The efficacy of mindfulness-based interventions in attention-deficit/hyperactivity disorder beyond core symptoms: A systematic review, meta-analysis, and meta-regression

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The efficacy of Mindfulness-Based Interventions on Attention-Deficit/Hyperactivity Disorder beyond core symptoms: A systematic review, meta-analysis, and meta-regression.

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Abstract:	Background: Mindfulness-Based Interventions (MBIs) have been increasingly proposed as treatment in patients with Attention-Deficit/Hyperactivity Disorder (ADHD), showing promising results on different proposed outcomes, in both children and adults. Objectives: to systematically review and meta-analyse studies concerning the effects of MBIs on either ADHD and associated features, associated clinical conditions, neurocognitive impairments, mindfulness skills, global functioning and quality of life. Methods: Searches were conducted on five databases, including controlled and observational studies on both adults and children populations. The review process was compliant to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). Meta-analyses and meta-regression models were conducted. Results: 31 full-texts were included. In both adults and children, MBIs showed to be more effective than waiting lists in improving ADHD symptoms and some other outcomes. In adults, a medium pooled effect size was shown by meta-analysis for ADHD symptoms but in some cases a publication bias was detected. Subgroup analysis and meta-regression confirmed the gap detected by our systematic review between the medium/large effect size of inactive-controlled studies and the low/negligible one of active-controlled studies. In children, no active-controlled studies have been conducted. Mindfulness Awareness Practice (MAP) and Mindfulness Based Cognitive Therapy (MBCT) were the most used protocols in adult studies, whereas a combination of MBCT and Mindfulness Based Stress Reduction (MBSR) was more preferred for children and adolescent patients. Conclusions: Even if further studies with a better methodology are needed, we can suggest the MBIs may be useful as complementation and not as replacement of other active interventions.
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Response to Reviewers:	Thank you for your useful comments that have improved the quality of our work.

Cover Letter

UNIVERSITA' DEGLI STUDI DI TORINO

DIPARTIMENTO DI SCIENZE CLINICHE E BIOLOGICHE

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Prof. Paola Brambilla, Editor-in-Chief

May 9, 2021

Dear Prof. Paola Brambilla,

Please consider for the publication in Journal of Affective Disorders the last reviewed version of the systematic review and meta-analysis entitled: "The efficacy of Mindfulness-Based Interventions on Attention-Deficit/Hyperactivity Disorder beyond core symptoms: A systematic review, meta-analysis, and meta-regression".
I believe that the results we present would be a good fit for your readers, and I hope you will consider evaluating the manuscript to see if it falls within your journal's scope.
Specifically, we have investigated the efficacy of Mindfulness-Based Interventions in children, adolescents, and adults with ADHD not only considering the core symptoms but also encompassing associated features (i.e., emotional dysregulation and sleep disruption), associated clinical conditions (i.e., anxiety and depression), neurocognitive impairments (executive functions and working memory), mindfulness skills, global functioning and quality of life. Subgroup analyses and meta-regressions were also performed to evaluate the impact of the type of control conditions on the pooled effect sizes heterogeneity.
The result is a detailed qualitative and quantitative analysis of the state of the art on the application of mindfulness-based protocols for the treatment of ADHD patients.
The reviewing process was compliant to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). The quality of studies was assessed using the Risk of Bias (RoB2) tool and the Methodological Index for Non-randomized Studies (MINORS) Scale.
All authors have agreed on the contents of the manuscript, and state there is no financial interest to declare.
The manuscript is original work, and it is not under review elsewhere.

Thank you in advance for your attention.

Very respectfully,
Francesco Oliva

Reviewer #1

General comments:
The authors had replied to most of my comments. However, here were still some minor concerns to be addressed.

Result:
In my previous comments on Result Comment 1 and 2, the unusually huge Hedges' g of some studies had caught my eyes. The authors replied that "it is truly great as it could be seen in their paper and our review. For instance, the highest effect size was reported for attention symptoms so much so that Mitchell et al., 2017 was detected as influential study and excluded in sensitivity analyses". If the actual data represent this finding, I would recommend the authors to add one section of discussion about the unusually huge Hedges' g of these studies (not only Mitchell 2017, but also Gu 2018, and Schonberg 2014).
The authors should discuss about the obviously significant treatment effect by mindfulness to symptoms of total ADHD symptoms (S2.1) and attention symptom (S2.13) compared to the traditional medication prescription, which had absolute value of Hedges' g less than 1.0.

- *We are fully in agreement with Reviewer #1 on the importance of such huge effect size observed by Mitchell, Gu and Schonberg. However, it is really difficult to explain this great effect, especially if compared with that of pharmacological treatments. Considering the relevant effect size reached by placebo add-on in some published studies (by Sandler et al.) and bearing in mind that all these three studies were inactive-controlled, we added a sentence suggesting that any type of intervention (i.e., pharmacological treatments, MBIs, psychoeducation, placebo) seems to have a significantly higher effect than WL.*

Reviewer #2

In this study the authors aimed at summarising the available evidence for the use of Mindfulness-Based Interventions in ADHD using a systematic review and meta-analyses. In summary, I believe the study brings important information to the field (mainly related to publication bias and difference in effect estimates among active- and inactive-controlled studies) and should be considered for publication after the revision of the following aspects.

Introduction:
1. In page 3 it says "with a prevalence of 2.2-7.2% among children (Faraone, 2004)". Please, substitute the reference for one of the meta-analyses on the prevalence of ADHD in children and adolescents. For instance: Polanczyk G, de Lima MS, Horta BL, et al (2007) The worldwide prevalence of ADHD: a systematic review and metaregression analysis. Am J Psychiatry 164:942-8. https://doi.org/10.1176/appi.ajp.164.6.942

- *Thanks to the Reviewer #2 for her/his suggestion. We changed the references accordingly.*

2. In page 3 it says "Notably, inattention appears to better respond in adults, whereas hyperactivity and impulsivity improve regardless of age (Chimiklis et al., 2018)". The sentence is not supported by the reference since the study by Chimiklis et al. includes studies performed in youths. Please, clarify.

- *We removed this misleading sentence and we reviewed the sentence before to underline the difference between evidence reported for adults (by Lee et al., 2017) and that described in children (by Chimiklis et al., 2018).*

Methods:
1. Please, clarify the following aspects from figure 1: 619 records screened and 518 excluded, however authors stated that 88 were assessed in the full-text. What about the other 13?

- *Thanks to the Reviewer #2's comment, we realized that we uploaded the wrong PRISMA file and forgot to update the numbers at the beginning of the paragraph on results. This error occurred during the update of the strings and results. We have corrected according to the final data.*

2. In figure 1 it says "Additional records identified through other sources (n = 0)". Please, include in the main text which additional methods were used to identify records.

- *We have added a sentence of explanation in the paragraph regarding the Search strategy used during the studies selection.*

3. Authors mention in figure 1 that 4 studies were excluded due to "Not retrieved". Please, clarify. Ideally, this should not be a reason for exclusion.

- *Thanks to the Reviewer #2 for giving us the opportunity to better explain this point. Initially, the fulltext could not be retrieved for 4 titles retrieved by the search string. During the update we were able to acquire these 4 full texts from international libraries with the aid of the School of Medicine Library. However, reading the full-text content, we had to exclude them because of different "Research issues'' (i.e., they were just review articles or study protocols). An explanation about the meaning and the content of the label "Research issues'' has been provided in response to comment 4 (Please see the next point). We have updated Figure 1, accordingly.*

4. Figure 1 also mentions that 20 studies were excluded due to "Research issues". Please, specify those issues.

- *When reading through 25 of the full texts found by the search string, it emerged that these were not articles on experimental or observational studies, but reviews, perspective articles, study protocols, case series or letters to the editor. Unfortunately, there was no way to tell from the title or abstract alone the reason why they had passed the previous selection stages.*

5. Authors stated that "Article authors were reached via email for any missing information." Please, specify how many contacts were attempted. In addition, please include how many authors were contacted and how many have answered.

- *Thanks to the Reviewer #2 for this comment. We contacted the authors by writing one email both to the corresponding author and to the lead author because, according to the guidelines for systematic reviews and meta-analyses, this procedure is not mandatory but only recommended to have a more inclusive review, and the minimum number of attempts required to exclude a title is not specified.*

Results:

1. In page 6 it says "The search retrieved 27 articles: 16 conducted on adults, ten on children, and one study on a mixed sample of adolescents and adults." However, table S3.1 has data from 15 studies, not 11. Please, clarify.

- *As reported in response to comment 1, we realized that we had not updated the text of the manuscript in line with the data obtained. Thus, we have modified the sentence only because data in the tables are already correct. The abstract has also been updated, accordingly.*

2. Please, recheck column "ADHD diagnosis" of tables S3.1 and S3.2. In the table authors mentioned that in the study by Janssen et al., 2017 the diagnosis was performed using CAARS-S, while in the referenced manuscript it says that "We included patients with a primary diagnosis of ADHD, according to the criteria of Diagnostic and Statistical Manual of Mental Disorders (4th ed., text rev.; DSM- IV-TR; American Psychiatric Association, 2000)." I have observed similar inconsistencies for ADHD diagnosis in the study of Mitchell 2017.

- *Considering both this comment and the following one, we have better specified in the eligibility criteria that we have included the studies concerning patients with a diagnosis of ADHD. Then we decided to rename the column "ADHD diagnosis" to "ADHD assessment", since it actually reports the specific ADHD tools used by the studies, rather than describing the criteria adopted to pose the clinical diagnosis.*

3. In the "ADHD diagnosis" column of table S3.1 it says "Not reported" for the study of Tarrasch et al., 2016. However, in the eligibility criteria authors mentioned that the diagnostic criteria for ADHD should be specified. From that I can conclude that this study should not have been included. Please, clarify.

- *Please, see the reply to the previous comment.*

Discussion:

1. In page 14 it says "The most relevant finding regarding children and adolescents is that no studies have evaluated the effect of MBIs on the most common ADHD diagnostic-associated features, i.e., emotional dysregulation, working memory, and sleep quality." However, the study of Huguet 2019 measures emotional dysregulation in youths. Please, clarify.

- *Sorry, there's nothing to clarify, it's a wrong statement. As reported in the results section ("Controlled studies on children and adolescents with ADHD" subsection, pp 11) Huguet et., 2019 detected a positive effect on emotional dysregulation. We rephrase the sentence consistently to what reported in results section and thus with that observed by Reviewer #2.*

Highlights

- Mindfulness-Based Interventions are effective add-on treatments for ADHD symptoms;
- MAP and MBCT are the most used protocols with adults with ADHD while MBCT and MBSR are the most used protocols with children and adolescents with ADHD;
- Further studies with a better methodology are needed.

Abstract

Background: Mindfulness-Based Interventions (MBIs) have been increasingly proposed as treatment in patients with Attention-Deficit/Hyperactivity Disorder (ADHD), showing promising results on different proposed outcomes, in both children and adults.

Objectives: to systematically review and meta-analyse studies concerning the effects of MBIs on either ADHD and associated features, associated clinical conditions, neurocognitive impairments, mindfulness skills, global functioning and quality of life.

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Conclusions: Even if further studies with a better methodology are needed, we can suggest the MBIs may be useful as complementation and not as replacement of other active interventions.

Keywords: ADHD, Attention Deficit Hyperactivity Disorder, Mindfulness, Mindfulness-Based Interventions, children, adolescents, adults, systematic review

Running head: Mindfulness-based intervention and ADHD

The efficacy of Mindfulness-Based Interventions on Attention-Deficit/Hyperactivity Disorder beyond core symptoms: A systematic review, meta-analysis, and meta-regression.

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Systematic review registration number: PROSPERO CRD42019130639.

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Keywords: ADHD, Attention Deficit Hyperactivity Disorder, Mindfulness, Mindfulness-Based Interventions, children, adolescents, adults, systematic review

Introduction

Attention-Deficit/Hyperactivity Disorder (ADHD) is a highly heritable neurodevelopmental disorder (Faraone, 2004; Faraone et al., 2005; Faraone and Doyle, 2001; Levy et al., 1997; Rietveld et al., 2004; Sprich et al., 2000). The onset of ADHD takes place during childhood (American Psychiatric Association, 2013) with a prevalence of 5.3 (95% CI=5.0–5.6, Polanczyk e al., 2007) ~~2.2-7.2% among children (Faraone, 2004)~~ and it persists into adulthood in two-thirds of the cases (Faraone et al., 2006) affecting 2.5% of the adult population (Simon et al., 2009). The clinical presentation of ADHD may vary between patients, as inattention or hyperactivity/impulsivity could prevail or both of them could be equally represented (Faraone et al., 2015; Franke et al., 2018; Kooij et al., 2019).

