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Child and Parent Mindfulness-Based Training Versus Medication for Childhood ADHD: A Randomised Clinical Trial

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Abstract

Objectives Medication is the predominant treatment for childhood attention-deficit hyperactivity disorder (ADHD) but has side effects and limited longer-term effects. Mindfulness for children and their parents could be an alternative as it targets children's core symptoms and supports parents. This study compared the effectiveness of a family mindfulness-based intervention to methylphenidate in children with ADHD.

Method We conducted a randomised controlled trial (RCT) and a preference trial (PT) for families who refused randomisation. Mindfulness ("MYmind") consisted of 2-months weekly group-based 1.5-hr mindfulness sessions for children and parallel mindful parenting for their parents, plus a follow-up session 2 months later. Medication concerned 4-months short-acting methylphenidate. Intention-to-treat (ITT) and per-protocol (PP) analyses were performed using multilevel modelling. Both parents and adolescents (not children) completed questionnaires on child ADHD pre-treatment, and at 2-, 4-, and 10-months follow-up, whereas teachers and blind observers completed these questionnaires at pre-treatment and 2-months follow-up only. Similarly, neuropsychological attention measures were administered pre-treatment and at 2-months follow-up only. **Results** In the RCT, 91 children with ADHD (M_{age} =11.29, range 9–18, 71% boys), 172 parents (91 mothers, 81 fathers), 81 teachers, and 85 observers participated, and in the PT, 29 children (M_{age} =11.57, 55% boys), 52 parents (28 mothers, 24 fathers), 24 teachers, and 26 observers. Medication was more effective than family mindfulness at 2 and 4 months on multi-informant questionnaires but not on objective (neuropsychological and blind observer) measures. Differences between treatments diminished at mid-term even though in the medication group treatment was continued after 2 months while the mindfulness training was already finished at 2 months. Differences between treatment groups disappeared at 10 months, but note that in the long-term, children from the mindfulness arm started taking medication and vice versa, so that we cannot be sure to what extent the long-term results are caused by mindfulness, medication, or its combination. Findings in the PT and according to PP analyses were similar. Note moreover that 1 in 4 children (26%) discontinued taking medication during the first 2 months versus almost no families (2%) discontinued mindfulness, suggesting that mindfulness was more easily accepted. Conclusions Overall, although mindfulness alone might not be sufficient for some families, family mindfulness training in general can be considered a non-pharmacological alternative or addition in the treatment of childhood ADHD.

Preregistration https://onderzoekmetmensen.nl/nl/trial/22179, 11.10.2013.

Keywords Childhood ADHD · Family mindfulness-based interventions · MYmind · Medication

Attention-deficit/hyperactivity disorder (ADHD) is very common in childhood (American Psychiatric Association, 2013). Children with ADHD show inattentive and/or impulsive and hyperactive behaviour that severely impacts

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their physical and mental health, and their cognitive, social, and family functioning (Danckaerts et al., 2010; Ruiz-Goikoetxea et al., 2018; Sciberras et al., 2009). Comorbid symptoms occur very frequently in children with ADHD; between 60 and 100% of these children also show signs of oppositional or conduct behaviour, or depression and anxiety (Gillberg et al., 2004). Further, it is known that children's ADHD symptoms severely affect parental quality of life and family functioning negatively (e.g., Peñuelas-Calvo et al., 2021). In addition to these large challenges on the personal



and family level, annual societal costs are extremely high: a study in the USA showed an annual cost of \$19.40 billion for children and \$13.80 billion for adolescents of costs associated with ADHD (Schein et al., 2022).

Effective treatment for ADHD is available. For children with ADHD and moderate impairments, or younger children, group-based behavioural parent training (BPT) is usually considered the first-line treatment for parents of the children with ADHD (e.g., National Institute for Health and Care Excellence [NICE], 2018). Meta-analyses examining the effectiveness of non-pharmacological interventions for ADHD generally show small to medium effect sizes on reducing core ADHD symptoms when assessed by individuals closest to the treatment but fail to demonstrate sufficient effectiveness with blinded measures (Daley et al., 2014; Sonuga-Barke et al., 2013). Parents are taught several behavioural techniques which in turn mediate reductions in child ADHD behaviour. A meta-analysis has shown that the most effective behavioural techniques are the ones that manipulate the triggers (antecedents) of the child behaviour and secondly, techniques that reinforce desired behaviour in the child (consequences) (Dekkers et al., 2022).

Although BPT is shown to be an effective intervention for ADHD and is therefore part of most international treatment guidelines (e.g., AACAP, 2007; NICE, 2018), meta-analyses also show that non-pharmacological interventions (such as BPT) are inferior compared to pharmacological treatment (Catalá-López et al., 2017; Van der Oord et al., 2008). Contradictory results were found on the additional value of psychological treatment to medication, as one meta-analysis showed the combined behavioural treatment with medication to be superior to medication alone (Catalá-López et al., 2017), but the other meta-analysis showed no additional value of psychological treatment in the reduction of ADHD symptoms as rated by teachers and parents (e.g., The Multimodal Treatment of ADHD (MTA) Cooperative Group, 2004; Van der Oord et al., 2008).

As for medication, efficacy and effectiveness (large effect sizes) of stimulants (methylphenidates) for childhood ADHD has been well documented (Maia et al., 2017; Shaw et al., 2012; Storebø et al., 2015). For more than 70% of children with ADHD, stimulant medication reduces inattention, hyperactivity, and impulsivity (Storebø et al., 2015). While guidelines stress the importance of environmental modifications, several clinical guidelines advise medication as treatment for childhood ADHD. The NICE guidelines state that medication is the first choice of treatment for children with severe ADHD (NICE, 2018).

