrials.gov registration: NCT03220308.

Participants

Children (aged 8–16 years) with a primary ADHD diagnosis and one of their parents were recruited. ADHD was clinically diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or DSM-IV) (American Psychiatric Association, 2013), confirmed with a structured interview conducted by trained researchers. ADHD medication was allowed if a stable dose was reached two weeks prior to inclusion. Children were eligible when they had remaining ADHD symptoms (average score>1.0 on the investigator-rated Conners' DSM-5 items) after prior CAU. Exclusion criteria for child and parent were: a) current psychosis, bipolar illness, active suicidality, untreated posttraumatic stress disorder or substance use disorder; b) estimated IQ<80; c) not Dutch-speaking; d) participated in an ≥8-week MBI in the past year or ever in a mindful parenting course; e) current participation in another intervention study. See Siebelink et al., (2018) for an extensive protocol description.

Procedure

Study settings and ethical considerations. Recruitment took place between January 2016 and June 2018 at a specialised child- and adolescent psychiatry clinic in the Netherlands. Recruitment ended when the target was met and the group size of the last MBI was sufficient. Written informed consent was obtained.

Randomisation and blinding. Randomisation with a 1:1 ratio was performed prior to T0 using a website developed by an independent statistician. Families and teachers were instructed not to communicate with each other about the allocation to achieve probably-blinded teacher ratings.

Treatment

Family MBI. MYmind is a protocolised family MBI specifically focussing on problems of children with ADHD and their parents (Bögels, 2020; van der Oord, Bögels, & Peijnenburg, 2012). Eight weekly 90-minute group sessions are followed by a booster session eight weeks later. Child-groups are led by a mindfulness teacher and a co-teacher; their parents participate in a parallel group with another mindfulness teacher, and sometimes the child- and parent-group meet. Homework of approximately 30–45 min/day for parents and 15 min/day for children is provided with workbooks and guided meditations.

The intervention was preceded by an individual introductory family interview of about 45 min with one of the mindfulness teachers. The mindfulness teachers met internationally agreed standards for good practice of the UK Network for Mindfulness-Based Teachers (2011). They were additionally trained in the MYmind programme and supervised during the whole trial by MYmind developer SB. Protocol adherence and mindfulness teacher competence were evaluated using the MBI:TAC (Crane et al., 2013) by an independent rater (see Appendix S1).

Care-as-usual. All children received treatment for ADHD prior to study participation (Table 1). At baseline, 81% of the children used ADHD medication. During the study, participants were allowed to seek outside treatment with the exception of MBI. Medication use and healthcare utilisation (number of general practitioner and psychiatric care visits) of child and parent were reported.

Measures

Extensive descriptions of the measures and their references are provided in Appendix S2. Measures with a Cronbach's alpha internal consistency below .70 at baseline were dropped post hoc.

Primary outcome. Child's *ADHD symptoms* were rated by parents using the 75-item Behaviour Rating Inventory of Executive Function (BRIEF) (Gioia, Isquith, Guy, & Kenworthy, 2000; Smidts & Huizinga, 2009) as a measure of self-control deficits. Cronbach's alpha internal consistency was excellent (.93).

Secondary child outcomes. Parents rated child's DSM *ADHD symptoms* – inattentiveness (9 items) and hyperactivity impulsivity (9 items) (α = .82 and .86, respectively) – using the Conners' Parent Rating Scale (CPRS) and the Strengths and Weaknesses of ADHD symptoms and Normal behaviour scale (SWAN) (α = .82 and .91). The SWAN is a more innovative and exploratory measure scored on a 7-point scale which may be more sensitive to capturing treatment effects because of wider possible range of scores. Further, parents rated child's *other psychological symptoms* including oppositional behaviour (10 items; α = .88), anxious-shy behaviour (8 items; α = .78), social problems (5 items; α = .78) and emotional lability (3 items; α = .73) using the CPRS, autism-symptoms using the 65-item Social Responsiveness Scale (α = .92), sleep problems assessed with a 2-item standard clinical care scale; and *well-being* using the 10-item KIDSCREEN (α = .76).

Teachers rated *ADHD symptoms* including child self-control deficits (75-item BRIEF) (α = .96) and inattentiveness and hyperactivity impulsivity using the 18 DSM items of the Conners' Teacher Rating Scale (CTRS) (α = .89 and .90) and SWAN (α = .88 and .93); and *other psychological symptoms* including oppositional behaviour (6 items; α = .86), anxious-shy behaviour (6 items; α = .73), social problems (5 items; α = .91), emotional lability (4 items; α = .71) (CTRS) and autism-symptoms (65-item Social Responsiveness Scale) (α = .93).

Children rated their own *mindfulness skills* with the 10-item Child and Adolescent Mindfulness Measure (α=.71).