ADHD treatment is multimodal, consisting of pharmacological and non-pharmacological approaches always associated with punctual psychoeducation (Kooij et al., 2019). The first-line medications are stimulants, i.e., methylphenidate (MPH) and amphetamines (Dalrymple et al., 2019). Non-pharmacological approaches (i.e., cognitive-behavioral therapy - CBT, and coaching) complement medications addressing not only ADHD symptoms but also DSM-5 associated features (e.g., emotional dysregulation), neuropsychological dysfunction (Willcutt et al., 2005), delayed sleep onset (Kooij and Bijlenga, 2013; Wynchank et al., 2018), and anxiety/depression (Fayyad et al., 2017; Katzman et al., 2017).

Growing interest has been given to Mindfulness-Based Interventions (MBIs) since they have been increasingly used in combination with conventional treatments in mental health (McClintock et al., 2016). MBIs could play a role as augmentation strategies in ADHD since they have shown they can improve attention, awareness, sense of self and executive functions, and reduce impulsivity, emotional dysregulation, and stress levels (Baijal and Gupta, 2008; Hylander et al., 2017; Kozasa et al., 2012; Krisanaprakornkit et al., 2010; Lutz et al., 2008; Rapport et al., 2002; Schonert-Reichl et al., 2015; Tang et al., 2014, 2007; Tsai and Chou, 2016), ameliorating also some comorbid psychiatric conditions such as anxiety, depression, and substance abuse (Bueno et al., 2015; Cole et al., 2016; de Lisle et al., 2012; Gu et al., 2016; Hesslinger et al., 2002; Hofmann et al., 2010; Philipsen et al., 2007; van de Weijer-Bergsma et al., 2012; Vøllestad et al., 2012; Witkiewitz et al., 2013; Zylowska et al., 2008), even in patients with bipolar disorder (Chu et al., 2018; Lovas and Schuman-Olivier, 2018; Xuan et al., 2020).

Some systematic reviews of studies on MBIs and ADHD have already been conducted with promising, albeit still not definitive, conclusions (Cairncross and Miller, 2016; Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019; Tercelli and Ferreira, 2019; Xue et al., 2019). Overall, existing reviews have mainly focused on the effectiveness of mindfulness (or related interventions, such as meditation and yoga) in improving ADHD symptoms. The evidence of MBIs efficacy among adult patients (Lee et al., 2017) seems to be stronger than that detected in children (Chimiklis et al., 2018) ~~(Lee et al., 2017)~~. ~~Notably, inattention appears to better respond in adults, whereas hyperactivity and impulsivity improve regardless of age (Chimiklis et al., 2018)~~. Age and type of control condition seemed to affect the overall effect size on ADHD symptoms according to a prior meta-regression analysis (Xue et al., 2019). Moreover, the majority of

these reviews claimed for the necessity of further investigations, pointing out the low quality and heterogeneity (Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019).
The aim of the present review was to evaluate the efficacy of MBIs in improving not only ADHD symptoms but also diagnostic associated features (i.e., emotional dysregulation, neuropsychological function impairment, circadian rhythm disorder with delayed sleep onset), health status and quality of life, and other associated conditions (e.g., anxiety and depression), focusing on the contribution of different control conditions to the overall effect.

Methods

Protocol registration

The review protocol was registered in the PROSPERO repository (CRD42019130639).

Search strategy for identification of studies

A literature search was performed on PubMed, Embase, CINAHL, PsycINFO, the Cochrane Central Register of Controlled Trials from the earliest dates available to June 25th, 2020 using keywords and text words for ADHD and MBIs. Moreover, we performed a search with the keywords 'ADHD', 'mindfulness' and 'attention deficit hyperactivity disorder' in Google Scholar in order to screen books and book chapters, scholarly articles, and other important grey literature related to the topic. From selected studies, cross-references were checked manually. The search strings are described in Supplementary material (S1.1).

Eligibility criteria

We included studies concerning patients with a diagnosis of ADHD. ~~The diagnostic tool used for ADHD diagnosis had to be specified.~~ There was neither restriction by concurrent organic disease nor limit in terms of participants' gender or age (i.e., children, adolescents, and adults).
We included studies that evaluated MBIs alone or in addition to another treatment in a pre-post design, in comparison with no intervention, Waiting List (WL), Treatment As Usual (TAU) or other types of intervention (e.g. antidepressant medication, CBT, Psychodynamic Therapy). We included studies that provided quantitative data, as measured by standardized psychometric scales, before and after the intervention/s.
Any type of health-related outcome was included. The reasons for exclusion were: 1) qualitative studies, 2) systematic reviews, 3) case reports. No year or language restrictions were applied.

Data collection

Two authors (FO and FM) independently conducted standardized assessments to determine study eligibility, according to the inclusion criteria. First, they screened the abstracts and then retrieved and analyzed the full-texts for all the records deemed relevant. Any disagreement was solved involving a third author (LO).

Data from the selected studies were inserted in a standard template by two independent researchers (FO and FM). Article authors were reached via email for any missing information.

Quality assessment

The internal validity of the Randomized Controlled Trials (RCTs) and the quality of non-RCT studies were assessed by the Version 2 of the Cochrane risk-of-bias tool for RCTs (Sterne et al., 2019) and the MINORS Scale (Slim et al., 2003; Zeng et al., 2015), respectively. Both quality assessment tools were used according to instructions provided by authors.

The risk of bias was assessed by two independent coders (FO and FM) and any disagreements were discussed and resolved with a third reviewer (LO).

Statistical analysis

All meta-analysis procedures were performed using meta (Balduzzi et al., 2019), metafor (Viechtbauer, 2010), and dmetar (Harrer et al., 2019b) packages of R (R Core Team (2020), R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project.org/).

We followed the same procedure for each eligible outcome (i.e., at least three controlled studies should have counted the outcome among those considered).

A random-effect-model based on inverse variance method with Hartung-Knapp-Sidik-Jonkman adjustment (Hartung, 1999) was performed to pooling effect sizes from post-intervention mean, standard deviation, and sample size of two compared groups (meta package). Hedges' g with 95% confidence interval (95%CI) and prediction interval with 95% confidence interval (95%CI) were calculated. Sidik-Jonkman method was used to estimate $\tau 2$ (Sidik and Jonkman, 2007). Heterogeneity was also assessed by Cochran's Q-statistic and Higgin's & Thompson's I^2 estimation (Higgins et al., 2003). No, low, moderate, and high heterogeneity were defined by 25%, between 25% and 50%, between 50 and 75%, and >75% I^2 values, respectively. Forest plots were used to present the model results.

Outliers were detected by checking for lack of overlap between studies and pooled confidence intervals using the dmetar package. Then, a conventional leaved-one-out (Viechtbauer and Cheung, 2010) with Baujat's graphical methods and, when possible, a more sophisticated Graphic Display of Heterogeneity (GOSH) plots with diagnostic methods (Harrer et al., 2019a; Olkin et al., 2012) were used for the influence analysis. Finally, an adjusted model and the respective forest plot were performed excluding outliers and influential studies for a sensitivity analysis.

A contour-enhanced funnel plot and the Egger's test were used to detect publication biases (Egger et al., 1997; Peters et al., 2008). The contour-enhanced funnel plots included three shaded contours marking areas, one for each different significance level of effect size (dark blue, $0.025<p<0.05$; blue, $0.01<p<0.025$; light blue, $p<0.01$) into which the effects size of each study falls. The Duval and Tweedie's trim-and-fill procedure (Duval and Tweedie, 2000) was adopted to calculate the bias-corrected effect size (meta package).

A subgroup analysis using a mixed-effects model (i.e., random-effects model without Hartung-Knapp-Sidik-Jonkman adjustment within subgroups, and fixed-effects model between subgroups) was conducted to evaluate the impact of the type of control condition on pooled effect size. A meta-regression model with control condition was performed and then it was compared through ANOVA test with a multiple meta-regression model using all possible dummy variables that can define subgroups (metafor package). ANOVA test included Akaike's Information Criterion with small sample adjustment (AICc) and Likelihood Ratio Test (LRT) calculations.

Results

Study selection and study characteristics

The PRISMA flowchart describing the selection process, including reasons for exclusion, is presented in Figure 1. The search retrieved ~~27~~ 31 articles: 16 conducted on adults, ~~ten~~ 14 on children, and one study on a mixed sample of adolescents and adults.

Adults

All the details about included studies involving adult patients are summarized in Supplementary material S3.1.

Overall, the studies involved a sample of 1336 patients, 1040 (77.84%) of whom completed the study. The age ranged from 18 to 68 years.

The most employed MBIs protocols were MBCT, MAP and DBT.

Controlled studies on adults with ADHD

ADHD symptoms

All twelve controlled studies investigated the effects of MBIs on ADHD symptoms. Two of them (Cole et al., 2016; Groß et al., 2017) did not provide the required data for the computation of effect sizes and therefore were not included in the meta-analysis. Since not all the eligible studies have reported results on both inattention and hyperactivity symptoms as well as ADHD total symptoms, we built three different models to include the maximum possible number of studies. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.1-S2.36).

The pooled effect size of MBIs on inattention (g=-0.69, 95%CI=-1.13/-0.25, p=0.006) was higher than either that on hyperactivity/impulsivity symptoms (g=-0.46, 95%CI=-0.80/-0.11, p=0.015) and that on ADHD total symptoms (g=-0.52, 95%CI=-0.96/-0.09, p=0.025)

Moderate and significant level of heterogeneity was detected for all three effect sizes (total symptoms, I^2=67.7%, Q=18.59, p=0.005; inattention, I^2=72.6%, Q=32.87, p<0.001; hyperactivity/impulsivity, I^2=57.1%, Q=18.67, p=0.017). No outliers were found in all three meta-analysis models, whereas some influential studies were identified. Sensitivity analysis excluding influential studies successfully reduced heterogeneity

of each outcome (total symptoms, I^2=57.5%, Q=11.76, p=0.038; inattention, I^2=69.5, Q=26.24, p=0.001; hyperactivity/impulsivity, I^2=0.0%, Q=3.59, p=0.609) without any change in term of effect size of MBIs on inattention symptoms (g=-0.60, 95%CI=-0.99/-0.20, p=0.008) and with a great reduction of the effect size on ADHD total symptoms (g=-0.42, 95%CI=-0.82/-0.01, p=0.046) and hyperactivity/impulsivity symptoms (g=-0.38, 95%CI=0.61/0.15, p=0.008). A certain skewness for small-sized impacting studies could be noticed at funnel plots beyond not significant Egger's tests (total, Egger's test=-1.78, 95%CI=-9.23/-5.67, p=0.657; inattention, Egger's test=-4.02, 95%CI=-7.94/-0.10, p=0.074; hyperactivity/impulsivity symptoms, Egger's test=-2.90, 95%CI=-6.82/-1.02, p=0.183), suggesting possible publication biases. The effect size obtained by controlling for selective publication according to the trim-and-fill procedure was unchanged for total (g=-0.52, 95%CI=-0.96/-0.09, p=0.025), medium for inattention symptoms (g=0.50, 95%CI=-0.96/-0.04, p=0.035), and under significance level for hyperactivity/impulsivity (g=-0.30, 95%CI=-0.70/0.09, p=0.114).

Subgroup analysis underlined the impact of control conditions on between-studies heterogeneity for all three ADHD symptoms outcomes. Heterogeneity in both active and inactive control subgroups was null for total (Figure 2) and attention symptoms (Figure 3), and really low for hyperactivity/impulsivity (Figure 4). Moreover, significant differences were found between studies with active and those with inactive control conditions in terms of effect size on total ($\chi2(1)$=11.84, p<0.001), inattention ($\chi2(1)$=15.99, p<0.001), and hyperactivity/impulsivity symptoms ($\chi2$ (1)=7.79, p=0.005).

Multiple meta-regression model including both control conditions (active and inactive) and rater (patient, clinician, observer) did not outperform that with control condition alone in explaining ADHD symptoms heterogeneity of total ADHD symptoms (AICc control+rater= 122.19, AICc control= 11.57, LRT=1.38, p=0.846), inattentive (AICc control+rater= 38.96, AICc control= 11.06, LRT 2.10, p=0.552) and hyperactivity/impulsivity (AICc control+rater= 53.19, AICc control= 12.15, LRT =2.17, p=0.539). Indeed, the model with control condition only explained 100% of the heterogeneity and showed a significant moderation effect for total symptoms (F(1,5)=17.79, p =0.008), inattention (F(1,8)=28.54, p<0.001) and hyperactivity/impulsivity (F(1,7)=9.62, p=0.017). Among all the investigated predictors, inactive control only had a significant predictive value for both inattention (b=-0.898, t=-5.34, p<0.001) and hyperactivity/impulsivity (b=-0.578, t=-3.10, p=0.017) as well as total ADHD symptoms (b=-0.722, t=-4.22, p=0.008).

