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Mindfulness-based cognitive therapy *v.* treatment as usual in adults with ADHD: a multicentre, single-blind, randomised controlled trial

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Abstract

Background. There is a high need for evidence-based psychosocial treatments for adult attention-deficit hyperactivity disorder (ADHD) to offer alongside treatment as usual (TAU). Mindfulness-based cognitive therapy (MBCT) is a promising psychosocial treatment. This trial investigated the efficacy of MBCT + TAU *v.* TAU in reducing core symptoms in adults with ADHD.

Methods. A multicentre, single-blind, randomised controlled trial (ClinicalTrials.gov: NCT02463396). Participants were randomly assigned to MBCT + TAU ($n = 60$), an 8-weekly group therapy including meditation exercises, psychoeducation and group discussions, or TAU only ($n = 60$), which reflected usual treatment in the Netherlands and included pharmacotherapy and/or psychoeducation. Primary outcome was ADHD symptoms rated by blinded clinicians. Secondary outcomes included self-reported ADHD symptoms, executive functioning, mindfulness skills, self-compassion, positive mental health and general functioning. Outcomes were assessed at baseline, post-treatment, 3- and 6-month follow-up. Post-treatment effects at group and individual level, and follow-up effects were examined.

Results. In MBCT + TAU patients, a significant reduction of clinician-rated ADHD symptoms was found at post-treatment [*M* difference = −3.44 (−5.75, −1.11), $p = 0.004$, $d = 0.41$]. This effect was maintained until 6-month follow-up. More MBCT + TAU (27%) than TAU participants (4%) showed a ⩽30% reduction of ADHD symptoms ($p = 0.001$). MBCT + TAU patients compared with TAU patients also reported significant improvements in ADHD symptoms, mindfulness skills, self-compassion and positive mental health at post-treatment, which were maintained until 6-month follow-up. Although patients in MBCT + TAU compared with TAU reported no improvement in executive functioning at post-treatment, they did report improvement at 6-month follow-up.

Conclusions. MBCT might be a valuable treatment option alongside TAU for adult ADHD aimed at alleviating symptoms.

Attention-deficit hyperactivity disorder (ADHD) is a neurodevelopmental disorder that can persist into adulthood and has an estimated prevalence of 2.5% at adult age (Simon *et al.* 2009). In several European countries and the United States, pharmacotherapy with stimulant medication is suggested as first-line treatment for adult ADHD (NICE, 2009; Kooij *et al.* 2010; UMHS, 2013). In the Netherlands, stimulant medication is often combined with psychoeducation and skills training after or parallel to pharmacotherapy (NVvP, 2015). Despite the demonstrated efficacy of stimulants in the short term (Faraone & Glatt, 2010; Moriyama *et al.* 2013), there is a call for evidence-based psychosocial treatments to offer in addition or as an alternative to pharmacotherapy (Matheson *et al.* 2013). Several patients experience adverse effects that can result in discontinuation (Gajria *et al.* 2014), some patients are reluctant to take medication (Matheson *et al.* 2013), or respond insufficiently to stimulants and experience residual symptoms (Wigal, 2009) and long-term beneficial effects have not been convincingly established (Moriyama *et al.* 2013). Consequently, the NICE guidelines (NICE, 2009) and the European consensus statement (Kooij *et al.* 2010) emphasise that pharmacotherapy should be part of a multimodal treatment approach.

A growing amount of evidence is showing that psychosocial treatments, like cognitive–behavioural therapy (CBT), can have an additional effect to pharmacotherapy in alleviating residual

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symptoms in adults with ADHD (Young *et al.* 2016), although a recent study did not find a difference between a group psychotherapy programme, including cognitive–behavioural elements and clinical management (Philipsen *et al.* 2015). Upcoming psychosocial treatments for ADHD are mindfulness-based interventions (MBIs). Mindfulness is defined as intentionally paying attention to present moment experiences in a non-judgemental way (Kabat-Zinn, 1990). Neuroscientific studies showed that in healthy subjects, MBIs can result in improved attention regulation, enhanced brain activity and altered attention-related brain areas such as greater cortical thickness and enhanced white-matter integrity in the anterior cingulated cortex (Fox *et al.* 2014; Tang *et al.* 2015). Bachmann *et al.* (2016) suggested that mindfulness meditation can strengthen functioning in brain regions that underlie neuropsychological deficits in ADHD, positioning MBI as a promising treatment for ADHD. Currently, the evidence for MBIs for ADHD is growing and a first meta-analysis including three studies in adults demonstrated preliminary evidence for the efficacy of MBIs in reducing core symptoms, especially inattentiveness, with moderate-to-large effect sizes (Cairncross & Miller, 2016). However, these findings should be interpreted with caution, as the included studies either lacked randomisation (Edel *et al.* 2017), were underpowered (Schoenberg *et al.* 2014; Mitchell *et al.* 2017), used different MBIs (Schoenberg *et al.* 2014; Edel *et al.* 2017; Mitchell *et al.* 2017) and/or lacked a follow-up period (Schoenberg *et al.* 2014; Edel *et al.* 2017; Mitchell *et al.* 2017). Mindfulness-based cognitive therapy (MBCT) combines mindfulness practice with elements of CBT (Segal *et al.* 2012). We previously reported moderate-to-large efficacy of a 12-weekly adapted version of MBCT in reducing ADHD symptoms and improving executive functioning in comparison to a waitlist control group (Hepark *et al.* 2015). These results were in line with a recent randomised controlled trial (RCT) in college students with ADHD that found a reduction of ADHD symptoms after an adapted 6 weeks version of MBCT. However, both studies had methodological limitations, such as a small sample size (Gu *et al.* 2018), the lack of a follow-up period, no outcome data for drop-outs and single-centre enrolment (Hepark *et al.* 2015). Therefore, the current RCT took account of these limitations. The main aim of our RCT was to examine the efficacy of MBCT added to treatment as usual (TAU) compared with TAU alone in reducing core symptoms as rated by a clinician in adults with ADHD. Secondary outcomes included self-reported ADHD symptoms, executive functioning, mindfulness skills, self-compassion, positive mental health and general functioning.