Secondary parent outcomes. All parent outcomes were self-rated. *ADHD symptoms* were assessed using the 75-item BRIEF–Adult Version as a measure of self-control deficits (α = .96), and the 23-item ADHD DSM-IV Rating Scale (ARS) of inattentiveness and hyperactivity impulsivity (α = .84 and .77). *Other psychological symptoms* were assessed using the 21-item Depression Anxiety Stress Scale (α = .89) and the 5-item Brooding subscale of the Ruminative Response Scale (α = .81). Parental *well-being* included quality of life assessed with the 5-item World Health Organization Well-Being Index (WHO-5) (α = .87) and positive mental health with the 14-item Mental Health Continuum-Short Form (MHC-SF) (α = .87). *Self-compassion* was assessed with a 6-item short version of the Self-Compassion Scale (α = .70) and *mindful parenting* with the 29-item Interpersonal Mindfulness in Parenting scale (α = .85).

Baseline characteristics. Demographics were collected via a standard questionnaire used in the clinic, together with a short survey prior to baseline completed by parents (Appendix S2). In case no valid IQ test result was available, full-scale IQ was estimated by two subtests of WISC-III or WAIS-III: Vocabulary and Block Design. If parents scored ≥25 (moderate) on the 10-item Kessler Psychological Distress Scale (K10) (α = .89) the structured Mini-International Neuropsychiatric Interview (MINI) was administered. To judge severity of baseline child symptoms, T-scores were determined (normal: T < 60,

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Table 1 Baseline sociodemographic and clinical characteristics of children and parents

Baseline characteristics		MBI+CAU (n = 55)	CAU-only (n = 48)
Sex child	Female n (%)	16 (29)	15 (31)
Age child	Years M (SD)	11.0 (1.8)	11.4 (1.8)
IQ child	Total M (SD)	104.8 (15.5)	101.3 (13.7)
Socioeconomic status[a]	Lower–Middle n (%)	10 (18)	9 (19)
	Middle n (%)	14 (25)	13 (27)
	Middle–Higher n (%)	31 (56)	26 (54)
Sex parent	Female n (%)	37 (69)	33 (69)
Age parent	Years M (SD)	43.0 (5.9)	43.8 (5.0)
IQ parent (n = 50;46)	Total M (SD)	106.7 (16.7)	102.9 (17.0)
Employment status	Employed n (%)	47 (87)	41 (85)
	Unemployed n (%)	1 (2)	5 (10)
	Other[b] n (%)	6 (11)	2 (4)
Marital status	Married n (%)	41 (76)	39 (81)
	Divorced n (%)	13 (24)	7 (15)
	Widowed n (%)	0 (0)	2 (4)
Clinical characteristics child			
Self-control deficits (BRIEF)	T-scores M (SD)	63.5 (7.5)	62.8 (8.7)
Inattentiveness (CPRS)	T-scores M (SD)	66.0 (9.4)	65.8 (9.9)
Hyperactivity impulsivity (CPRS)	T-scores M (SD)	69.7 (12.4)	70.8 (12.8)
Oppositional behaviour (CPRS)	T-scores M (SD)	57.2 (9.3)	59.2 (11.6)
Anxious-shy behaviour (CPRS)	T-scores M (SD)	59.2 (10.4)	59.0 (13.4)
Other co-occurrence	Autism (diagnosed/suspected) n (%)	4/4 (7/7)	4/2 (8/4)
	Tic Disorder n (%)	2 (4)	2 (4)
	Dyslexia n (%)	14 (25)	11 (23)
Current/previous treatment for child ADHD			
Current ADHD medication	Yes n (%)	45 (82)	38 (79)
Previous use ADHD medication	Yes n (%)	50 (91)	44 (92)
Previous ADHD psychoeducation	Yes n (%)	34 (62)	30 (63)
Previous other ADHD treatment(s)	Yes n (%)	39 (71)	35 (73)
Clinical characteristics parent			
Psychological distress (K10)	M (SD)	17.2 (6.5)	16.8 (5.7)
Current depressive episode[c]	Yes n (%)	1 (2)	1 (2)
Current anxiety disorder[c]	Yes n (%)	4 (7)	2 (4)
Current ADHD[d]	Yes n (%)	7 (13)	5 (10)

BRIEF, Behaviour Rating Inventory of Executive Function; CAU, care-as-usual; CPRS, Conners' Parent Rating Scale; K10, 10-item Kessler Psychological Distress Scale; MBI, mindfulness-based intervention.
[a]Based on educational level of both parents.
[b]Houseman/-wife or N.A.
[c]Based on Mini-International Neuropsychiatric Interview (MINI), administered when K10≥25.
[d]Based on MINI, current use of ADHD medication or ARS (a score 'often' or 'very often' on ≥5/9 inattentiveness and/or ≥5/9 hyperactivity-impulsivity DSM items).

subclinical: T = 60–64, clinical: T ≥ 65). Demographic and clinical characteristics are in Table 1 and Table S1a and b.

Statistical analyses

Data were analysed using R (R Core Team, 2019), and reported according to CONSORT guidelines (Schulz, Altman, & Moher, 2010). To investigate both the effect of the assigned and actually received intervention, the main analyses (ANCOVAs) were conducted on intention-to-treat (ITT) and per-protocol (PP) samples. The latter consisted of completers (attended ≥4 MYmind sessions) plus control-group participants who adhered to not seeking outside MBI. Handling of missing data is described in Appendix S3.