Neuropsychological functions

Overall eight studies (Bachmann et al., 2018; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Mitchell et al., 2017; Schoenberg et al., 2014) investigated neuropsychological functions. A meta-analysis on the effect of MBIs on neuropsychological functions was not conducted because of the extreme between-study difference in assessment tools and outcomes (See supplementary materials S3.1). However, four controlled studies (Fleming et al., 2015; Hepark et al., 2019; Janssen et al., 2018; Mitchell et al., 2017) have properly assessed pre-post intervention variations of

executive functions with consistent tools and thus were meta-analytically investigated. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.37-S2.45). Pooled effect size was medium (g=-0.65, 95%CI=-1.24/-0.06, p=0.038) with low and non-significant heterogeneity (I^2=55.4%, Q=6.73, p=0.081). No outliers were detected and one influential study was identified and excluded in the sensitivity analysis, which showed a null heterogeneity (I^2=0.0%, Q=0.36, p=0.836) and an increased effect size (g=-0.89, 95%CI=-1.20/-0.57, p=0.007). However, a publication bias was detected and the model corrected according to trim-and-fill analysis presented a small effect size (g=-0.38, 95%CI=-0.97/0.22, p=0.164) and considerable heterogeneity (I^2=75.6%, Q=20.51, p=0.001).
Subgroup analysis showed a higher effect size for studies comparing MBI with inactive control conditions (χ2(1)=6.18, p=0.013; Figure 5). The two groups presented a negligible heterogeneity (Figure 5).
The meta-regression model with control conditions (active, inactive) fully explained the heterogeneity of effect size, but did not find any significant moderator effect (R^2=100.0%, F(1,4)= 7.90, p=0.107). No other models could be built with the available variables.

Associated conditions

Anxiety and depression were the only two associated conditions, which were investigated by at least three controlled studies.
The meta-analysis on five studies (Bueno et al., 2015; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018) investigating the efficacy of MBIs on depression showed a small effect size (g=-0.35, 95%CI=-0.64/-0.06, p=0.028) without between-studies heterogeneity (I^2=0.0%, Q=3.06, p=0.548). No outliers were detected and one possible influential study was found. Sensitivity analysis without the influential study showed a smaller effect size (g=-0.26, 95%CI=-0.43/-0.09, p=0.028) while maintaining null heterogeneity (I^2=0.0%, Q=0.55, p=0.90).
As regards anxiety, four studies (Bueno et al., 2015; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019) were pooled showing a medium effect size (g=-0.61, 95%CI=-0.87/-0.35, p=0.005) without heterogeneity (I^2=0.0%, Q=1.08, p=0.782). No outliers were detected and one possible influential study was identified and excluded in sensitive analysis. The resulting model confirmed a moderate effect size (g=-0.53, 95%CI=-0.61/-0.46, p=0.001) without heterogeneity (I^2=0.0%, Q=0.02; p=0.988). No publication biases were found for both anxiety and depression meta-analyses. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.46-S2.63).
No subgroup analyses and meta-regressions were conducted considering the lack of between-study heterogeneity.
Anger and hopelessness (Cole et al., 2016), health status (Janssen et al., 2018), emotional dysregulation (Mitchell et al., 2017), and perceived stress (Schoenberg et al., 2014) were investigated in one study each. All authors reported a better outcome for MBIs than for control conditions.

Mindfulness related outcome

Two controlled studies (Cole et al., 2016; Edel et al., 2017) and sixfive RCTs (Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Schoenberg et al., 2014) investigated mindfulness related outcomes. A meta-analysis was conducted on sevensix controlled studies (see Supplementary material S2.64-S2.72 for details) as the study by Cole et al. (Cole et al., 2016) did not provide the necessary data. A medium effect size (g=0.586, 95%CI=0.2517/.916, p=0.0315) with a certainconsiderable heterogeneity (I^2=56.563.1%, Q=13.7856, p=0.03219) was estimated. No outliers were found and one possible influential study was identified. Sensitive analysis without the influential study showed a similar effect size (g=0.66, 95%CI=0.3729/0.951.03, p=0.0027) with a not significant heterogeneity (I^2=313.945.1%, Q=7.3429, p=0.19621). A publication bias was detected and the model adjusted according to trim-and-fill procedure showed a low effect size (g=0.5149, 95%CI=0.180/0.847, p=0.00821) with significant heterogeneity (I^2=60.15.8%, Q=17.565, p=0.01407).
Subgroup analysis focusing on control conditions showed a significantly high effect size for studies comparing MBI with inactive control condition ($\chi2(1)$=4.915.45, p<0.02619; Figure 6). This subgroup analysis really impacted on between-studies heterogeneity as both groups presented low and not significant heterogeneity (Figure 6).
The meta-regression model with control conditions (active, inactive) fully explained the heterogeneity of effect sizes, without showing a significant moderator effect (R^2=100.0%, F(1,54)= 4.885.35, p=0.07881). The full model including also assessment tool and intervention as factors did not outperform that with control condition alone in explaining effect size heterogeneity (AICc control+assessment+intervention=119.2964.08, AICc control=136.736, LRT= 6.454.68, p=0.168096) and in revealing significant predictors.

General functioning and quality of life

Two controlled studies (Bueno et al., 2015; Cole et al., 2016) and four RCTs (Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Schoenberg et al., 2014) also included these two outcomes.
A meta-analysis was conducted despite the low number of studies showing data on changes of quality of life and global functioning after MBI (see Supplementary material S2.73-S2.85 for details). The pooled effect size of the three studies considering quality of life was large (g=0.86, 95%CI=-0.59/2.31, p=0.125) and with considerable heterogeneity (I^2=75%, Q=8.06, p=0.018). No outliner was detected and one influential study was excluded. Sensitive analysis showed a large and significant effect size (g=1.24, 95%CI=0.46/2.01, p=0.031) without heterogeneity (I^2=0.0%, Q=0.06, p=0.809). A publication bias was detected and the trim-and-fill adjusted model had a small but not significant effect size (g=0.26, 95%CI=-0.94/1.46, p=0.579) with a considerable heterogeneity (I^2=86.7%, Q=30.02, p<0.001).
The pooled effect size of the three studies considering global functioning was low and not significant (g=-0.28, 95%CI=-0.82/0.26, p=0.156) and no heterogeneity was found (I^2=0.0%, Q=1.70, p=0.428). No outliner was identified and one influential study was excluded from the sensitive analysis model, which showed a large but not significant effect size (g=-0.40, 95%CI=-2.26/1.47, p=0.225) without heterogeneity (I^2=0.0%,

Q=0.65, p=0.421). A publication bias was detected and the trim-and-fill adjusted model had a negligible effect size (g=-0.12, 95%CI=-0.52/0.28, p=0.449) with a certain heterogeneity (I^2=31.3%, Q=5.83, p=0.213). No subgroup analysis and meta-regression were conducted considering the number of studies and the lack of between-study heterogeneity.
Lastly, only one study considered self-efficacy (Edel et al., 2017) finding no significant differences between MBI and control conditions in improving this outcome.

Observational studies on adults with ADHD

ADHD symptoms

All five studies found improvement in ADHD symptoms, reporting a significant reduction in both attention deficit and hyperactivity/ impulsivity after MBIs (Hepark et al., 2014; Janssen et al., 2018; Philipsen et al., 2007; Tarrasch et al., 2016; Zylowska et al., 2008). One study specified the effect size to be large for both the symptoms domains (Hepark et al., 2014).

Neuropsychological functions

Two studies considered neuropsychological functioning (Janssen et al., 2017; Zylowksa et al., 2008) finding a significant enhancement of executive functions.

Associated conditions

Three studies (Philipsen et al., 2007; Tarrasch et al., 2016; Zylowska et al., 2008) reported a significant improvement in depressive symptoms, whereas anxiety responded to MBIs only in one out of three studies (Zylowska et al., 2008).
Two studies investigated health status (Janssen et al., 2017; Philipsen et al., 2007), finding significant improvements.
Other associated conditions were investigated in single studies (supplementary materials S3.1)

Mindfulness related outcomes

Two studies (Janssen et al., 2017; Tarrasch et al., 2016) observed a significant improvement in mindfulness related outcomes after MBI.

General functioning and quality of life

Quality of life (Hepark et al., 2014), general functioning (Janssen et al., 2017), and satisfaction with life (Tarrasch et al., 2016) were investigated in single studies (supplementary materials S3.1).

Risk of bias and quality of the studies on adults with ADHD

Nine RCTs were assessed with RoB2 (Supplementary material S1.2). As can be seen in Supplementary material S1.3, several methodological weaknesses were found. No study reached an overall low risk of bias.

Similarly, all eight observational and controlled studies showed a high risk of bias (Supplementary material S1.4).

Children and adolescents

Fifteen studies were included on children and adolescents with ADHD (see Supplementary material S3.2 for details). The whole population was composed by 412 children and adolescents, 384 (93.2%) of whom completed the study. The age ranged from seven to 16 years.

The most adopted protocol was a combination of MBSR and MBCT.

Controlled studies on children and adolescents with ADHD

ADHD symptoms

ADHD symptoms were measured in seven (Huguet et al., 2019; Muratori et al., 2020; Sidhu 2015; Rynczak, 2013; van der Oord et al., 2012; Vanzin et al., 2020a, Vanzin et al., 2020b) out of the eight controlled studies included. Two studies (Rynczak, 2013; Muratori et al., 2020) also considered impulsivity as a separate outcome, whereas Sibalis et al. (Sibalis et al., 2019), Sidhu (Sidhu 2015), and Vanzin et al. (Vanzin et al., 2020b) measured attention alone. In particular, the latter investigated focused and sustained attention, attention inhibition and flexibility. MBI outperformed any control condition, the only two exceptions being Vanzin et al. (Vanzin et al., 2020a; Vanzin et al., 2020b) who did not find any difference between ACT and placebo drugs.

Associated conditions

Only one controlled study considered emotion dysregulation as its outcome and found MBI significantly outperformed control condition in improving emotional dysregulation (Huguet et al., 2019).

Mindfulness related outcomes

Mindfulness level among children was measured in two studies (Muratori et al., 2020; van der Oord et al., 2012).

Observational studies on children and adolescents with ADHD

ADHD symptoms

Overall, these were the most investigated outcomes. Inattention was considered in seven studies (Haydicky et al., 2015; Huguet et al., 2017; van de Weijer-Bergsma et al., 2012; Vanzin et al., 2020b; Worth, 2014; Zhang et al., 2017; Zylowska et al., 2008) whilst hyperactivity/impulsivity was investigated only in four of them (Haydicky et al., 2015; Huguet et al., 2017; Worth, 2014; Zylowska et al., 2008). ADHD symptoms were always reduced after MBIs, only in one study the control condition outperformed MBI in ameliorating hyperactivity/impulsivity (Haydicky et al., 2015).

Neuropsychological functions

Executive functions were investigated in four studies (Huguet et al., 2017; van de Weijer-Bergsma et al., 2012; Worth, 2014; Zhang et al., 2017). Only Worth (Worth, 2014) did not find MBI outperforming the control condition.

Behavioral problems were considered in three studies (Carboni et al., 2013; van de Weijer-Bergsma et al., 2012; Zhang et al., 2017), however, only one of them found this outcome to significantly respond to MBI (Carboni et al., 2013).

Associated conditions

Three studies evaluated anxiety response to MBI (Haydicky et al., 2015; Huguet et al., 2017; Zylowska et al., 2008). Post-treatment anxiety levels were lower only in one study (Zylowska et al., 2008) as Huguet et al. (Huguet et al., 2017) noticed a statistically significant reduction of parent-reported but not of self-reported anxiety symptoms and Haydicky et al. (Haydicky et al., 2015) did not find any change from baseline.

The same three studies also evaluated depressive symptoms and again only Zylowska et al. (Zylowska et al., 2008) did find a significant pre-post intervention reduction.

Fatigue was considered in a single study (van de Weijer-Bergsma et al., 2012), which did not find any improvement after MBI (van de Weijer-Bergsma et al., 2012).

Mindfulness related outcomes

Mindful skills (Worth, 2014), acceptance level (Haydicky et al., 2015), and mindfulness awareness (van de Weijer-Bergsma et al., 2012) were considered in one study each, with conflicting results.