Method

Trial design

A multicentre, single-blind, parallel-group, randomised controlled superiority trial was conducted comparing MBCT + TAU with TAU alone (allocation ratio 1 : 1). The study protocol has been published previously (Janssen *et al.* 2015) and has been approved by the local medical ethics committee CMO Arnhem-Nijmegen for all participating centres (2014/206). The methodology is described briefly below, for more detail see our protocol (Janssen *et al.* 2015).

Participants

Patients were eligible when they were 18 years or older and met DSM-IV (APA, 2000) criteria for ADHD as their primary diagnosis assessed with the semi-structured Diagnostic Interview for ADHD in adults (DIVA) (Kooij, 2010). This interview was only conducted in those patients that had not received an ADHD diagnosis based on the DIVA before. For the other patients, the previously determined diagnosis was maintained. Exclusion criteria were: (a) not capable of filling out questionnaires in Dutch; (b) current depressive disorder with psychotic symptoms or suicidality; (c) current manic episode; (d) borderline or antisocial personality disorder assessed with the Clinical Interview for DSM-IV Axis II Disorders (SCID-II) (First & Gibbon, 2004); (e) substance dependence; (f) autism spectrum disorder; (g) tic disorder with vocal tics; (h) learning difficulties or other cognitive impairments; and (i) former participation in MBCT or other MBI or workshop (>2 h). Criteria b, c and e were assessed with a psychiatric structured diagnostic interview (MINI-Plus) (Van Vliet & De Beurs, 2007).

Procedure

Participants were recruited between September 2014 and December 2015 by referral via three specialised outpatient clinics for adults with ADHD: the Department of Psychiatry of the Radboud university medical centre in Nijmegen, Reinier van Arkel Group in 's-Hertogenbosch, Dimence in Deventer and by self-selection through media advertisements (website, social media) and presentations at regional thematic meetings of the Dutch association of adults with ADHD 'Impuls & Woortblind'. Currently and previously treated patients were informed about the study by their attending clinician in various stages of their treatment process. Eligibility was assessed in a research interview conducted by the researcher or a research assistant. Each participant provided written informed consent after receiving detailed information about the trial.

Randomisation and blinding

Random assignment to MBCT or TAU was performed by a website specifically developed for this study by an independent statistician. Randomisation was stratified by centre, after which block randomisation with varying predefined block sizes was used combined with minimisation for use of medication for ADHD (yes/no); previous participation in a psychoeducation training (yes/no); gender and ADHD subtype (combined/inattentive/hyperactive–impulsive/not otherwise specified). The researcher was blind for the block sizes and filled-out the online form.

Blinded assessments by a psychiatrist or specialist nurse took place at baseline (T0), post-treatment (T1), 3 (T2) and 6 (T3) months follow-up. Randomisation took place after enrolment, but participants were not informed about the assigned condition until after completion of T0. To ensure the blinding of the interviewers, participants were instructed not to share information about allocation with the interviewer.

Intervention

Mindfulness-based cognitive therapy

The programme was primarily based on MBCT (Segal *et al.* 2012), consisting of 8-weekly sessions of 2.5 h and a 6 h silent day between the sixth and seventh sessions. The programme included meditation exercises (bodyscan, sitting meditation, mindful movement) combined with psychoeducation, CBT techniques and group discussions. In addition to the group sessions, participants were instructed to practice 6 days a week at home

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for approximately 30 min a day with guided exercises. Some modifications were made based on our pilot study (Janssen *et al.* 2017) and the Mindful Awareness Practices for ADHD programme (MAPs) (Zylowska *et al.* 2008; Mitchell *et al.* 2015) to make the intervention more suitable for adults with ADHD, like the more gradual increase of the duration of meditation exercises, replacement of psychoeducation about depression by psychoeducation about ADHD, more emphasis on mindfulness awareness in daily life and inclusion of one session on mindful listening and speaking. See our study protocol for more details (Janssen *et al.* 2015). MBCT was taught in 10 groups with approximately nine individuals per group (consisting of both study and non-study participants with ADHD to strive for a group size of 8–12 patients) by four mindfulness teachers, who all met the advanced criteria of the internationally agreed good practice guidelines of the UK Network for Mindfulness-Based Teachers (http://mindfulnessteachersuk.org.uk/pdf/teacher-guidelines-2015.pdf). Once every 3 weeks, the teachers participated in peer supervision. Teacher competence and adherence to the protocol were assessed by the Mindfulness-Based Interventions-Teaching Assessment Criteria (MBI: TAC) (Crane *et al.* 2012). Two videotaped sessions per teacher were randomly selected to be rated independently by two assessors with experience in teaching mindfulness. The assessors discussed possible differences in their evaluations to arrive at an agreed evaluation. The competence levels of the teachers were advanced (taught nine participants), competent (taught 21 participants), advanced beginner (taught 22 participants) and beginner (taught six participants).

Treatment as usual

TAU was designed to reflect the usual treatments of adults with ADHD in various mental health centres across the Netherlands. All participants were open to start, continue and stop a treatment if desired and the research team did not influence participants' decisions. We monitored TAU with additional online questions about pharmacological and psychosocial treatments during the last 3 months. Participants in the TAU group were offered MBCT after completing the T3 assessments.

Outcome measures

Primary outcome

The investigator-rated screening version of the Conners' Adult ADHD Rating Scale (CAARS-INV: SV) (Adler *et al.* 2007) was used by blinded clinicians ($n = 12$) to assess ADHD symptoms at each time point. Ratings can be organised in a DSM-IV symptom score (which served as the primary outcome) and in the subscales: inattention and hyperactivity/impulsivity. To reduce inter-rater variance, two training workshops were provided by two expert raters, and as far as possible, the same assessor conducted all interviews with a particular participant. A random sample of audiotaped CAARS-INV interviews ($n = 25$) was rated by blinded raters ($n = 5$) from another centre. The intraclass correlation coefficient was 0.73 [95% confidence interval (CI) 0.48–0.87].

