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Effects of Behavioral Parent Training for children and adolescents with attention-deficit/hyperactivity disorder on Parenting Behavior: A protocol for an Individual Participant Data Meta-analysis

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Abstract

Introduction: Behavioral Parent Training (BPT) is a well-established treatment for children with attention-deficit/hyperactivity disorder (ADHD). BPT is based on the hypothesis that improvements in parenting are mediators of improvements in children's behaviors. However, meta-analyses show considerate heterogeneity in effects of BPT on child outcomes, and meta-analyses on parenting outcomes are scarce. Also, few studies have investigated parenting factors as mediators of child outcomes. This study aims to examine the effects and moderators of BPT on parenting outcomes and whether improvements in parenting mediate amelioration of behavior and impairment in children and adolescents with ADHD.

Methods and analyses: We will conduct an individual participant data meta-analysis (IPDMA), making use of individual data of existing trials, and giving the opportunity for highly powered moderator analyses. This IPDMA will be performed by the Psychosocial ADHD INTervention (PAINT) collaboration. We will include randomized controlled trials of BPT, for individuals with ADHD below 18 years old. Systematic searches have been performed to locate relevant papers. Authors are currently contacted to share their data with the PAINT-IPDMA project. We will examine effects of BPT on parenting outcomes (e.g., positive and negative parenting, management of affect, perceived parenting competence, parenting stress), moderators of these effects (e.g., parental depression, parenting stress, severity of the child's ADHD symptoms) and subsequently perform mediation analyses where parenting outcomes are modelled as mediators of child outcomes (e.g., symptoms and severity of ADHD, comorbid psychopathology and impairment).

Ethics and Dissemination: We will include data from RCTs for which ethical approval has been received and consent forms have been signed. De-identified data will be provided by the original investigators. We aim to disseminate through peer-reviewed scientific journals, presentations at (inter)national scientific meetings, newsletters, the website of our project and the Dutch academic workspace ADHD.

Article summary

Strengths and limitations of this study:

- There is a need for well powered studies into the effects of behavioral parent training for ADHD on parenting outcomes, which is the aim of the current IPDMA.
- We will examine potential moderators (such as parental depression, parenting stress and ADHD severity) of parenting outcomes.
- We will investigate whether changes in parenting mediate treatment outcomes of children's ADHD and behavioral symptoms.
- Our IPDMA is limited to the examination of those variables that are reported consistently across all included studies.

Introduction

Behavioral parent training (BPT) is a well-established intervention for children with attention-deficit/hyperactivity disorder (ADHD) and recommended as first line treatment by many international guidelines [1–3]. In BPT, parents are trained to apply behavioral techniques meant to increase prosocial and adaptive child behaviors and to reduce disruptive and maladaptive child behaviors. In addition, BPT focusses on nurturing and positive parent-child relationships [4]. Several meta-analyses on BPT for children with ADHD have shown medium to large effect sizes on parent reported reductions of ADHD symptoms, comorbid problems, impairment and parenting behaviors [3,5–7]. However, the full range of relevant parenting outcomes of BPT has not been assessed in meta-analyses [7,8]. Moreover, while improvements in parenting are thought to mediate improvements in children's behaviors and associated impairments [3,9], studies investigating these mediation effects are scarce. Another problem is that individual studies commonly lack the statistical power to adequately assess moderators of improvements of parenting outcomes. Knowing which moderators impact the effectiveness of BPT for child [5] and parenting outcomes [3,6], in addition to knowing which mediators drive the effects of BPT will give more insight into for whom BPT works best and the working mechanisms underlying this, therefore contributing to personalized treatment of children with ADHD. Also, more insight is needed regarding the effects of BPT on different parenting outcomes.

BPT aims to increase positive parenting and reduce negative parenting behaviors, improve management of affect, reduce parenting stress and enhance parenting self-efficacy [9], in order to positively influence children's behaviors and decrease impairment. Parents are trained to modify environmental antecedents (e.g., providing structure) and consequences (e.g., positive rewards for adaptive behavior). Positive parenting consists of praise, encouragement, effective communication, positive affect and physical affirmations [10,11], whereas negative parenting is described as inconsistent discipline, verbal criticism, corporal punishment, poor supervision and negative affect [12–14]. Essential to positive parenting is the effective management of parental affect, which is often a specific target of BPT [15]. Parents are taught to express positive emotions (e.g., love, affection and warmth) and to inhibit expressions of negative and unsupportive emotions (e.g., anger, frustration and irritability) [16]. Parenting stress (i.e. stress arising from the feeling that the demands of parenting outweigh the resources [17]) is often reported by parents of children with ADHD [18] and is also an important target of BPT. Lastly, parenting self-efficacy is an important target of BPT [19]; parents should feel more confident and competent in carrying out their parenting tasks.

When assessing parenting outcomes of BPT, it is important to consider a range of outcomes, particularly positive and negative parenting, management of affect, parenting stress and parenting

self-efficacy. However, treatment trials of BPT have not uniformly assessed all parenting outcomes that are explicit targets of BPT [3,6]. Recently, two meta-analyses examined the effectiveness of behavioral interventions (mostly consisting of BPT) on parenting outcomes in ADHD, either assessed by raters unblinded to the treatment condition (e.g. parents involved in BPT [9]) or by blinded raters (e.g. independent raters coding video-taped interactions between the parent and child [3,6]). The first meta-analysis [3] considered effects on positive and negative parenting and parenting self-efficacy, immediately post-intervention. Results indicated improvements in positive parenting (effect size (ES) of 0.68 and 0.63 for unblinded and blinded raters, respectively), reductions in negative parenting (ES of 0.57 and 0.43 for unblinded and for blinded raters, respectively), and improvements in parenting self-efficacy (ES of 0.37 for unblinded raters). The other meta-analysis [6] investigated the effects of BPT for preschool children with (or at risk for) ADHD, and reported ESs of 0.63 and 0.33 by unblinded and blinded raters, respectively, for reductions in negative parenting. In addition, long-term effects (up to 12 months) on negative parenting was reported by unblinded raters with an ES of 0.12. Overall, both unblinded and blinded parent outcomes show improvements after BPT, although the effects on blinded outcomes generally appeared smaller than the effects on unblinded outcomes. Improvements in parenting stress and parental affect following BPT have not been addressed in meta-analyses. Moreover, individual studies demonstrate that parenting stress can be effectively alleviated with BPT [19], and that mothers who participated in BPT have less negative affect and better emotion regulation abilities post-treatment [20].

Heterogeneity in effect sizes is common in meta-analyses investigating parenting outcomes of BPT for children with ADHD [3,6]. More knowledge on factors associated with treatment effects will yield more insight into for whom BPT works best, and allows clinicians to make better treatment choices tailored to individuals. So far, very few randomized control trials (RCTs) were adequately powered for moderator analyses, and existing moderator analyses were mostly limited to child behavioral outcomes [21–23]. While traditional methods of addressing heterogeneity in meta-analyses (such as excluding extreme ESs, subgroup analyses, or meta-regression) may resolve heterogeneity (i.e. reduce I^2), they reveal little about the cause of this heterogeneity. Individual participant data meta-analysis (IPDMA) includes data at an individual level rather than at study level, which enables exploration of moderators, therefore yielding more information about the cause of heterogeneity. Moreover, IPDMA performs a uniform analysis across all studies. IPDMA also has enough power to perform subgroup analyses, which most individual RCTs lack. Due to the collaborative nature of an IPDMA, collaborators can provide input on all phases of the research (including design, analyses, interpretation and manuscript preparation), leading to a high quality product [24–26]. So far, no IPDMA has been conducted for parenting outcomes of BPT for children with ADHD.

In this paper, we present our protocol for an IPDMA on BPT for children with ADHD. The current IPDMA will explore several child- and parent-related moderators on parenting outcomes of BPT. Given that the examination of moderators on parenting outcomes is scarce, the choice of possible moderators to be investigated in this IPDMA will also be drawn from BPT trials on child outcomes. First, age of the child might be an important moderator [27], as parents may have more influence on younger children, and younger children may have less engrained symptoms. A meta-analysis indeed demonstrated that BPT had more effect on positive parenting for younger children with ADHD [3]. Second, medication use of the child may moderate BPT outcomes, as parents of children on medication might find it easier to adapt their parenting styles and experience less resistance when doing so, although there could also be a floor effect as that children with medication might already function better. Previous studies indeed suggested that medication use may positively contribute to BPT outcomes on child's ADHD symptoms [28], although results have been mixed [21]. Third, it seems plausible that intelligence of the child is positively associated with a treatment that involves learning associations between behaviors and consequences and new skills [29]. There is some evidence that higher children's IQ is associated with more improvement in ADHD symptoms following behavioral treatment, but only for specific subgroups of children, such as anti-social girls [23,30,31]. Fourth, pretreatment ADHD severity and presence of comorbidities could moderate BPT, as parents might find it easier to change their parenting behavior when the child has less complex symptomatology. Previous individual studies have indeed confirmed that comorbidities at baseline negatively impacted the outcome of BPT treatment with regard to child symptoms [21,22,32]. In addition, a recent IPDMA by our group [5] confirmed that comorbidities are associated with worse outcomes for the child in behavioral treatments for ADHD.

There are several parent-related moderators that may have an effect on parenting outcomes of BPT. First, parental mental health problems (depression, ADHD, parental stress) are likely to affect how well parents are able to grasp new information and impact their ability to learn new methods of parenting and skills [21,22,33–35]. Second, low socio-economic status (SES) and limited parental education may moderate outcomes of BPT, as this may increase family strain and impact the availability of family resources. There is mixed evidence of the moderating effect of low SES on the effects of BPT on ADHD symptoms and related problems, showing either no effect [23], or better outcomes for parents with lower education [36]. Effects of low SES in relation to parenting outcomes of BPT have not been investigated. Third, single parenthood may also moderate outcomes of BPT, as individual studies have demonstrated that single mothers are less likely to respond to BPT [37,38], and maintain treatment gains over time [39] in terms of parenting behavior. Fourth, there is evidence that lower parenting self-efficacy at baseline has a negative impact on improvements in behavioral problems in children with ADHD following BPT [40] and one could expect similar results

for parenting outcomes. On the other hand, it is also possible that lower parenting abilities at baseline yields more room for improvement in BPT, and thus both directions of the effect could be expected.

Following the investigation of parenting outcomes of BPT as part of our IPDMA, the next step will be to examine mediators of improvements in child's behavior following BPT. Currently, there are no meta-analyses analyzing whether improvements in parenting mediate improvements of BPT on symptoms of ADHD of the child. Some evidence of individual studies shows that reductions in parenting or parenting attributions mediate improvements on outcomes in behavioral interventions [12,34,41]. This IPDMA aims to synthesize the available data regarding the association between improvements in parent outcomes and improvements in child's outcomes following BPT.

The specific aims of our IPDMA include:

(1) to investigate effects of BPT on parenting outcomes (positive and negative parenting, parental affect, parenting stress and parenting self-efficacy). Given that BPT for ADHD has shown different effects when assessed by unblinded raters and by more blinded raters [3,6,7], we aim to distinguish (if possible) between unblinded and blinded assessments of parenting and parental affect;

(2) to investigate possible child (including age, medication use, IQ, ADHD severity, presence and severity of comorbidities) and parent (including depression, ADHD, socio-economic status, single parenthood, and parenting measures) moderators of parenting outcomes;

(3) to investigate whether improvements in parenting mediate the effect of BPT on behavioral child outcomes following treatment.

For aims 1-3, outcomes of BPT will be examined immediately post-treatment and at long-term where possible.

Methods and Analysis

For this IPDMA we will build on the Psychosocial ADHD INTervention IPD (PAINT-IPD) database which is registered in prospero: https://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017069877&ID=CRD42017069877. In this project we collect data on psychosocial treatments for children with ADHD: the search is regularly updated and the database continues to expand. For the purpose of the current IPDMA on parenting outcomes, we will use the same methods and search strategy. This protocol is written in line with the PRISMA-P 2015 checklist [42] (see supplementary checklist). The current study is planned to commence April 2020.

Inclusion criteria

We will include RCTs of behavioral treatments of individuals aged below 18 with ADHD, corroborated by clinical cutoffs on questionnaires or (semi)-structured interviews. We will include studies that compared BPT with a control condition (i.e., all conditions that are labeled control, including active treatment), and studies that compared BPT to another behavioral intervention (head to head comparisons). We excluded studies or intervention arms that used optimized medication treatment next to BPT as part of their study design or as a control condition. We define BPT as interventions directed at changing children's/adolescents' behaviors (i.e., increasing desirable behaviors and decreasing undesirable behaviors), using (cognitive) behavioral therapeutic techniques which parents are trained in [43]. Multimodal interventions (consisting of both parent and/or teacher and/or child training), will be included if the time spent on parent training within the intervention was at least equal to other types of training.

Selection and screening of studies

The last systematic search was performed on August 1st 2019. Currently, we are contacting the authors of the newly identified studies. Two authors (AG and RH) performed the selection and screening of studies, disagreement was resolved by consensus. A two-step approach to identifying relevant articles was used. First, Medline, CINAHL, PsycINFO, EMBASE+EMBASE CLASSIC, ERIC, Web of Science [Science Citation Index Expanded] was searched for relevant papers using a combination of the following search terms and their synonyms, as well as hierarchical family form (e.g. MeSH terms): treatment specific terms (e.g., behavioral treatment, psychosocial treatment, and parent training), ADHD, child and adolescent, and randomized controlled trial. No date restrictions were applied. English, German and Dutch language publications published in peer-reviewed journals were included. Second, literature lists of all selected studies and relevant systematic reviews and meta-analyses were hand-searched to identify possible missing articles (complete search criteria for each database are available in Supplement 1).

Data collection and management

Author contact

We will contact the corresponding authors of all eligible trials to ask for their participation in the current IPD meta-analyses. If after several weeks we have had no response, we will send a reminder to the corresponding author. If we have failed to establish contact with the corresponding author, we will email the other authors of the study. Furthermore, we will contact researchers during conferences, and through our personal network to retrieve all eligible databases.

Data format and management

Part of the data has already been received in light of our previous IPDMA [5]. For newly identified data that we have not yet received, we will use the best, safest way to transfer the data. The most convenient way for most authors will be to transfer the encrypted data per email to the project management, but we will be open to other options (e.g. face to face transfer). A copy of our data collection manual for the PAINT-IPD database can be found in Supplement 2. We will allow authors to send the data in all possible formats, although the most preferable format would be one in which each subject represents a row and each variable a column.

If authors are not included in the PAINT collaborators group yet [5], we will offer one or two authors of each included study a place in our PAINT collaborators group. We plan yearly telephone calls and/or meetings at large international conferences to keep the working group up to date and discuss design and methodological issues. Members of the working group who have provided data on BPT trials with parenting outcomes will have the opportunity to provide feedback on the first draft of the manuscript and will be sent a copy of the final manuscript before submission. Only authors in the IPD steering committee group (APG, BvdH, SvdO, ML and PH) will have access to the data.