Risk of bias and quality of the studies on children and adolescents with ADHD

Three RCTs were assessed with RoB2 (Supplementary material S1.2). The study showed a high risk of bias. Conversely, two studies showed some concerns only (Huguet et al., 2019; Muratori et al., 2020). All eleven observational and controlled studies showed a high risk of bias (Supplementary material S1.4).

Discussion

Consistently with previous systematic reviews and meta-analysis (Cairncross and Miller, 2016; Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019; Tercelli and Ferreira, 2019; Xue et al., 2019) ADHD symptoms are confirmed to be the most studied outcomes. As regards adults, the highest efficacy of MBIs was detected on attention symptoms and total ADHD symptoms (medium effect size). The small effect on hyperactivity-impulsivity disappeared when publication bias adjustment was applied as well as sensitivity analysis greatly reduced the effect size on hyperactivity-impulsivity and even that on total ADHD. Overall, MBIs confirmed their efficacy on ADHD symptoms regardless of the different adjustments, though its effect seems to be higher on attention symptoms.

Subgroup analysis and meta-regression were consistent in supporting a significantly higher efficacy of MBIs vs. inactive controls than vs. active controls, which seemed to fully explain the pooled effect size heterogeneity. According to our findings in the majority of active-controlled studies, MBIs failed to outperform psychoeducation and skills training groups. The confidence interval of pooled effect size of studies with active controls included the null value in total ADHD symptoms and hyperactivity/impulsivity subgroup analysis, but not in that of attention symptoms. This small advantage of MBIs on psychoeducation should be confirmed by future and better designed RCTs, however, MBIs option should be taken into account in patients with predominantly inattentive presentation or if residual attention symptoms persist after psychoeducation or skills training. Among the inactive-controlled RCTs, three studies stood out for their large effect size on attention and total symptoms (Gu et al., 2018; Mitchell et al., 2017; Schoenberg et al., 2014), which was greater than that reached by the most efficacious stimulant treatments (see Cortese et al., 2018 for a comprehensive meta-analysis). Quality and size mainly explain this results, but differences between control groups (i.e., WL for aforementioned MBIs' studies and placebo drugs for stimulants RCTs) should be also taken into account, since some studies have reported a considerable pre-post effect of placebo drug at least in children (Sandler et al., 2010; Sandler and Bodfish, 2008). It could be suggested that any intervention seems to have a significantly higher effect than WL in improving ADHD symptoms.

Beyond ADHD symptoms, mindfulness skills, neuropsychological performance, and depression were the most studied outcomes in the adult ADHD population.

Concerning mindfulness skills, a medium effect size was estimated by meta-analysis that persisted after sensitivity analysis and publication bias adjustment, but it was affected by heterogeneity due to control conditions: MBIs showed a large effect size when compared to inactive control, whereas had no effect when compared to active control. Future studies should investigate this aspect, also evaluating the actual amount of mindfulness daily practice.

Only half of active-controlled studies found MBIs more effective in improving executive functions. Meta-analysis partially solved this issue as both of those active-controlled studies had a confidence interval of effect size that included the null value. Overall sample size was medium without heterogeneity but both sensitivity analysis and publication bias adjustment really affected this estimation. Subgroup analysis found a large effect size for inactive-controlled studies, which contributed significantly to the overall effect size. Conversely, active-controlled studies did not show any effect. Meta-regression did not confirm a moderator effect of control condition on heterogeneity. Further studies are needed to confirm MBIs efficacy in ameliorating this outcome, regardless of the control condition. Moreover, a possible latency of the response could be involved as in a longitudinal study MBI showed a positive effect on executive functions only at follow-up but not at post-treatment. Only one study considered working memory, revealing that MBI and psychoeducation are similarly effective.

The poor performance of MBIs on depression levels suggested by systematic review was confirmed by meta-analysis conducted on controlled studies that found a small and homogeneous effect size, regardless of sensitivity analysis and without publication bias. Conversely, anxiety levels seemed to remarkably improve

according to meta-analysis conducted on controlled studies, which showed a medium effect size without heterogeneity and publication bias, which persisted after sensitivity analysis. Further active-controlled studies should include this outcome to provide data on the efficacy size of MBIs on anxiety in ADHD patients.

According to our findings, MBIs seemed not to confirm in ADHD patients the efficacy found in other clinical populations in reducing depressive and anxiety symptoms (Hofmann and Gómez, 2017).

Global functioning and quality of life are both improved by MBIs in all observational studies and once again MBIs were more effective than inactive but not than active controls. A meta-analytic subgroup analysis to confirm systematic review findings was not allowed due to the paucity of studies for either quality of life and global functioning. The meta-analysis showed a large effect size on quality of life with a lot of heterogeneity due to low effect reported by one active-controlled study, that was greatly reduced after publication bias adjustment, confirming the need for further controlled studies investigating this outcome. As regards global functioning, no effect of MBI was detected by meta-analysis even after publication bias adjustment.

Particularly noteworthy is that few authors have studied emotional dysregulation (Mitchell et al., 2017; Philipsen et al., 2007), anger outbursts (Cole et al., 2016), and sleep onset (Tarrasch et al., 2016).

No study has considered self-esteem as an outcome, which is instead a common condition in ADHD, and can also lead to misdiagnosis (i.e., dysthymia, depression), significantly affecting patients' functioning and quality of life (Kooij et al., 2019).

As regards children and adolescents, the number of studies and the overall sample was really smaller than those including adults and no active-controlled studies have been conducted yet. As with adults, ADHD symptoms confirmed to be the most studied outcome. All the controlled and about half of observational studies found significant improvements. Notably, MBIs showed to be more effective on inattention than on hyperactivity/impulsivity. A meta-analytic investigation on children studies could not be performed because of the low number of studies.

With regard to other outcomes, really few observational studies considered depression, anxiety (in one study reported as internalizing symptoms), mindfulness related outcomes, and executive functions, whereas no controlled studies have investigated neuropsychological functions, general functioning and quality of life.

The most relevant finding regarding children and adolescents is that only one RCT considered emotional dysregulation, whereas none have evaluated the effect of MBIs on the other ADHD diagnostic-associated features, i.e., working memory and sleep quality.

The included studies had several limitations. The risk of bias assessment revealed that 75% of the RCTs have at least some concerns and that all controlled or observational studies have a high risk of bias. Only few studies performed a follow-up and the sample size was small in almost all of the included studies. Ad-hoc mindfulness protocols have often been used instead of already validated protocols to fit the studied populations (e.g., protocols adapted to children, to the school context or, more generally, to ADHD) without providing sufficient details on the adopted interventions and that reduces the methods reproducibility.

No studies compared mindfulness different protocols with each other or focused on the efficacy of mindfulness single components (self-judgment, self-compassion, participatory attention and observation, non-judgmental labeling, acceptance, etc.). Moreover, the number and the duration of sessions varied considerably across the studies. Few studies reported data on acceptability rate and adherence. Altogether, these limitations have important consequences on the possibility to draw a solid conclusion regarding the effectiveness of MBIs in ADHD and on the estimation of a true effect size during meta-analytic evaluation. The selected studies also had some strengths. In most of the articles the outcome evaluation criteria were well explained and the assessment tools were validated. Furthermore, each study investigated a wide variety of outcomes, offering an overview of the potential that MBIs could have in treating patients with ADHD.

Limitations and strengths of this review

To our knowledge, this is the first systematic review that included any type of study design, MBI protocol, outcome, and age of the population. According to previous reviews findings about age, data were collected separately for adults and children, and subgroup analysis and meta-regression were performed to evaluate the impact of the type of control population on effect size. Moreover, unlike prior meta-analyses (Xue et al., 2019), influential studies were detected using different levels of methods (leave-one-out, Baujat's graphical method, and GOSH method).

Implications for clinical practice and research

This systematic review offers new perspectives for future research. The low general methodological quality highlights the need to conduct more active-controlled studies, on larger sample sizes with measurement at follow-up. Future studies should choose validated mindfulness protocols in order to reduce the heterogeneity and increase replicability and comparability.

Concerning outcomes, the systematic review highlights the importance of a deeper investigation on the most common ADHD associated features (i.e., emotional dysregulation, executive functions and working memory, late sleep onset). Future studies should also include among their outcomes the commonly present low self-esteem, especially when anxiety and depression are investigated.

From a clinical standpoint, according to the poor available evidence, we cannot conclude that MBIs are superior to other active interventions in ameliorating all the considered outcomes, suggesting a role as complementation and not as replacement of the psychoeducation in the management of patients with ADHD, consistently with some current guidelines' recommendations (Kooij et al., 2019).

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Conflicts of interest

The authors declare that they have no conflict of interest.

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Running head: Mindfulness-based intervention and ADHD

The efficacy of Mindfulness-Based Interventions on Attention-Deficit/Hyperactivity Disorder beyond core symptoms: A systematic review, meta-analysis, and meta-regression.

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Abstract

Background: Mindfulness-Based Interventions (MBIs) have been increasingly proposed as treatment in patients with Attention-Deficit/Hyperactivity Disorder (ADHD), showing promising results on different proposed outcomes, in both children and adults.

Objectives: to systematically review and meta-analyse studies concerning the effects of MBIs on either ADHD and associated features, associated clinical conditions, neurocognitive impairments, mindfulness skills, global functioning and quality of life.

Methods: Searches were conducted on five databases, including controlled and observational studies on both adults and children populations. The review process was compliant to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA). Meta-analyses and meta-regression models were conducted.

Results: 31 full-texts were included. In both adults and children, MBIs showed to be more effective than waiting lists in improving ADHD symptoms and some other outcomes. In adults, a medium pooled effect size was shown by meta-analysis for ADHD symptoms but in some cases a publication bias was detected. Subgroup analysis and meta-regression confirmed the gap detected by our systematic review between the medium/large effect size of inactive-controlled studies and the low/negligible one of active-controlled studies. In children, no active-controlled studies have been conducted. Mindfulness Awareness Practice (MAP) and Mindfulness Based Cognitive Therapy (MBCT) were the most used protocols in adult studies, whereas a combination of MBCT and Mindfulness Based Stress Reduction (MBSR) was more preferred for children and adolescent patients.

Conclusions: Even if further studies with a better methodology are needed, we can suggest the MBIs may be useful as complementation and not as replacement of other active interventions.

Keywords: ADHD, Attention Deficit Hyperactivity Disorder, Mindfulness, Mindfulness-Based Interventions, children, adolescents, adults, systematic review

Introduction

Attention-Deficit/Hyperactivity Disorder (ADHD) is a highly heritable neurodevelopmental disorder (Faraone, 2004; Faraone et al., 2005; Faraone and Doyle, 2001; Levy et al., 1997; Rietveld et al., 2004; Sprich et al., 2000). The onset of ADHD takes place during childhood (American Psychiatric Association, 2013) with a prevalence of 5.3 (95% CI=5.0–5.6, Polanczyk e al., 2007) and it persists into adulthood in two-thirds of the cases (Faraone et al., 2006) affecting 2.5% of the adult population (Simon et al., 2009). The clinical presentation of ADHD may vary between patients, as inattention or hyperactivity/impulsivity could prevail or both of them could be equally represented (Faraone et al., 2015; Franke et al., 2018; Kooij et al., 2019).

ADHD treatment is multimodal, consisting of pharmacological and non-pharmacological approaches always associated with punctual psychoeducation (Kooij et al., 2019). The first-line medications are stimulants, i.e., methylphenidate (MPH) and amphetamines (Dalrymple et al., 2019). Non-pharmacological approaches (i.e., cognitive-behavioral therapy - CBT, and coaching) complement medications addressing not only ADHD symptoms but also DSM-5 associated features (e.g., emotional dysregulation), neuropsychological dysfunction (Willcutt et al., 2005), delayed sleep onset (Kooij and Bijlenga, 2013; Wynchank et al., 2018), and anxiety/depression (Fayyad et al., 2017; Katzman et al., 2017).

Growing interest has been given to Mindfulness-Based Interventions (MBIs) since they have been increasingly used in combination with conventional treatments in mental health (McClintock et al., 2016). MBIs could play a role as augmentation strategies in ADHD since they have shown they can improve attention, awareness, sense of self and executive functions, and reduce impulsivity, emotional dysregulation, and stress levels (Baijal and Gupta, 2008; Hylander et al., 2017; Kozasa et al., 2012; Krisanaprakornkit et al., 2010; Lutz et al., 2008; Rapport et al., 2002; Schonert-Reichl et al., 2015; Tang et al., 2014, 2007; Tsai and Chou, 2016), ameliorating also some comorbid psychiatric conditions such as anxiety, depression, and substance abuse (Bueno et al., 2015; Cole et al., 2016; de Lisle et al., 2012; Gu et al., 2016; Hesslinger et al., 2002; Hofmann et al., 2010; Philipsen et al., 2007; van de Weijer-Bergsma et al., 2012; Vøllestad et al., 2012; Witkiewitz et al., 2013; Zylowska et al., 2008), even in patients with bipolar disorder (Chu et al., 2018; Lovas and Schuman-Olivier, 2018; Xuan et al., 2020).