Secondary outcomes

The following self-report questionnaires were administered online as secondary outcomes at each time point: Conners' Adult ADHD Rating Scale-Self-Report: Screening Version (CAARS-S:SV) (Adler *et al.* 2007) assessing the DSM-IV AHDH symptom score, Inattention and Hyperactivity/Impulsivity; the Behaviour Rating Inventory of Executive Function-Adult Version (BRIEF-A) (Roth & Gioia, 2005); the Five Facet Mindfulness Questionnaire-Short Form (FFMQ-SF) (Bohlmeijer *et al.* 2011); the Self-Compassion Scale-Short Form (SCS-SF) (Raes *et al.* 2011); the Mental Health Continuum-Short Form (MHC-SF) (Lamers *et al.* 2011) assessing positive mental health; and the Outcome Questionnaire (OQ 45.2) (Lambert *et al.* 1996) measuring general functioning. Further details about these outcome measures can be found in our study protocol (Janssen *et al.* 2015).

Statistical analyses

All analyses were performed at a significance threshold of 5% (two-tailed) and two-sided 95% CIs were used.

Sample size calculation

The power calculation was based on an estimated minimum clinically relevant difference of four points (S.D. = 7.5) on the DSM-IV symptom score of the CAARS-INV, based on our previous RCT (Hepark *et al.* 2015). Using an α of 0.5, a power of 80% and an analysis of covariance (ANCOVA) controlling for baseline levels with an assumed correlation of 0.5 between T0 and T1, 45 participants per treatment group were required. Taking account of an anticipated drop-out rate of 25%, a total number of 120 participants was necessary, 60 per treatment group.

Treatment effects at T1

All analyses were performed on both the intention-to-treat (ITT) sample, consisting of all participants who completed the questionnaire at T0 and T1, and additionally the per protocol (PP) sample (MBCT + TAU: participants who attended $\geqslant$4 MBCT sessions; TAU: participants who did not attend an MBI). In the primary analyses, scores at T1 were compared between groups, using an ANCOVA while controlling for baseline levels, centre and minimisation variables (use of ADHD medication, previous participation in a psychoeducation training, gender and ADHD subtype). Cohens' *d* effect size was calculated by dividing the adjusted group difference at T1 by the pooled standard deviation at T0. The reliable change index (RCI; Jacobson & Truax, 1991) was calculated for the primary outcome between T0 and T1, using Cronbach's α for calculating the standard error of the difference, to determine which participants changed reliably. The number of improved (RCI <-1.96) and deteriorated (RCI >1.96) participants between groups was tested with χ^2 tests. Additionally, the number of participants per group that showed a symptom reduction of $\geqslant$30% on the primary outcome was calculated to determine which participants showed a clinical significant change (Zylowska *et al.* 2008; Hepark *et al.* 2015; Mitchell *et al.* 2017). The symptomatic remission rate per group was calculated. Remission was defined by a mean total score $\leqslant$1 on the 18 DSM-IV symptom scores of the CAARS-INV (Ramos-Quiroga & Casas, 2011). Sensitivity analyses were performed by imputing missing data according to Last Observation Carried Forward (LOCF) and Multiple Imputation (MI) techniques.

Follow-up effects

The consolidation of treatment effects over the follow-up period for primary and secondary outcomes was evaluated with multilevel modelling with time point as repeated measurement in the ITT and PP samples, controlling for baseline levels, centre and minimisation variables (use of ADHD medication, previous participation in a psychoeducation training, gender and ADHD

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subtype). An unstructured covariance matrix was used. When no group × time interaction was found, the interaction term was dropped from the analysis for the respecting outcome variable. Cohens' *d* effect size was calculated by dividing the adjusted group difference between the pooled means (T1, T2, T3) by the pooled standard deviation at T0.

Moderation analysis

Moderation analyses, while controlling for baseline ADHD symptoms, were performed by adding potential predictors and its interaction with group to the models for testing treatment effects at T1 and follow-up effects. The following predictors were used: gender, age, ADHD subtype, use of ADHD medication, comorbid depressive disorder and comorbid anxiety disorder.

Results

Sample characteristics and TAU

Of the 120 participants who met the eligibility criteria, the majority was referred by the participating specialised outpatient clinics ($n = 67$; 56%). The remaining participants were referred by their general practitioner or another health care professional ($n = 18$; 15%); or were self-referrals ($n = 35$; 29%). The participants were randomly assigned to MBCT + TAU ($n = 60$) or TAU ($n = 60$) (Fig. 1). At baseline, there were no significant differences in demographic and clinical characteristics between both groups (Table 1). From T0 to T1, TAU did not differ between groups, apart from the fact that more participants in the MBCT + TAU group than in the TAU group kept their medication stable, $\chi^2(1) = 5.83$, $p = 0.016$ (online Supplementary Table S1). A minority of participants received psychosocial treatment for ADHD.

Within the MBCT + TAU group, participants who dropped-out of MBCT ($n = 9$; 15%) were less likely to use ADHD medication at T0 than MBCT completers, $\chi^2(1) = 6.30$, $p = 0.023$. There were no differences in characteristics between those with missing data at T1 on all outcomes ($n = 7$) and those included in at least one of the ITT analyses at T1 ($n = 113$).

Treatment effects at T1

Primary outcome

ITT analyses revealed that participants in the MBCT + TAU group demonstrated significantly less clinician-rated ADHD symptoms than those in the TAU group, with an effect size of $d = 0.41$ (Table 2). Analysis based on the PP sample ($p = 0.007$, $d = 0.39$) and sensitivity analyses based on LOCF ($p = 0.005$, $d = 0.37$) and MI ($p = 0.046$, $d = 0.29$) resulted in similar findings. Based on the RCI, the number of participants who had improved was higher in the MBCT + TAU group ($n = 16$; 31%) than in the TAU group ($n = 3$; 5%), $\chi^2(1) = 11.73$, $p = 0.001$, see online Supplementary Fig. S1. There was no difference between the two groups in the number of participants deteriorating (MBCT + TAU: $n = 6$; 12%; TAU: $n = 3$; 5%), $\chi^2(1) = 1.28$, $p = 0.311$. More