Sample size calculation. Power analyses were based on the assumption that MBI, relative to control, will lead to improvement in self-control deficits at T1 with an effect size of 0.4 (power of 80%, two-tailed α = .05). N = 50 families per group (total N = 100) was taken as recruitment target.

Analyses of the primary outcome. Our primary analysis was an ANCOVA comparing post-treatment BRIEF scores between the two groups with baseline BRIEF scores as covariate. Cohens' d effect size was calculated by dividing the adjusted group difference at T1 by the readjusted standard deviation (SD) defined as:

$$SD(\text{within}) = \frac{\sqrt{(n[\text{MBI}]-1)*(SD[\text{MBI}])^2 + (n[\text{control}]-1)*(SD[\text{control}])^2}}{n[\text{MBI}]+n[\text{control}]-2}$$

To understand the pattern of individual response, we calculated the Reliable Change Index (RCI) (Jacobson & Truax, 1991) for the BRIEF pre–post-treatment change scores in the

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ITT sample. Cronbach's α was used for calculating the standard error of the difference between T0 and T1 scores. The differences between groups in the number of children who reliably improved (RCI < −1.96), deteriorated (RCI>1.96) or did not change was tested with χ^2. In addition, the Number-Needed-to-Treat was calculated by taking the inverse of the Absolute Risk Reduction (ARR), where ARR is the percentage of children that did not show statistically reliable improvement in the control-group minus this percentage in the intervention-group.

To explore long-term treatment effects (at T2 and T3), ANCOVAs were conducted with group and baseline scores as independent variables, like the primary analysis. We repeated this analysis using a two-way repeated-measures ANOVA, which neither changed our results nor our conclusions (Appendix S4).

Analysis of secondary outcomes. Secondary outcomes at T1, T2 and T3 were analysed with ANCOVAs in the same manner as the primary outcome, except child sleep problems which were analysed with binary logistic regressions with group and baseline scores as independent variables. All analyses on secondary outcomes are considered exploratory, for which no correction for multiple comparisons is indicated (Feise, 2002).

Complementary analyses. We explored associations between baseline child variables (age, sex, IQ, medication at T0 (yes/no), inattentiveness, hyperactivity impulsivity, autism-symptoms, oppositional behaviour and anxious-shy behaviour) and treatment response (Appendix S5 and Table S2). Further, Spearman's correlation coefficients were calculated within the MBI group between change on the primary outcome and (a) MBI home practice adherence (Appendix S6), (b) change in mindful parenting.

Results

Sample and treatment characteristics

Participants. Ultimately, 55 families were randomly allocated to MBI+CAU and 48 to CAU-only, resulting in $N = 103$ (Figure 1). Self-report data from one father in the MBI group were excluded from analyses because of inadequate Dutch reading skills.

Treatment. Twelve family MBI courses were provided with four to eight families per group. No significant effect of MBI course-group on the primary outcome was found ($F(11, 40) = 0.87$; $p = .57$). On average 6.9 ($SD = 1.7$) and 6.8 ($SD = 1.7$) of eight sessions were attended by children and parents, respectively. Fifty families (91%) completed the MBI (i.e. ≥4 sessions). Twenty-four families (44%) attended the booster session. MBI home practice adherence is presented in Table S3. The average MBI:TAC score for parent sessions was 4.1 ($SD = 0.76$) and for child sessions 3.5 ($SD = 1.00$), where a score of 1 refers to 'incompetent' and 6 to 'advanced'.

Medication use and healthcare utilisation of children and parents during study participation did not differ between MBI and CAU (Appendix S7, Table S4a–d).

No CAU- or MBI-related Serious Adverse Events were spontaneously reported by the participants or mindfulness teachers.

Primary outcome

Our primary analysis revealed that children in the MBI group showed better self-control at post-treatment than those in the CAU group, but not statistically significant (ITT: $d = 0.27$, $p = .18$; PP: $d = 0.33$, $p = .11$) (Table 2, full version in the Table S5a and b). The number of children that reliably changed from pre- to post-treatment was significantly larger in the MBI than in the CAU group, χ^2 (2, $N = 100$) = 7, $p = .03$) (Figure 2 and Table 3). The Number-Needed-to-Treat was 4.7. Regarding long-term effects, mean-based group differences first increased at 2-month follow-up, and then decreased again at 6-month follow-up, but remained non-significant in both the ITT and PP analyses (Table 2).

Secondary outcomes

For all secondary outcomes, ITT results at post-treatment are described first, followed by those at follow-up, and finally the PP results. Described effects are always relative to the control condition. Tables focus on child ADHD symptoms and parent outcomes; other child outcomes are presented in the Supporting Information.

Parent-rated child outcomes. Group differences on DSM *ADHD symptoms* (CPRS) were not statistically significant in the ITT sample at all timepoints (Table 2). SWAN results were similar to CPRS for inattentiveness, but for hyperactivity-impulsivity group differences were larger and significant in favour of MBI at post-treatment and 6-month follow-up. According to the PP analyses, significant improvement was observed for inattentiveness at post-treatment (CPRS) and for hyperactivity impulsivity at post-treatment (CPRS and SWAN) and 6-month follow-up (SWAN).