Ethics and Dissemination

The original investigators will be asked for de-identified data, so that only the original investigator knows the link between data and participant. We will only include RCTs where ethical approval has been given and participants signed consent forms. Since the current IPDMA is an extension of the original purpose of the eligible studies, we do not expect any ethical issues with the current IPDMA.

An expert panel consisting of parents of children with ADHD was organized at the conception of the idea in which feedback was given to the plans and changes were made accordingly. Results of our study will be disseminated through peer-reviewed scientific journals and presentations and (inter)national scientific and/or clinical expert meetings. Our results will be communicated to clinicians, clients and their parents through newsletters, and through the academic workplace “ADHD en druk gedrag” (also see https://adhdendrukgedrag.nl/) in which many parents, client organizations, and mental health care professionals are represented.

Variables

For the PAINT-IPD database, a data request form will be sent to all authors of the original studies, containing a list of variables that will be requested (see Supplement 2a). This list was determined by reviewing the literature and the IPDMA steering committee (authors APG, SvdO, ML , PH and BvdH) assessed these outcomes domains for suitability and interest. The final list of variables will depend on the available data of all studies.

For the current protocol, the following parenting variables will be selected:

Positive and Negative Parenting will be assessed using unblinded and blinded measures. For unblinded parenting measures, we will select questionnaires such as the Alabama Parenting Questionnaire [10]. For blinded measures, we will select assessments used to observe and code parent behavior, such as the Dyadic Parent-Child Interaction Coding System [44].

Positive and Negative Parental Affect will be assessed with measures specifically designed to capture parental affect (e.g. 5 min speech sample of expressed emotion; [15]) or a subscale of an existing parenting scale (e.g. attachment domain of the Parenting-Relationship Questionnaire [45]).

Parental Stress will be assessed using measures specifically designed to capture stress from parenting, such as the Parenting Stress Index (PSI; [46]), but also measures assessing stress in the caregiver more generally (Depression and Anxiety Stress Scales, DASS; [47]).

Parenting Self-Efficacy will be assessed using measures specifically designed to capture parenting self-efficacy, such as the Parental Sense of Competence Scale (PSOC; [48]), a subscale of an existing parenting scale (e.g. the Parenting-Relationship Questionnaire, [45]), or a scale designed to assess parenting competence in specific contexts, such as education (e.g. Parent as Educator Scale, [49]).

Parental Depression will be assessed using measures to capture depressive symptoms, such as the Beck Depression Inventory (BDI; [50]), a subscale of an existing mental health questionnaire (e.g. depression subscale of the Depression and Anxiety Stress Scales, DASS; [51]) or a mental health questionnaire for which the overall score can be used as a proxy for depression (e.g. the General Health Questionnaire, GHQ; [52]).

Parental ADHD will be assessed using an adult measure of ADHD, such as the Adult Self-Report Scale (ASRS) Screener [53].

The remaining parent variables, including *single parenthood* and *socio-economic status,* are commonly assessed with demographic questionnaires or items.

Note that *Parenting, Parental Affect, Parental Stress* and *Parenting Self-efficacy* will serve as baseline moderators (to predict parenting outcomes), mediators (in the relationship between BPT and child outcomes) and outcome variables (in the moderator analysis). *Parental Depression, Parental ADHD, single parenthood and socio-economic status* will serve as baseline moderators to predict parenting outcomes.

Additionally the following child variables will be selected:

Child ADHD severity will be assessed using a parent-rated measure of childhood ADHD, such as the ADHD subscale of the Connors Parent Rating Scale [54].

Comorbidity will be assessed using symptoms of Oppositional Defiant Disorder (ODD) and/or Conduct Disorder (CD), by for example the ODD subscale of the Connors Parent Rating Scale [54], or the CD subscale of the Disruptive Behavior Disorder Rating Scale [55]. In addition, internalizing symptoms will be assessed, using for example the internalizing subscale of the Child Behavior Checklist [56].

Global Impairment will be assessed using a parent- or clinician-rated measure of global impairment, such as the Impairment Rating Scale [57].

The remaining child variables, including *child age, medication use and IQ* are commonly assessed with demographic questionnaires or items.

Child ADHD severity, comorbidity and global impairment will serve as baseline moderators (to predict parenting outcomes) and outcome variables (in the mediation analysis). *Child age, medication use and IQ* will solely serve as baseline moderators to predict parenting outcomes.

For all variables (moderators and outcomes), when a study reports multiple measures to capture the same concept, the measure which is most often used by other studies will be included. Regarding harmonization, for each dataset continuous measures will be converted into z-scores, using pre-intervention-score standard deviations within studies.

Quality assessment

Quality assessment will be done independently by three authors (a combination of AG, RH and LAS) using Cochrane risk of bias. Any disagreement will be resolved by consensus. Once the data has been received, all raw data sets will be checked for impossible, missing, or extreme values. We will collect data on all randomized participants, and subsequently adopt the intention to treat principle. As this will possibly reintroduce participants who were previously excluded, we will also check randomization parameters (e.g., age, gender, and ADHD severity of the participants). If any unexpected deviations are found between our results and the published results, the original researcher will be contacted to locate the origin of this deviation.

Analysis

Effects of BPT will be calculated using a one-stage IPDMA, in which data from participants across studies will be analyzed in one stage, clustered by study. A linear multilevel analysis will be used to examine the effects of BPT on parenting outcome measures. A random intercept for study will be added to each model. Post intervention outcome measures will be used as dependent variables in these models, and pre-intervention outcome measures and intervention group will be added. The interaction between intervention group and moderators of interest will be added to the model to assess their moderating effect on treatment outcomes. To analyze changes in parenting as

a potential mediator in the relationship between BPT and child outcomes, the change in parenting (post-treatment score – baseline score) will be used. An interaction between intervention group and change in parenting will be added to the model to determine whether change in parenting had a main effect on child outcomes and/or an interactive effective with treatment [58,59]. We will conduct sensitivity analyses between studies that provided data and those that did not, for demographic characteristics (e.g., age) and reported effect sizes.

Discussion

The current protocol presents the first IPDMA to synthesize research findings on treatment effects of BPT for children with ADHD on parenting outcomes. Both child and parent moderators of parenting outcomes will be explored and a mediation analysis will be conducted to examine whether changes in parenting mediate the effect of BPT on child behaviors and impairment. Previous efforts to identify moderators of parenting outcomes are scarce, as there are few well powered RCTs and only two meta-analyses on this topic [3,6]. The heterogeneity found in parenting outcomes in previous meta-analyses suggest that there is not a "one size fits all" solution of BPT for children with ADHD. Parents and children who differ with regard to their personal, clinical and demographic characteristics, are also likely to differ in their response to BPT. Clearly, an IPDMA approach is needed to further examine the effects of BPT on parenting outcomes, to elucidate potential sources of heterogeneity amongst children and parents, and to investigate potential mechanisms of change in BPT for children with ADHD. A previous IPDMA of our group [5] has already shown that behavioral interventions indeed have worse outcomes for the child, when the presence and severity of comorbid (symptoms of) conduct disorder is considered, in addition to the severity of ADHD symptoms and/or single-parent status. Ultimately, both research and clinical practice may be informed by the knowledge of which child and/or parent responds best to a certain treatment, thereby contributing to the overall goal of providing the best care to children with ADHD and their parents.

An additional important aim of the current IPDMA will be to examine a crucial assumption about the working mechanism of BPT, namely whether improvements in parenting mediate improvements in child behavior and impairment. So far, single studies have examined this assumption, finding some supportive evidence [12,19], but this hypothesis has never been addressed in a meta-analysis, let alone by using an IPDMA approach. By synthesizing all available (raw) data from RCTs, we will conduct highly sophisticated and powered statistical analyses, to provide insight into the working mechanisms of BPT. This knowledge will allow us to further improve and refine BPT programs for children with ADHD.

Despite clear strengths of the IPDMA approach, such as high-powered moderator, mediation and subgroup analyses, there are some limitations as well [24,26,60]. First, IPDMA cannot change anything about the way the study was originally conducted. Second, it is unclear whether enough studies measured the variables of interest, and thus whether all intended outcomes can be examined. Third, if investigators of trials are unwilling to share their data (or may not be able to share their data), not all relevant data can be included in the synthesis.

Notwithstanding these limitations, this study has the potential to elucidate clinically relevant questions concerning the efficacy of BPT for children with ADHD and their parents and to provide insight in moderators and mediators of treatment effects. This knowledge may improve and optimize current treatment programs and could eventually lead to advances in personalized treatment for children with ADHD.

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Supplement 1- Search terms per database

Behavioral interventions

PubMed

("Attention Deficit Disorder with Hyperactivity"[Mesh] OR ADHD[tiab] OR ADD[tiab] OR attention deficit*[tiab] OR hyperactiv*[tiab] OR hyperkinetic*[tiab] OR minimal brain deficit*[tiab] OR minimal brain dysfunction*[tiab])

AND

(("Psychotherapy"[Mesh] OR psychotherap*[tiab] OR psychological therap*[tiab] OR psychological intervent*[tiab] OR psychoeduca*[tiab] OR mentoring*[tiab] OR coaching*[tiab] OR mindful*[tiab] OR relax*[tiab] OR meditat*[tiab])

OR

((parent*[tiab] OR mother[tiab] OR father[tiab] OR teacher*[tiab] OR school*[tiab])

AND

(program*[tiab] OR train*[tiab] OR educa*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab]OR intervention*[tiab] OR coaching*[tiab] OR counseling*[tiab]))

OR

((behavio*[tiab] OR cognit*[tiab] OR "acceptance and commitment"[tiab] OR dialectica*[tiab])

AND

(program*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR intervention*[tiab] OR treatment*[tiab] OR train*[tiab]))

OR

(psychosocial[tiab]

AND

(treatment*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR train*[tiab] OR intervention*[tiab] OR program*[tiab]))

OR

((skill*[tiab] OR organization*[tiab] OR organisation*[tiab] OR planning*[tiab] OR play*[tiab])

AND

(train*[tiab] OR intervention*[tiab] OR program*[tiab])))

AND

("Adolescent"[Mesh] OR "Child"[Mesh] OR child*[tiab] OR school*[tiab] OR infan*[tiab] OR adolescen*[tiab] OR pediatri*[tiab] OR paediatr*[tiab] OR boy[tiab] OR boys[tiab] OR boyhood[tiab] OR girl[tiab] OR girls[tiab] OR girlhood[tiab] OR youth[tiab] OR youths[tiab] OR teen[tiab] OR teens[tiab] OR teenage*[tiab] OR puberty[tiab] OR preschool*[tiab] OR toddler*[tiab] OR juvenile*[tiab] OR kids[tiab])

AND

("Controlled Clinical Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Follow-Up Studies"[Mesh] OR follow-up[tiab] OR followup[tiab] OR control group*[tiab] OR "Random Allocation"[Mesh] OR random*[tiab] OR trial[ti])

EMBASE EMBASE.com (losse delen combineren op website)
('attention deficit disorder'/exp OR (ADHD OR ADD OR 'attention deficit*'
OR hyperactiv* OR hyperkinetic* OR 'minimal brain deficit*' OR 'minimal brain dysfunction*'):ab,ti)
AND

('psychotherapy'/exp OR (psychotherap* OR 'psychological therap*' OR 'psychological intervent*'
OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*):ab,ti)
OR
((((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention*
OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR
train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR
program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))):ab,ti)

AND
('juvenile'/exp OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR
boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage*
OR puberty OR preschool* OR toddler* OR juvenile* OR kids):ab,ti)

AND
('controlled clinical trial'/exp OR 'randomization'/exp OR ('control group*' OR random*):ab,ti OR
trial:ti)

EBSCO PsycINFO

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(DE "Psychotherapy" OR DE "Child Psychotherapy" OR DE "Play Therapy" OR DE "Behavior Therapy" OR DE "Aversion Therapy" OR DE "Conversion Therapy" OR DE "Dialectical Behavior Therapy" OR DE "Exposure Therapy" OR DE "Implosive Therapy" OR DE "Reciprocal Inhibition Therapy" OR DE "Response Cost" OR DE "Systematic Desensitization Therapy" AND DE "Cognitive Behavior Therapy" OR DE "Cognitive Therapy" OR DE "Group Psychotherapy" OR DE "Neurotherapy" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR ‘acceptance and commitment’ OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

(psychosocial

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*))

AND

(AG (childhood OR adolescence) OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(“control group*” OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO CINAHL

(MH "Attention Deficit Hyperactivity Disorder" OR "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(MH "Psychotherapy+" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))

AND

(AG child OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(MH "Clinical Trials+" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO ERIC

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Hyperactivity Disorder" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

(DE "Psychotherapy" OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)
OR
((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND

(train* OR intervention* OR program*))

AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

("control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

Web of Science

(TS=("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*"))

AND

(TS=(psychotherap* OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

(psychosocial

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*))))

AND

(TS=(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(TS=("clinical trial*" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design"))

Cochrane Central register of Controlled Trials *(CENTRAL)*

("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

((psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

((psychosocial)

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*)))

AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids)

Supplement 2. Data sharing manual

Data collection form

Content

Thank you for taking place in our Psychosocial ADHD INTerverntions (PAINT) collaborators group. We are very grateful that you are willing to put your time into this project. We believe that this group will be fruitful and successful collaboration with the aim to get more insight into psychosocial interventions for ADHD.
With this manual, we hope to provide you with guidance on the data collection. However, if you have any questions regarding the data handling, despite reading this manual, please let us know so we can help you further, and adapt our manual accordingly. You can reach us at paint@accare.nl.

Most of the choices we have made concerning data collection are driven by a need to keep methods and measures similar across trials. Every study is designed slightly different, with different measures, different in- and exclusion criteria, different methods to handle missing data, etc..
To harmonize measures and methods, at some point we will have to make choices regarding data analysis, that differ from the choices made in the original study. For example, we will do intention to treat analysis, while it may be possible that you did not do this in your original analysis. This means that, if available, we will ask for data or participants not included in the original analysis. Furthermore, it is important to mention that we will not report on results from a single trial, although we can report a forestplot displaying all effect sizes of included studies.

How do I transfer my data?
Preferably, we would receive the information electronically. We can work with any kind of data file (STATA, SPSS, etc.), but we prefer a layout, where each line represents a subject.

You can email the data file once you encrypted it using a program such as 7-zip (an explanation on how to do this is included in supplement B). It is important that the password with which you will protect your data file, will be send in a separate email from the email that contains the data file (as attachment). Another important point in transferring the data is that the data should be anonymized. This means that there is no information with which we could trace a single participant back to the individual. This means that no names should be included in the file. However, all other information that can identify a person should be left out of this file. This can mean combinations of variables, for example postal code and date of birth. Please make sure that this kind of information is not present in the data file. If these kinds of examples arise, please contact us, so we can think with you on what best to do.

Which participants do we need?
We want the data of all included participants. This means all participants that have a baseline measure and were randomized. It could be possible that this is a different approach than you took in

your analysis of the data. Because we want to perform intention to treat analysis, we need all data from included participants.

Which data do we need?