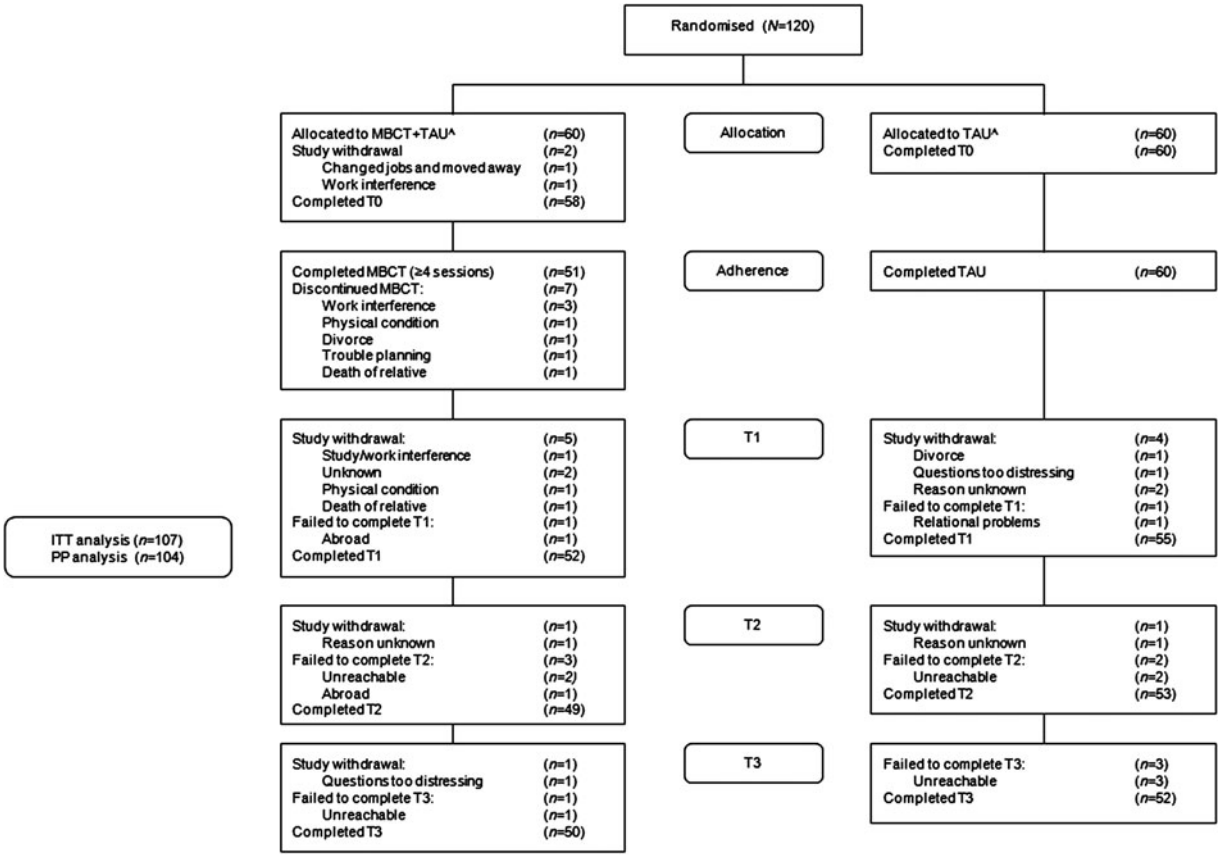

Fig. 1. CONSORT flow diagram. *Note.* ITT, intention-to-treat; PP, per protocol.

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Table 1. Baseline sociodemographic and clinical characteristics

Demographic characteristics[a]	MBCT + TAU ($n = 60$) n (%)	TAU ($n = 60$) n (%)	p
Female gender	32 (53)	32 (53)	1.000
Age; M (s.d)[b]	39.7 (11.1)	39.0 (10.1)	0.699
Married/living together[a]	31 (52)	36 (60)	0.473
Employment status[a]			0.674
Employed	36 (60)	31 (52)	
Unemployed	7 (12)	9 (15)	
(Partially) disabled	7 (12)	11 (18)	
Other (student/housewife-man/retired)	8 (13)	9 (15)	
Educational level[a,c]			0.573
Low	8 (14)	5 (8)	
Middle	25 (43)	30 (50)	
High	25 (43)	25 (42)	
Clinical characteristics[a]	**n (%)**	**n (%)**	**p**
Subtype of ADHD, DSM-IV			0.298
Inattentive type	23 (38)	29 (48)	
Hyperactive/impulsive type	5 (8)	1 (2)	
Combined type	30 (50)	27 (45)	
Not otherwise specified type[d]	2 (3)	3 (5)	
Comorbidity Axis I, DSM-IV			
Current depression	9 (15)	9 (15)	1.000
Recurrent depression, in remission	14 (23)	19 (32)	0.307
Dysthymia	1 (2)	2 (3)	1.000
Bipolar disorder	1 (2)	1 (2)	1.000
Anxiety disorder	8 (13)	14 (23)	0.157
Somatoform disorder	4 (70)	6 (10)	0.509
Eating disorder	1 (2)	1 (2)	1.000
No comorbidity	28 (47)	22 (37)	0.267
Years since ADHD diagnosis; M (s.d.)[b]	1.8 (2.8)	2.8 (5.7)	0.235
Use of ADHD medication	36 (60)	29 (48)	0.200
Previous and current psychoeducation/skills training	36 (60)	35 (58)	0.853
Previous and current psychosocial treatment ADHD	35 (58)	31 (52)	0.463
Outcome measures[b,e]	**M (s.d.)**	**M (s.d.)**	**p**
ADHD symptoms (CAARS-INV)	30.8 (9.0)	32.8 (7.8)	0.196
ADHD symptoms (CAARS-S)	28.7 (7.0)	29.0 (6.0)	0.828
Executive functioning (BRIEF-A)	147.6 (18.3)	146.2 (18.8)	0.681
Mindfulness skills (FFMQ-SF)	72.0 (9.2)	74.0 (9.6)	0.255
Self-compassion (SCS-SF)	44.8 (12.7)	44.8 (12.7)	0.970
Positive mental health (MHC-SF)	3.7 (0.9)	3.6 (0.9)	0.511
General functioning (OQ 45.2)	61.4 (15.4)	63.7 (21.8)	0.510

BRIEF-A, Behaviour Rating Inventory of Executive Function-Adult; CAARS-INV, Conners' Adult ADHD Rating Scale-Investigator; CAARS-S, Conners' Adult ADHD-Self-report; FFMQ-SF, Five Facet Mindfulness Questionnaire-Short Form; MHC-SF, Mental Health Continuum-Short Form; OQ 45.2, Outcome Questionnaire 45.2; SCS-SF, Self Compassion Scale-Short Form.