Post-treatment group differences on *other psychological symptoms* were consistently in favour of the MBI group and significant for anxious-shy behaviour and problems falling asleep, but non-significant for oppositional behaviour, social problems, emotional lability, autism symptoms and sleeping less than peers. The post-treatment effect on *well-being* was non-significant. At 2- and 6-month follow-up, no significant differences in other psychological symptoms and well-being between the two groups were found. The analyses with the PP sample yielded similar results. (Table S6a).

Teacher-rated child outcomes. In the ITT sample, self-control deficits were lower following MBI, but this group difference did not reach significance. No significant post-treatment effects were found for the other *ADHD symptoms* and *other psychological symptoms*. At follow-up, also no significant effects were found. In the PP sample, self-control deficits

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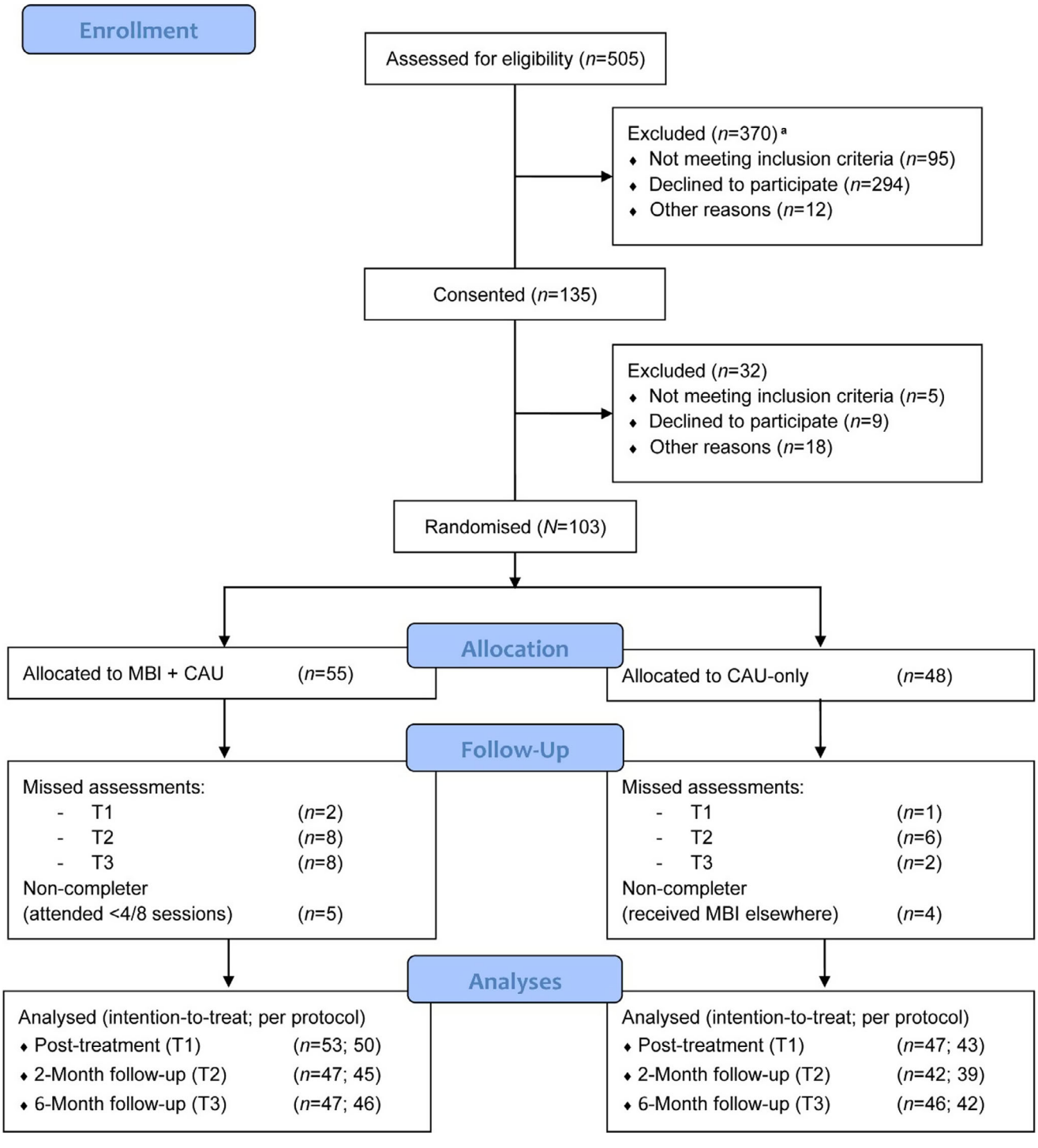

Figure 1 Participant flow through the study. Note. MBI, mindfulness-based intervention; CAU, care-as-usual. [a]Multiple reasons possible, numbers do not add up

were significantly improved post-treatment. (Table 2 and Table S6b).

Self-rated child outcome. No significant differences were found on *mindfulness skills* at any timepoint (PP and ITT) (Table S6c).