We ask you for clean data (please contact us if this provides you with any questions). We want sum scores and if available norm-scores of questionnaires. Proper labeling is important. In the Table below we provide you with an overview of constructs that we are interested in. It could be possible that the measure or instrument used in your study is not mentioned in this Table, this does not mean that we are not interested, the measures mentioned are mere examples. If there are any remarks on this measure (e.g. certain items were not used) please mention these in the column "remarks". Please indicate which informants filled out the questionnaires, when multiple informants are used please provide us with data from all informants. If multiple instruments have been used to measure a certain construct, we would really like to receive all instruments (for example a self and a proxy version, or multiple ADHD measures). This could aid us in the harmonization process (see above). If a construct is measured with an in-house instrument or if you made any adjustments on the instrument, could you also provide us this instrument?

For questionnaires, we would like to receive the, sum scores and norm-scores and if available item scores. We would always like to receive the full questionnaire if possible, and not just certain subscales. In the future, it could be possible that we will ask you about norming tables, we hope however, that we will not need these.

For (structured) interviews we would like to receive items scores, sum scores and outcomes. We would like to receive information on the full interview, not only certain outcomes.

Concerning cognitive measures, we would like to receive calculated outcomes variables across trials and conditions, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean (and SD) of reaction time on Go trials, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We fill also need information about the task such as number of conditions, number of trials, and how the outcome variables were calculated.

For variables that are available on multiple time points, please provide us with all relevant data. For example, if an ADHD measure is taken at baseline, right after the intervention and after 3 months, we would like to receive this measure assessed at all time points. Again, proper labelling is very important. Please label the data in English (or Dutch).

The constructs and variables that we are interested in for the IPD meta-analysis are shown below. We understand that not all studies have included all measures. The table below will provide you with a list you can keep on hand when preparing the data before sending it. Next to the constructs are examples of instruments. Please remember that this is not a complete list, and that it could be possible that you have used an instrument that is not in our list, but that would still be very valuable for this IPD meta-analysis. Please remember that you do not have to recode your data. We will do this for all datasets.

What will we do with the data?

Once we receive the data we will do some basic data checks. These will include checking missing and impossible values. If we will have any questions concerning the data during or after these checks we will contact you for clarification. After that we will harmonize the data with the other datasets. This harmonization process depends on the available data. For example, this could mean that we have to dichotomize data, or making norm deviation scores (translating raw questionnaire scores on one

scale into raw questionnaire scores on another scale using norm scores). Harmonization is easiest if the same measure has been used across studies. If you have used multiple instruments to measure a certain outcome (e.g. more than 1 ADHD scale), we ask you to provide us both measures. This could mean that we may be able use a latent variable for some measures, or we could calculate correlations between measures.

The original dataset will be saved as the original file. Any harmonization will take place in a separate file, which are only later merged into one big data file.

Supplement 2A.

Tabel 1 Measures.

Descriptive measures	
Participant ID	
Date of randomization	Dd/mm/yyyy
Date of treatment start	Dd/mm/yyyy
Date post-intervention measurement	Dd/mm/yyyy
Date follow up measurement	Dd/mm/yyyy
Date baseline measurement	Dd/mm/yyyy
Treatment allocation	0- Control 1- Intervention
Age	Age in years
Gender	1-Male 2-Female
IQ	Norm score of WISC
Verbal IQ	Norm score of WISC
Performance IQ	Norm score of WISC
Ethnicity	
Socioeconomic status	
ADHD severity at baseline	
Comorbidities	ODD/CD/Anxiety/Depression/PDD/Tics/ etc.
Number of children living with the family	Total number of children in the household
Primary care-taker education	
Secundary care-taker education	
Household income	Combined income of primary caretaker and (if applicable) secundary caretaker
Parental psychopathology (diagnosis)	Parental ADHD/ anxiety/depression/ etc
Marital status	
Education primary caretaker	
Education secondary caretaker	
Age Father	Age in years
Age mother	Age in years
Psychoactive Medication use pre- intervention	Yes/no, if yes which medication, mg MPH if applicable, x times per day, for the last month,

	duration
Previous care use of the child	Care use in mental health.
Medication use during intervention	Yes/no, if yes, mg per day
Treatment expectancy	
Stable medication use during intervention	Yes/No/NA
Other descriptive measures	
Individual child outcomes- behavioral	
Measured constructs	**Examples of instruments**
ADHD	Conners, CBCL, DBD, ACTeRS, ARS, BASC, SNAP, SWAN, Werry Weiss Peters activity scale, Behavioral checklist, PACS, Parent daily report, KSADS, standardized behavioral observations
Disruptive disorders/ behavior	Conners, CBCL, DBD, EDBI, SNAP, SSRS, ACTeRS, KSADS, behavior problem checklist, aggression and conduct problems scale, behavioral checklist, PACS, parent daily reports, standardized behavioral observations
Social skills	DSAS, Behavior problem checklist, BASC, ACTeRS, SSRS, CBCL
Internalizing problems	Conners, CBCL, SSRS, BASC, Behavior problem checklist, MASC, PACS, KSADS, SCARED, CDI
Attachment	
Quality of life	HONOSCA, kidsscreen, EQ-5d, IRS
Selfconcept	Piers-Harris
Which other child behavioral outcomes are available?	
Individual child outcomes- academic outcomes	
Measured Construct	Examples of measures
Grades on core courses	Math, Spelling, Reading
Standardized Academic Achievement tests	Reading, spelling, math scores, woodcock johnson, WRAT, WISC Durrel
On and off task behaviors	Classroom observations, SOAPs
Academic competence	Academic rating scale, classroom performance survey
Which other academic outcomes are available?	

Individual child outcomes- cognitive outcomes[a]	
Higher cognitive functions	Working memory, executive functions, inhibition, planning, set shifting, reward sensitivity, emotion regulation
Intellectual functioning	IQ (WISC, RAVEN)
Motor skills	Fine motor skills, precision, gross motor skills
Memory	Visuospatial, verbal
Basic cognitive functions	Attention, reaction time, speed, perception
Child individual outcomes- other measures	
Adverse events	Types of adverse events reported
Treatment fidelity	
Treatment satisfaction	
Number of sessions attended	
Drop out	Yes/no
Date of discontinuation of the intervention	
Reason for discontinuation	
Parental outcome measures	
Measured constructs	Examples of measures
Parental psychopathology	DASS, GHQ, BDI, PSI, CSS, AARS, SCL90,
Parent child interaction, parenting behaviors, parenting style, parenting affect	DPICS or other observational measure, parenting practices inventory (PPI), parent interaction style, PS (parenting scale), measures parental sensitivity/reponsivity
Parental competence/ self efficacy	PSI-subscale parental competence, PSOC
Spouse relationship	locke wallace marital adjustment, PSI-subscale
Parental self esteem	Rosenberg self esteem scale (RSE)
Parenting stress	PSI
Which other parenting outcomes are available?	

[a] concerning cognitive measures, we would like to receive calculated outcomes measures, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean reaction time, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We will also need information on the conditions of the task, how the outcome was calculated, etc.

PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item	Location in manuscript
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Page 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Page 2
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Page 2
Sponsor	5b	Provide name for the review funder and/or sponsor	Page 2
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Page 2
Introduction			

Section and topic	Item No	Checklist item	Location in manuscript
Rationale	6	Describe the rationale for the review in the context of what is already known	Page 5-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Page 8
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Page 9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Page 9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Page 9 (and supplement)
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Page 10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Page 9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done	Page 8-9 (and supplement)

Section and topic	Item No	Checklist item	Location in manuscript
		independently, in duplicate), any processes for obtaining and confirming data from investigators	
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Page 10-12 (and supplement)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Page 10-12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Page 12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Page 12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Page 12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Page 12-13
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias	Page 13

Section and topic	Item No	Checklist item	Location in manuscript
		across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Page 12

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Effects of Behavioral Parent Training for children with attention-deficit/hyperactivity disorder on Parenting Behavior: A protocol for an Individual Participant Data Meta-analysis

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Effects of Behavioral Parent Training for children with attention-deficit/hyperactivity disorder on Parenting Behavior: A protocol for an Individual Participant Data Meta-analysis

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Abstract

Introduction: Behavioral Parent Training (BPT) is a well-established treatment for children with attention-deficit/hyperactivity disorder (ADHD). BPT is based on the hypothesis that improvements in parenting are mediators of improvements in children's behaviors. However, meta-analyses show considerate heterogeneity in effects of BPT on child outcomes, and meta-analyses on parenting outcomes are scarce. Also, few studies have investigated parenting factors as mediators of child outcomes. This study aims to examine the effects and moderators of BPT on parenting outcomes and whether improvements in parenting mediate amelioration of behavior and impairment in children with ADHD.

Methods and analyses: We will conduct an individual participant data meta-analysis (IPDMA), making use of individual data of existing trials, and giving the opportunity for highly powered moderator analyses. This IPDMA will be performed by the Psychosocial ADHD INTervention (PAINT) collaboration. We will include randomized controlled trials of BPT, for individuals with ADHD below 18 years old. Systematic searches have been performed to locate relevant papers. Authors are currently contacted to share their data with the PAINT-IPDMA project. We will examine effects of BPT on parenting outcomes (e.g., positive and negative parenting, management of affect, perceived parenting competence, parenting stress), moderators of these effects (e.g., parental depression, parenting stress, severity of the child's ADHD symptoms) and subsequently perform mediation analyses where parenting outcomes are modelled as mediators of child outcomes (e.g., symptoms and severity of ADHD, comorbid psychopathology, and impairment).

Ethics and Dissemination: We will include data from RCTs for which ethical approval has been received and consent forms have been signed. De-identified data will be provided by the original investigators. We aim to disseminate our findings through peer-reviewed scientific journals, presentations at (inter)national scientific meetings, newsletters, the website of our project and the Dutch academic workspace ADHD.

Article summary

Strengths and limitations of this study:

- To our knowledge this is the first IPDMA that examines the effects of behavioral parent training for ADHD on parenting outcomes.
- By using IPDMA, we are able to conduct highly powered moderation analysis.
- By collecting individual participant data from randomized controlled trials, we have the opportunity to perform uniform analyses across studies.
- Our IPDMA includes only variables that are reported consistently across the majority of studies in the database.
- Representativeness of the database will depend partly on the willingness and ability of investigators to share their data.

Introduction

Behavioral parent training (BPT) is a well-established intervention for children with attention-deficit/hyperactivity disorder (ADHD) and recommended as first line treatment by many international guidelines [1–3]. In BPT, parents are trained to apply behavioral techniques meant to increase prosocial and adaptive child behaviors and to reduce disruptive and maladaptive child behaviors. In addition, BPT focusses on nurturing and positive parent-child relationships [4]. Several meta-analyses on BPT for children with ADHD have shown medium to large effect sizes on parent reported reductions of ADHD symptoms, comorbid problems, impairment and parenting behaviors [3,5–7]. However, the full range of relevant parenting outcomes of BPT has not been assessed in meta-analyses [7,8]. Moreover, while improvements in parenting behaviors are thought to mediate improvements in children's behaviors and associated impairments [3,9], studies investigating these mediation effects are scarce. Another unresolved issue is that individual studies commonly lack the statistical power to adequately assess moderators of improvements of parenting outcomes. Knowing which moderators impact the effectiveness of BPT for child [5] and parenting outcomes [3,6], in addition to knowing which mediators drive the effects of BPT will give more insight into for whom BPT works best and into the working mechanisms underlying this, therefore contributing to personalized treatment of children with ADHD.

BPT aims to increase the demonstration of positive parenting behaviors and to inhibit negative parenting behaviors, improve the management of affect, reduce parenting stress and enhance parenting self-efficacy [9], in order to positively influence children's behaviors and decrease impairment. Parents are trained to modify environmental antecedents (e.g., providing structure) and consequences (e.g., positive rewards for adaptive behavior) of behavior. Positive parenting behaviors consist of providing praise, encouragement, effective communication, demonstrating positive affect and offering physical affirmations [10,11], whereas negative parenting behaviors are described as providing inconsistent discipline, verbal criticism, corporal punishment, poor supervision, and demonstrating negative affect [12–14]. Essential to positive parenting behavior is the effective management of parental affect, which is often a specific target of BPT [15]. Parents are taught to express positive emotions (e.g., love, affection and warmth) and to inhibit expressions of negative and unsupportive emotions (e.g., anger, frustration and irritability) [16]. Parenting stress (i.e. stress arising from the feeling that the demands of parenting outweigh the resources [17]) is often reported by parents of children with ADHD [18] and is also an important target of BPT. Lastly, parenting self-efficacy is an important target of BPT [19]; parents should feel more confident and competent in carrying out their parenting tasks.

When assessing parenting outcomes of BPT, it is important to consider a range of outcomes, particularly positive and negative parenting behaviors, management of affect, parenting stress and parenting self-efficacy. However, treatment trials of BPT have not uniformly assessed all parenting outcomes that are explicit targets of BPT [3,6], although BPT outcomes may differ for these different domains. For example, a recent systematic review investigated multiple parenting outcomes (display of parental affect, parenting stress, and parenting self-efficacy) of BPT and showed positive results for outcomes most closest to the target of BPT (e.g., parenting self-efficacy), but less so for more distal outcomes (e.g., parental psychopathology) [20]. Notably, studies in that review were not specifically conducted in ADHD samples, nor were outcomes quantified using a (individual participant data) meta-analytic approach, which will be the analytic approach in the current study. Recently, two meta-analyses examined the effectiveness of behavioral interventions (mostly consisting of BPT) on parenting outcomes in samples of children with ADHD, either assessed by raters unblinded to the treatment condition (e.g., parents involved in BPT [9]) or by blinded raters (e.g., independent raters coding video-taped interactions between the parent and child [3,6]). The first meta-analysis [3] considered effects on positive and negative parenting behaviors and parenting self-efficacy, immediately post-intervention. Results indicated improvements in positive parenting behaviors (medium effect sizes (ES) of 0.68 and 0.63 for unblinded and blinded raters, respectively), reductions in negative parenting behaviors (medium to small ES of 0.57 and 0.43 for unblinded and for blinded raters, respectively), and improvements in parenting self-efficacy (small ES of 0.37 for unblinded raters). The other meta-analysis [6] investigated the effects of BPT for preschool children with (or at risk for) ADHD, and reported medium to small ES of 0.63 and 0.33 by unblinded and blinded raters, respectively, for reductions in negative parenting behaviors. In addition, long-term effects (up to 12 months) on negative parenting behaviors were reported by unblinded raters with an ES of 0.12 (very small). Overall, both unblinded and blinded parent outcomes show improvements after BPT, although the effects on blinded outcomes generally appeared somewhat smaller than the effects on unblinded outcomes. Improvements on other relevant domains such as parenting stress and display of parental affect have not been addressed in meta-analyses, although individual studies demonstrated that parenting stress can be effectively alleviated with BPT [19], and that mothers who participated in BPT have less negative affect and better emotion regulation abilities post-treatment [21].