A study examining trends in ADHD medication in different Western countries showed that usage was highest in 10–14-year-olds, particularly in the Netherlands (7.1%) and the USA (8.8%). While in European countries methylphenidate was most often used, in the USA, the

use of amphetamines was almost as common as the use of methylphenidate (Bachmann et al., 2017). Although medication for ADHD is widely used, it comes with disadvantages: severe side effects such as insomnia, loss of appetite, headache, anxiety, abdominal pain, and nervousness (e.g., Graham et al., 2011; Storebø et al., 2015). Another disadvantage is the low treatment adherence; systematic reviews show that overall 50%f people with ADHD chose to discontinue with their medication (Parkin et al., 2022), as well as the fact that symptoms return once medication is discontinued (Taylor et al., 2004). Further, medication is ineffective for 20–35% of children (Childress & Sallee, 2014). Finally, there is debate about whether it is effective in the long run (Swanson, 2019).

Although medication has been shown to effectively reduce symptoms of ADHD, with its substantial numbers of children taking these drugs worldwide and its significant disadvantages, it is desirable to have more effective non-pharmacological options available for these families. Mindfulness-based training is an innovative approach for children with ADHD and their families and targets the core symptoms of ADHD (Cairneross & Miller, 2016). Originally, mindfulness-based training aims to heighten one's awareness, improve concentration, and reduce ones' automatic responding (Kabat-Zinn, 2003). Mindfulness is sometimes translated as an attention training, in which practitioners learn to be aware of where their attention is, focus their attention intentionally on an anchor (e.g., body or breath), notice mind wandering, and then redirect their attention to whatever they intended to focus on. ADHD is characterised primarily by difficulties in attention, which therefore seems a logical fit with a mindfulness approach in which children learn to better control and deepen their attention and apply this skill in, for example, the classroom. Also, regarding hyperactivity and impulsivity, a mindfulness approach seems a logical fit. That is, during mindfulness training, children learn to become aware of thoughts, bodily feelings, emotions, and behaviour impulses (such as fidgeting or talking) rather than to instantly react, which can help them inhibit their first responses.

Some studies started to combine group-based BPT for parents of children with ADHD with mindfulness elements and it was found that parents in the BPT + mindfulness group had decreased harsh discipline practices and improved self-regulation compared to parents in the BPT only group. Both groups improved in parenting sense of competence and child ADHD symptoms and groups did not differ on mindful parenting or parenting stress. The authors concluded that enhancing regular BPT with mindfulness elements is beneficial for these families (Mah et al., 2021).

Mindful parenting training can be of additional value as parents learn to cope with the stress of parenting a child with ADHD; cultivate a more accepting, non-judgemental,



and non-reactive stance towards their child's behaviour; become mindful role models; help generalise mindfulness skills into children's daily life; and replenish their energy levels (Bögels et al., 2010; Emerson et al., 2019). As ADHD runs in families (Epstein et al., 2000; Yang et al., 2011), and children referred with ADHD have an eightfold chance that at least one of their parents has ADHD (Thapar et al., 2007), participating in the parallel mindful parenting training helps reduce parents' own ADHD symptoms, if present (Bögels et al., 2021).

Studies in the burgeoning field of mindfulness-based training for children with attention and hyperactivity/impulsivity problems or ADHD (and their parents) in a clinical setting show promising results. Reductions are found in child ADHD symptoms, externalizing and internalizing problems, stress, oppositional defiant problems, and conduct problems. Children's happiness, mindful awareness, compliance, and peer relationships improve. Effects obtained directly after training are generally maintained at follow-up measurements, ranging from 6-week to 1-year follow-up. Additionally, when a mindful parenting training is offered parallel to the child training (usually with the program called MYmind), parents report improvements in their own ADHD symptoms, stress, over-reactivity, and self-control (Bögels et al., 2021; Haydicky et al., 2013; Shecter, 2013; Siebelink et al., 2021; Singh et al., 2009; van de Weijer-Bergsma et al., 2012; van der Oord et al., 2012; Valero et al., 2022; Zhang et al., 2018). Although some effects were generally smaller or absent at follow-ups (e.g., Siebelink et al., 2021), teacher ratings were sometimes non-significant (e.g., van der Oord et al., 2012) and adolescents themselves reported no direct but only long-term effects of the mindfulness training (e.g., Haydicky et al., 2013), overall, these studies highlight the possible benefits of mindfulness training for children with ADHD. However, systematic reviews state that randomised trials with active control interventions, large sample sizes, and objective/blinded measures are still fairly limited (Burke, 2010; Evans et al., 2018; Mak et al., 2018; Oliva et al., 2021; Zhang et al., 2018; Zoogman et al., 2014).

A first meta-analysis in this field included children and adults with ADHD, aged 8–50 years, showing moderate effects of mindfulness-based programs in the reduction of inattentive and hyperactive/impulsive behaviours (Cairncross & Miller, 2016). However, only a limited number of studies with children was included, and most studies were lacking control groups. Another meta-analysis showed small to moderate effects of mindfulness-based and yoga programs on the decreases of ADHD symptoms in children of 5–17-year-old (Chimiklis et al., 2018). However, many of the included studies in this meta-analysis were nonrandomised. Therefore, the meta-analysis of Vekety et al. (2021) included RCT's only, assessing the effects of mindfulness-based interventions delivered in the school context

for children aged 3–12 years. Although this meta-analysis did not focus on clinical ADHD samples, the main outcome measures were inattentive and hyperactive-impulsive behaviours for which significant small effects were reported. The most recent systematic review and meta-analysis including only RCTs of children with ADHD reported medium to large effects of mindfulness-based interventions on symptoms of ADHD (Lee et al., 2022).