Self-rated parent outcomes. At post-treatment, *ADHD symptoms* were reduced, with larger and significant group differences for hyperactivity impulsivity, and smaller group differences for inattentiveness (non-significant) and self-control deficits (significant) (Table 4). Regarding *other psychological symptoms*, no significant post-treatment effects occurred. *Well-being* significantly improved at post-treatment according to the WHO-5 but not the MHC-SF scale. Post-treatment group differences in favour of MBI+CAU were found for *self-compassion* (non-significant) and *mindful parenting* (significant). For both a significant interaction was found between group and baseline outcome scores. This indicated a larger positive MBI effect compared with control for

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Table 2 Treatment effects of family MBI+CAU compared with CAU-only on parent- and teacher-rated child ADHD symptoms at post-treatment (T1), two (T2) and six month (T3) follow-up compared with baseline. Abbreviated table (In full: Table S5a and b)

	Intention-to-treat			Per-protocol		
	Cohen's *d* effect size[a]			Cohen's *d* effect size[a]		
Parent-rated ADHD symptoms	T1 (*N* = 100)	T2 (*N* = 89)	T3 (*N* = 93)	T1 (*N* = 93)	T2 (*N* = 84)	T3 (*N* = 88)
Self-control deficits	*0.27*	0.36†	0.21	*0.33*	0.38†	0.22
Inattentiveness (CPRS)	0.32	0.42†	0.19	**0.42***	0.39†	0.26
Inattentiveness (SWAN)	0.36	—	0.14	0.39†	—	0.12
Hyp-imp (CPRS)	0.39†	0.04	0.20	**0.43***	0.09	0.21
Hyp-imp (SWAN)	**0.54***	—	**0.64****	**0.75****	—	**0.70****
Teacher-rated ADHD symptoms	(*N* = 92)	(*N* = 79)		(*N* = 84)	(*N* = 72)	
Self-control deficits	0.36†	−0.04	—	**0.52***	0.07	—
Inattentiveness (CTRS)	0.07	−0.29	—	0.24	−0.22	—
Inattentiveness (SWAN)	0.07	—	—	0.15	—	—
Hyp-imp (CTRS)	−0.02	−0.02	—	0.15	0.14	—
Hyp-imp (SWAN)	0.03	—	—	0.07	—	—

Italic values: primary analysis. CP/TRS, Conners' Parent/Teacher Rating Scale; Hyp-imp, hyperactivity impulsivity; SWAN, Strengths and Weakness of ADHD Symptoms and Normal behaviour.
Significance of main effects: $^{\dagger}p < .10$, $^{*}p < .05$, $^{**}p < .01$.
[a]Displayed positively when the effect is in favour of MBI+CAU (e.g. fewer symptoms).