[a]χ^2 test.

[b]Independent samples t test.

[c]Educational level was classified as low (no education, elementary school, lower secondary education), middle (intermediate vocational education, upper secondary education) and high (higher vocational education, university).

[d]Reasons were: difficulty with recalling the presence of ADHD symptoms in childhood and no collateral history available ($n = 1$), ADHD symptoms in adulthood were aggravated by physical injury ($n = 1$), not displaying sufficient symptoms in childhood and symptoms emerging after meningitis in adulthood ($n = 1$), not displaying sufficient symptoms in childhood and no collateral history available ($n = 2$).

[e]Two participants in the MBCT + TAU group did not complete the baseline questionnaires. Data are based on $n = 58$.

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Table 2. Intention-to-treat analyses on primary and secondary outcomes at post-treatment

	MBCT + TAU ($n = 52$)	TAU ($n = 55$)	Group difference	Analysis			Effect size
	M (s.d.)	*M* (s.d.)	*M* [95% CI][a]	*F*	df	*p*	*d*
Primary outcome							
ADHD symptoms (CAARS-INV), $n = 107$							
Baseline	31.0 (9.1)	32.6 (7.9)					
Post-treatment	27.4 (10.2)	31.5 (8.6)	−3.4 [−5.8 to −1.1]	8.6	96	0.004	0.41
Secondary outcomes							
Inattention (CAARS-INV)							
Baseline	17.3 (5.3)	18.0 (4.2)					
Post-treatment	14.8 (5.6)	17.0 (4.4)	−2.1 [−3.5 to −0.7]	8.6	96	0.004	0.45
Hyperactive/impulsive (CAARS-INV)							
Baseline	13.8 (6.1)	14.6 (5.5)					
Post-treatment	12.7 (6.6)	14.5 (5.6)	−1.4 [−2.7 to −0.1]	4.4	96	0.039	0.24
ADHD symptoms (CAARS-S), $n = 106$							
Baseline	28.8 (6.9)	29.3 (6.1)					
Post-treatment	25.5 (6.8)	28.1 (6.3)	−2.4 [−4.2 to −0.6]	7.1	95	0.009	0.37
Inattention (CAARS-S)							
Baseline	15.6 (3.6)	15.5 (3.3)					
Post-treatment	13.8 (3.9)	14.9 (3.8)	−1.2 [−2.3 to −0.1]	4.4	95	0.038	0.33
Hyperactive/impulsive (CAARS-S)							
Baseline	13.2 (5.0)	13.7 (4.6)					
Post-treatment	11.6 (4.1)	13.2 (4.0)	−1.3 [−2.3 to −0.3]	6.2	95	0.014	0.26
Executive functioning (BRIEF-A), $n = 105$							
Baseline	146.2 (17.8)	147.2 (18.4)					
Post-treatment	140.9 (22.5)	145.9 (19.3)	−3.8 [−8.8 to 1.3]	2.2	94	0.140	0.20
Mindfulness skills (FFMQ-SF), $n = 104$							
Baseline	72.6 (8.7)	74.1 (9.6)					
Post-treatment	76.0 (10.9)	73.5 (9.8)	3.4 [0.1 to 6.7]	4.2	93	0.043	0.36
Self-compassion (SCS-SF) $n = 104$							
Baseline	45.7 (12.8)	44.0 (12.7)					
Post-treatment	50.2 (13.0)	43.5 (13.7)	5.3 [1.5 to 9.1]	7.8	93	0.006	0.42
Positive mental health (MHC-SF), $n = 105$							
Baseline	3.7 (0.9)	3.6 (0.9)					
Post-treatment	3.9 (0.9)	3.5 (0.9)	0.3 [0.04 to 0.5]	5.4	94	0.023	0.32
General functioning (OQ 45.2), $n = 106$							
Baseline	61.7 (15.6)	63.4 (21.4)					
Post-treatment	59.1 (18.2)	61.4 (21.0)	−1.0 [−6.0 to 4.0]	0.2	95	0.693	0.05

BRIEF-A, Behaviour Rating Inventory of Executive Function-Adult; CAARS-INV, Conners' Adult ADHD Rating Scale-Investigator; CAARS-S, Conners' Adult ADHD-Self-report; FFMQ-SF, Five Facet Mindfulness Questionnaire-Short Form; MHC-SF, Mental Health Continuum-Short Form; OQ 45.2, Outcome Questionnaire 45.2; SCS-SF, Self Compassion Scale-Short Form.
[a]Differences between MBCT + TAU and TAU at T1 based on the adjusted means, controlling for baseline levels, centre, use of ADHD medication, previous psychoeducation, gender and ADHD subtype.

participants in MBCT + TAU ($n = 14$; 27%) than in TAU ($n = 2$; 4%) showed a symptom reduction of ⩾30%, $\chi^2(1) = 11.40$, $p = 0.001$. Symptomatic remission was achieved by more participants in MBCT + TAU ($n = 11$; 21%) than in TAU ($n = 4$; 7%), $\chi^2(1) = 4.27$, $p = 0.039$.

Secondary outcomes

ITT analyses revealed that participants in the MBCT + TAU group demonstrated a significant larger reduction of self-reported ADHD symptoms and improvements of mindfulness skills, self-compassion and positive mental health compared with those receiving TAU only,

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with effect sizes varying from $d = 0.32$ to 0.42 (Table 2). No effects were found on executive functioning and general functioning. The PP analyses showed similar results, except for the effect on mindfulness skills ($p = 0.051$, $d = 0.35$). No effects were found for mindfulness skills in the LOCF analyses and for mental health in the MI analyses. The MI analyses did, however, show a small effect on total executive functioning ($p = 0.040$, $d = 0.27$).

Follow-up effects

ITT analyses revealed that the significant difference between MBCT + TAU and TAU in clinician-rated ADHD symptoms remained stable over the course of the 6-month follow-up period (Fig. 2 and Table 3). The same pattern was found for mindfulness skills, self-compassion and positive mental health. A significant group × time interaction was found for self-reported ADHD symptoms, showing that self-reported ADHD symptoms further decreased over time in MBCT + TAU compared with TAU resulting in an effect size of $d = 0.79$ at 6-month follow-up. Over the course of the follow-up period, the difference between groups became significant for executive functioning with improvement of executive functioning in MBCT + TAU compared with TAU.