Heterogeneity in effect sizes is common in meta-analyses investigating parenting outcomes of BPT for children with ADHD [3,6]. More knowledge on factors associated with treatment effects will yield more insight into for whom BPT works best, and may allow clinicians to make better treatment choices tailored to individuals. So far, very few randomized control trials (RCTs) were adequately powered for moderator analyses, and existing moderator analyses were mostly limited to

child behavioral outcomes [22–24]. While traditional methods of addressing heterogeneity in meta-analyses (such as excluding extreme ES, subgroup analyses, or meta-regression) may resolve heterogeneity (i.e. reduce I^2), they reveal little about the cause of this heterogeneity. Individual participant data meta-analysis (IPDMA) includes data at an individual level rather than at study level, which enables exploration of moderators, therefore yielding more information about the cause of heterogeneity. Moreover, IPDMA performs a uniform analysis across all studies. IPDMA also has enough power to perform subgroup analyses, which most individual RCTs lack. Due to the collaborative nature of an IPDMA, collaborators can provide input on all phases of the research (including design, analyses, interpretation and manuscript preparation), leading to a high quality product [25–27]. So far, no IPDMA has been conducted for parenting outcomes of BPT for children with ADHD.

In this paper, we present our protocol for an IPDMA on BPT for children with ADHD. The current IPDMA will explore several child- and parent-related moderators on parenting outcomes of BPT. Given that the examination of moderators on parenting outcomes is scarce, the choice of possible moderators to be investigated in this IPDMA will also be drawn from BPT trials on child outcomes. First, age of the child might be an important moderator [28], as parents may have more influence on younger children, and younger children may have less engrained symptoms. A meta-analysis indeed demonstrated that BPT had more effect on positive parenting behaviors for younger compared to older children with ADHD [3]. Second, medication use of the child may moderate BPT outcomes, as parents of children on medication might find it easier to adapt their parenting styles and experience less resistance when doing so, although there could also be a floor effect as that children with medication might already function better. Previous studies suggested that medication use may positively contribute to BPT outcomes on child's ADHD symptoms [29], although results have been mixed [22]. Third, it seems plausible that intelligence of the child is positively associated with a treatment that involves learning associations between behaviors and consequences and new skills [30]. There is some evidence that higher children's IQ is associated with more improvement in ADHD symptoms following behavioral treatment, but only for specific subgroups of children, such as girls with more anti-social symptoms [24,31,32]. Fourth, pretreatment ADHD severity and presence of comorbidities could moderate BPT, as parents might find it easier to change their parenting behavior when the child has less complex symptomatology. Previous individual studies have indeed confirmed that comorbidities at baseline negatively impacted the outcome of BPT treatment with regard to child symptoms [22,23,33].

There are several parent-related moderators that may have an effect on parenting outcomes of BPT. First, parental mental health problems (depression, ADHD, parental stress) are likely to affect how well parents are able to grasp new information and impact their ability to learn new methods of

parenting behaviors and skills [22,23,34–36]. Second, low socio-economic status (SES) and limited parental education may moderate outcomes of BPT, as this may increase family strain and impact the availability of family resources. There is mixed evidence of the moderating effect of low SES on the effects of BPT on ADHD symptoms and related problems, showing either no effect [24], or better outcomes for parents with lower education [37]. Effects of low SES in relation to parenting outcomes of BPT have not been investigated. Third, single parenthood may also moderate outcomes of BPT, as individual studies have demonstrated that single mothers are less likely to respond to BPT [38,39], and maintain treatment gains over time [40] in terms of parenting behavior. Indeed, research suggests that single parents benefit more from enhanced BPT programs, suited to their specific needs (STEPP; [41,42]), compared to standard BPT programs. Fourth, there is evidence that lower parenting self-efficacy at baseline has a negative impact on improvements in behavioral problems in children with ADHD following BPT [43] and one could expect similar results for parenting outcomes. On the other hand, it is also possible that lower parenting abilities at baseline yields more room for improvement in BPT, and thus both directions of the effect could be expected.

Following the investigation of parenting outcomes of BPT as part of our IPDMA, the next step will be to examine mediators of improvements in child's behavior following BPT. Currently, there are no meta-analyses analyzing whether improvements in parenting behavior mediate improvements of BPT on symptoms of ADHD of the child. Some evidence of individual studies shows that reductions in parenting behaviors or parenting attributions mediate improvements on child outcomes in behavioral interventions [12,35,44]. This IPDMA aims to synthesize the available data regarding the association between improvements in parent outcomes and improvements in child's outcomes following BPT.

The specific aims of our IPDMA include:

(1) to investigate effects of BPT on parenting outcomes (positive and negative parenting behaviors, display of parental affect, parenting stress and parenting self-efficacy). Given that BPT for ADHD has shown different effects when assessed by unblinded raters and by more blinded raters [3,6,7], we aim to distinguish (if possible) between unblinded and blinded assessments of parenting behavior and display of parental affect;

(2) to investigate possible child (including age, medication use, IQ, ADHD severity, presence and severity of comorbidities) and parent (including depression, ADHD, socio-economic status, single parenthood, and parenting measures) moderators of parenting outcomes;

(3) to investigate whether improvements in parenting behaviors mediate the effect of BPT on behavioral child outcomes and impairment following treatment.

For aims 1-3, outcomes of BPT will be examined immediately post-treatment and at long-term where possible.

Methods and Analysis

For this IPDMA we will build on the Psychosocial ADHD INTervention IPD (PAINT-IPD) database which is registered in prospero: https://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017069877&ID=CRD42017069877. In this project we collect data on psychosocial treatments for children with ADHD: the search is regularly updated and the database continues to expand. For the purpose of the current IPDMA on parenting outcomes, we will use the same methods and search strategy. This protocol is written in line with the PRISMA-P 2015 checklist [45] (see supplementary checklist). The current study is planned to commence September 2020.

Inclusion criteria

We will include RCTs of behavioral treatments of individuals aged below 18 with ADHD, corroborated by clinical cutoffs on questionnaires or (semi)-structured interviews. We will include studies that compared BPT with a control condition (i.e., all conditions that are labeled control, including active treatment), and studies that compared BPT to another behavioral intervention (head to head comparisons). We excluded studies or intervention arms that used optimized medication treatment next to BPT as part of their study design or as a control condition. We define BPT as interventions directed at changing children's behaviors (i.e., increasing desirable behaviors and decreasing undesirable behaviors), using (cognitive) behavioral therapeutic techniques which parents are trained in [46]. Multimodal interventions (consisting of both parent and/or teacher and/or child training), will be included if the time spent on parent training within the intervention was at least equal to other types of training.

Selection and screening of studies

The last systematic search was performed on August 1st 2019. Currently, we are contacting the authors of the newly identified studies. Two authors (AG and RH) performed the selection and screening of studies, disagreement was resolved by consensus. A two-step approach to identifying relevant articles was used. First, Medline, CINAHL, PsycINFO, EMBASE+EMBASE CLASSIC, ERIC, Web of Science [Science Citation Index Expanded] was searched for relevant papers using a combination of the following search terms and their synonyms, as well as hierarchical family form (e.g., MeSH terms): treatment specific terms (e.g., behavioral treatment, psychosocial treatment, and parent training), ADHD, child, and randomized controlled trial. No date restrictions were applied. English, German and Dutch language publications published in peer-reviewed journals were included.

Second, literature lists of all selected studies and relevant systematic reviews and meta-analyses were hand-searched to identify possible missing articles (complete search criteria for each database are available in Supplement 1).

Data collection and management

Author contact

We will contact the corresponding authors of all eligible trials to ask for their participation in the current IPD meta-analyses. If after several weeks we have had no response, we will send a reminder to the corresponding author. If we have failed to establish contact with the corresponding author, we will email the other authors of the study. Furthermore, we will contact researchers during conferences, and through our personal network to retrieve all eligible databases.

Data format and management

Part of the data has already been received in light of our previous IPDMA [5]. For newly identified data that we have not yet received, we will use the best, safest way to transfer the data. The most convenient way for most authors will be to transfer the encrypted data per email to the project management, but we will be open to other options (e.g., face to face transfer). A copy of our data collection manual for the PAINT-IPD database can be found in Supplement 2. We will allow authors to send the data in all possible formats, although the most preferable format would be one in which each subject represents a row and each variable a column.

If authors are not included in the PAINT collaborators group yet [5], we will offer one or two authors of each included study a place in our PAINT collaborators group. We plan yearly telephone calls and/or meetings at large international conferences to keep the working group up to date and discuss design and methodological issues. Members of the working group who have provided data on BPT trials with parenting outcomes will have the opportunity to provide feedback on the first draft of the manuscript and will be sent a copy of the final manuscript before submission. Only authors in the IPD steering committee group (APG, BvdH, SvdO, ML and PH) will have access to the data.

Ethics and Dissemination

The original investigators will be asked for de-identified data, so that only the original investigator knows the link between data and participant. We will only include RCTs where ethical approval has been given and participants signed consent forms. Since the current IPDMA is an extension of the original purpose of the eligible studies, we do not expect any ethical issues with the current IPDMA. Results of our study will be disseminated through peer-reviewed scientific journals, and presentations on (inter)national scientific and/or clinical expert meetings.

Patient and Public Involvement

An expert panel consisting of parents of children with ADHD was organized at the conception of the idea in which feedback was given to the plans and changes were made accordingly. Our results will be communicated to clinicians, clients and their parents through newsletters, and through the academic workplace "ADHD en druk gedrag" (also see https://adhdendrukgedrag.nl/) in which many parents, client organizations, and mental health care professionals are represented.

Variables

For the PAINT-IPD database, a data request form will be sent to all authors of the original studies, containing a list of variables that will be requested (see Supplement 2a). This list was determined by reviewing the literature and the IPDMA steering committee (authors APG, SvdO, ML, PH and BvdH) assessed these outcomes domains for suitability and interest. The final list of variables will depend on the available data of all studies.

For the current protocol, the following parenting variables will be selected:

Positive and negative parenting behaviors will be assessed using unblinded and blinded measures. For unblinded parenting measures, we will select questionnaires such as the Alabama Parenting Questionnaire [10]. For blinded measures, we will select assessments used to observe and code parent behavior, such as the Dyadic Parent-Child Interaction Coding System [47].

Display of Positive and negative parental affect will be assessed with measures specifically designed to capture parental affect (e.g., 5 min speech sample of expressed emotion; [15]) or a subscale of an existing parenting scale (e.g., attachment domain of the Parenting-Relationship Questionnaire [48]).

Parental stress will be assessed using measures specifically designed to capture stress from parenting, such as the Parenting Stress Index (PSI; [49]), but also measures assessing stress in the caregiver more generally (Depression and Anxiety Stress Scales, DASS; [50]).

Parenting self-efficacy will be assessed using measures specifically designed to capture parenting self-efficacy, such as the Parental Sense of Competence Scale (PSOC; [51]), a subscale of an existing parenting scale (e.g., the Parenting-Relationship Questionnaire, [48]), or a scale designed to assess parenting competence in specific contexts, such as education (e.g., Parent as Educator Scale, [52]).

Parental depression will be assessed using measures to capture depressive symptoms, such as the Beck Depression Inventory (BDI; [53]), a subscale of an existing mental health questionnaire (e.g., depression subscale of the Depression and Anxiety Stress Scales, DASS; [54]) or a mental health

questionnaire for which the overall score can be used as a proxy for depression (e.g., the General Health Questionnaire, GHQ; [55]).

Parental ADHD will be assessed using an adult measure of ADHD, such as the Adult Self-Report Scale (ASRS) Screener [56].

The remaining parent variables, including *single parenthood* and *socio-economic status (SES),* are commonly assessed with demographic questionnaires or items. SES will be conceptualized in line with previous work of our group and following recommendations in health research [5,57], as low (<high school), medium (high school graduate or college education), or high (>college graduate).

Note that *parenting behaviors, parental affect, parental stress* and *parenting self-efficacy* will serve as moderators (to predict parenting outcomes), mediators (in the relationship between BPT and child outcomes) and outcome variables (in the moderator analysis). *Parental depression, parental ADHD, single parenthood and socio-economic status* will serve as baseline moderators to predict parenting outcomes.

Additionally the following child variables will be selected:

Child ADHD severity will be assessed using a parent-rated measure of childhood ADHD, such as the ADHD subscale of the Connors Parent Rating Scale [58].

Comorbidity will be assessed using symptoms of Oppositional Defiant Disorder (ODD) and/or Conduct Disorder (CD), by for example the ODD subscale of the Connors Parent Rating Scale [58], or the CD subscale of the Disruptive Behavior Disorder Rating Scale [59]. In addition, internalizing symptoms will be assessed, using for example the internalizing subscale of the Child Behavior Checklist [60].

Global impairment will be assessed using a parent- or clinician-rated measure of global impairment, such as the Impairment Rating Scale [61].

The remaining child variables, including *child age, medication use and IQ* are commonly assessed with demographic questionnaires or items.

Child ADHD severity, comorbidity and global impairment will serve as moderators (to predict parenting outcomes) and outcome variables (in the mediation analysis). *Child age, medication use and IQ* will solely serve as moderators to predict parenting outcomes.

For all variables (moderators and outcomes), when a study reports multiple measures to capture the same concept, the measure which is most often used by other studies will be included. If multiple raters (mothers and fathers) are included to assess the same concept, the assessment by the mother will be preferred as they are more often the primary caregiver and more often take part in BPT. Regarding harmonization, for each dataset continuous measures will be converted into z-scores, using pre-intervention-score standard deviations within studies.

Quality assessment

Quality assessment will be done independently by three authors (a combination of AG, RH and LAS) using Cochrane risk of bias. Any disagreement will be resolved by consensus. Once the data has been received, all raw data sets will be checked for impossible, missing, or extreme values. We will collect data on all randomized participants, and subsequently adopt the intention to treat principle. As this will possibly reintroduce participants who were previously excluded, we will also check randomization parameters (e.g., age, gender, and ADHD severity of the participants). If any unexpected deviations are found between our results and the published results, the original researcher will be contacted to locate the origin of this deviation.

Analysis

Effects of BPT will be calculated using a one-stage IPDMA, in which data from participants across studies will be analyzed in one stage, clustered by study. A linear multilevel analysis will be used to examine the effects of BPT on parenting outcome measures. A random intercept for study will be added to each model. Post intervention outcome measures will be used as dependent variables in these models, and pre-intervention outcome measures and intervention group will be added. The interaction between intervention group and moderators of interest will be added to the model to assess their moderating effect on treatment outcomes. To analyze changes in parenting behaviors as a potential mediator in the relationship between BPT and child outcomes, the change in parenting behaviors (post-treatment score – baseline score) will be used. An interaction between intervention group and change in parenting behaviors will be added to the model to determine whether change in parenting behaviors had a main effect on child outcomes and/or an interactive effective with treatment [62,63]. We will conduct sensitivity analyses between studies that provided data and those that did not, for demographic characteristics (e.g., age), and for inclusion criteria (cut-off on measures versus meeting diagnostic criteria for ADHD) and reported effect sizes. If sufficient data is available, a subgroup analysis for child age will be conducted, where all analyses will be repeated separately for pre-school children (<6 years of age), school aged children (6-12 years of age) and adolescents (>12 years of age).