Some systematic reviews of studies on MBIs and ADHD have already been conducted with promising, albeit still not definitive, conclusions (Cairncross and Miller, 2016; Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019; Tercelli and Ferreira, 2019; Xue et al., 2019). Overall, existing reviews have mainly focused on the effectiveness of mindfulness (or related interventions, such as meditation and yoga) in improving ADHD symptoms. The evidence of MBIs efficacy among adult patients (Lee et al., 2017) seems to be stronger than that detected in children (Chimiklis et al., 2018). . Age and type of control condition seemed to affect the overall effect size on ADHD symptoms according to a prior meta-regression analysis (Xue et al., 2019). Moreover, the majority of these reviews claimed for the necessity of further

investigations, pointing out the low quality and heterogeneity (Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019).

The aim of the present review was to evaluate the efficacy of MBIs in improving not only ADHD symptoms but also diagnostic associated features (i.e., emotional dysregulation, neuropsychological function impairment, circadian rhythm disorder with delayed sleep onset), health status and quality of life, and other associated conditions (e.g., anxiety and depression), focusing on the contribution of different control conditions to the overall effect.

Methods

Protocol registration

The review protocol was registered in the PROSPERO repository (CRD42019130639).

Search strategy for identification of studies

A literature search was performed on PubMed, Embase, CINAHL, PsycINFO, the Cochrane Central Register of Controlled Trials from the earliest dates available to June 25th, 2020 using keywords and text words for ADHD and MBIs. Moreover, we performed a search with the keywords 'ADHD', 'mindfulness' and 'attention deficit hyperactivity disorder' in Google Scholar in order to screen books and book chapters, scholarly articles, and other important grey literature related to the topic. From selected studies, cross-references were checked manually. The search strings are described in Supplementary material (S1.1).

Eligibility criteria

We included studies concerning patients with a diagnosis of ADHD. There was neither restriction by concurrent organic disease nor limit in terms of participants' gender or age (i.e., children, adolescents, and adults).

We included studies that evaluated MBIs alone or in addition to another treatment in a pre-post design, in comparison with no intervention, Waiting List (WL), Treatment As Usual (TAU) or other types of intervention (e.g. antidepressant medication, CBT, Psychodynamic Therapy). We included studies that provided quantitative data, as measured by standardized psychometric scales, before and after the intervention/s.

Any type of health-related outcome was included. The reasons for exclusion were: 1) qualitative studies, 2) systematic reviews, 3) case reports. No year or language restrictions were applied.

Data collection

Two authors (FO and FM) independently conducted standardized assessments to determine study eligibility, according to the inclusion criteria. First, they screened the abstracts and then retrieved and analyzed the full-texts for all the records deemed relevant. Any disagreement was solved involving a third author (LO).

Data from the selected studies were inserted in a standard template by two independent researchers (FO and FM). Article authors were reached via email for any missing information.

Quality assessment

The internal validity of the Randomized Controlled Trials (RCTs) and the quality of non-RCT studies were assessed by the Version 2 of the Cochrane risk-of-bias tool for RCTs (Sterne et al., 2019) and the MINORS Scale (Slim et al., 2003; Zeng et al., 2015), respectively. Both quality assessment tools were used according to instructions provided by authors.

The risk of bias was assessed by two independent coders (FO and FM) and any disagreements were discussed and resolved with a third reviewer (LO).

Statistical analysis

All meta-analysis procedures were performed using meta (Balduzzi et al., 2019), metafor (Viechtbauer, 2010), and dmetar (Harrer et al., 2019b) packages of R (R Core Team (2020), R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. https://www.R-project.org/).

We followed the same procedure for each eligible outcome (i.e., at least three controlled studies should have counted the outcome among those considered).

A random-effect-model based on inverse variance method with Hartung-Knapp-Sidik-Jonkman adjustment (Hartung, 1999) was performed to pooling effect sizes from post-intervention mean, standard deviation, and sample size of two compared groups (meta package). Hedges' g with 95% confidence interval (95%CI) and prediction interval with 95% confidence interval (95%CI) were calculated. Sidik-Jonkman method was used to estimate $\tau 2$ (Sidik and Jonkman, 2007). Heterogeneity was also assessed by Cochran's Q-statistic and Higgin's & Thompson's I^2 estimation (Higgins et al., 2003). No, low, moderate, and high heterogeneity were defined by 25%, between 25% and 50%, between 50 and 75%, and >75% I^2 values, respectively. Forest plots were used to present the model results.

Outliers were detected by checking for lack of overlap between studies and pooled confidence intervals using the dmetar package. Then, a conventional leaved-one-out (Viechtbauer and Cheung, 2010) with Baujat's graphical methods and, when possible, a more sophisticated Graphic Display of Heterogeneity (GOSH) plots with diagnostic methods (Harrer et al., 2019a; Olkin et al., 2012) were used for the influence analysis. Finally, an adjusted model and the respective forest plot were performed excluding outliers and influential studies for a sensitivity analysis.

A contour-enhanced funnel plot and the Egger's test were used to detect publication biases (Egger et al., 1997; Peters et al., 2008). The contour-enhanced funnel plots included three shaded contours marking areas, one for each different significance level of effect size (dark blue, $0.025<p<0.05$; blue, $0.01<p<0.025$; light blue, $p<0.01$) into which the effects size of each study falls. The Duval and Tweedie's trim-and-fill procedure (Duval and Tweedie, 2000) was adopted to calculate the bias-corrected effect size (meta package).

A subgroup analysis using a mixed-effects model (i.e., random-effects model without Hartung-Knapp-Sidik-Jonkman adjustment within subgroups, and fixed-effects model between subgroups) was conducted to evaluate the impact of the type of control condition on pooled effect size. A meta-regression model with control condition was performed and then it was compared through ANOVA test with a multiple meta-regression model using all possible dummy variables that can define subgroups (metafor package). ANOVA test included Akaike's Information Criterion with small sample adjustment (AICc) and Likelihood Ratio Test (LRT) calculations.

Results

Study selection and study characteristics

The PRISMA flowchart describing the selection process, including reasons for exclusion, is presented in Figure 1. The search retrieved 31 articles: 16 conducted on adults, 14 on children, and one study on a mixed sample of adolescents and adults.

Adults

All the details about included studies involving adult patients are summarized in Supplementary material S3.1.

Overall, the studies involved a sample of 1336 patients, 1040 (77.84%) of whom completed the study. The age ranged from 18 to 68 years.

The most employed MBIs protocols were MBCT, MAP and DBT.

Controlled studies on adults with ADHD

ADHD symptoms

All twelve controlled studies investigated the effects of MBIs on ADHD symptoms. Two of them (Cole et al., 2016; Groß et al., 2017) did not provide the required data for the computation of effect sizes and therefore were not included in the meta-analysis. Since not all the eligible studies have reported results on both inattention and hyperactivity symptoms as well as ADHD total symptoms, we built three different models to include the maximum possible number of studies. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.1-S2.36).

The pooled effect size of MBIs on inattention (g=-0.69, 95%CI=-1.13/-0.25, p=0.006) was higher than either that on hyperactivity/impulsivity symptoms (g=-0.46, 95%CI=-0.80/-0.11, p=0.015) and that on ADHD total symptoms (g=-0.52, 95%CI=-0.96/-0.09, p=0.025)

Moderate and significant level of heterogeneity was detected for all three effect sizes (total symptoms, I^2=67.7%, Q=18.59, p=0.005; inattention, I^2=72.6%, Q=32.87, p<0.001; hyperactivity/impulsivity, I^2=57.1%, Q=18.67, p=0.017). No outliers were found in all three meta-analysis models, whereas some influential studies were identified. Sensitivity analysis excluding influential studies successfully reduced heterogeneity

of each outcome (total symptoms, I^2=57.5%, Q=11.76, p=0.038; inattention, I^2=69.5, Q=26.24, p=0.001; hyperactivity/impulsivity, I^2=0.0%, Q=3.59, p=0.609) without any change in term of effect size of MBIs on inattention symptoms (g=-0.60, 95%CI=-0.99/-0.20, p=0.008) and with a great reduction of the effect size on ADHD total symptoms (g=-0.42, 95%CI=-0.82/-0.01, p=0.046) and hyperactivity/impulsivity symptoms (g=-0.38, 95%CI=0.61/0.15, p=0.008). A certain skewness for small-sized impacting studies could be noticed at funnel plots beyond not significant Egger's tests (total, Egger's test=-1.78, 95%CI=-9.23/-5.67, p=0.657; inattention, Egger's test=-4.02, 95%CI=-7.94/-0.10, p=0.074; hyperactivity/impulsivity symptoms, Egger's test=-2.90, 95%CI=-6.82/-1.02, p=0.183), suggesting possible publication biases. The effect size obtained by controlling for selective publication according to the trim-and-fill procedure was unchanged for total (g=-0.52, 95%CI=-0.96/-0.09, p=0.025), medium for inattention symptoms (g=0.50, 95%CI=-0.96/-0.04, p=0.035), and under significance level for hyperactivity/impulsivity (g=-0.30, 95%CI=-0.70/0.09, p=0.114).

Subgroup analysis underlined the impact of control conditions on between-studies heterogeneity for all three ADHD symptoms outcomes. Heterogeneity in both active and inactive control subgroups was null for total (Figure 2) and attention symptoms (Figure 3), and really low for hyperactivity/impulsivity (Figure 4). Moreover, significant differences were found between studies with active and those with inactive control conditions in terms of effect size on total ($\chi2(1)$=11.84, p<0.001), inattention ($\chi2(1)$=15.99, p<0.001), and hyperactivity/impulsivity symptoms ($\chi2$ (1)=7.79, p=0.005).

Multiple meta-regression model including both control conditions (active and inactive) and rater (patient, clinician, observer) did not outperform that with control condition alone in explaining ADHD symptoms heterogeneity of total ADHD symptoms (AICc control+rater= 122.19, AICc control= 11.57, LRT=1.38, p=0.846), inattentive (AICc control+rater= 38.96, AICc control= 11.06, LRT 2.10, p=0.552) and hyperactivity/impulsivity (AICc control+rater= 53.19, AICc control= 12.15, LRT =2.17, p=0.539). Indeed, the model with control condition only explained 100% of the heterogeneity and showed a significant moderation effect for total symptoms (F(1,5)=17.79, p =0.008), inattention (F(1,8)=28.54, p<0.001) and hyperactivity/impulsivity (F(1,7)=9.62, p=0.017). Among all the investigated predictors, inactive control only had a significant predictive value for both inattention (b=-0.898, t=-5.34, p<0.001) and hyperactivity/impulsivity (b=-0.578, t=-3.10, p=0.017) as well as total ADHD symptoms (b=-0.722, t=-4.22, p=0.008).

Neuropsychological functions

Overall eight studies (Bachmann et al., 2018; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Mitchell et al., 2017; Schoenberg et al., 2014) investigated neuropsychological functions. A meta-analysis on the effect of MBIs on neuropsychological functions was not conducted because of the extreme between-study difference in assessment tools and outcomes (See supplementary materials S3.1). However, four controlled studies (Fleming et al., 2015; Hepark et al., 2019; Janssen et al., 2018; Mitchell et al., 2017) have properly assessed pre-post intervention variations of

executive functions with consistent tools and thus were meta-analytically investigated. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.37-S2.45). Pooled effect size was medium (g=-0.65, 95%CI=-1.24/-0.06, p=0.038) with low and non-significant heterogeneity (I^2=55.4%, Q=6.73, p=0.081). No outliers were detected and one influential study was identified and excluded in the sensitivity analysis, which showed a null heterogeneity (I^2=0.0%, Q=0.36, p=0.836) and an increased effect size (g=-0.89, 95%CI=-1.20/-0.57, p=0.007). However, a publication bias was detected and the model corrected according to trim-and-fill analysis presented a small effect size (g=-0.38, 95%CI=-0.97/0.22, p=0.164) and considerable heterogeneity (I^2=75.6%, Q=20.51, p=0.001).
Subgroup analysis showed a higher effect size for studies comparing MBI with inactive control conditions ($\chi 2(1)=6.18$, p=0.013; Figure 5). The two groups presented a negligible heterogeneity (Figure 5).
The meta-regression model with control conditions (active, inactive) fully explained the heterogeneity of effect size, but did not find any significant moderator effect (R^2=100.0%, F(1,4)= 7.90, p=0.107). No other models could be built with the available variables.