A first RCT using the combined child and parent program MYmind randomised children with remaining ADHD symptoms after care as usual (CAU) to MYmind next to further CAU versus further CAU alone (Siebelink et al., 2021). They found the family mindfulness training to be superior on the reduction of attention problems and hyperactivity/impulsivity, particularly in the per-protocol analysis. However, as many children continued to use methylphenidate, this study does not answer the question whether family mindfulness can be an alternative to medication. Lo et al. (2020) conducted an RCT in Hong Kong where it was shown that families in the mindfulness group reported larger reductions in children's ADHD symptoms and parenting stress and larger improvements in parental psychological well-being compared to those in the waitlist control group. Another Hong Kong-based RCT compared family-based mindfulness to an active control group using a CBT program. Primary and secondary outcomes included children's attention, ADHD-related symptoms, behaviours, executive function, and mindfulness levels as well as parental stress, parenting styles, and parent's own ADHD-related symptoms and wellbeing (Chan et al., 2018). Results showed that both programs significantly improved children's attention and most other outcomes, with no difference in effectiveness between the CBT and the family mindfulness program up to the 6-month follow-up assessment (Wong et al., 2023).

In the current study, we conducted a randomised clinical trial to compare the effectiveness of the family mindfulness-based training MYmind with methylphenidate on the primary measures of inattention and hyperactivity/impulsivity in childhood ADHD (see Meppelink et al., 2016, for protocol description). As a substantial number of eligible families refused randomisation (see flowchart) due to a strong preference for one of the treatments, a common issue in clinical trials (Fairhurst & Dowrick, 1996), we also ran a parallel preference trial (PT).

Method

Participants

Recruitment took place via referrals to two outpatient child and family mental health care centres, one more urban and more rurally located. Referrals came through general



practitioners, mental health care professionals, the study website, local media, posters, and flyers. As can be read in the study protocol of Meppelink et al. (2016):

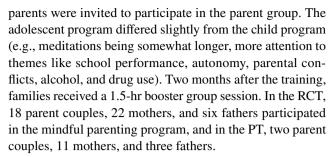
"Inclusion criteria were a primary ADHD classification of the child made by a multidisciplinary team of psychiatrists and psychologists, based on the DSM; ADHD was verified by the child/adolescent version of the Structured Clinical Interview for DSM - 5 (SCID-junior; Wante et al., 2021); the child's age was between 9 and 18; (estimated) IQ was over 80; at least one parent was willing to participate in the mindful parenting training or accompany the child to the medical consultations. Exclusion criteria were: inadequate mastery of the Dutch language by the child or parent(s); suffering from acute psychosis, schizophrenia, or untreated post-traumatic stress disorder; co-morbid conduct/behaviour problems that were so severe, already during intake, that interaction/talking between the parent, child and interviewer at intake was not possible; current or previous use of methylphenidate in the past year; current or previous participation in mindfulness training in the past year; participation in a currently active other psychological intervention. To verify the IO-criterion, an abbreviated version of the Wechsler Intelligence Scale for Children - Third edition (WISC-III-NL; Kort et al., 2002) was used" (p. 7).

In the RCT, 91 children; $M_{\rm age}$ =11.29, 71% boys, average IQ 103, 172 parents; $M_{\rm age}$ =45.33, 91 mothers and 81 fathers, and 81 teachers participated (Table 1, Fig. 1). The PT included 29 children; $M_{\rm age}$ =11.57, range 9–18, 55% boys, average IQ 108, 52 parents; $M_{\rm age}$ =44.27, 28 mothers and 24 fathers, and 24 teachers (Table 1, Fig. S1).

Procedure

Families were randomised to medication or mindfulness treatment (Fig. 1 and Fig. S1). Questionnaires were administered just before treatment (pre-test), and subsequently at 2-, 4-, and 10-month follow-up. Neuropsychological assessment took place at pre-test and 2-month follow-up only. Families were asked to stick to the prescribed protocol of either mindfulness or medication for the first 4 months. After this, they were free to choose their own course of treatment between the 4-month and 10-month follow-up. At this long-term period, one could argue the RCT was no longer a comparative efficacy study, and we therefore report and interpret the 10-month follow-up findings separately.

The mindfulness-based intervention MYmind was used (Bögels, 2020). In the first 2 months, children attended 8 weekly 1.5-hr mindfulness group sessions and their parents a parallel group mindful parenting training including daily homework meditation practice. In the following 2 months, families were encouraged to keep practicing according to a meditation plan made during the last session. Groups consisted of around 6 children or 8 to 10 adolescents, and both



For children, 66% of the mindfulness sessions were videotaped, as well as 70% of the parent sessions to assess treatment integrity using the MYmind-Treatment Adherence and Competence Scale (MYmind-TACS) (Ridderinkhof et al., 2018). Interrater reliability of the MYmind-TACS was assessed. RM scored seven randomly selected child sessions groups, and Assessor 1 and 3; Master's psychology students scored seven randomly selected parent sessions. Absolute agreement percentages for the child and parent groups were respectively 93.2% and 94.7% for adherence, 73.5% and 86.6% for competence, intraclass-correlations (ICC) were excellent, i.e., 0.83 and 0.86 for adherence, 0.80 and 0.88 for competence. Subsequently, 50 extra child and 50 extra parent sessions were randomly selected and rated by Assessor 2 and 3. For the child sessions, 85.8% of the program was adhered to by the trainers, 9.8% was partially adhered to, and 4.4% was not delivered, for the parent sessions this was 91.6%, 3.8%, and 4.7% respectively. Reasons for partial or no adherence to the protocol included running out of time and alignment with the group needs. Trainer's competence (5-point scale) was 4.29 (SD=0.60) for children's sessions and 4.60 (SD=0.27) for parents' sessions.

Short-acting methylphenidate was administered by a psychiatrist, following "Multidisciplinary guidelines ADHD" (Trimbos-instituut, 2005). After the first consultation with the psychiatrist, children received a prescription of three daily doses of methylphenidate (2.5 or 5 mg), 7 days a week. The psychiatrist called families weekly until optimal titration was obtained, and every 4 weeks they met face-to-face. If methylphenidate was not effective or side effects outbalanced beneficial effects, dose or medication type was changed or medication use was discontinued completely.