Discussion

The current protocol presents the first IPDMA to synthesize research findings on treatment effects of BPT for children with ADHD on parenting outcomes. Both child and parent moderators of parenting outcomes will be explored and a mediation analysis will be conducted to examine whether changes in parenting behaviors mediate the effect of BPT on child behaviors and impairment.

Previous efforts to identify moderators of parenting outcomes are scarce, as there are few well powered RCTs and only two meta-analyses on this topic [3,6]. The heterogeneity found in parenting outcomes in previous meta-analyses suggest that there is not a "one size fits all" solution of BPT for children with ADHD. Parents and children who differ with regard to their personal, clinical and demographic characteristics, are also likely to differ in their response to BPT. Clearly, an IPDMA approach is needed to further examine the effects of BPT on parenting outcomes, to elucidate potential sources of heterogeneity amongst children and parents, and to investigate potential mechanisms of change in BPT for children with ADHD. Ultimately, both research and clinical practice may be informed by the knowledge of which child and/or parent responds best to a certain treatment, thereby contributing to the overall goal of providing the best care to children with ADHD and their parents.

An additional important aim of the current IPDMA will be to examine a crucial assumption about the working mechanism of BPT, namely whether improvements in parenting behaviors mediate improvements in child behavior and impairment. So far, single studies have examined this assumption, finding some supportive evidence [12,19], but this hypothesis has never been addressed in a meta-analysis, let alone by using an IPDMA approach. By synthesizing all available (raw) data from RCTs, we will conduct highly sophisticated and powered statistical analyses, to provide insight into the working mechanisms of BPT. This knowledge will allow us to further improve and refine BPT programs for children with ADHD.

Despite clear strengths of the IPDMA approach, such as high-powered moderator, mediation and subgroup analyses, there are some limitations as well [25,27,64]. First, IPDMA cannot change anything about the way the study was originally conducted. Second, it is unclear whether enough studies measured the variables of interest, and thus whether all intended outcomes can be examined. Third, if investigators of trials are unwilling to share their data (or may not be able to share their data), not all relevant data can be included in the synthesis. Fourth, not all factors which may affect study outcomes can be conceptualized as a moderator, such as efficacy versus effectiveness trials (i.e., studies often do not fit exactly into one of both categories).

Notwithstanding these limitations, this study has the potential to elucidate clinically relevant questions concerning the efficacy of BPT for children with ADHD and their parents and to provide insight in moderators and mediators of treatment effects. This knowledge may improve and optimize current treatment programs and could eventually lead to advances in personalized treatment for children with ADHD.

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Supplement 1- Search terms per database

Behavioral interventions

PubMed

("Attention Deficit Disorder with Hyperactivity"[Mesh] OR ADHD[tiab] OR ADD[tiab] OR attention deficit*[tiab] OR hyperactiv*[tiab] OR hyperkinetic*[tiab] OR minimal brain deficit*[tiab] OR minimal brain dysfunction*[tiab])

AND

(("Psychotherapy"[Mesh] OR psychotherap*[tiab] OR psychological therap*[tiab] OR psychological intervent*[tiab] OR psychoeduca*[tiab] OR mentoring*[tiab] OR coaching*[tiab] OR mindful*[tiab] OR relax*[tiab] OR meditat*[tiab])

OR

((parent*[tiab] OR mother[tiab] OR father[tiab] OR teacher*[tiab] OR school*[tiab])

AND

(program*[tiab] OR train*[tiab] OR educa*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab]OR intervention*[tiab] OR coaching*[tiab] OR counseling*[tiab]))

OR

((behavio*[tiab] OR cognit*[tiab] OR "acceptance and commitment"[tiab] OR dialectica*[tiab])

AND

(program*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR intervention*[tiab] OR treatment*[tiab] OR train*[tiab]))

OR

(psychosocial[tiab]

AND

(treatment*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR train*[tiab] OR intervention*[tiab] OR program*[tiab]))

OR

((skill*[tiab] OR organization*[tiab] OR organisation*[tiab] OR planning*[tiab] OR play*[tiab])

AND

(train*[tiab] OR intervention*[tiab] OR program*[tiab])))

AND

("Adolescent"[Mesh] OR "Child"[Mesh] OR child*[tiab] OR school*[tiab] OR infan*[tiab] OR adolescen*[tiab] OR pediatri*[tiab] OR paediatr*[tiab] OR boy[tiab] OR boys[tiab] OR boyhood[tiab] OR girl[tiab] OR girls[tiab] OR girlhood[tiab] OR youth[tiab] OR youths[tiab] OR teen[tiab] OR teens[tiab] OR teenage*[tiab] OR puberty[tiab] OR preschool*[tiab] OR toddler*[tiab] OR juvenile*[tiab] OR kids[tiab])

AND

("Controlled Clinical Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Follow-Up Studies"[Mesh] OR follow-up[tiab] OR followup[tiab] OR control group*[tiab] OR "Random Allocation"[Mesh] OR random*[tiab] OR trial[ti])

EMBASE EMBASE.com (losse delen combineren op website)
('attention deficit disorder'/exp OR (ADHD OR ADD OR 'attention deficit*'
OR hyperactiv* OR hyperkinetic* OR 'minimal brain deficit*' OR 'minimal brain dysfunction*'):ab,ti)
AND

('psychotherapy'/exp OR (psychotherap* OR 'psychological therap*' OR 'psychological intervent*'
OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*):ab,ti)
OR
((((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention*
OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR
train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR
program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))):ab,ti)

AND
('juvenile'/exp OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR
boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage*
OR puberty OR preschool* OR toddler* OR juvenile* OR kids):ab,ti)

AND
('controlled clinical trial'/exp OR 'randomization'/exp OR ('control group*' OR random*):ab,ti OR
trial:ti)

EBSCO PsycINFO

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(DE "Psychotherapy" OR DE "Child Psychotherapy" OR DE "Play Therapy" OR DE "Behavior Therapy" OR DE "Aversion Therapy" OR DE "Conversion Therapy" OR DE "Dialectical Behavior Therapy" OR DE "Exposure Therapy" OR DE "Implosive Therapy" OR DE "Reciprocal Inhibition Therapy" OR DE "Response Cost" OR DE "Systematic Desensitization Therapy" AND DE "Cognitive Behavior Therapy" OR DE "Cognitive Therapy" OR DE "Group Psychotherapy" OR DE "Neurotherapy" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

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((behavio* OR cognit* OR ‘acceptance and commitment’ OR dialectica*)

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((skill* OR organization* OR organisation* OR planning* OR play*)

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(train* OR intervention* OR program*))

AND

(AG (childhood OR adolescence) OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(“control group*” OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO CINAHL

(MH "Attention Deficit Hyperactivity Disorder" OR "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(MH "Psychotherapy+" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
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(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
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(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))

AND

(AG child OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(MH "Clinical Trials+" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO ERIC

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Hyperactivity Disorder" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

(DE "Psychotherapy" OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)
OR
((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
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(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
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(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND

(train* OR intervention* OR program*))

AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

("control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

Web of Science

(TS=("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*"))

AND

(TS=(psychotherap* OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

(psychosocial

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*))))

AND

(TS=(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(TS=("clinical trial*" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design"))

Cochrane Central register of Controlled Trials *(CENTRAL)*

("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

((psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

((psychosocial)

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*)))

AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids)

Supplement 2. Data sharing manual

Data collection form

Content

Thank you for taking place in our Psychosocial ADHD INTerverntions (PAINT) collaborators group. We are very grateful that you are willing to put your time into this project. We believe that this group will be fruitful and successful collaboration with the aim to get more insight into psychosocial interventions for ADHD.
With this manual, we hope to provide you with guidance on the data collection. However, if you have any questions regarding the data handling, despite reading this manual, please let us know so we can help you further, and adapt our manual accordingly. You can reach us at paint@accare.nl.

Most of the choices we have made concerning data collection are driven by a need to keep methods and measures similar across trials. Every study is designed slightly different, with different measures, different in- and exclusion criteria, different methods to handle missing data, etc..
To harmonize measures and methods, at some point we will have to make choices regarding data analysis, that differ from the choices made in the original study. For example, we will do intention to treat analysis, while it may be possible that you did not do this in your original analysis. This means that, if available, we will ask for data or participants not included in the original analysis. Furthermore, it is important to mention that we will not report on results from a single trial, although we can report a forestplot displaying all effect sizes of included studies.

How do I transfer my data?
Preferably, we would receive the information electronically. We can work with any kind of data file (STATA, SPSS, etc.), but we prefer a layout, where each line represents a subject.

You can email the data file once you encrypted it using a program such as 7-zip (an explanation on how to do this is included in supplement B). It is important that the password with which you will protect your data file, will be send in a separate email from the email that contains the data file (as attachment). Another important point in transferring the data is that the data should be anonymized. This means that there is no information with which we could trace a single participant back to the individual. This means that no names should be included in the file. However, all other information that can identify a person should be left out of this file. This can mean combinations of variables, for example postal code and date of birth. Please make sure that this kind of information is not present in the data file. If these kinds of examples arise, please contact us, so we can think with you on what best to do.

Which participants do we need?
We want the data of all included participants. This means all participants that have a baseline measure and were randomized. It could be possible that this is a different approach than you took in

your analysis of the data. Because we want to perform intention to treat analysis, we need all data from included participants.

Which data do we need?

We ask you for clean data (please contact us if this provides you with any questions). We want sum scores and if available norm-scores of questionnaires. Proper labeling is important. In the Table below we provide you with an overview of constructs that we are interested in. It could be possible that the measure or instrument used in your study is not mentioned in this Table, this does not mean that we are not interested, the measures mentioned are mere examples. If there are any remarks on this measure (e.g. certain items were not used) please mention these in the column "remarks". Please indicate which informants filled out the questionnaires, when multiple informants are used please provide us with data from all informants. If multiple instruments have been used to measure a certain construct, we would really like to receive all instruments (for example a self and a proxy version, or multiple ADHD measures). This could aid us in the harmonization process (see above). If a construct is measured with an in-house instrument or if you made any adjustments on the instrument, could you also provide us this instrument?

For questionnaires, we would like to receive the, sum scores and norm-scores and if available item scores. We would always like to receive the full questionnaire if possible, and not just certain subscales. In the future, it could be possible that we will ask you about norming tables, we hope however, that we will not need these.

For (structured) interviews we would like to receive items scores, sum scores and outcomes. We would like to receive information on the full interview, not only certain outcomes.

Concerning cognitive measures, we would like to receive calculated outcomes variables across trials and conditions, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean (and SD) of reaction time on Go trials, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We fill also need information about the task such as number of conditions, number of trials, and how the outcome variables were calculated.

For variables that are available on multiple time points, please provide us with all relevant data. For example, if an ADHD measure is taken at baseline, right after the intervention and after 3 months, we would like to receive this measure assessed at all time points. Again, proper labelling is very important. Please label the data in English (or Dutch).

The constructs and variables that we are interested in for the IPD meta-analysis are shown below. We understand that not all studies have included all measures. The table below will provide you with a list you can keep on hand when preparing the data before sending it. Next to the constructs are examples of instruments. Please remember that this is not a complete list, and that it could be possible that you have used an instrument that is not in our list, but that would still be very valuable for this IPD meta-analysis. Please remember that you do not have to recode your data. We will do this for all datasets.

What will we do with the data?

Once we receive the data we will do some basic data checks. These will include checking missing and impossible values. If we will have any questions concerning the data during or after these checks we will contact you for clarification. After that we will harmonize the data with the other datasets. This harmonization process depends on the available data. For example, this could mean that we have to dichotomize data, or making norm deviation scores (translating raw questionnaire scores on one

scale into raw questionnaire scores on another scale using norm scores). Harmonization is easiest if the same measure has been used across studies. If you have used multiple instruments to measure a certain outcome (e.g. more than 1 ADHD scale), we ask you to provide us both measures. This could mean that we may be able use a latent variable for some measures, or we could calculate correlations between measures.

The original dataset will be saved as the original file. Any harmonization will take place in a separate file, which are only later merged into one big data file.

Supplement 2A.

Tabel 1 Measures.

Descriptive measures	
Participant ID	
Date of randomization	Dd/mm/yyyy
Date of treatment start	Dd/mm/yyyy
Date post-intervention measurement	Dd/mm/yyyy
Date follow up measurement	Dd/mm/yyyy
Date baseline measurement	Dd/mm/yyyy
Treatment allocation	0- Control 1- Intervention
Age	Age in years
Gender	1-Male 2-Female
IQ	Norm score of WISC
Verbal IQ	Norm score of WISC
Performance IQ	Norm score of WISC
Ethnicity	
Socioeconomic status	
ADHD severity at baseline	
Comorbidities	ODD/CD/Anxiety/Depression/PDD/Tics/ etc.
Number of children living with the family	Total number of children in the household
Primary care-taker education	
Secundary care-taker education	
Household income	Combined income of primary caretaker and (if applicable) secundary caretaker
Parental psychopathology (diagnosis)	Parental ADHD/ anxiety/depression/ etc
Marital status	
Education primary caretaker	
Education secondary caretaker	
Age Father	Age in years
Age mother	Age in years

Psychoactive Medication use pre- intervention	Yes/no, if yes which medication, mg MPH if applicable, x times per day, for the last month, duration
Previous care use of the child	Care use in mental health.
Medication use during intervention	Yes/no, if yes, mg per day
Treatment expectancy	
Stable medication use during intervention	Yes/No/NA
Other descriptive measures	
Individual child outcomes- behavioral	
Measured constructs	**Examples of instruments**
ADHD	Conners, CBCL, DBD, ACTeRS, ARS, BASC, SNAP, SWAN, Werry Weiss Peters activity scale, Behavioral checklist, PACS, Parent daily report, KSADS, standardized behavioral observations
Disruptive disorders/ behavior	Conners, CBCL, DBD, EDBI, SNAP, SSRS, ACTeRS, KSADS, behavior problem checklist, aggression and conduct problems scale, behavioral checklist, PACS, parent daily reports, standardized behavioral observations
Social skills	DSAS, Behavior problem checklist, BASC, ACTeRS, SSRS, CBCL
Internalizing problems	Conners, CBCL, SSRS, BASC, Behavior problem checklist, MASC, PACS, KSADS, SCARED, CDI
Attachment	
Quality of life	HONOSCA, kidsscreen, EQ-5d, IRS
Selfconcept	Piers-Harris
Which other child behavioral outcomes are available?	
Individual child outcomes- academic outcomes	
Measured Construct	Examples of measures
Grades on core courses	Math, Spelling, Reading
Standardized Academic Achievement tests	Reading, spelling, math scores, woodcock johnson, WRAT, WISC Durrel
On and off task behaviors	Classroom observations, SOAPs
Academic competence	Academic rating scale, classroom performance survey

Which other academic outcomes are available?	
Individual child outcomes- cognitive outcomes[a]	
Higher cognitive functions	Working memory, executive functions, inhibition, planning, set shifting, reward sensitivity, emotion regulation
Intellectual functioning	IQ (WISC, RAVEN)
Motor skills	Fine motor skills, precision, gross motor skills
Memory	Visuospatial, verbal
Basic cognitive functions	Attention, reaction time, speed, perception
Child individual outcomes- other measures	
Adverse events	Types of adverse events reported
Treatment fidelity	
Treatment satisfaction	
Number of sessions attended	
Drop out	Yes/no
Date of discontinuation of the intervention	
Reason for discontinuation	
Parental outcome measures	
Measured constructs	Examples of measures
Parental psychopathology	DASS, GHQ, BDI, PSI, CSS, AARS, SCL90,
Parent child interaction, parenting behaviors, parenting style, parenting affect	DPICS or other observational measure, parenting practices inventory (PPI), parent interaction style, PS (parenting scale), measures parental sensitivity/reponsivity
Parental competence/ self efficacy	PSI-subscale parental competence, PSOC
Spouse relationship	locke wallace marital adjustment, PSI-subscale
Parental self esteem	Rosenberg self esteem scale (RSE)
Parenting stress	PSI
Which other parenting outcomes are available?	