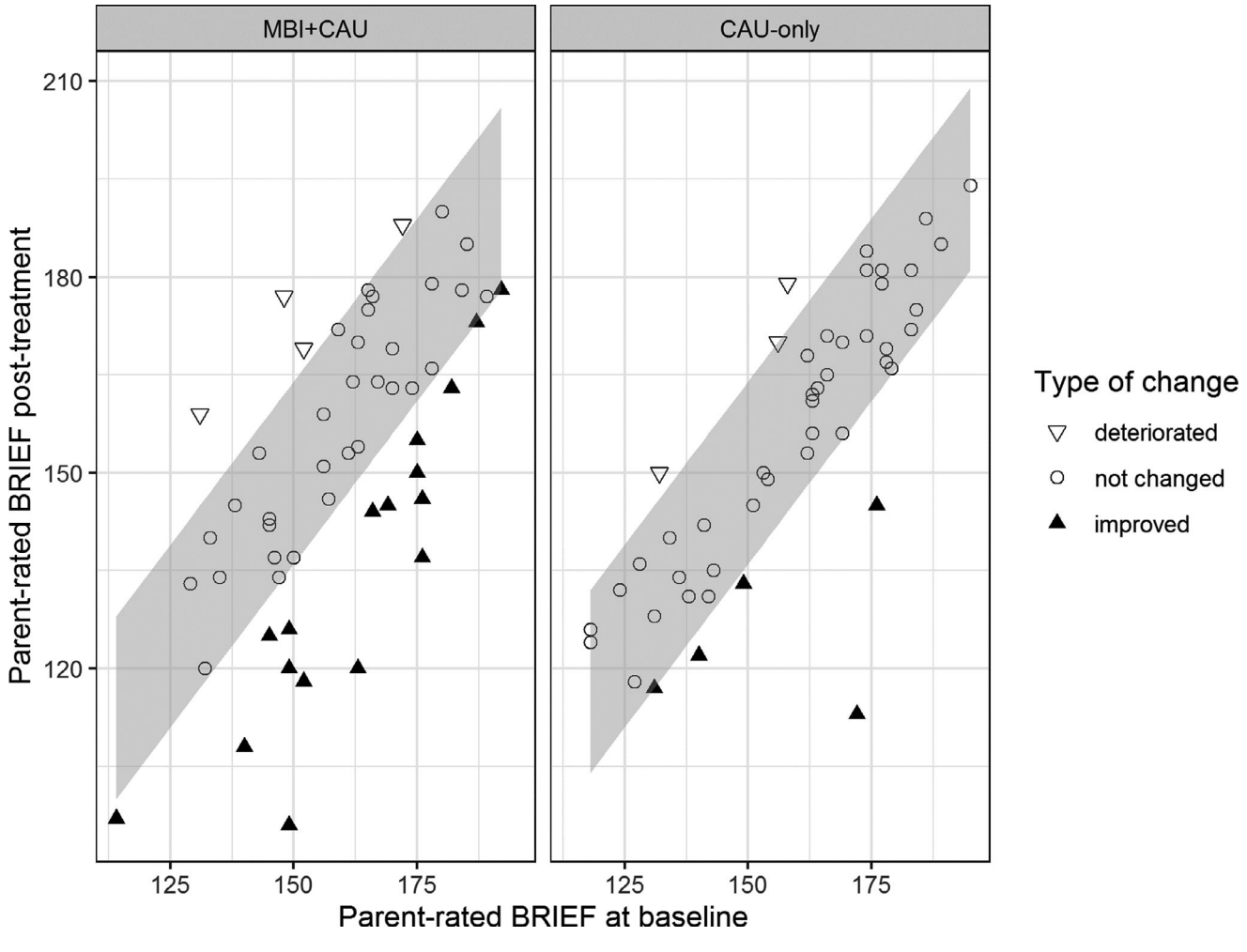

Figure 2 Parent-rated self-control deficits (BRIEF) at baseline and post-treatment for children who received family MBI+CAU versus CAU-only. *Note*. The grey zone represents the 95% confidence interval of the Reliable Change Index

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Table 3 Pre- to post-treatment change of parent-rated child self-control deficits in the family MBI+CAU and CAU-only groups, based on the Reliable Change Index, also displayed in Figure 2

	Improved (▲)	Not changed (○)	Deteriorated (▽)
MBI+CAU, *n* (%)	17 (32)	32 (60)	4 (8)
CAU-only, *n* (%)	5 (11)	39 (83)	3 (6)

χ^2 (2, N = 100) = 7, p = .03.

parents with lower pre-treatment self-compassion or mindful parenting scores.

At follow-ups, the improvement of self-control and hyperactivity impulsivity decreased, but the effect on inattentiveness remained stable (Table 4). Improvement of depression anxiety stress at 6-month follow-up was significantly greater in the MBI group; brooding was not different between the two groups. There were no significant group differences in well-being at follow-up. The treatment effect on self-compassion increased with time and was significant at 6-month follow-up; the significant heterogeneity of regression slopes remained. The treatment effect on mindful parenting slightly decreased but remained significant.

The results of the PP analyses were comparable to ITT, with somewhat larger effects for parental inattentiveness (significant at both post-treatment and 6-month follow-up), depression anxiety stress, and self-compassion (Table 4).

Complementary analyses

Higher age, less oppositional behaviour and lower IQ were significantly associated with a larger post-treatment reduction in self-control deficits in both groups, but no differential predictors were detected (Appendix S5). In addition, no significant differences were found between responders and non-responders in the MBI group (Table S2). No significant correlations were found between change of child self-control deficits and MBI home practice adherence (Table S3). Further, reduction in child self-control deficits was not significantly correlated with improvement of mindful parenting at T1 (r_s = −.17; p = .24) and T2 (r_s = −.14; p = .38) but did significantly correlate at T3 (r_s = −.34, p = .02).

Discussion

This RCT examined the effectiveness of a family MBI for children with ADHD who had remaining symptoms after prior treatment and their parents. We hypothesised that parent-rated self-control deficits of the child would significantly reduce following MBI compared with CAU-only. This primary hypothesis was not confirmed, as the small positive post-treatment effect was non-significant. However, the number of children who reliably improved on the primary outcome was higher in the MBI than CAU group, with a Number-Needed-to-Treat of about five. Regarding secondary outcomes for children, we found significant small to medium post-treatment effects on parent-rated inattentiveness (PP only), hyperactivity impulsivity, anxious-shy behaviour, problems falling asleep and teacher-rated self-control deficits (PP only). Treatment effects were generally smaller or absent at follow-ups. Regarding secondary outcomes for parents, significant small to large effects on ADHD symptoms and medium effects on quality of life and mindful parenting were found at post-treatment in favour of MBI. At follow-

Table 4 Treatment effects of family MBI+CAU compared with CAU-only on self-rated parent outcomes at post-treatment (T1), two (T2) and six month (T3) follow-up compared with baseline. Abbreviated table (In full: Table S7)