Associated conditions

Anxiety and depression were the only two associated conditions, which were investigated by at least three controlled studies.
The meta-analysis on five studies (Bueno et al., 2015; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018) investigating the efficacy of MBIs on depression showed a small effect size (g=-0.35, 95%CI=-0.64/-0.06, p=0.028) without between-studies heterogeneity (I^2=0.0%, Q=3.06, p=0.548). No outliers were detected and one possible influential study was found. Sensitivity analysis without the influential study showed a smaller effect size (g=-0.26, 95%CI=-0.43/-0.09, p=0.028) while maintaining null heterogeneity (I^2=0.0%, Q=0.55, p=0.90).
As regards anxiety, four studies (Bueno et al., 2015; Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019) were pooled showing a medium effect size (g=-0.61, 95%CI=-0.87/-0.35, p=0.005) without heterogeneity (I^2=0.0%, Q=1.08, p=0.782). No outliers were detected and one possible influential study was identified and excluded in sensitive analysis. The resulting model confirmed a moderate effect size (g=-0.53, 95%CI=-0.61/-0.46, p=0.001) without heterogeneity (I^2=0.0%, Q=0.02; p=0.988). No publication biases were found for both anxiety and depression meta-analyses. All respective forest plots, influential and sensitivity analyses, and funnel plots were presented in the Supplementary material S2 (S2.46-S2.63).
No subgroup analyses and meta-regressions were conducted considering the lack of between-study heterogeneity.
Anger and hopelessness (Cole et al., 2016), health status (Janssen et al., 2018), emotional dysregulation (Mitchell et al., 2017), and perceived stress (Schoenberg et al., 2014) were investigated in one study each. All authors reported a better outcome for MBIs than for control conditions.

Mindfulness related outcome

Two controlled studies (Cole et al., 2016; Edel et al., 2017) and six RCTs (Fleming et al., 2015; Gu et al., 2018; Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Schoenberg et al., 2014) investigated mindfulness related outcomes. A meta-analysis was conducted on seven controlled studies (see Supplementary material S2.64-S2.72 for details) as the study by Cole et al. (Cole et al., 2016) did not provide the necessary data. A medium effect size (g=0.58, 95%CI=0.25/.91, p=0.03) with a certain heterogeneity (I^2=56.5%, Q=13.78, p=0.032) was estimated. No outliers were found and one possible influential study was identified. Sensitive analysis without the influential study showed a similar effect size (g=0.66, 95%CI=0.37/0.95, p=0.002) with a not significant heterogeneity (I^2=313.9%, Q=7.34, p=0.196). A publication bias was detected and the model adjusted according to trim-and-fill procedure showed a low effect size (g=0.51, 95%CI=0.18/0.84, p=0.008) with significant heterogeneity (I^2=60.1%, Q=17.56, p=0.014).

Subgroup analysis focusing on control conditions showed a significantly high effect size for studies comparing MBI with inactive control condition ($\chi 2(1)=4.91$, $p<0.026$; Figure 6). This subgroup analysis really impacted on between-studies heterogeneity as both groups presented low and not significant heterogeneity (Figure 6).

The meta-regression model with control conditions (active, inactive) fully explained the heterogeneity of effect sizes, without showing a significant moderator effect (R^2=100.0%, F(1,5)= 4.88, p=0.078). The full model including also assessment tool and intervention as factors did not outperform that with control condition alone in explaining effect size heterogeneity (AICc control+assessment+intervention=119.29 AICc control=13.73, LRT= 6.45, p=0.168) and in revealing significant predictors.

General functioning and quality of life

Two controlled studies (Bueno et al., 2015; Cole et al., 2016) and four RCTs (Hepark et al., 2019; Hoxhaj et al., 2018; Janssen et al., 2018; Schoenberg et al., 2014) also included these two outcomes.

A meta-analysis was conducted despite the low number of studies showing data on changes of quality of life and global functioning after MBI (see Supplementary material S2.73-S2.85 for details). The pooled effect size of the three studies considering quality of life was large (g=0.86, 95%CI=-0.59/2.31, p=0.125) and with considerable heterogeneity (I^2=75%, Q=8.06, p=0.018). No outliner was detected and one influential study was excluded. Sensitive analysis showed a large and significant effect size (g=1.24, 95%CI=0.46/2.01, p=0.031) without heterogeneity (I^2=0.0%, Q=0.06, p=0.809). A publication bias was detected and the trim-and-fill adjusted model had a small but not significant effect size (g=0.26, 95%CI=-0.94/1.46, p=0.579) with a considerable heterogeneity (I^2=86.7%, Q=30.02, p<0.001).

The pooled effect size of the three studies considering global functioning was low and not significant (g=-0.28, 95%CI=-0.82/0.26, p=0.156) and no heterogeneity was found (I^2=0.0%, Q=1.70, p=0.428). No outliner was identified and one influential study was excluded from the sensitive analysis model, which showed a large but not significant effect size (g=-0.40, 95%CI=-2.26/1.47, p=0.225) without heterogeneity (I^2=0.0%,

Q=0.65, p=0.421). A publication bias was detected and the trim-and-fill adjusted model had a negligible effect size (g=-0.12, 95%CI=-0.52/0.28, p=0.449) with a certain heterogeneity (I^2=31.3%, Q=5.83, p=0.213). No subgroup analysis and meta-regression were conducted considering the number of studies and the lack of between-study heterogeneity.
Lastly, only one study considered self-efficacy (Edel et al., 2017) finding no significant differences between MBI and control conditions in improving this outcome.

Observational studies on adults with ADHD

ADHD symptoms

All five studies found improvement in ADHD symptoms, reporting a significant reduction in both attention deficit and hyperactivity/ impulsivity after MBIs (Hepark et al., 2014; Janssen et al., 2018; Philipsen et al., 2007; Tarrasch et al., 2016; Zylowska et al., 2008). One study specified the effect size to be large for both the symptoms domains (Hepark et al., 2014).

Neuropsychological functions

Two studies considered neuropsychological functioning (Janssen et al., 2017; Zylowksa et al., 2008) finding a significant enhancement of executive functions.

Associated conditions

Three studies (Philipsen et al., 2007; Tarrasch et al., 2016; Zylowska et al., 2008) reported a significant improvement in depressive symptoms, whereas anxiety responded to MBIs only in one out of three studies (Zylowska et al., 2008).
Two studies investigated health status (Janssen et al., 2017; Philipsen et al., 2007), finding significant improvements.
Other associated conditions were investigated in single studies (supplementary materials S3.1)

Mindfulness related outcomes

Two studies (Janssen et al., 2017; Tarrasch et al., 2016) observed a significant improvement in mindfulness related outcomes after MBI.

General functioning and quality of life

Quality of life (Hepark et al., 2014), general functioning (Janssen et al., 2017), and satisfaction with life (Tarrasch et al., 2016) were investigated in single studies (supplementary materials S3.1).

Risk of bias and quality of the studies on adults with ADHD

Nine RCTs were assessed with RoB2 (Supplementary material S1.2). As can be seen in Supplementary material S1.3, several methodological weaknesses were found. No study reached an overall low risk of bias.

Similarly, all eight observational and controlled studies showed a high risk of bias (Supplementary material S1.4).

Children and adolescents

Fifteen studies were included on children and adolescents with ADHD (see Supplementary material S3.2 for details). The whole population was composed by 412 children and adolescents, 384 (93.2%) of whom completed the study. The age ranged from seven to 16 years.

The most adopted protocol was a combination of MBSR and MBCT.

Controlled studies on children and adolescents with ADHD

ADHD symptoms

ADHD symptoms were measured in seven (Huguet et al., 2019; Muratori et al., 2020; Sidhu 2015; Rynczak, 2013; van der Oord et al., 2012; Vanzin et al., 2020a, Vanzin et al., 2020b) out of the eight controlled studies included. Two studies (Rynczak, 2013; Muratori et al., 2020) also considered impulsivity as a separate outcome, whereas Sibalis et al. (Sibalis et al., 2019), Sidhu (Sidhu 2015), and Vanzin et al. (Vanzin et al., 2020b) measured attention alone. In particular, the latter investigated focused and sustained attention, attention inhibition and flexibility. MBI outperformed any control condition, the only two exceptions being Vanzin et al. (Vanzin et al., 2020a; Vanzin et al., 2020b) who did not find any difference between ACT and placebo drugs.

Associated conditions

Only one controlled study considered emotion dysregulation as its outcome and found MBI significantly outperformed control condition in improving emotional dysregulation (Huguet et al., 2019).

Mindfulness related outcomes

Mindfulness level among children was measured in two studies (Muratori et al., 2020; van der Oord et al., 2012).

Observational studies on children and adolescents with ADHD

ADHD symptoms

Overall, these were the most investigated outcomes. Inattention was considered in seven studies (Haydicky et al., 2015; Huguet et al., 2017; van de Weijer-Bergsma et al., 2012; Vanzin et al., 2020b; Worth, 2014; Zhang et al., 2017; Zylowska et al., 2008) whilst hyperactivity/impulsivity was investigated only in four of them (Haydicky et al., 2015; Huguet et al., 2017; Worth, 2014; Zylowska et al., 2008). ADHD symptoms were always reduced after MBIs, only in one study the control condition outperformed MBI in ameliorating hyperactivity/impulsivity (Haydicky et al., 2015).

Neuropsychological functions

Executive functions were investigated in four studies (Huguet et al., 2017; van de Weijer-Bergsma et al., 2012; Worth, 2014; Zhang et al., 2017). Only Worth (Worth, 2014) did not find MBI outperforming the control condition.

Behavioral problems were considered in three studies (Carboni et al., 2013; van de Weijer-Bergsma et al., 2012; Zhang et al., 2017), however, only one of them found this outcome to significantly respond to MBI (Carboni et al., 2013).

Associated conditions

Three studies evaluated anxiety response to MBI (Haydicky et al., 2015; Huguet et al., 2017; Zylowska et al., 2008). Post-treatment anxiety levels were lower only in one study (Zylowska et al., 2008) as Huguet et al. (Huguet et al., 2017) noticed a statistically significant reduction of parent-reported but not of self-reported anxiety symptoms and Haydicky et al. (Haydicky et al., 2015) did not find any change from baseline.

The same three studies also evaluated depressive symptoms and again only Zylowska et al. (Zylowska et al., 2008) did find a significant pre-post intervention reduction.

Fatigue was considered in a single study (van de Weijer-Bergsma et al., 2012), which did not find any improvement after MBI (van de Weijer-Bergsma et al., 2012).

Mindfulness related outcomes

Mindful skills (Worth, 2014), acceptance level (Haydicky et al., 2015), and mindfulness awareness (van de Weijer-Bergsma et al., 2012) were considered in one study each, with conflicting results.

Risk of bias and quality of the studies on children and adolescents with ADHD

Three RCTs were assessed with RoB2 (Supplementary material S1.2). The study showed a high risk of bias. Conversely, two studies showed some concerns only (Huguet et al., 2019; Muratori et al., 2020). All eleven observational and controlled studies showed a high risk of bias (Supplementary material S1.4).

Discussion

Consistently with previous systematic reviews and meta-analysis (Cairncross and Miller, 2016; Chimiklis et al., 2018; Evans et al., 2018; Lee et al., 2017; Poissant et al., 2019; Tercelli and Ferreira, 2019; Xue et al., 2019) ADHD symptoms are confirmed to be the most studied outcomes. As regards adults, the highest efficacy of MBIs was detected on attention symptoms and total ADHD symptoms (medium effect size). The small effect on hyperactivity-impulsivity disappeared when publication bias adjustment was applied as well as sensitivity analysis greatly reduced the effect size on hyperactivity-impulsivity and even that on total ADHD. Overall, MBIs confirmed their efficacy on ADHD symptoms regardless of the different adjustments, though its effect seems to be higher on attention symptoms.