[a] concerning cognitive measures, we would like to receive calculated outcomes measures, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean reaction time, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We will also need information on the conditions of the task, how the outcome was calculated, etc.

PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item	Location in manuscript
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Page 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Page 2
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Page 2
Sponsor	5b	Provide name for the review funder and/or sponsor	Page 2
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Page 2
Introduction			

Section and topic	Item No	Checklist item	Location in manuscript
Rationale	6	Describe the rationale for the review in the context of what is already known	Page 5-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Page 8
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Page 9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Page 9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Page 9 (and supplement)
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Page 10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Page 9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done	Page 8-9 (and supplement)

Section and topic	Item No	Checklist item	Location in manuscript
		independently, in duplicate), any processes for obtaining and confirming data from investigators	
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Page 10-12 (and supplement)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Page 10-12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Page 12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Page 12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Page 12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Page 12-13
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias	Page 13

Section and topic	Item No	Checklist item	Location in manuscript
		across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Page 12

BMJ Open

Effects of Behavioral Parent Training for children with attention-deficit/hyperactivity disorder on Parenting Behavior: A protocol for an Individual Participant Data Meta-analysis

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Effects of Behavioral Parent Training for children with attention-deficit/hyperactivity disorder on Parenting Behavior: A protocol for an Individual Participant Data Meta-analysis

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Abstract

Introduction: Behavioral Parent Training (BPT) is a well-established treatment for children with attention-deficit/hyperactivity disorder (ADHD). BPT is based on the hypothesis that improvements in parenting are mediators of improvements in children's behaviors. However, meta-analyses show considerate heterogeneity in effects of BPT on child outcomes, and meta-analyses on parenting outcomes are scarce. Also, few studies have investigated parenting factors as mediators of child outcomes. This study aims to examine the effects and moderators of BPT on parenting outcomes and whether improvements in parenting mediate amelioration of behavior and impairment in children with ADHD.

Methods and analyses: We will conduct an individual participant data meta-analysis (IPDMA), making use of individual data of existing trials, and giving the opportunity for highly powered moderator analyses. This IPDMA will be performed by the Psychosocial ADHD INTervention (PAINT) collaboration. We will include randomized controlled trials of BPT, for individuals with ADHD below 18 years old. Systematic searches have been performed to locate relevant papers. Authors are currently contacted to share their data with the PAINT-IPDMA project. We will examine effects of BPT on parenting outcomes (e.g., positive and negative parenting, management of affect, perceived parenting competence, parenting stress), moderators of these effects (e.g., parental depression, parenting stress, severity of the child's ADHD symptoms) and subsequently perform mediation analyses where parenting outcomes are modelled as mediators of child outcomes (e.g., symptoms and severity of ADHD, comorbid psychopathology, and impairment).

Ethics and Dissemination: We will include data from RCTs for which ethical approval has been received and consent forms have been signed. De-identified data will be provided by the original investigators. We aim to disseminate our findings through peer-reviewed scientific journals, presentations at (inter)national scientific meetings, newsletters, the website of our project and the Dutch academic workspace ADHD.

Article summary

Strengths and limitations of this study:

- To our knowledge this is the first IPDMA that examines the effects of behavioral parent training for ADHD on parenting outcomes.
- By using IPDMA, we are able to conduct highly powered moderation analysis.
- By collecting individual participant data from randomized controlled trials, we have the opportunity to perform uniform analyses across studies.
- Our IPDMA includes only variables that are reported consistently across the majority of studies in the database.
- Representativeness of the database will depend partly on the willingness and ability of investigators to share their data.

Introduction

Behavioral parent training (BPT) is a well-established intervention for children with attention-deficit/hyperactivity disorder (ADHD) and recommended as first line treatment by many international guidelines [1–3]. In BPT, parents are trained to apply behavioral techniques meant to increase prosocial and adaptive child behaviors and to reduce disruptive and maladaptive child behaviors. In addition, BPT focusses on nurturing and positive parent-child relationships [4]. Several meta-analyses on BPT for children with ADHD have shown medium to large effect sizes on parent reported reductions of ADHD symptoms, comorbid problems, impairment and parenting behaviors [3,5–7]. However, the full range of relevant parenting outcomes of BPT has not been assessed in meta-analyses [7,8]. Moreover, while improvements in parenting behaviors are thought to mediate improvements in children's behaviors and associated impairments [3,9], studies investigating these mediation effects are scarce. Another unresolved issue is that individual studies commonly lack the statistical power to adequately assess moderators of improvements of parenting outcomes. Knowing which moderators impact the effectiveness of BPT for child [5] and parenting outcomes [3,6], in addition to knowing which mediators drive the effects of BPT will give more insight into for whom BPT works best and into the working mechanisms underlying this, therefore contributing to personalized treatment of children with ADHD.

BPT aims to increase the demonstration of positive parenting behaviors and to inhibit negative parenting behaviors, improve the management of affect, reduce parenting stress and enhance parenting self-efficacy [9], in order to positively influence children's behaviors and decrease impairment. Parents are trained to modify environmental antecedents (e.g., providing structure) and consequences (e.g., positive rewards for adaptive behavior) of behavior. Positive parenting behaviors consist of providing praise, encouragement, effective communication, demonstrating positive affect and offering physical affirmations [10,11], whereas negative parenting behaviors are described as providing inconsistent discipline, verbal criticism, corporal punishment, poor supervision, and demonstrating negative affect [12–14]. Essential to positive parenting behavior is the effective management of parental affect, which is often a specific target of BPT [15]. Parents are taught to express positive emotions (e.g., love, affection and warmth) and to inhibit expressions of negative and unsupportive emotions (e.g., anger, frustration and irritability) [16]. Parenting stress (i.e. stress arising from the feeling that the demands of parenting outweigh the resources [17]) is often reported by parents of children with ADHD [18] and is also an important target of BPT. Lastly, parenting self-efficacy is an important target of BPT [19]; parents should feel more confident and competent in carrying out their parenting tasks.

When assessing parenting outcomes of BPT, it is important to consider a range of outcomes, particularly positive and negative parenting behaviors, management of affect, parenting stress and parenting self-efficacy. However, treatment trials of BPT have not uniformly assessed all parenting outcomes that are explicit targets of BPT [3,6], although BPT outcomes may differ for these different domains. For example, a recent systematic review investigated multiple parenting outcomes (display of parental affect, parenting stress, and parenting self-efficacy) of BPT and showed positive results for outcomes most closest to the target of BPT (e.g., parenting self-efficacy), but less so for more distal outcomes (e.g., parental psychopathology) [20]. Notably, studies in that review were not specifically conducted in ADHD samples, nor were outcomes quantified using a (individual participant data) meta-analytic approach, which will be the analytic approach in the current study. Recently, two meta-analyses examined the effectiveness of behavioral interventions (mostly consisting of BPT) on parenting outcomes in samples of children with ADHD, either assessed by raters unblinded to the treatment condition (e.g., parents involved in BPT [9]) or by blinded raters (e.g., independent raters coding video-taped interactions between the parent and child [3,6]). The first meta-analysis [3] considered effects on positive and negative parenting behaviors and parenting self-efficacy, immediately post-intervention. Results indicated improvements in positive parenting behaviors (medium effect sizes (ES) of 0.68 and 0.63 for unblinded and blinded raters, respectively), reductions in negative parenting behaviors (medium to small ES of 0.57 and 0.43 for unblinded and for blinded raters, respectively), and improvements in parenting self-efficacy (small ES of 0.37 for unblinded raters). The other meta-analysis [6] investigated the effects of BPT for preschool children with (or at risk for) ADHD, and reported medium to small ES of 0.63 and 0.33 by unblinded and blinded raters, respectively, for reductions in negative parenting behaviors. In addition, long-term effects (up to 12 months) on negative parenting behaviors were reported by unblinded raters with an ES of 0.12 (very small). Overall, both unblinded and blinded parent outcomes show improvements after BPT, although the effects on blinded outcomes generally appeared somewhat smaller than the effects on unblinded outcomes. Improvements on other relevant domains such as parenting stress and display of parental affect have not been addressed in meta-analyses, although individual studies demonstrated that parenting stress can be effectively alleviated with BPT [19], and that mothers who participated in BPT have less negative affect and better emotion regulation abilities post-treatment [21].

Heterogeneity in effect sizes is common in meta-analyses investigating parenting outcomes of BPT for children with ADHD [3,6]. More knowledge on factors associated with treatment effects will yield more insight into for whom BPT works best, and may allow clinicians to make better treatment choices tailored to individuals. So far, very few randomized control trials (RCTs) were adequately powered for moderator analyses, and existing moderator analyses were mostly limited to

child behavioral outcomes [22–24]. While traditional methods of addressing heterogeneity in meta-analyses (such as excluding extreme ES, subgroup analyses, or meta-regression) may resolve heterogeneity (i.e. reduce I^2), they reveal little about the cause of this heterogeneity. Individual participant data meta-analysis (IPDMA) includes data at an individual level rather than at study level, which enables exploration of moderators, therefore yielding more information about the cause of heterogeneity. Moreover, IPDMA performs a uniform analysis across all studies. IPDMA also has enough power to perform subgroup analyses, which most individual RCTs lack. Due to the collaborative nature of an IPDMA, collaborators can provide input on all phases of the research (including design, analyses, interpretation and manuscript preparation), leading to a high quality product [25–27]. So far, no IPDMA has been conducted for parenting outcomes of BPT for children with ADHD.

In this paper, we present our protocol for an IPDMA on BPT for children with ADHD. The current IPDMA will explore several child- and parent-related moderators on parenting outcomes of BPT. Given that the examination of moderators on parenting outcomes is scarce, the choice of possible moderators to be investigated in this IPDMA will also be drawn from BPT trials on child outcomes. First, age of the child might be an important moderator [28], as parents may have more influence on younger children, and younger children may have less engrained symptoms. A meta-analysis indeed demonstrated that BPT had more effect on positive parenting behaviors for younger compared to older children with ADHD [3]. Second, medication use of the child may moderate BPT outcomes, as parents of children on medication might find it easier to adapt their parenting styles and experience less resistance when doing so, although there could also be a floor effect as that children with medication might already function better. Previous studies suggested that medication use may positively contribute to BPT outcomes on child's ADHD symptoms [29], although results have been mixed [22]. Third, it seems plausible that intelligence of the child is positively associated with a treatment that involves learning associations between behaviors and consequences and new skills [30]. There is some evidence that higher children's IQ is associated with more improvement in ADHD symptoms following behavioral treatment, but only for specific subgroups of children, such as girls with more anti-social symptoms [24,31,32]. Fourth, pretreatment ADHD severity and presence of comorbidities could moderate BPT, as parents might find it easier to change their parenting behavior when the child has less complex symptomatology. Previous individual studies have indeed confirmed that comorbidities at baseline negatively impacted the outcome of BPT treatment with regard to child symptoms [22,23,33].

There are several parent-related moderators that may have an effect on parenting outcomes of BPT. First, parental mental health problems (depression, ADHD, parental stress) are likely to affect how well parents are able to grasp new information and impact their ability to learn new methods of

parenting behaviors and skills [22,23,34–36]. Second, low socio-economic status (SES) may moderate outcomes of BPT, as this may increase family strain and impact the availability of family resources. There is mixed evidence of the moderating effect of low SES on the effects of BPT on ADHD symptoms and related problems, showing either no effect [24], or better outcomes for parents with lower SES [37]. So far, effects of low SES in relation to parenting outcomes of BPT for children with ADHD have not been investigated. For the present IPDMA we will rely on an imperfect measure of SES, i.e., parental education, as we are reliant on the measures that are consistently used across studies Third, single parenthood may also moderate outcomes of BPT, as individual studies have demonstrated that single mothers are less likely to respond to BPT [38,39], and maintain treatment gains over time [40] in terms of parenting behavior. Indeed, research suggests that single parents benefit more from enhanced BPT programs, suited to their specific needs (STEPP; [41,42]), compared to standard BPT programs. Fourth, there is evidence that lower parenting self-efficacy at baseline has a negative impact on improvements in behavioral problems in children with ADHD following BPT [43] and one could expect similar results for parenting outcomes. On the other hand, it is also possible that lower parenting abilities at baseline yields more room for improvement in BPT, and thus both directions of the effect could be expected.

Following the investigation of parenting outcomes of BPT as part of our IPDMA, the next step will be to examine mediators of improvements in child's behavior following BPT. Currently, there are no meta-analyses analyzing whether improvements in parenting behavior mediate improvements of BPT on symptoms of ADHD of the child. Some evidence of individual studies shows that reductions in parenting behaviors or parenting attributions mediate improvements on child outcomes in behavioral interventions [12,35,44]. This IPDMA aims to synthesize the available data regarding the association between improvements in parent outcomes and improvements in child's outcomes following BPT.

The specific aims of our IPDMA include:

(1) to investigate effects of BPT on parenting outcomes (positive and negative parenting behaviors, display of parental affect, parenting stress and parenting self-efficacy). Given that BPT for ADHD has shown different effects when assessed by unblinded raters and by more blinded raters [3,6,7], we aim to distinguish (if possible) between unblinded and blinded assessments of parenting behavior and display of parental affect;

(2) to investigate possible child (including age, medication use, IQ, ADHD severity, presence and severity of comorbidities) and parent (including depression, ADHD, socio-economic status, single parenthood, and parenting measures) moderators of parenting outcomes;

(3) to investigate whether improvements in parenting behaviors mediate the effect of BPT on behavioral child outcomes and impairment following treatment.

For aims 1-3, outcomes of BPT will be examined immediately post-treatment and at long-term where possible.

Methods and Analysis

For this IPDMA we will build on the Psychosocial ADHD INTervention IPD (PAINT-IPD) database which is registered in prospero: https://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017069877&ID=CRD42017069877. In this project we collect data on psychosocial treatments for children with ADHD: the search is regularly updated and the database continues to expand. For the purpose of the current IPDMA on parenting outcomes, we will use the same methods and search strategy. This protocol is written in line with the PRISMA-P 2015 checklist [45] (see supplementary checklist). The current study is planned to commence September 2020.