	Intention-to-treat			Per=protocol		
	Cohen's *d* effect size[a]			Cohen's *d* effect size[a]		
	T1 (N = 98)	T2 (N = 86)	T3 (N = 92)	T1 (N = 92)	T2 (N = 81)	T3 (N = 87)
ADHD symptoms						
Self-control deficits	**0.41***	0.17	0.13	0.39†	0.14	0.16
Inattentiveness	0.40†	0.37†	0.37†	**0.49***	0.40†	**0.45***
Hyperactivity impulsivity	**0.72*****	**0.47***	0.37†	**0.79*****	**0.44***	0.40†
Other psychological symptoms						
Depression anxiety stress[c]	0.19	—	**0.42***	0.24	—	**0.51***
Brooding	−0.06	—	0.03 [b]	−0.06	—	0.07 [b]
Well-being						
Quality of life	**0.55****	—	0.25	**0.52***	—	0.33
Positive mental health	0.09	—	0.05	0.12	—	0.08
Self-compassion	0.30[b]	—	**0.66**** [b]	0.37†	—	**0.84***** [b]
Mindful parenting	**0.58**** [b]	**0.45***	**0.45***	**0.58****	0.44†	**0.45***

Significance of main effects: $^{\dagger}p < .10$, $^{*}p < .05$, $^{**}p < .01$, $^{***}p < .001$.

[a]Displayed positively when the effect is in favour of MBI+CAU.

[b]A significant covariate × group interaction effect was found, indicating a larger positive CAU-controlled treatment effect for those with worse scores at baseline.

[c]Only Depression-Anxiety-Stress (DASS-21) was based on square root transformed data.

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ups, significant small/medium positive effects were found on inattentiveness (PP only), hyperactivity impulsivity, depression anxiety stress, mindful parenting and slightly larger for self-compassion.

One third of children in the MBI group responded to the intervention (i.e. reliable pre–post improvement on the primary outcome). Our Number-Needed-to-Treat of five is considered low and comparable with that of pharmacotherapy for ADHD (Faraone, 2008). A similar response pattern was found in an RCT comparing MBI+CAU with CAU-only on core ADHD symptom decrease in adults (Janssen et al., 2019). Long-term follow-up research is necessary to study if MBI at child age could prevent ADHD symptom persistence into adulthood.

Compared with meta-analyses on MBI for youth with ADHD described in the introduction (Cairncross & Miller, 2020; Zhang et al., 2018), we found similar effects on child hyperactivity impulsivity, but smaller effects on inattentiveness. The high medication use (±80%) in our sample may have led to less room for improvement, mainly on inattentiveness for which pharmacotherapy is most effective (Storebo et al., 2015). In contrast with those of Cairncross and Miller (2020), clinical hyperactivity impulsivity was more common than clinical inattentiveness in our sample. The effect on hyperactivity impulsivity was larger according to the SWAN compared with the CPRS and remained at 6-month follow-up. Because of the wider response scale, the SWAN may have been better in capturing small improvements (Brites, Salgado-Azoni, Ferreira, Lima, & Ciasca, 2015). We found mainly non-significant small effect sizes for other child psychological symptoms, although MBIs can target other domains than ADHD symptoms in children as well (Dunning et al., 2019). A more homogeneous sample regarding co-occurring symptoms may yield larger effects. Further, in contrast to Dunning et al., (2019) we did not find any positive effect on children's mindfulness skills. We previously showed that attention captured by dispositional mindfulness scales is phenotypically and genetically distinct from attention as assessed with ADHD scales (Siebelink et al., 2018). This might be an explanation for the fact that ADHD symptom reduction was found despite a lack of improvement in dispositional mindfulness. However, self-report of dispositional mindfulness has also been criticised for insufficient validity and reliability (Van Dam et al., 2018).

According to probably-blinded ratings (teachers), we found positive effects on self-control deficits, but not on inattentiveness/hyperactivity impulsivity or other psychological outcomes. One other RCT on family MBI for ADHD included teacher ratings (Muratori et al., 2020). They found improved teacher-rated hyperactivity, but not conduct behaviour, of 8–12-year-old boys with ADHD and oppositional deviant disorder who did not receive pharmacotherapy. It is important to consider this in the context of the effects of current behavioural interventions for ADHD. These have been found non-effective in reducing core ADHD symptoms, but effective in reducing conduct problems in children with ADHD according to probably-blinded ratings (Daley et al., 2014). An upcoming trial may give more insight into the differential value of family MBI compared with behavioural interventions for ADHD, but does not include teacher ratings (Chan et al., 2018). Hence, future MBI and behavioural intervention trials that include teacher ratings are relevant.

MBI as a treatment of child ADHD is offered to the child and/or parent, but few studies examined effects on parent outcomes. Our results confirm preliminary findings that family MBI can reduce psychological symptoms of parents (Haydicky, Shecter, Wiener, & Ducharme, 2015; Lo et al., 2017; van de Weijer-Bergsma, Formsma, de Bruin, & Bögels, 2012; van der Oord et al., 2012). Few parents met criteria for a clinical disorder in our sample, but even reducing subclinical parental symptoms can be of benefit to their children with ADHD (Tarver, Daley, & Sayal, 2015). In contrast to the literature (Cairncross & Miller, 2020), post-treatment effects were larger for parental hyperactivity impulsivity than inattentiveness. The first MYmind studies, however, also showed a larger reduction in parental hyperactivity impulsivity and additionally large reductions in maternal over-reactivity (van van der Oord et al., 2012; de Weijer-Bergsma et al., 2012).