PP analyses resulted in a similar finding for the primary outcome, $F(1, 94) = 11.9$, $p = 0.001$, $d = 0.40$ and for the secondary outcomes, except for the effect on executive functioning. A significant group × time interaction, $F(2, 95) = 3.5$, $p = 0.034$, showed that executive functioning further improved over time in MBCT + TAU compared with TAU resulting in an effect size of $d = 0.49$ at 6-month follow-up.

Moderation of treatment outcome

Clinician-rated ADHD symptoms at T1 were not predicted by gender, $F(1,102) = 0.1$, $p = 0.783$; age, $F(1,102) = 1.8$, $p = 0.189$; ADHD subtype, $F(3,98) = 0.2$, $p = 0.878$; use of ADHD medication, $F(1,102) = 0.08$, $p = 0.782$; comorbid depressive disorder, $F(1,102) = 2.2$, $p = 0.145$ and comorbid anxiety disorder, $F(1,102) = 0.2$, $p = 0.632$. Similar results were found for clinician-rated ADHD symptoms over the course of the 6-month follow-up period and in the PP sample.

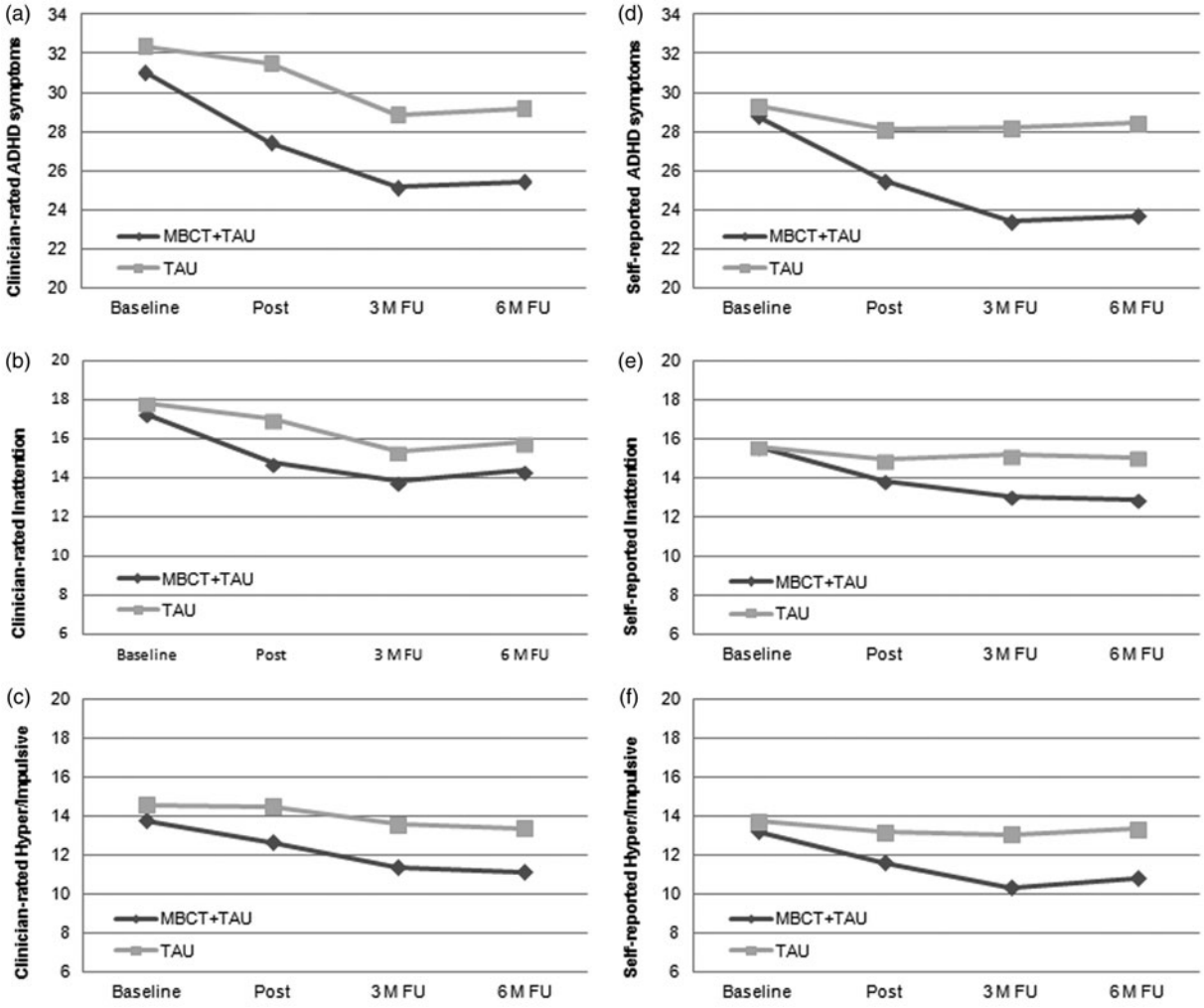

Fig. 2. Unadjusted means for participants in MBCT + TAU and TAU at baseline, post-treatment, 3- and 6-month follow-up of ADHD Symptoms. *Note.* (a) clinician-rated ADHD symptoms, (b) clinician-rated symptoms of inattention, (c) clinician-rated symptoms of hyperactivity/impulsivity, (d) self-reported ADHD symptoms, (e) self-reported symptoms of inattention, (f) self-reported symptoms of hyperactivity/impulsivity.