Inclusion criteria

We will include RCTs of behavioral treatments of individuals aged below 18 with ADHD, corroborated by clinical cutoffs on questionnaires or (semi)-structured interviews. We will include studies that compared BPT with a control condition (i.e., all conditions that are labeled control, including active treatment), and studies that compared BPT to another behavioral intervention (head to head comparisons). We excluded studies or intervention arms that used optimized medication treatment next to BPT as part of their study design or as a control condition. We define BPT as interventions directed at changing children's behaviors (i.e., increasing desirable behaviors and decreasing undesirable behaviors), using (cognitive) behavioral therapeutic techniques which parents are trained in [46]. Multimodal interventions (consisting of both parent and/or teacher and/or child training), will be included if the time spent on parent training within the intervention was at least equal to other types of training.

Selection and screening of studies

The last systematic search was performed on August 1st 2019. Currently, we are contacting the authors of the newly identified studies. Two authors (AG and RH) performed the selection and screening of studies, disagreement was resolved by consensus. A two-step approach to identifying relevant articles was used. First, Medline, CINAHL, PsycINFO, EMBASE+EMBASE CLASSIC, ERIC, Web of Science [Science Citation Index Expanded] was searched for relevant papers using a combination of the following search terms and their synonyms, as well as hierarchical family form (e.g., MeSH terms): treatment specific terms (e.g., behavioral treatment, psychosocial treatment, and parent

training), ADHD, child, and randomized controlled trial. No date restrictions were applied. English, German and Dutch language publications published in peer-reviewed journals were included. Second, literature lists of all selected studies and relevant systematic reviews and meta-analyses were hand-searched to identify possible missing articles (complete search criteria for each database are available in Supplement 1).

Data collection and management

Author contact

We will contact the corresponding authors of all eligible trials to ask for their participation in the current IPD meta-analyses. If after several weeks we have had no response, we will send a reminder to the corresponding author. If we have failed to establish contact with the corresponding author, we will email the other authors of the study. Furthermore, we will contact researchers during conferences, and through our personal network to retrieve all eligible databases.

Data format and management

Part of the data has already been received in light of our previous IPDMA [5]. For newly identified data that we have not yet received, we will use the best, safest way to transfer the data. The most convenient way for most authors will be to transfer the encrypted data per email to the project management, but we will be open to other options (e.g., face to face transfer). A copy of our data collection manual for the PAINT-IPD database can be found in Supplement 2. We will allow authors to send the data in all possible formats, although the most preferable format would be one in which each subject represents a row and each variable a column.

If authors are not included in the PAINT collaborators group yet [5], we will offer one or two authors of each included study a place in our PAINT collaborators group. We plan yearly telephone calls and/or meetings at large international conferences to keep the working group up to date and discuss design and methodological issues. Members of the working group who have provided data on BPT trials with parenting outcomes will have the opportunity to provide feedback on the first draft of the manuscript and will be sent a copy of the final manuscript before submission. Only authors in the IPD steering committee group (APG, BvdH, SvdO, ML and PH) will have access to the data.

Ethics and Dissemination

The original investigators will be asked for de-identified data, so that only the original investigator knows the link between data and participant. We will only include RCTs where ethical approval has been given and participants signed consent forms. Since the current IPDMA is an extension of the original purpose of the eligible studies, we do not expect any ethical issues with the

current IPDMA. Results of our study will be disseminated through peer-reviewed scientific journals, and presentations on (inter)national scientific and/or clinical expert meetings.

Patient and Public Involvement

An expert panel consisting of parents of children with ADHD was organized at the conception of the idea in which feedback was given to the plans and changes were made accordingly. Our results will be communicated to clinicians, clients and their parents through newsletters, and through the academic workplace "ADHD en druk gedrag" (also see https://adhdendrukgedrag.nl/) in which many parents, client organizations, and mental health care professionals are represented.

Variables

For the PAINT-IPD database, a data request form will be sent to all authors of the original studies, containing a list of variables that will be requested (see Supplement 2a). This list was determined by reviewing the literature and the IPDMA steering committee (authors APG, SvdO, ML, PH and BvdH) assessed these outcomes domains for suitability and interest. The final list of variables will depend on the available data of all studies.

For the current protocol, the following parenting variables will be selected:

Positive and negative parenting behaviors will be assessed using unblinded and blinded measures. For unblinded parenting measures, we will select questionnaires such as the Alabama Parenting Questionnaire [10]. For blinded measures, we will select assessments used to observe and code parent behavior, such as the Dyadic Parent-Child Interaction Coding System [47].

Display of Positive and negative parental affect will be assessed with measures specifically designed to capture parental affect (e.g., 5 min speech sample of expressed emotion; [15]) or a subscale of an existing parenting scale (e.g., attachment domain of the Parenting-Relationship Questionnaire [48]).

Parental stress will be assessed using measures specifically designed to capture stress from parenting, such as the Parenting Stress Index (PSI; [49]), but also measures assessing stress in the caregiver more generally (Depression and Anxiety Stress Scales, DASS; [50]).

Parenting self-efficacy will be assessed using measures specifically designed to capture parenting self-efficacy, such as the Parental Sense of Competence Scale (PSOC; [51]), a subscale of an existing parenting scale (e.g., the Parenting-Relationship Questionnaire, [48]), or a scale designed to assess parenting competence in specific contexts, such as education (e.g., Parent as Educator Scale, [52]).

Parental depression will be assessed using measures to capture depressive symptoms, such as the Beck Depression Inventory (BDI; [53]), a subscale of an existing mental health questionnaire

(e.g., depression subscale of the Depression and Anxiety Stress Scales, DASS; [54]) or a mental health questionnaire for which the overall score can be used as a proxy for depression (e.g., the General Health Questionnaire, GHQ; [55]).

Parental ADHD will be assessed using an adult measure of ADHD, such as the Adult Self-Report Scale (ASRS) Screener [56].

The remaining parent variables, including *single parenthood* and *socio-economic status (SES),* are commonly assessed with demographic questionnaires or items. SES can be assessed in different ways (e.g. based on income, occupation, neighborhood or education) and due to our IPDMA methodology we are reliant on choosing the assessment measure that is most consistently used across studies. Given that data on parental education is often available, and is deemed acceptable as a proxy for SES [5,57], parental education level will serve as a proxy measure for SES in the current study.SES will be conceptualized as low (<high school), medium (high school graduate or college education), or high (>college graduate).

Note that *parenting behaviors, parental affect, parental stress* and *parenting self-efficacy* will serve as moderators (to predict parenting outcomes), mediators (in the relationship between BPT and child outcomes) and outcome variables (in the moderator analysis). *Parental depression, parental ADHD, single parenthood and socio-economic status* will serve as baseline moderators to predict parenting outcomes.

Additionally the following child variables will be selected:

Child ADHD severity will be assessed using a parent-rated measure of childhood ADHD, such as the ADHD subscale of the Connors Parent Rating Scale [57].

Comorbidity will be assessed using symptoms of Oppositional Defiant Disorder (ODD) and/or Conduct Disorder (CD), by for example the ODD subscale of the Connors Parent Rating Scale [57], or the CD subscale of the Disruptive Behavior Disorder Rating Scale [58]. In addition, internalizing symptoms will be assessed, using for example the internalizing subscale of the Child Behavior Checklist [59].

Global impairment will be assessed using a parent- or clinician-rated measure of global impairment, such as the Impairment Rating Scale [60].

The remaining child variables, including *child age, medication use and IQ* are commonly assessed with demographic questionnaires or items.

Child ADHD severity, comorbidity and global impairment will serve as moderators (to predict parenting outcomes) and outcome variables (in the mediation analysis). *Child age, medication use and IQ* will solely serve as moderators to predict parenting outcomes.

For all variables (moderators and outcomes), when a study reports multiple measures to capture the same concept, the measure which is most often used by other studies will be included. If multiple raters (mothers and fathers) are included to assess the same concept, the assessment by the mother will be preferred as they are more often the primary caregiver and more often take part in BPT. Regarding harmonization, for each dataset continuous measures will be converted into z-scores, using pre-intervention-score standard deviations within studies.

Quality assessment

Quality assessment will be done independently by three authors (a combination of AG, RH and LAS) using Cochrane risk of bias. Any disagreement will be resolved by consensus. Once the data has been received, all raw data sets will be checked for impossible, missing, or extreme values. We will collect data on all randomized participants, and subsequently adopt the intention to treat principle. As this will possibly reintroduce participants who were previously excluded, we will also check randomization parameters (e.g., age, gender, and ADHD severity of the participants). If any unexpected deviations are found between our results and the published results, the original researcher will be contacted to locate the origin of this deviation.

Analysis

Effects of BPT will be calculated using a one-stage IPDMA, in which data from participants across studies will be analyzed in one stage, clustered by study. A linear multilevel analysis will be used to examine the effects of BPT on parenting outcome measures. A random intercept for study will be added to each model. Post intervention outcome measures will be used as dependent variables in these models, and pre-intervention outcome measures and intervention group will be added. The interaction between intervention group and moderators of interest will be added to the model to assess their moderating effect on treatment outcomes. To analyze changes in parenting behaviors as a potential mediator in the relationship between BPT and child outcomes, the change in parenting behaviors (post-treatment score – baseline score) will be used. An interaction between intervention group and change in parenting behaviors will be added to the model to determine whether change in parenting behaviors had a main effect on child outcomes and/or an interactive effective with treatment [61,62]. We will conduct sensitivity analyses between studies that provided data and those that did not, for demographic characteristics (e.g., age), and for inclusion criteria (cut-off on measures versus meeting diagnostic criteria for ADHD) and reported effect sizes. If sufficient data is available, a subgroup analysis for child age will be conducted, where all analyses will be repeated separately for pre-school children (<6 years of age), school aged children (6-12 years of age) and adolescents (>12 years of age).

Discussion

The current protocol presents the first IPDMA to synthesize research findings on treatment effects of BPT for children with ADHD on parenting outcomes. Both child and parent moderators of parenting outcomes will be explored and a mediation analysis will be conducted to examine whether changes in parenting behaviors mediate the effect of BPT on child behaviors and impairment. Previous efforts to identify moderators of parenting outcomes are scarce, as there are few well powered RCTs and only two meta-analyses on this topic [3,6]. The heterogeneity found in parenting outcomes in previous meta-analyses suggest that there is not a "one size fits all" solution of BPT for children with ADHD. Parents and children who differ with regard to their personal, clinical and demographic characteristics, are also likely to differ in their response to BPT. Clearly, an IPDMA approach is needed to further examine the effects of BPT on parenting outcomes, to elucidate potential sources of heterogeneity amongst children and parents, and to investigate potential mechanisms of change in BPT for children with ADHD. Ultimately, both research and clinical practice may be informed by the knowledge of which child and/or parent responds best to a certain treatment, thereby contributing to the overall goal of providing the best care to children with ADHD and their parents.

An additional important aim of the current IPDMA will be to examine a crucial assumption about the working mechanism of BPT, namely whether improvements in parenting behaviors mediate improvements in child behavior and impairment. So far, single studies have examined this assumption, finding some supportive evidence [12,19], but this hypothesis has never been addressed in a meta-analysis, let alone by using an IPDMA approach. By synthesizing all available (raw) data from RCTs, we will conduct highly sophisticated and powered statistical analyses, to provide insight into the working mechanisms of BPT. This knowledge will allow us to further improve and refine BPT programs for children with ADHD.

Despite clear strengths of the IPDMA approach, such as high-powered moderator, mediation and subgroup analyses, there are some limitations as well [25,27,63]. First, IPDMA cannot change anything about the way the study was originally conducted. Second, it is unclear whether enough studies measured the variables of interest, and thus whether all intended outcomes can be examined. Third, if investigators of trials are unwilling to share their data (or may not be able to share their data), not all relevant data can be included in the synthesis. Fourth, not all factors which may affect study outcomes can be conceptualized as a moderator, such as efficacy versus effectiveness trials (i.e., studies often do not fit exactly into one of both categories). Fifth, since parental education levels are easy to collect, they are omnipresent in the data. Ideally several aspects

of SES are taken into account, such as income, occupation, and/or neighborhood [64,65], but this data is available in only few datasets.

Notwithstanding these limitations, this study has the potential to elucidate clinically relevant questions concerning the efficacy of BPT for children with ADHD and their parents and to provide insight in moderators and mediators of treatment effects. This knowledge may improve and optimize current treatment programs and could eventually lead to advances in personalized treatment for children with ADHD.

Contributorship statement

BvdH is the guarantor. APG wrote the first draft of the manuscript, and LAS wrote a revised and final version. APG, RH and LAS are performing the systematic search and data extraction. PJH, ML, SvdO, BvdH acquired funding for the PAINT-IPDMA project; an international database including individual participant data from RCTs examining psychosocial interventions for the treatment of ADHD in children. The current study is a part of the PAINT-IPDMA project. PJH, ML, SvdO, BvdH, and APG setup the initial design for the IPDMA. All authors worked together to design this IPDMA, contributed to the intellectual content of the current manuscript and approved the final version.

Competing interests

None declared.

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Data sharing statement

No data is available, as this is a study protocol.