A systematic review of RCTs on group-based parenting programmes ($N = 4{,}937$) showed that short-term effects on parental depression anxiety stress were lost at follow-up (Barlow, Smailagic, Huband, Roloff, & Bennett, 2014). In contrast, our significant effect on depression anxiety stress only emerged at follow-up. A possible explanation is that it takes time to develop mindfulness and self-compassion which then reduce psychological symptoms (Sevel, Finn, Smith, Ryden, & McKernan, 2020). Notably, we found larger CAU-controlled treatment effects for parents who scored lower on self-compassion or mindful parenting at baseline. So, family MBI can enhance self-compassion and mindful parenting in those parents who need it most.

Future studies on moderators and mediators of MBI are important, as our study shows that not all children benefit from MBI. Although Dunning et al., (2019) found that older age was associated with larger treatment effect, we could not confirm this in our study even though we included a broad age range (8–16 years). The mindful parenting training component may have compensated the possible lack of effectiveness for the younger children. It would be interesting to look into more detail at relations within and between child- and parent outcomes. For example, Autoregressive Latent Trajectory models (Garland, Geschwind, Peeters, & Wichers, 2015) could be

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used to test autoregressive effects (e.g. parent-to-parent, child-to-child), and cross-lagged effects (e.g. parent-to-child, child-to-parent) across different timepoints.

Strengths and limitations

This is the first RCT studying family MBI as an addition to CAU for child ADHD. Strengths of this study are: its pre-registered RCT design with a sample based on power analyses; a protocolised intervention, provided by qualified mindfulness teachers; and assessment of other healthcare and medication use during the study period. Next to our primary outcome measure which is ecologically valid and has cross-disorder relevance (Sullivan & Riccio, 2007), we included a broad range of clinically relevant outcomes and more objective probably-blinded teacher ratings. Effects were assessed at short and longer term, up to 6 months following the end of treatment. Limitations are that participants could obviously not be blinded to treatment condition and most outcomes were based on 'subjective' rating scales. Future studies with a matched active control condition are necessary to examine whether effects are specific to MBI. Our assessment of adverse effects may be an underestimation due to relying on spontaneous reporting (Van Dam et al., 2018). However, active inquiry in our qualitative study that included a subsample of this RCT did not reveal any serious adverse effects either (Siebelink et al., 2020). Larger scale multisite studies are needed to confirm the effectiveness of MBI for children with ADHD and their parents.

Conclusion

Among children with ADHD and insufficient response to prior treatment, family MBI was not more effective than CAU-only in reducing mean parent-rated child self-control deficits at group level, but family MBI had added value in terms of the proportion of children who reliably improved. Moreover, beneficial effects on child ADHD symptoms were found for teacher-rated self-control deficits and parent-rated inattentiveness and hyperactivity impulsivity. In addition, family MBI may complement current treatment for families with a child with ADHD in terms of long-term improvement of parental psychological symptoms, self-compassion and mindful parenting.

Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article:

Appendix S1. Assessment of protocol adherence and mindfulness teacher competence.
Appendix S2. Measures.
Appendix S3. Handling of missing data.
Appendix S4. Longitudinal analyses of the primary outcome.
Appendix S5. Methods and results of predictor analyses.
Appendix S6. MBI home practice adherence.
Appendix S7. Healthcare use during study participation.
Table S1. Baseline sociodemographic and clinical characteristics.
Table S2. Comparison of responders and non-responders from the MBI group.
Table S3. MBI home practice adherence of parents and children and correlations between higher adherence and decrease in parent-rated child self-control deficits.
Table S4. Healthcare use during study participation.
Table S5. Full version of Table 2.
Table S6. Results of secondary child outcomes.
Table S7. Treatment effects of MBI+CAU compared with CAU-only on self-rated parental outcomes at post-treatment (T1), two (T2) and six month (T3) follow-up compared with baseline (full version of Table 4).

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J.B. has been in the past 3 years a consultant to / member of advisory board of / and/or speaker for Takeda/Shire, Roche, Janssen, Medice, Angelini and Servier. He is not an employee of any of these companies, and not a stock shareholder of any of these companies. He has no other financial or material support, including expert testimony, patents, royalties. S.B. is shareholder of UvA minds, in which MYmind is offered to families, and provides teacher training in MYmind to professionals. A.S. is the founder and clinical director of the Radboudumc Center for Mindfulness. The remaining authors have declared that they have no competing or potential conflicts of interest.

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Key points

- Previous findings in underpowered and partly uncontrolled studies show effects of mindfulness-based interventions (MBIs) on child ADHD symptoms.
- This is the first pre-registered randomised controlled trial studying the added value of a family MBI to care-as-usual (CAU) for children with remaining ADHD symptoms after prior treatment and their parents.
- Family MBI did not outperform CAU-only in reducing parent-rated child self-control deficits according to our primary (group-level) analysis.
- However, person-centred analyses revealed that one out of three children reliably improved on self-control following family MBI, whereas one out of ten improved following CAU-only: Number-Needed-to-Treat=4.7.
- Positive short- and long-term effects were found on parental mental health outcomes, parental self-compassion and mindful parenting.

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