Measures

Questionnaires

Disruptive Behaviour Disorder Rating Scale (DBDRS) The DBDRS (Oosterlaan et al., 2000) assessed children's ADHD and disruptive behaviour disorder symptoms, as reported by parents and teachers. The 42-items DBDRS consists of 4 subscales of which only the sub scales Inattention and Hyperactivity/Impulsivity were used in the current study.



Table 1 Participant characteristics and covariates at pre-test in the randomised controlled trial and preference trial

Variable	Intention to treat (RCT) no. (%)	Preference trial no. (%)	
Total no. of children	91	29	
Age, mean (SD)	11.29 (2.35)	11.57 (2.63)	
Total no. of parents	172 (91 mothers, 81 fathers)	52 (28 mothers, 24 fathers)	
Age, mean (SD)	45.33 (5.20)	44.27 (6.53)	
Child IQ, mean (SD)	103.29 (12.68)	108.72 (13.27)	
ODD (DBDRS norm score)	13.52 (2.45)	13.39 (2.56)	
CD (DBDRS norm score)	15.34 (1.52)	14.96 (1.47)	
Child sex			
Boy	65 (71.40)	16 (55.20)	
Girl	26 (28.60)	13 (44.80)	
Child ADHD subtype			
ADD	43 (47.30)	13 (44.80)	
ADHD	48 (52.70)	16 (55.20)	
Child school type			
Primary school	63 (69.20)	16 (55.20)	
Secondary school	27 (29.70)	12 (41.40)	
Missing	1 (1.10)	1 (3.40)	
Child's treatment preference			
Preference mindfulness	39 (42.90)	11 (37.90)	
No preference	23 (25.30)	4 (13.80)	
Preference medication	29 (31.90)	13 (44.80)	
Missing	-	1 (3.40)	
Parents' treatment preference (aggregate score both parents)	2		
Preference mindfulness	73 (80.30)	16 (55.20)	
No preference	12 (13.20)	3 (10.30)	
Preference medication	6 (6.60)	9 (31.00)	
Missing	-	1 (3.40)	
Treatment expectations family			
Positive expectations mindfulness	36 (78.30)	16 (100.00)	
Barely/not beneficial mindfulness	10 (21.70)	0	
Positive expectations medication	39 (86.70)	13 (100.00)	
Barely/not beneficial medication	6 (13.30)	0	
Educational level parents			
University or college	109 (63.30)	24 (46.20)	
Vocational school	32 (18.60)	12 (23.10)	
Secondary school or less	30 (17.40)	15 (28.80)	
Missing	1 (0.60)	1 (1.90)	

Notes. ADD, attention-deficit disorder; *ADHD*, attention-deficit/hyperactivity disorder; *CD*, conduct disorder; *ODD*, oppositional defiant disorder; *PT*, preference trial; *RCT*, randomised controlled trial

Internal reliabilities for Inattention and Hyperactivity/ Impulsivity at respectively pre-test, 2 months, 4 months, and 10 months for parents were: α =0.87, 0.89, 0.91, 0.88, and for teachers were: α =0.93, 0.95.

Achenbach System of Empirically Based Assessment (ASEBA) This is a battery of tests consisting of The Child Behaviour Checklist (CBCL, 113 items, parents' report (Achenbach, 1991)), Youth Self Report (YSR, 112 items,

self-report for adolescents 11 years and older (Achenbach, 1991)), Teacher's Report Form (TRF, 113 items, teacher report (Achenbach, 1991)), and Test Observation Form (TOF, 125 items, observer report (McConaughy & Achenbach, 2004)), all consist of eight syndrome scales of which Attention Problems was used in this study. Internal reliabilities for this scale at respectively pre-test, 2 months, 4 months, and 10 months were: CBCL, α =0.66, 0.77, 0.77, 0.77; YSR, α =0.62, 0.64, 0.75, 0.59; TRF, α =0.92,



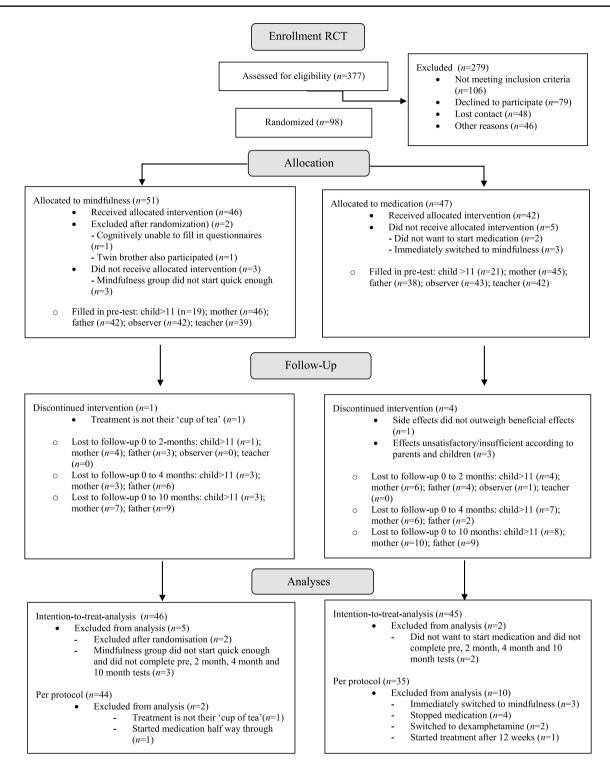


Fig. 1 CONSORT flowchart randomised controlled trial

0.94; TOF, α =0.92, 0.87. All questionnaires are part of the Achenbach System of Empirically Based Assessment and will be referred to as ASEBA questionnaires. The TOF was completed after the objective measures by an observer, a psychologist.