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Table 3. Follow-up results of primary and secondary outcomes in the intention-to-treat sample

	MBCT + TAU ($n = 52$)	TAU ($n = 56$)	Group difference	Analysis			Effect size
	M (s.d)	*M* (s.d)	*M* [95% CI][a]	*F*	df	*p*	*d*
Primary outcome							
ADHD symptoms (CAARS-INV)			−3.6 [−5.6 to −1.7]	13.4	97	<0.001	0.43
Baseline	31.0 (9.1)	32.4 (7.9)					
Post-treatment	27.4 (10.2)	31.5 (8.6)					
3-month follow-up	25.2 (9.7)	28.9 (7.4)					
6-month follow-up	25.4 (9.5)	29.2 (6.8)					
Secondary outcome							
Inattention (CAARS-INV)			−1.7 [−2.8 to −0.5]	7.8	97	0.006	0.35
Baseline	17.3 (5.3)	17.8 (4.2)					
Post-treatment	14.8 (5.6)	17.0 (4.4)					
3-month follow-up	13.8 (5.4)	15.3 (3.8)					
6-month follow-up	14.4 (5.2)	15.8 (3.5)					
Hyperactive/impulsive (CAARS-INV)			−1.9 [−3.0 to −0.9]	12.7	97	0.001	0.34
Baseline	13.8 (6.1)	14.6 (5.6)					
Post-treatment	12.7 (6.6)	14.5 (5.6)					
3-month follow-up	11.3 (5.8)	13.5 (5.1)					
6-month follow-up	11.1 (5.6)	13.4 (4.9)					
ADHD symptoms (CAARS-S)[b], $n = 107$				6.3	98	0.003	
Baseline	28.8 (6.9)	29.3 (6.1)					
Post-treatment	25.5 (6.8)	28.1 (6.3)	−2.4 [−4.2 to −0.6]	2.7	97	0.008	0.37
3-month follow-up	23.4 (8.0)	28.2 (6.1)	−4.6 [−6.8 to −2.5]	4.3	99	<0.001	0.71
6-month follow-up	23.7 (8.0)	28.4 (5.8)	−5.2 [−7.3 to −3.0]	4.7	98	<0.001	0.79
Inattention (CAARS-S)[b]				3.5	99	0.035	
Baseline	15.6 (3.6)	15.6 (3.3)					
Post-treatment	13.8 (3.9)	14.9 (3.8)	−1.2 [−2.3 to −0.1]	2.2	96	0.033	0.34
3-month follow-up	13.0 (4.6)	15.2 (3.9)	−2.3 [−3.6 to −0.9]	3.3	98	0.001	0.65
6-month follow-up	12.9 (4.4)	15.1 (3.6)	−2.5 [−3.8 to −1.1]	3.6	95	<0.001	0.70
	M (s.d.)	*M* (s.d.)	*M* [95% CI][a]	*F*	df	*p*	*d*
Hyperactive/impulsive (CAARS-S)[b]				4.7	98	0.012	
Baseline	13.2 (5.0)	13.7 (4.5)					
Post-treatment	11.6 (4.6)	13.2 (4.0)	−1.2 [−2.2 to −0.3]	2.5	97	0.015	0.26
3-month follow-up	10.3 (4.6)	13.0 (3.9)	−2.4 [−3.6 to −1.3]	4.1	96	<0.001	0.50
6-month follow-up	10.8 (4.9)	13.3 (3.8)	−2.7 [−3.8 to −1.6]	4.8	99	<0.001	0.56
Executive functioning (BRIEF-A) $n = 106$			−5.3 [−10.1 to −0.5]	4.8	96	0.032	0.29
Baseline	146.2 (17.8)	147.6 (18.5)					
Post-treatment	141.0 (22.3)	145.9 (19.3)					
3-month follow-up	136.6 (25.7)	147.3 (17.6)					
6-month follow-up	137.4 (23.7)	146.7 (18.3)					
Mindfulness skills (FFMQ-SF), $n = 105$			4.0 [1.1 to 7.0]	7.7	93	0.007	0.43
Baseline	72.6 (8.7)	74.3 (9.6)					
Post-treatment	76.1 (10.7)	73.5 (9.8)					

(*Continued*)

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Table 3. (*Continued.*)

	M (s.d.)	*M* (s.d.)	*M* [95% CI][a]	*F*	df	*p*	*d*
3-month follow-up	78.0 (10.3)	72.5 (9.2)					
6-month follow-up	76.7 (11.0)	74.9 (9.0)					
Self-compassion (SCS-SF), *n* = 105			5.9 [2.8 to 9.1]	13.7	94	<0.001	0.47
Baseline	45.7 (12.8)	43.9 (12.6)					
Post-treatment	50.4 (12.9)	43.5 (13.7)					
3-month follow-up	52.0 (13.3)	43.4 (12.1)					
6-month follow-up	53.8 (13.8)	47.0 (14.4)					
Positive mental health (MHC-SF), *n* = 106			0.2 [0.02 to 0.4]	4.6	94	0.034	0.23
Baseline	3.7 (0.9)	3.6 (0.9)					
Post-treatment	3.9 (0.9)	3.5 (0.9)					
3-month follow-up	3.9 (1.1)	3.8 (0.9)					
6-month follow-up	3.9 (0.9)	3.7 (0.9)					
General functioning (OQ 45.2), *n* = 107			−2.4 [−6.7 to 2.0]	1.2	93	0.284	0.12
Baseline	61.7 (15.6)	64.1 (21.7)					
Post-treatment	59.1 (18.2)	61.4 (21.0)					
3-month follow-up	54.7 (20.6)	60.7 (20.8)					
6-month follow-up	54.7 (19.1)	61.5 (21.0)					

BRIEF-A, Behaviour Rating Inventory of Executive Function-Adult; CAARS-INV, Conners' Adult ADHD Rating Scale-Investigator; CAARS-S, Conners' Adult ADHD-Self-report; FFMQ-SF, Five Facet Mindfulness Questionnaire-Short Form; MHC-SF, Mental Health Continuum-Short Form; OQ 45.2, Outcome Questionnaire 45.2; SCS-SF, Self Compassion Scale-Short Form.
[a]Differences between the pooled scores in MBCT + TAU and TAU based on the adjusted means, controlling for baseline levels, centre, use of ADHD medication, previous psychoeducation, gender and ADHD subtype.
[b]A group × time interaction was found. Therefore, we reported the *F*-statistic for the interaction effect and the group differences per time point with the corresponding test-statistics (*t*, df, *p*) instead of the main effect of group.

Discussion

Principal findings

This first well-powered, multicentre, single-blind RCT with follow-up assessments on MBCT for adult ADHD showed that MBCT + TAU is effective in reducing core ADHD symptoms rated by a blinded clinician. The PP and sensitivity analyses underscore the robustness of this finding. The effect on core ADHD symptoms was maintained beyond completion of MBCT until 6-month follow-up.