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Supplement 1- Search terms per database

Behavioral interventions

PubMed

("Attention Deficit Disorder with Hyperactivity"[Mesh] OR ADHD[tiab] OR ADD[tiab] OR attention deficit*[tiab] OR hyperactiv*[tiab] OR hyperkinetic*[tiab] OR minimal brain deficit*[tiab] OR minimal brain dysfunction*[tiab])

AND

(("Psychotherapy"[Mesh] OR psychotherap*[tiab] OR psychological therap*[tiab] OR psychological intervent*[tiab] OR psychoeduca*[tiab] OR mentoring*[tiab] OR coaching*[tiab] OR mindful*[tiab] OR relax*[tiab] OR meditat*[tiab])

OR

((parent*[tiab] OR mother[tiab] OR father[tiab] OR teacher*[tiab] OR school*[tiab])

AND

(program*[tiab] OR train*[tiab] OR educa*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab]OR intervention*[tiab] OR coaching*[tiab] OR counseling*[tiab]))

OR

((behavio*[tiab] OR cognit*[tiab] OR "acceptance and commitment"[tiab] OR dialectica*[tiab])

AND

(program*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR intervention*[tiab] OR treatment*[tiab] OR train*[tiab]))

OR

(psychosocial[tiab]

AND

(treatment*[tiab] OR therapy*[tiab] OR therapies*[tiab] OR therapeu*[tiab] OR train*[tiab] OR intervention*[tiab] OR program*[tiab]))

OR

((skill*[tiab] OR organization*[tiab] OR organisation*[tiab] OR planning*[tiab] OR play*[tiab])

AND

(train*[tiab] OR intervention*[tiab] OR program*[tiab])))

AND

("Adolescent"[Mesh] OR "Child"[Mesh] OR child*[tiab] OR school*[tiab] OR infan*[tiab] OR adolescen*[tiab] OR pediatri*[tiab] OR paediatr*[tiab] OR boy[tiab] OR boys[tiab] OR boyhood[tiab] OR girl[tiab] OR girls[tiab] OR girlhood[tiab] OR youth[tiab] OR youths[tiab] OR teen[tiab] OR teens[tiab] OR teenage*[tiab] OR puberty[tiab] OR preschool*[tiab] OR toddler*[tiab] OR juvenile*[tiab] OR kids[tiab])

AND

("Controlled Clinical Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Follow-Up Studies"[Mesh] OR follow-up[tiab] OR followup[tiab] OR control group*[tiab] OR "Random Allocation"[Mesh] OR random*[tiab] OR trial[ti])

EMBASE EMBASE.com (losse delen combineren op website)
('attention deficit disorder'/exp OR (ADHD OR ADD OR 'attention deficit*'
OR hyperactiv* OR hyperkinetic* OR 'minimal brain deficit*' OR 'minimal brain dysfunction*'):ab,ti)
AND

('psychotherapy'/exp OR (psychotherap* OR 'psychological therap*' OR 'psychological intervent*'
OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*):ab,ti)
OR
((((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention*
OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR
train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR
program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))):ab,ti)

AND
('juvenile'/exp OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR
boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage*
OR puberty OR preschool* OR toddler* OR juvenile* OR kids):ab,ti)

AND
('controlled clinical trial'/exp OR 'randomization'/exp OR ('control group*' OR random*):ab,ti OR
trial:ti)

EBSCO PsycINFO

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(DE "Psychotherapy" OR DE "Child Psychotherapy" OR DE "Play Therapy" OR DE "Behavior Therapy" OR DE "Aversion Therapy" OR DE "Conversion Therapy" OR DE "Dialectical Behavior Therapy" OR DE "Exposure Therapy" OR DE "Implosive Therapy" OR DE "Reciprocal Inhibition Therapy" OR DE "Response Cost" OR DE "Systematic Desensitization Therapy" AND DE "Cognitive Behavior Therapy" OR DE "Cognitive Therapy" OR DE "Group Psychotherapy" OR DE "Neurotherapy" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR ‘acceptance and commitment’ OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

(psychosocial

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*))

AND

(AG (childhood OR adolescence) OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(“control group*” OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO CINAHL

(MH "Attention Deficit Hyperactivity Disorder" OR "Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR “attention deficit*” OR hyperactiv* OR hyperkinetic* OR “minimal brain deficit*” OR “minimal brain dysfunction*”)

AND

(MH "Psychotherapy+" OR psychotherap* OR “psychological therap*” OR “psychological intervent*” OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))

AND

(AG child OR (child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))

AND

(MH "Clinical Trials+" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

EBSCO ERIC

(DE "Attention Deficit Disorder" OR DE "Attention Deficit Hyperactivity Disorder" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

(DE "Psychotherapy" OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)
OR
((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND

(train* OR intervention* OR program*))
AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))
AND

("control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design" OR TI trial)

Web of Science
(TS=("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*"))
AND

(TS=(psychotherap* OR psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*
OR
((parent* OR mother OR father OR teacher* OR school*)
AND
(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))
OR
((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)
AND
(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))
OR
(psychosocial
AND
(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))
OR
((skill* OR organization* OR organisation* OR planning* OR play*)
AND
(train* OR intervention* OR program*))))
AND
(TS=(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenager* OR puberty OR preschool* OR toddler* OR juvenile* OR kids))
AND
(TS=("clinical trial*" OR "control group*" OR random* OR "controlled trial" OR "controlled study" OR "experimental study" OR "experimental design"))

Cochrane Central register of Controlled Trials *(CENTRAL)*

("Attention Deficit Disorder with Hyperactivity" OR ADHD OR ADD OR "attention deficit*" OR hyperactiv* OR hyperkinetic* OR "minimal brain deficit*" OR "minimal brain dysfunction*")

AND

((psychotherap* OR "psychological therap*" OR "psychological intervent*" OR psychoeduca* OR mentoring* OR coaching* OR mindful* OR relax*)

OR

((parent* OR mother OR father OR teacher* OR school*)

AND

(program* OR train* OR educa* OR therapy* OR therapies* OR therapeu*OR intervention* OR coaching* OR counseling*))

OR

((behavio* OR cognit* OR 'acceptance and commitment' OR dialectica*)

AND

(program* OR therapy* OR therapies* OR therapeu* OR intervention* OR treatment* OR train*))

OR

((psychosocial)

AND

(treatment* OR therapy* OR therapies* OR therapeu* OR train* OR intervention* OR program*))

OR

((skill* OR organization* OR organisation* OR planning* OR play*)

AND

(train* OR intervention* OR program*)))

AND

(child* OR school* OR infan* OR adolescen* OR pediatri* OR paediatr* OR boy OR boys OR boyhood OR girl OR girls OR girlhood OR youth OR youths OR teen OR teens OR teenage* OR puberty OR preschool* OR toddler* OR juvenile* OR kids)

Supplement 2. Data sharing manual

Data collection form

Content

Thank you for taking place in our Psychosocial ADHD INTerverntions (PAINT) collaborators group. We are very grateful that you are willing to put your time into this project. We believe that this group will be fruitful and successful collaboration with the aim to get more insight into psychosocial interventions for ADHD.
With this manual, we hope to provide you with guidance on the data collection. However, if you have any questions regarding the data handling, despite reading this manual, please let us know so we can help you further, and adapt our manual accordingly. You can reach us at paint@accare.nl.

Most of the choices we have made concerning data collection are driven by a need to keep methods and measures similar across trials. Every study is designed slightly different, with different measures, different in- and exclusion criteria, different methods to handle missing data, etc..
To harmonize measures and methods, at some point we will have to make choices regarding data analysis, that differ from the choices made in the original study. For example, we will do intention to treat analysis, while it may be possible that you did not do this in your original analysis. This means that, if available, we will ask for data or participants not included in the original analysis. Furthermore, it is important to mention that we will not report on results from a single trial, although we can report a forestplot displaying all effect sizes of included studies.

How do I transfer my data?
Preferably, we would receive the information electronically. We can work with any kind of data file (STATA, SPSS, etc.), but we prefer a layout, where each line represents a subject.

You can email the data file once you encrypted it using a program such as 7-zip (an explanation on how to do this is included in supplement B). It is important that the password with which you will protect your data file, will be send in a separate email from the email that contains the data file (as attachment). Another important point in transferring the data is that the data should be anonymized. This means that there is no information with which we could trace a single participant back to the individual. This means that no names should be included in the file. However, all other information that can identify a person should be left out of this file. This can mean combinations of variables, for example postal code and date of birth. Please make sure that this kind of information is not present in the data file. If these kinds of examples arise, please contact us, so we can think with you on what best to do.

Which participants do we need?
We want the data of all included participants. This means all participants that have a baseline measure and were randomized. It could be possible that this is a different approach than you took in

your analysis of the data. Because we want to perform intention to treat analysis, we need all data from included participants.

Which data do we need?

We ask you for clean data (please contact us if this provides you with any questions). We want sum scores and if available norm-scores of questionnaires. Proper labeling is important. In the Table below we provide you with an overview of constructs that we are interested in. It could be possible that the measure or instrument used in your study is not mentioned in this Table, this does not mean that we are not interested, the measures mentioned are mere examples. If there are any remarks on this measure (e.g. certain items were not used) please mention these in the column "remarks". Please indicate which informants filled out the questionnaires, when multiple informants are used please provide us with data from all informants. If multiple instruments have been used to measure a certain construct, we would really like to receive all instruments (for example a self and a proxy version, or multiple ADHD measures). This could aid us in the harmonization process (see above). If a construct is measured with an in-house instrument or if you made any adjustments on the instrument, could you also provide us this instrument?

For questionnaires, we would like to receive the, sum scores and norm-scores and if available item scores. We would always like to receive the full questionnaire if possible, and not just certain subscales. In the future, it could be possible that we will ask you about norming tables, we hope however, that we will not need these.

For (structured) interviews we would like to receive items scores, sum scores and outcomes. We would like to receive information on the full interview, not only certain outcomes.

Concerning cognitive measures, we would like to receive calculated outcomes variables across trials and conditions, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean (and SD) of reaction time on Go trials, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We fill also need information about the task such as number of conditions, number of trials, and how the outcome variables were calculated.

For variables that are available on multiple time points, please provide us with all relevant data. For example, if an ADHD measure is taken at baseline, right after the intervention and after 3 months, we would like to receive this measure assessed at all time points. Again, proper labelling is very important. Please label the data in English (or Dutch).

The constructs and variables that we are interested in for the IPD meta-analysis are shown below. We understand that not all studies have included all measures. The table below will provide you with a list you can keep on hand when preparing the data before sending it. Next to the constructs are examples of instruments. Please remember that this is not a complete list, and that it could be possible that you have used an instrument that is not in our list, but that would still be very valuable for this IPD meta-analysis. Please remember that you do not have to recode your data. We will do this for all datasets.

What will we do with the data?

Once we receive the data we will do some basic data checks. These will include checking missing and impossible values. If we will have any questions concerning the data during or after these checks we will contact you for clarification. After that we will harmonize the data with the other datasets. This harmonization process depends on the available data. For example, this could mean that we have to dichotomize data, or making norm deviation scores (translating raw questionnaire scores on one

scale into raw questionnaire scores on another scale using norm scores). Harmonization is easiest if the same measure has been used across studies. If you have used multiple instruments to measure a certain outcome (e.g. more than 1 ADHD scale), we ask you to provide us both measures. This could mean that we may be able use a latent variable for some measures, or we could calculate correlations between measures.

The original dataset will be saved as the original file. Any harmonization will take place in a separate file, which are only later merged into one big data file.

Supplement 2A.

Tabel 1 Measures.

Descriptive measures	
Participant ID	
Date of randomization	Dd/mm/yyyy
Date of treatment start	Dd/mm/yyyy
Date post-intervention measurement	Dd/mm/yyyy
Date follow up measurement	Dd/mm/yyyy
Date baseline measurement	Dd/mm/yyyy
Treatment allocation	0- Control 1- Intervention
Age	Age in years
Gender	1-Male 2-Female
IQ	Norm score of WISC
Verbal IQ	Norm score of WISC
Performance IQ	Norm score of WISC
Ethnicity	
Socioeconomic status	
ADHD severity at baseline	
Comorbidities	ODD/CD/Anxiety/Depression/PDD/Tics/ etc.
Number of children living with the family	Total number of children in the household
Primary care-taker education	
Secundary care-taker education	
Household income	Combined income of primary caretaker and (if applicable) secundary caretaker
Parental psychopathology (diagnosis)	Parental ADHD/ anxiety/depression/ etc
Marital status	
Education primary caretaker	
Education secondary caretaker	
Age Father	Age in years
Age mother	Age in years

Psychoactive Medication use pre- intervention	Yes/no, if yes which medication, mg MPH if applicable, x times per day, for the last month, duration
Previous care use of the child	Care use in mental health.
Medication use during intervention	Yes/no, if yes, mg per day
Treatment expectancy	
Stable medication use during intervention	Yes/No/NA
Other descriptive measures	
Individual child outcomes- behavioral	
Measured constructs	**Examples of instruments**
ADHD	Conners, CBCL, DBD, ACTeRS, ARS, BASC, SNAP, SWAN, Werry Weiss Peters activity scale, Behavioral checklist, PACS, Parent daily report, KSADS, standardized behavioral observations
Disruptive disorders/ behavior	Conners, CBCL, DBD, EDBI, SNAP, SSRS, ACTeRS, KSADS, behavior problem checklist, aggression and conduct problems scale, behavioral checklist, PACS, parent daily reports, standardized behavioral observations
Social skills	DSAS, Behavior problem checklist, BASC, ACTeRS, SSRS, CBCL
Internalizing problems	Conners, CBCL, SSRS, BASC, Behavior problem checklist, MASC, PACS, KSADS, SCARED, CDI
Attachment	
Quality of life	HONOSCA, kidsscreen, EQ-5d, IRS
Selfconcept	Piers-Harris
Which other child behavioral outcomes are available?	
Individual child outcomes- academic outcomes	
Measured Construct	Examples of measures
Grades on core courses	Math, Spelling, Reading
Standardized Academic Achievement tests	Reading, spelling, math scores, woodcock johnson, WRAT, WISC Durrel
On and off task behaviors	Classroom observations, SOAPs
Academic competence	Academic rating scale, classroom performance survey

Which other academic outcomes are available?	
Individual child outcomes- cognitive outcomes[a]	
Higher cognitive functions	Working memory, executive functions, inhibition, planning, set shifting, reward sensitivity, emotion regulation
Intellectual functioning	IQ (WISC, RAVEN)
Motor skills	Fine motor skills, precision, gross motor skills
Memory	Visuospatial, verbal
Basic cognitive functions	Attention, reaction time, speed, perception
Child individual outcomes- other measures	
Adverse events	Types of adverse events reported
Treatment fidelity	
Treatment satisfaction	
Number of sessions attended	
Drop out	Yes/no
Date of discontinuation of the intervention	
Reason for discontinuation	
Parental outcome measures	
Measured constructs	Examples of measures
Parental psychopathology	DASS, GHQ, BDI, PSI, CSS, AARS, SCL90,
Parent child interaction, parenting behaviors, parenting style, parenting affect	DPICS or other observational measure, parenting practices inventory (PPI), parent interaction style, PS (parenting scale), measures parental sensitivity/reponsivity
Parental competence/ self efficacy	PSI-subscale parental competence, PSOC
Spouse relationship	locke wallace marital adjustment, PSI-subscale
Parental self esteem	Rosenberg self esteem scale (RSE)
Parenting stress	PSI
Which other parenting outcomes are available?	

[a] concerning cognitive measures, we would like to receive calculated outcomes measures, not mere trial to trial performance. For example, in the stop task, we would like to receive measures such as SSRT, mean reaction time, number of commissions and omissions, but not the individual performance on a single trial of the stop task. We will also need information on the conditions of the task, how the outcome was calculated, etc.

PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item	Location in manuscript
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	Page 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	Page 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	Page 2
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	Page 2
Sponsor	5b	Provide name for the review funder and/or sponsor	Page 2
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	Page 2
Introduction			

Section and topic	Item No	Checklist item	Location in manuscript
Rationale	6	Describe the rationale for the review in the context of what is already known	Page 5-8
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	Page 8
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	Page 9
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	Page 9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Page 9 (and supplement)
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	Page 10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	Page 9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done	Page 8-9 (and supplement)

Section and topic	Item No	Checklist item	Location in manuscript
		independently, in duplicate), any processes for obtaining and confirming data from investigators	
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	Page 10-12 (and supplement)
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	Page 10-12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	Page 12
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	Page 12-13
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	Page 12-13
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	Page 12-13
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias	Page 13

Section and topic	Item No	Checklist item	Location in manuscript
		across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Page 12