Neuropsychological Measures

TEA-Ch Four subtasks of The Test of Everyday Attention for Children (TEA-Ch; Manly et al., 1994) were used to assess selective attention: Sky Search, sustained attention;



Score!, attention control/switching; Creature Counting, and Opposite Worlds. Test-retest correlations between parallel versions of the tests were: Sky Search (r=0.81, p<0.001), Score! (r=0.44, p<0.001), Creature Counting (r=0.60, p<0.001), and Opposite Worlds (r=0.81, p<0.001).

d2 Test of Attention The d2 is a paper-and-pencil task to assess sustained and selective attention (Brickenkamp & Zillmer, 1998), consisting of 14 lines in which the child evaluates certain targets within a 20-s time span. Test-retest correlation was r=0.70, p<0.001.

Data Analyses

Multilevel modelling was used (mixed models) to test the main and interaction effects of time, reporter (mother, father, teacher, observer), and treatment type on the questionnaire outcomes and objective neuropsychological outcomes, with pre-test, mothers, and mindfulness as reference. Scores on dependent variables were standardised to zero mean and unit variance, so that effects can be interpreted in terms of standard deviations. We also tested whether the covariates treatment expectations, parental educational level, child gender, age (elementary/high school), IQ, ADHD type, and oppositional/conduct problems level interacted with effect of treatment type. Since we included a broad age range (9-18 years), the variables of age and school type (elementary and high school) were also examined as moderators. The intention-to-treat (ITT) principle was followed, and in a secondary per-protocol analyses (PP), only participants who fully adhered (took part in all sessions) to the protocol were included. Twelve children (26%) randomised to medication did not start or prematurely stopped treatment because of serious discomfort, as did one family (2%) randomised to mindfulness. These treatment dropouts were approached for further assessment for ITT analysis.

Results

Questionnaires

Results for the RCT-ITT analyses of DBDRS (Inattention and Hyperactivity/Impulsivity) and ASEBA (Attention problems) are displayed in Table 2 (see Fig. 2a–f and Tables S1 and S3 for detailed sizes of effects per reporter). A main effect for time indicated children's symptoms consistently decreased at 2 and 4 months. A main effect for respondent on Inattention and Attention problems indicated overall less problems reported by fathers, teachers, and observers (vs. mothers). The critical time by condition interaction showed that at 2 and 4 months effects of medication were larger than those of mindfulness. With mother-reports as reference, the 4 months

effects of medication were no longer significantly superior to mindfulness on Inattention and Attention problems, but for the other reports they were (see Tables S1 and S3 for separate effects for different reporters). Three-way interactions between time, condition, and respondent were not significant. At pre-test, 58.3% of the children in the mindfulness condition scored above the cut-off for ADHD on the DBDRS and after the mindfulness training (2 months post-test) this decreased to 38.5%. At pre-test, 59.5% of the children in the medication condition scored above this cut-off for ADHD and after medication treatment (2 months post-test) this was reduced to 20%. Number of children exceeding the DBDRS ADHD threshold did not differ between conditions at pretest nor at post-test. However, within groups, a corrected McNemar chi-square showed no difference between pre- and post-test DBDRS ADHD classifications for children in the mindfulness group, but in the medication group, pre-versus post-test showed a significant decrease in DBDRS clinical ADHD classifications, χ^2 (1, n = 41) = 11.53, p < 0.01.

Covariates

Of the covariates treatment expectations, parental educational level, child gender, age, IQ, ADHD type, and only children's level of Oppositional/Conduct Problems affected the effects of treatment type on Hyperactivity/Impulsivity, showing that children with low Oppositional/Conduct Problems in the medication condition improved more than children with low Oppositional/Conduct Problems in the mindfulness condition, whereas for those high on Oppositional/Conduct Problems, no difference between treatments occurred (Figure S2a-d, Table S2). Further, we found that mindfulness worked just as well for older versus younger children with ADHD (age or school type were no significant moderators). Adding DBDRS clinical cut-off scores as a covariate did also not improve the model.

Neuropsychological Measures

At 2 months, children performed better at the Sky Search, Opposite Worlds, and d2 tasks, but on Creature Counting and Score!, no effects were found. Treatment effects did not differ between groups (Tables 1 and 3).

Preference Trial and Per-Protocol Analyses

Overall, PT and PP analyses yielded comparable results as RCT and ITT analyses, supporting the robustness of findings (Tables S4–S11). For example: for families taking part in the PT where they received the treatment of their preference instead of being randomised, it was found that both mindfulness and medication treatment significantly reduced symptoms of ADHD, with medication being more



Table 2 Fixed effects and standardised parameter estimates of medication versus mindfulness treatment at 2-, 4-, and 10-months follow-up on questionnaires (DBDRS and ASEBA), RCT ITT analysis