Subgroup analysis and meta-regression were consistent in supporting a significantly higher efficacy of MBIs vs. inactive controls than vs. active controls, which seemed to fully explain the pooled effect size heterogeneity. According to our findings in the majority of active-controlled studies, MBIs failed to outperform psychoeducation and skills training groups. The confidence interval of pooled effect size of studies with active controls included the null value in total ADHD symptoms and hyperactivity/impulsivity subgroup analysis, but not in that of attention symptoms. This small advantage of MBIs on psychoeducation should be confirmed by future and better designed RCTs, however, MBIs option should be taken into account in patients with predominantly inattentive presentation or if residual attention symptoms persist after psychoeducation or skills training. Among the inactive-controlled RCTs, three studies stood out for their large effect size on attention and total symptoms (Gu et al., 2018; Mitchell et al., 2017; Schoenberg et al., 2014), which was greater than that reached by the most efficacious stimulant treatments (see Cortese et al., 2018 for a comprehensive meta-analysis). Quality and size mainly explain this results, but differences between control groups (i.e., WL for aforementioned MBIs' studies and placebo drugs for stimulants RCTs) should be also taken into account, since some studies have reported a considerable pre-post effect of placebo drug at least in children (Sandler et al., 2010; Sandler and Bodfish, 2008). It could be suggested that any intervention seems to have a significantly higher effect than WL in improving ADHD symptoms.

Beyond ADHD symptoms, mindfulness skills, neuropsychological performance, and depression were the most studied outcomes in the adult ADHD population.

Concerning mindfulness skills, a medium effect size was estimated by meta-analysis that persisted after sensitivity analysis and publication bias adjustment, but it was affected by heterogeneity due to control conditions: MBIs showed a large effect size when compared to inactive control, whereas had no effect when compared to active control. Future studies should investigate this aspect, also evaluating the actual amount of mindfulness daily practice.

Only half of active-controlled studies found MBIs more effective in improving executive functions. Meta-analysis partially solved this issue as both of those active-controlled studies had a confidence interval of effect size that included the null value. Overall sample size was medium without heterogeneity but both sensitivity analysis and publication bias adjustment really affected this estimation. Subgroup analysis found a large effect size for inactive-controlled studies, which contributed significantly to the overall effect size. Conversely, active-controlled studies did not show any effect. Meta-regression did not confirm a moderator effect of control condition on heterogeneity. Further studies are needed to confirm MBIs efficacy in ameliorating this outcome, regardless of the control condition. Moreover, a possible latency of the response could be involved as in a longitudinal study MBI showed a positive effect on executive functions only at follow-up but not at post-treatment. Only one study considered working memory, revealing that MBI and psychoeducation are similarly effective.

The poor performance of MBIs on depression levels suggested by systematic review was confirmed by meta-analysis conducted on controlled studies that found a small and homogeneous effect size, regardless of sensitivity analysis and without publication bias. Conversely, anxiety levels seemed to remarkably improve

according to meta-analysis conducted on controlled studies, which showed a medium effect size without heterogeneity and publication bias, which persisted after sensitivity analysis. Further active-controlled studies should include this outcome to provide data on the efficacy size of MBIs on anxiety in ADHD patients.

According to our findings, MBIs seemed not to confirm in ADHD patients the efficacy found in other clinical populations in reducing depressive and anxiety symptoms (Hofmann and Gómez, 2017).

Global functioning and quality of life are both improved by MBIs in all observational studies and once again MBIs were more effective than inactive but not than active controls. A meta-analytic subgroup analysis to confirm systematic review findings was not allowed due to the paucity of studies for either quality of life and global functioning. The meta-analysis showed a large effect size on quality of life with a lot of heterogeneity due to low effect reported by one active-controlled study, that was greatly reduced after publication bias adjustment, confirming the need for further controlled studies investigating this outcome. As regards global functioning, no effect of MBI was detected by meta-analysis even after publication bias adjustment.

Particularly noteworthy is that few authors have studied emotional dysregulation (Mitchell et al., 2017; Philipsen et al., 2007), anger outbursts (Cole et al., 2016), and sleep onset (Tarrasch et al., 2016).

No study has considered self-esteem as an outcome, which is instead a common condition in ADHD, and can also lead to misdiagnosis (i.e., dysthymia, depression), significantly affecting patients' functioning and quality of life (Kooij et al., 2019).

As regards children and adolescents, the number of studies and the overall sample was really smaller than those including adults and no active-controlled studies have been conducted yet. As with adults, ADHD symptoms confirmed to be the most studied outcome. All the controlled and about half of observational studies found significant improvements. Notably, MBIs showed to be more effective on inattention than on hyperactivity/impulsivity. A meta-analytic investigation on children studies could not be performed because of the low number of studies.

With regard to other outcomes, really few observational studies considered depression, anxiety (in one study reported as internalizing symptoms), mindfulness related outcomes, and executive functions, whereas no controlled studies have investigated neuropsychological functions, general functioning and quality of life.

The most relevant finding regarding children and adolescents is that only one RCT considered emotional dysregulation, whereas none have evaluated the effect of MBIs on the other ADHD diagnostic-associated features, i.e., working memory and sleep quality.

The included studies had several limitations. The risk of bias assessment revealed that 75% of the RCTs have at least some concerns and that all controlled or observational studies have a high risk of bias. Only few studies performed a follow-up and the sample size was small in almost all of the included studies. Ad-hoc mindfulness protocols have often been used instead of already validated protocols to fit the studied populations (e.g., protocols adapted to children, to the school context or, more generally, to ADHD) without providing sufficient details on the adopted interventions and that reduces the methods reproducibility.

No studies compared mindfulness different protocols with each other or focused on the efficacy of mindfulness single components (self-judgment, self-compassion, participatory attention and observation, non-judgmental labeling, acceptance, etc.). Moreover, the number and the duration of sessions varied considerably across the studies. Few studies reported data on acceptability rate and adherence. Altogether, these limitations have important consequences on the possibility to draw a solid conclusion regarding the effectiveness of MBIs in ADHD and on the estimation of a true effect size during meta-analytic evaluation. The selected studies also had some strengths. In most of the articles the outcome evaluation criteria were well explained and the assessment tools were validated. Furthermore, each study investigated a wide variety of outcomes, offering an overview of the potential that MBIs could have in treating patients with ADHD.

Limitations and strengths of this review

To our knowledge, this is the first systematic review that included any type of study design, MBI protocol, outcome, and age of the population. According to previous reviews findings about age, data were collected separately for adults and children, and subgroup analysis and meta-regression were performed to evaluate the impact of the type of control population on effect size. Moreover, unlike prior meta-analyses (Xue et al., 2019), influential studies were detected using different levels of methods (leave-one-out, Baujat's graphical method, and GOSH method).

Implications for clinical practice and research

This systematic review offers new perspectives for future research. The low general methodological quality highlights the need to conduct more active-controlled studies, on larger sample sizes with measurement at follow-up. Future studies should choose validated mindfulness protocols in order to reduce the heterogeneity and increase replicability and comparability.

Concerning outcomes, the systematic review highlights the importance of a deeper investigation on the most common ADHD associated features (i.e., emotional dysregulation, executive functions and working memory, late sleep onset). Future studies should also include among their outcomes the commonly present low self-esteem, especially when anxiety and depression are investigated.

From a clinical standpoint, according to the poor available evidence, we cannot conclude that MBIs are superior to other active interventions in ameliorating all the considered outcomes, suggesting a role as complementation and not as replacement of the psychoeducation in the management of patients with ADHD, consistently with some current guidelines' recommendations (Kooij et al., 2019).

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Conflicts of interest

The authors declare that they have no conflict of interest.

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Figure 1

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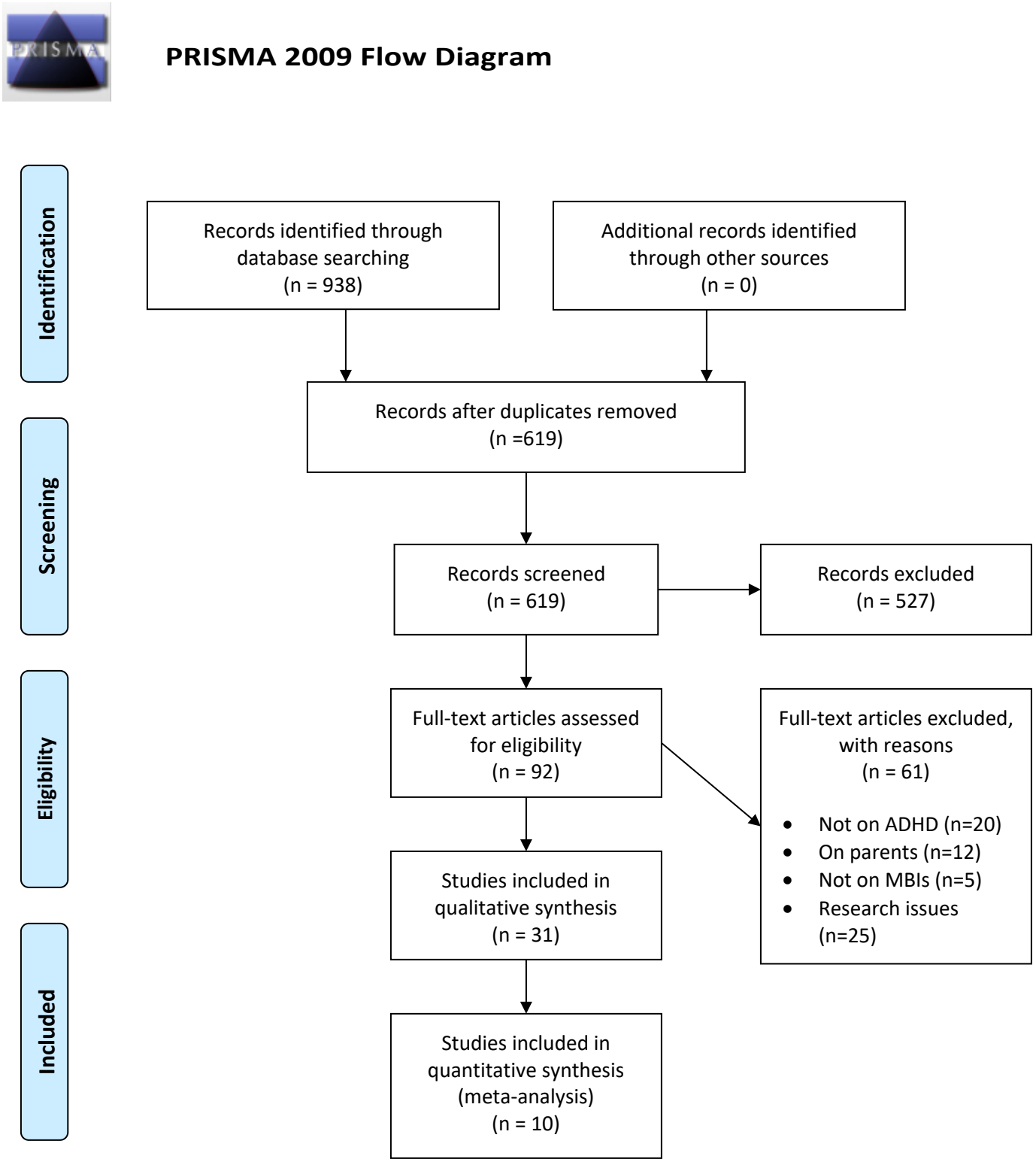

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Figure 2

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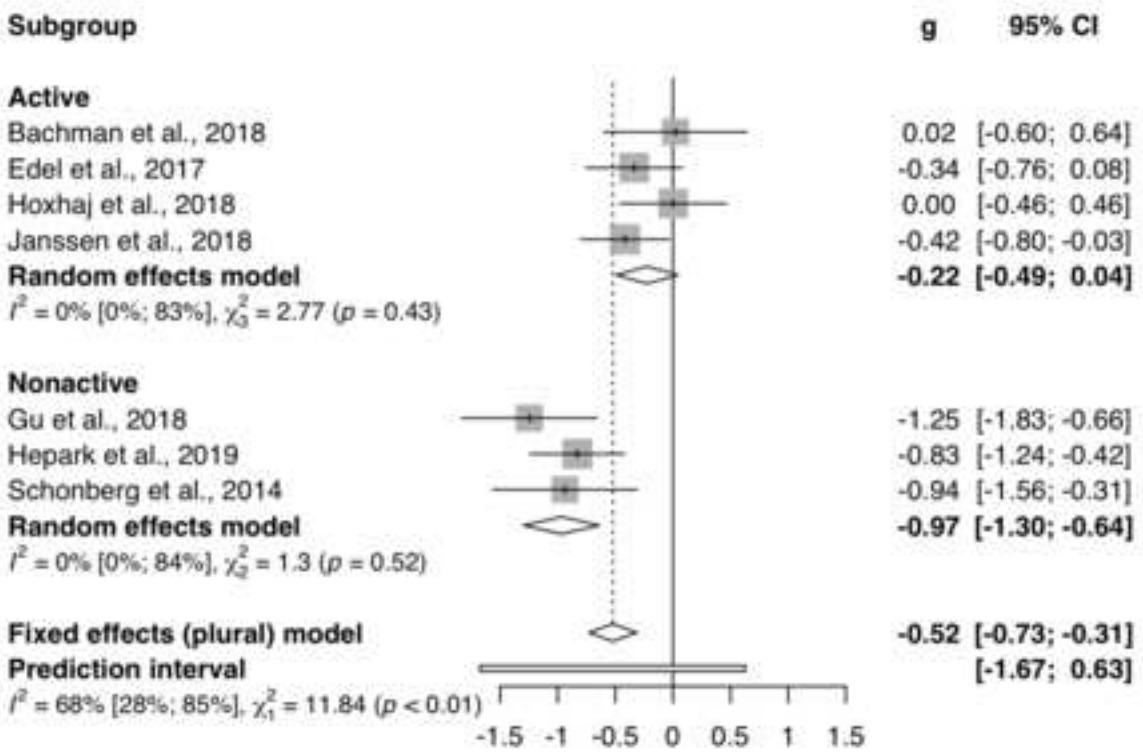