Additionally, MBCT + TAU resulted in a significant reduction of self-reported ADHD symptoms and improvements of mindfulness skills, self-compassion and positive mental health at post-treatment. While most differences between groups remained stable over the 6-month follow-up period, self-reported ADHD symptoms further decreased in MBCT + TAU compared with TAU. Although no effects were found on executive functioning at post-treatment, over the follow-up period executive functioning was significantly better in the MBCT + TAU group than in the TAU group.

These results were largely in accordance with the findings of the two previous RCTs on MBIs for adults with ADHD (Hepark *et al.* 2015; Mitchell *et al.* 2017), which also found significant reductions of clinician-rated and self-reported core symptoms in comparison to a non-active control group. In contrast with these two studies, which also reported an immediate post-treatment improvement of executive functioning, we only found this over the course of the 6-month follow-up. This could be explained by the application of a more rigorous methodological design and the use of the regular 8-week MBCT programme instead of the 12-week programme (Hepark *et al.* 2015). The found effect at follow-up in participants who completed the MBCT might suggest that it takes more time and practice before MBCT results in improvements of executive functioning; however, this hypothesis needs further investigation, for example, by combining observational clinician-rated and self-reported measures with neurocognitive tasks.

Limitations and strengths

Unfortunately, no data were collected on the number and characteristics of people who were excluded from participation or who declined to be enrolled, which would have provided additional information about the generalizability of our findings. However, since the recruitment for the study was very successful and only lasted 16 months, there seemed to be a substantial interest in MBIs among participants with ADHD. This is in line with the findings of a qualitative study (Matheson *et al.* 2013) under adults with ADHD that there is an unmet need for additional psychosocial interventions alongside medication to improve functioning, since for many access to non-pharmacological treatment is lacking. The ecological validity of this study was also enhanced by the multicentre design with specialised outpatient clinics for adult ADHD located in an academic hospital and in two centres for mental health care across the Netherlands, the relatively broad eligibility criteria including patients with most of the Axis I and II comorbidities according to the DSM-IV and the participation of patients in varying stages of their treatment process. In this way we stayed close to the daily clinical practice.

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A second limitation was that, although we did our best to ensure the blinding of the clinicians, we did not assess the success of blinding as recommended by Boutron *et al.* (2005). This information would have increased the confidence in the validity of our main results. An aspect to reflect on is the range of competence levels of the teachers. This may be considered as a limitation; however, a current study did not find robust effects of teacher competence on possible mediators and outcomes in MBCT for recurrent depression (Huijbers *et al.* 2017). Furthermore, the found range may be representative of mindfulness teachers in daily clinical practice. Another factor to reflect on is the study design with TAU as comparison group. This pragmatic choice enabled us to determine whether MBCT adds incremental benefit to the usual treatments in ADHD (Dimidjian & Segal, 2015), which is an advantage over the comparison with an active control group. It has, however, also limitations, such as the diminished internal validity due to possible differences in TAU between the two conditions. We did, nonetheless, not find any differences in TAU between the two conditions during the intervention period, except for stability of medication. Therefore, an effect of a change in medication could not be completely eliminated.

Research and clinical implications

Interestingly, the participants who dropped-out of the MBCT were less likely to use ADHD medication during the intervention than completers. This suggests that MBCT might be more feasible for patients on ADHD medication. This is in accordance with a recent study that demonstrated that psychological interventions result in better outcomes when combined with methylphenidate instead of a placebo (Philipsen *et al.* 2015). Although we did not find that baseline use of ADHD medication predicted the treatment outcome, future research should further explore the possible interaction between pharmacological and psychosocial interventions in ADHD and the optimal combination of the two. For example, future RCTs could examine to what extent MBCT is suitable as a stand-alone treatment or as an additional intervention to pharmacotherapy to diminish residual symptoms. A 2×2 design, where the effects of MBCT and TAU with and without pharmacotherapy are compared, might be suitable to answer this issue.

In addition, it would be relevant to compare MBCT with an active control group to control for both amount of treatment time and non-specific therapeutic effects such as peer support and home practice exercises. A possible control condition would be CBT, since CBT is the best examined (Young *et al.* 2016) upcoming psychosocial intervention for adult ADHD. As is common in pharmacological studies in ADHD, potential side effects of MBCT should be systematically monitored. In this study, no structural monitoring of side effects was conducted, apart from serious side effects such as suicidal attempts. This information would be helpful for patients to make a well-informed decision whether MBCT is appropriate at this moment (Hanley *et al.* 2016).

Overall, this RCT demonstrated that MBCT has significant benefits to adults with ADHD up to 6 months after post-treatment, with regard to both ADHD symptoms and positive outcomes. So far, research on the consolidation of treatment effects of psychosocial interventions in adults with ADHD is scarce (Philipsen *et al.* 2015; Young *et al.* 2016), although highly relevant for clinical practice to complement the shortcomings of pharmacotherapy as a standalone treatment. So, the results of this RCT indicate that psychosocial interventions, like MBCT, might be valuable additional treatments alongside TAU for adults with ADHD.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0033291718000429

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Declaration of Interest. The research team declares it had no part in developing the original MBCT programme. AS, LJ and SH made small modifications to this programme as described in our pilot study (Janssen *et al.* 2017). The team does not gain income from the sale of books on MBCT, nor does it gain income from giving lectures or workshops about it. AS is the founder and clinical director of the Radboudumc Centre for Mindfulness. LJ and MS are affiliated with this centre. JB has been in the past 4 years a consultant to/member of advisory board of/and/or speaker for Janssen Cilag BV, Eli Lilly, Lundbeck, Shire, Medice 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 and royalties. CK has also been a member of the advisory board and consultancy team of Eli Lilly BV and was a speaker at the Adult-ADHD Academy of Eli Lilly. The other authors declare that they had no competing interests.

About the authors. LJ, CK, PC, BS, SH, RD, JB and AS contributed to the design of the study. AS was the principal investigator of the study. LJ, CK, PC, BS and SH were involved in recruiting participants. LJ took care of the logistics of the project and data collection. LJ and MS analysed and interpreted the data under supervision of RD. LJ drafted the paper, which was critically modified and supplemented by all other authors. All authors read and approved the final version of the manuscript.

Ethical standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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