	Inattention (DBDRS)	Hyperactivity/Impulsivity (DBDRS)	Attention problems (ASEBA) $b = 0.52^{***} (0.14)$	
Intercept	$b = 0.67^{***} (0.12)$	$b = 0.34^* (0.15)$		
Time (T)				
2-mo. follow-up (vs. pretest)	$b = -0.42^{**} (0.13)$	$b = -0.25^* (0.12)$	b = -0.20 (0.14)	
4-mo. follow-up (vs. pretest)	$b = -0.57^{***} (0.14)$	$b = -0.23^* (0.10)$	$b = -0.46^{***} (0.14)$	
10-mo. follow-up (vs. pretest)	$b = -0.73^{***} (0.12)$	$b = -0.45^{***} (0.10)$	$b = -0.64^{***} (0.15)$	
Group (G)				
Medication (vs. mindfulness)	b = -0.06 (0.18)	b = 0.10 (0.22)	b = 0.23 (0.20)	
Respondent (R)				
Father (vs. mother)	$b = -0.50^{***} (0.13)$	$b = -0.25^{+} (0.13)$	$b = -0.43^* (0.19)$	
Teacher (vs. mother)	$b = -0.32 (0.18)^{+}$	b = -0.13 (0.17)	$b = -0.64^{**} (0.20)$	
Adolescent (vs. mother)	a	a	b = -0.21 (0.25)	
Observer (vs. mother)	a	a	$b = -0.50^* (0.19)$	
$\Gamma \times G$				
Medication * 2-mo. follow-up	$b = -0.50^{**} (0.18)$	$b = -0.41^* (0.17)$	$b = -0.76^{***} (0.20)$	
Medication * 4-mo. follow-up	$b = -0.28 \; (0.20)$	$b = -0.53^{**} (0.15)$	$b = -0.39^* (0.20)$	
Medication * 10-mo. follow-up	b = 0.05 (0.18)	b = -0.14 (0.15)	b = -0.06 (0.22)	
$T \times R$				
2-mo. follow-up * father	b = 0.18 (0.15)	b = 0.12 (0.14)	b = 0.11 (0.20)	
4-mo. follow-up * father	$b = 0.33 (0.17)^{+}$	b = -0.03 (0.15)	$b = 0.38^{+} (0.20)$	
10-mo. follow-up * father	b = 0.03 (0.17)	b = -0.00 (0.15)	b = 0.33 (0.22)	
2-mo. follow-up * teacher	b = 0.20 (0.16)	b = 0.12 (0.17)	b = 0.05 (0.21)	
4-mo. follow-up * teacher	a	a	a	
10-mo. follow-up * teacher	a	a	a	
2-mo. follow-up * adolescent	a	a	b = -0.04 (0.26)	
4-mo. follow-up * adolescent	a	a	b = -0.22 (0.26)	
10-mo. follow-up * adolescent	a	a	b = -0.12 (0.28)	
2-mo. follow-up * observer	a	a	b = 0.16 (0.20)	
4-mo. follow-up * observer	a	a	a	
10-mo. follow-up * observer	a	a	a	
$G \times R$				
Medication * father	b = 0.21 (0.19)	b = 0.27 (0.19)	b = 0.07 (0.28)	
Medication * teacher	b = -0.00 (0.26)	$b = -0.21 \ (0.24)$	b = -0.15 (0.28)	
Medication * adolescent	a	a	b = 0.53 (0.35)	
Medication * observer	a	a	b = -0.39 (0.27)	
$\Gamma \times G \times R$				
2-mo. follow-up * father * medication	b = -0.14 (0.22)	b = -0.20 (0.21)	b = 0.23 (0.29)	
4-mo. follow-up * father * medication	b = -0.22 (0.24)	b = -0.00 (0.21)	b = -0.32 (0.28)	
10-mo. follow-up * father * medication	b = -0.34 (0.25)	$b = -0.37^{+} (0.22)$	b = -0.45 (0.32)	
2-mo. follow-up * teacher * medication	b = 0.00 (0.23)	b = 0.04 (0.23)	b = 0.32 (0.29)	
4-mo. follow-up * teacher * medication	a	a	a	
10-mo. follow-up * teacher * medication	a	a	a	
2-mo. follow-up * adolescent * medication	a	a	b = -0.27 (0.37)	
4-mo. follow-up * adolescent * medication	a	a	b = -0.50 (0.37)	
10-mo. follow-up * adolescent * medication	a	a	b = -0.48 (0.40)	
2-mo. follow-up * observer * medication	a	a	$b = 0.48^{+} (0.29)$	
4-mo. follow-up * observer * medication	a	a	a	
10-mo. follow-up * observer * medication	a	a	a	

Notes. Reference categories are mother, mindfulness, and pretest. Parameter estimates can be interpreted as Cohen's effect sizes, with 0.2, 0.5, and 0.8 indicating small, medium, and large effects. Negative estimates indicate reduction in symptoms at follow-ups. ^+p <0.10, *p <0.05, *p <0.01, **p <0.01, * not measured. Example of interpretation: The superior effect of medication compared to mindfulness at 4 months on Attention problems (ASEBA) according to mother is -0.38 (medication * 4 months follow-up), so small to medium sized effect, whereas according to father it is -0.38 (medication *4 months follow-up) + -0.33 (4 months follow-up * father * medication) = -0.71, so medium to large sized effect



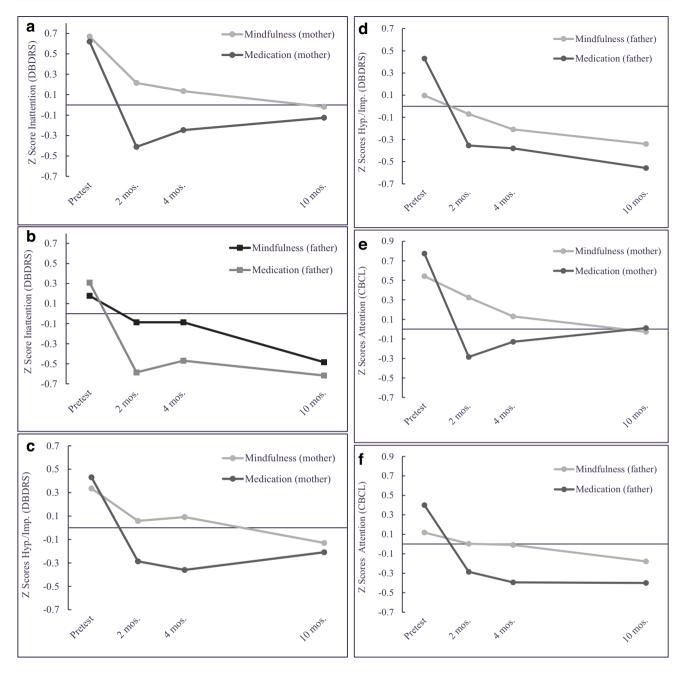


Fig. 2 a-f Effects of medication versus mindfulness on the main outcome measure DBDRS, Inattention and Hyperactivity/Impulsivity, and CBCL Attention problems reported by mothers and fathers

effective in the short- and mid-term. Also, in line with the RCT findings, on the neuropsychological measures of attention, no significant differences were found between the two conditions in the PT.