Figure 3

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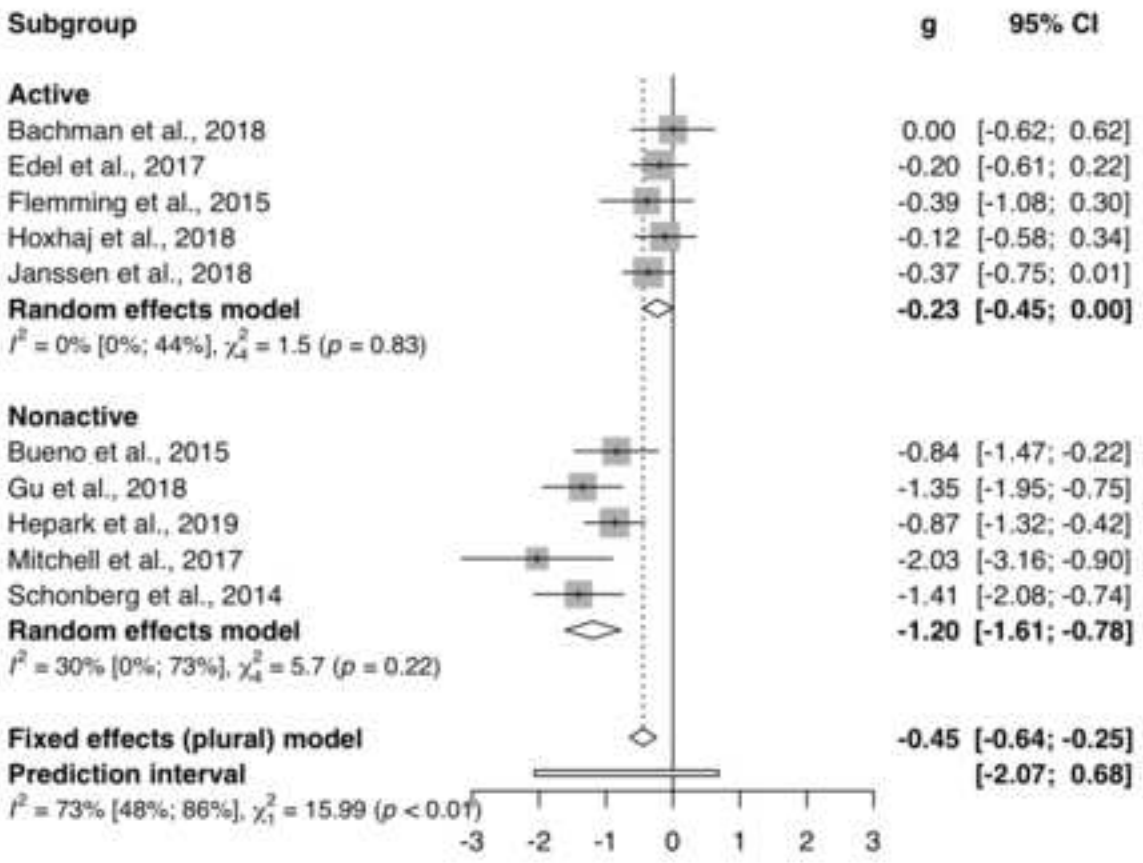

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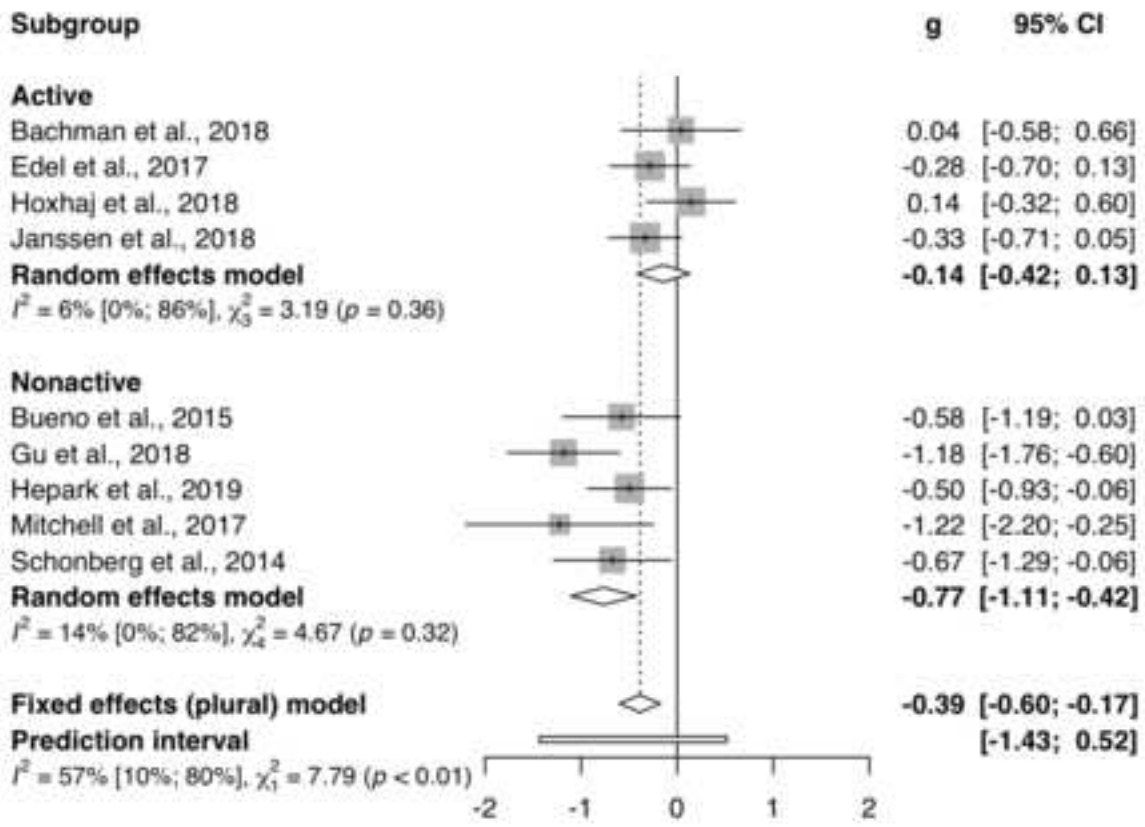

Figure 5

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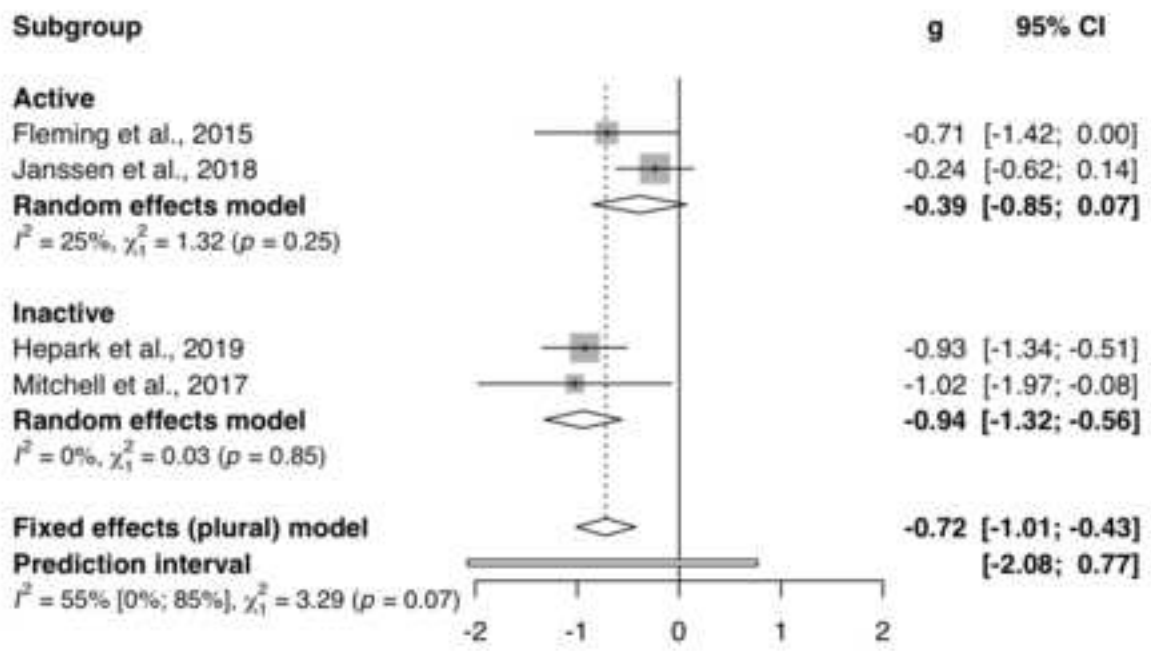

Figure 6

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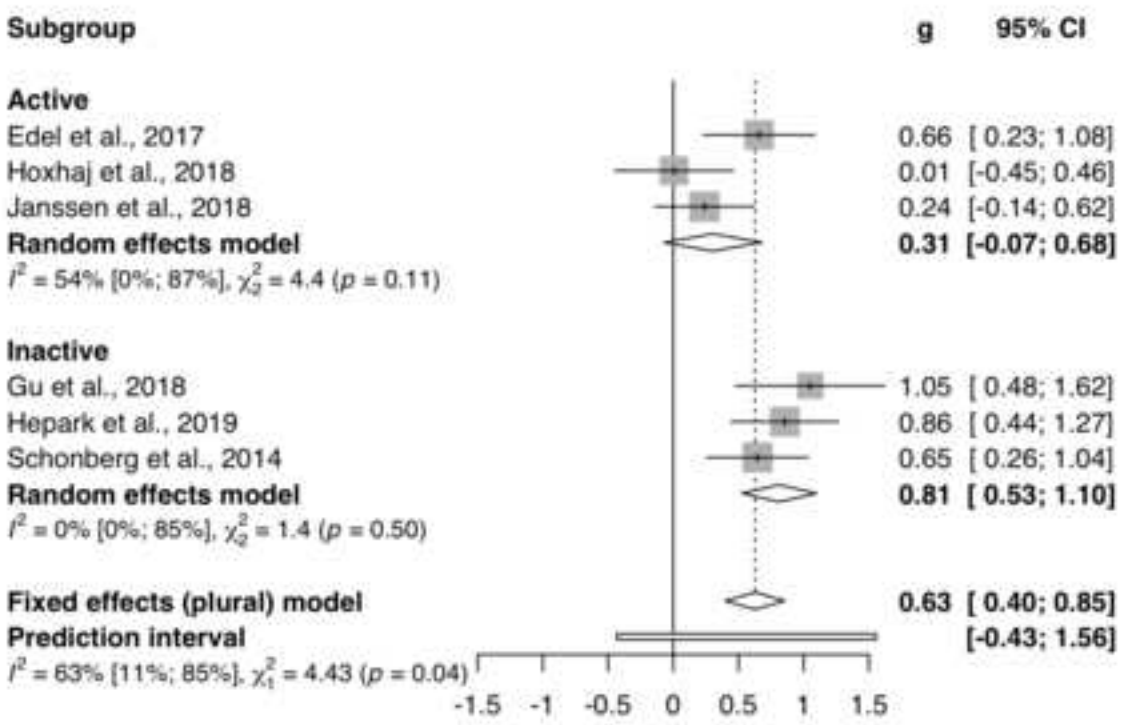

Declaration of interest

The authors declare that they have no conflict of interest.

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Writing - review & editing: FM, FO, GdG, SC