Results After the Free Treatment Period (4–10 Months)

The main time effect parameters indicated children's symptoms decreased at 10 months. Differences between

the two groups were not significant according to motherreports (the chosen reference category). Fathers found medication more effective than mindfulness on Hyperactivity/Impulsivity and Attention problems, but not on Inattention. Three-way interactions between time, condition, and respondent were not significant.

As families had free choice of treatment after 4 months, we conducted a post hoc exploration of the effects of medication usage long-term. To that end, children were divided into four groups separating



Table 3 Standardised parameter estimates of medication versus mindfulness treatment on neuropsychological measures, RCT ITT analysis

	Sky Search PE (SE)	Score! PE (SE)	Creature Counting <i>PE</i> (<i>SE</i>)	Opposite Worlds PE (SE)	d2 PE (SE)
2-mo. follow-up (vs. pretest) Mindfulness 2-mo. follow-up (vs. pretest) Medication Medication (vs. Mindfulness) at Pretest Medication * 2-mo. follow-up (vs. Mindful-	0.72*** (0.10)	-0.08 (0.17)	0.27 ⁺ (0.14)	0.38*** (0.10)	0.83*** (0.11)
	0.70*** (0.10)	0.05 (0.17)	0.40** (0.15)	0.38*** (0.11)	1.11*** (0.11)
	0.34+ (0.20)	0.10 (0.22)	0.21 (0.20)	-0.01 (0.20)	0.05 (0.20)
	-0.02 (0.14)	0.13 (0.24)	0.13 (0.21)	-0.00 (0.15)	0.28+ (0.16)

Notes. Parameter estimates can be interpreted as Cohen's *d* effect size. Positive estimates indicate improvement at follow-ups. ^+p <0.10, *p <0.05, *p <0.01, **p <0.001; a not measured

those from either treatment arm that were or were not taking medication at 8-10 months: (1) mindfulnessarm, no medication at long-term (53.5%, n=23), (2) mindfulness-arm, medication at long-term (46.5%, n=20), (3) medication-arm, continued medication at longterm (76.3%, n=29), and (4) medication-arm, stopped medication at long-term (23.7%, n=9) (Figures S2e-g). Treatment effects remained stable at 10 months for those in the mindfulness group that did not add medication and those in the continued-medication group (e.g., those who stayed with their original treatment with respect to medication). Those in the mindfulness group that at longterm took medication had deteriorated at 4 months but saw improvements at 10-months follow-up, while those in the medication group that discontinued medication had deteriorated at 4-months follow-up and/or saw deterioration at 10-months follow-up.

We also checked what other treatments families were seeking in the 2 months before the 10-months follow-up. Of the families originally assigned to medication, 34.6% (n=11) had mindfulness-related contacts, versus 0% (n=0) families originally assigned to mindfulness, $\chi^2(2)$ =16.80, p < 0.001. Other psychosocial treatment (e.g., CBT, behaviour parent training) was sought by 22.9% (n=8) of the original medication group versus 35% (n=14) of the mindfulness group, $\chi^2(2)$ =2.30, $\chi^2(2)$ =2.30. As more precise information about the intensity of these additional treatments was unavailable, we did not further explore these patterns.

Discussion

The main study findings are (1) both mindfulness and medication were shown to effectively reduce core symptoms of childhood ADHD, (2) on neuropsychological tasks and according to blind observers no differences between treatments were found, (3) in the short- and

mid-term, medication was more effective than mindfulness on multi-informant questionnaires, (4) in the mid-term, when mindfulness treatment had already finished but medication was still taken, differences between medication and mindfulness diminished according to mother-reports (our reference), so that differences were no longer significant on Inattention and only borderline so on Attention problems, and (5) in the long-term, differences between the original treatment groups further diminished or disappeared, but crossing over to other treatments may have influenced these results.

The fact that medication outperformed mindfulness after 2 months was not surprising given the large effects of medication reported in previous studies (e.g., Storebø et al., 2015). One can even draw a parallel with the long-standing MTA study comparing the leading treatments for ADHD. Families were randomly assigned to one of four groups: medication, medication plus behaviour therapy, behaviour therapy alone, and "community care". In the first phase, children were treated for 14 months, after which formal treatment ended and crossovers were accepted. After this first phase, medication was shown to be the most effective treatment for ADHD (The MTA Cooperative Group, 1999).

Effects of mindfulness, from small to large sized, were comparable to those found in other studies on non-pharmacological therapies for childhood ADHD (Daley et al., 2014) and specifically mindfulness (Cairncross & Miller, 2016; Evans et al., 2018; Zhang et al., 2018). That the differences between mindfulness and medication became smaller at 4-month follow-up is remarkable, as the mindfulness training ended at the 2-months follow-up (except for a follow-up meeting at 4 months), whereas medication continued for another 2 months. This may be explained by the finding that medication can lose its effect over time (Handelman & Sumiya, 2022) or by the continued effect of mindfulness over time, after training has ended (e.g., Bögels et al., 2021). Learning mindfulness skills requires,



like any other skill, effort, time, and dedication and is not a quick fix, as medication appears to be, since it came with an immediate large effect.

In the long-term, 10 months after the start of the 2-month family mindfulness training or 4-month medication treatment, differences between the original conditions had disappeared. A first explanation is that the skills that were learned in the family mindfulness program continued to deliver effects in the long-term. A second explanation is that medication in the long-term does not provide extra effects or even loses (part of) its effects. A third explanation concerns the effects of additional treatments that families were free to seek after the 4-month follow-up. Almost half of the children from the original mindfulness condition took medication in the two months before the 10-month follow-up, which, as post hoc inspection suggests, may have contributed to the long-term outcomes in the original mindfulness group. In a similar vein, one-third of the original medication condition sought mindfulness in the 2 months before the 10-month follow-up, and a quarter discontinued medication, which both may have influenced the 10-month outcomes in the original medication group. At minimum, we can conclude that over half of the children in the mindfulness group continued to do well without medication, the treatment of choice for children with ADHD currently. A cost-effectiveness study (see Meppelink et al., 2016) will shed further light on the longterm effects in relation to the (treatment) costs of family mindfulness versus medication for childhood ADHD.

The equally strong short-term improvement in attention found for both treatments in the neuropsychological tasks is interesting for two reasons. First, the task does not know whether the child received mindfulness or medication, so this result is the most objective. Second, whereas questionnaires measure attention on a behavioural level, to be observed externally, neuropsychological tasks measure attention on a cognitive level, referring to internal processes. A meta-analysis on meditation-based therapies for ADHD did not find significant effects on neuropsychological measures of inattention (Zhang et al., 2018). Furthermore, a systematic review of healthy and clinical individuals found that selective and sustained attention, but not attention switching, generally improved after receiving a short-term (e.g., 2 months) mindfulness meditation practice (Chiesa et al., 2011). For medication, previous studies on neuropsychological tasks in children with ADHD also showed mixed results (Paton et al., 2014). However, the current study found improvements on all three types of attention (i.e., selective attention, attention switching, and sustained attention) for both treatments, but not on sustained attention as measured with Score!. The low reliability of Score! may explain the latter finding.

Only one co-variate, the level of children's oppositional/conduct problems, interacted with the effect of treatment type, showing that medication works better than mindfulness for those low on oppositional/conduct problems but not differently for those high on oppositional/conduct problems. An explanation is that in mindful parenting, parents learn to inhibit overreactive parenting, which might be triggered by children's misbehaviour, and may maintain children's oppositional/conduct problems (e.g., Heath et al., 2014).

Notable differences were found between mothers' and fathers' reports of differential improvement by treatment, as fathers found medication relatively better than meditation compared to mothers. This may be explained by the fact that more mothers than fathers participated in the parallel mindful parenting training, as through the mindful parenting training, parents may become more understanding, accepting and less overreactive towards their children's ADHD symptoms, or simply their time investment in the training may make them rate their child's improvement after family mindfulness training higher. Alternatively, fathers may believe more in the effects of medication or mothers may be more concerned about the side effects of medication. In any case, it appears important to include fathers as respondents about their child's progress.

Strengths of the current study are the RCT with a parallel PT, which makes the findings more generalisable to real-world practice where families often choose their treatment. Other strengths are the multiple reporters including reporters further away from the treatment setting, as informants closest to the therapeutic setting (e.g., parents) are found to be more likely to report treatment effects compared to those not involved in the treatment (e.g., teachers) (Sonuga-Barke et al., 2013), the objective neuropsychological tasks, and the longer-term assessments.

To conclude, medication is more effective than family mindfulness in the short- and mid-term on multi-informant questionnaires but not on objective (neuropsychological and blind observer) measures. However, differences between treatments diminish at mid-term even though in the medication group treatment is continued after 2 months while the mindfulness training is already finished at 2 months. Differences between treatment groups disappear at long-term, but note that in the long-term, children from the mindfulness arm started taking medication and vice versa, so that we cannot be sure to what extent the longterm results are caused by mindfulness, medication, or its combination. Note moreover that one in four children discontinued taking medication during the first 2 months versus almost no families discontinued mindfulness, suggesting that mindfulness is more easily accepted. Overall, although mindfulness alone might not be sufficient for some families, family mindfulness training can in



general be considered a non-pharmacological alternative or addition in the treatment of childhood ADHD.

Limitations and Future Research

Limitations of the study were that no longer-term measurement of neuropsychological tasks and observers took place, and that as families had free choice of treatment at long-term, the 10-month follow-up does not represent the "pure" effects of mindfulness versus medication. Another limitation is the relatively lower alpha scores for adolescent and parental ASEBA Inattention, as compared to the teachers and observers alpha scores. This might be due to the lower number of items used in this construct for adolescent and parent rating. It might also be related to a drop-off in response rate by adolescents over time. We should therefore interpret these findings with a little more caution. Future research calls for including a third arm, that is, medication and mindfulness combined, and ideally also a no treatment or waitlist condition. Another suggestion for future research is to disentangle the contributing effects of the mindfulness training for the parents versus the training for the children.

Abbreviations ITT analyses: Intention-to-treat analyses; PP analyses: Per-protocol analyses; PT: Preference trial; RCT: Randomised clinical trial

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Use of Artificial Intelligence AI tools were not used during this study.

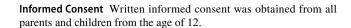
Author Contribution SB, as principle investigator of the study, developed the MYmind training, and trained and supervised the facilitators. EB wrote the grant application and supervised RM and BKZ. All authors contributed to study protocol. FO supervised the statistical analyses. RM collected the data, conducted the analyses (as did BKZ), and drafted the paper (as did BKZ). The paper was modified and supplemented by all other authors. All authors approved the final manuscript.

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Data Availability Data of this study are stored in the University's repository.

Declarations

Ethics Approval The RCT was approved by the Medical Ethical Committee of the Amsterdam Medical Center (2013_383), and the PT by the Ethics Review Board of the University of Amsterdam (2014-CDE-3658). The trial was registered in the Dutch Register: https://onderzoekmetmensen.nl/nl/trial/22179, 11.10.2013.



Conflict of Interest Renée Meppelink, Brett Kosterman Zoller, and Frans J. Oort have no conflict of interest. Susan M. Bögels owns shares in UvA minds, one of the participating treatment centres, teaches professionals in MYmind, for which she earns a salary, and has published the MYmind manual, for which she receives royalties. Esther I. de Bruin is the director of UvA minds.

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