**Definition of response in randomized controlled trials of medications for ADHD across the lifespan: A systematic review**

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 **Running title:** ADHD pharmacological treatment resposne definition in RCTs

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**ABSTRACT**

**Objectives:** Randomized controlled Trials (RCTs) are the gold standard for evaluating medication efficacy. The absence of a universal definition of treatment response, based on the degree of symptom improvement measured by standardized rating scales in the field of ADHD, makes it difficult to compare treatment outcomes across RCTs. Here, we aimed to assess to what extent and how “treatment response” is defined across RCTs of ADHD medications.

**Methods:** We identified eligible RCTs via theMED-ADHD database (<https://med-adhd.org/>), which compiles RCTs evaluating the efficacy and safety of pharmacological treatments for children, adolescents and adults with ADHD, based on a comprehensive search in multiple electronic databases, including PubMed, BIOSIS Previews, CINAHL, the Cochrane Central Registry of Controlled Trials, EMBASE, up to 17 January 2025, alongside additional unpublished information gathered from manufacturers/study authors.

**Results:** Out of 167 RCTs in MED-ADHD, 88 defined treatment response based on reductions in ADHD core symptom severity using rating scale scores. The most frequently used threshold was a ≥30% reduction in ADHD-RS scores, with other RCTs using ≥25%, ≥40%, or ≥50%. Additionally RCTs applied similar cutoff values to alternative scales, including CAARS, SNAP-IV, AISRS, and WRAADS. However, 79 studies did not specify any response threshold

**Conclusion:** Our review underscores and quantitively defines the inconsistency in the definition of treatment response across ADHD medication trials, highlighting the urgent need for the field of a consensus on the use of a standardized definition of “treatment response” for each rating scale, based on the percentage reduction in ADHD core symptom severity.

**Keywords:** Attention-deficit/hyperactivity disorder (ADHD); randomized controlled trials (RCTs); pharmacological treatment; treatment response; standardized definition.

**INTRODUCTION**

Attention-deficit/hyperactivity disorder (ADHD), the most prevalent neurodevelopmental condition, impacts at least 5% of school-aged children globally (Cortese et al., 2023) with recent meta-analytic evidence pointing to a prevalence of 8% in children and adolescents (Ayano et al., 2023). It is marked by developmentally inappropriate levels of inattention and/or hyperactivity-impulsivity that interfere with daily functioning (American Psychiatric Association, 2022).

The treatment of ADHD involves both pharmacological and non-pharmacological approaches. Medications approved for managing ADHD include stimulants, such as methylphenidate and amphetamines, as well as non-stimulants, like atomoxetine, clonidine, guanfacine, and viloxazine (Cortese, 2020).

Randomized controlled trials (RCTs) are widely regarded as the benchmark for assessing the efficacy and tolerability of a treatment. Nevertheless, RCTs present several limitations, including their often strict inclusion and exclusion criteria, which may restrict the applicability of the findings to the clinical populations commonly encountered in routine practice (Garcia-Argibay et al., 2025). In RCTs of ADHD medications, common exclusion criteria include participants presenting psychiatric or neurodevelopmental comorbidities (e.g., autism spectrum disorder, intellectual disability, psychosis, or major depressive disorder) and medical conditions such as cardiovascular disease (Cortese et al., 2018). These conditions often coexist with ADHD (Faraone et al., 2021, Garcia-Argibay et al., 2024, Garcia-Argibay et al., 2023, Li et al., 2023), making a significant portion of individuals with ADHD ineligible for these RCTs.

One important issue in current research based on RCTs of ADHD medications is represented by substantial heterogeneity across available RCTs. A network meta-analysis (NMA) conducted by (Cortese et al., 2018), including data from a total of 10,068 children (aged > 5 y) and adolescents, and 8,131 adults, found variability in trial duration, psychiatric comorbidities, dosage, trial design (crossover vs. parallel), and methods for handling missing data. Indeed, a significant statistical heterogeneity was found, partly due to differences in participants’ prior exposure to ADHD medications; while this reflects real-world diversity, it adds complexity to direct comparisons. Although missing data was mitigated with unpublished information and this reduced overall bias, the authors noted that such challenges still limit straightforward comparisons across trials. Additionally, the scarcity of long-term studies and the potential confounding effects of concurrent medications (such as antidepressants or antipsychotics) complicate the assessment and comparison of the sustained effects of ADHD medications in real-world clinical settings.

Another limitation in terms of comparability among trials in the current research on ADHD medication is the lack of a consistent definition of “treatment response” across trials. Understanding the differences between responders, non-responders, and those with an ineffective response requires careful consideration of efficacy measures, the types of raters (such as an investigator, parent, or teacher), and the improvement criteria applied in each trial. Many ADHD studies use the ADHD-RS-IV as the primary efficacy measure, with response typically defined by a specific percentage improvement. However, comparing these trials is challenging because the threshold for defining a response can vary across studies (Childress and Sallee, 2014). The lack of consensus on the definition of response hampers the comparison across trial results. To inform future initiatives in the field aimed at establishing a consensus on the definition of response in RCTs of ADHD, this study aimed to quantitatively assess how “treatment response” is defined and measured across RCTs of ADHD medications and to what extent this definition varies in terms of the percentage reduction in ADHD core symptom severity measurements using the standardized rating scales.

**METHODS**

To identify eligible RCTs, we relied on theMED-ADHD database *(*[*https://med-adhd.org/*](https://med-adhd.org/)*)*, a repository of double-blind RCTs on ADHD medications, originally developed for a network meta-analysis conducted by (Cortese et al., 2018), on behalf of the European ADHD Guidelines Group (EAGG). Originally, Cortese et al. systematically searched multiple electronic databases, including PubMed, BIOSIS Previews, CINAHL, the Cochrane Central Register of Controlled Trials, EMBASE, ERIC, MEDLINE, PsycINFO, OpenGrey, the Web of Science Core Collection, and ProQuest Dissertations and Theses (both UK & Ireland and international abstracts). Additionally, records were retrieved from the WHO International Trials Registry Platform and ClinicalTrials.gov, and manufacturers or/and or study authors were contacted for any relevant unpublished information or data. The search did not use any language restrictions. Details on search terms and syntax are reported in the supplemental material 1.

Eligible RCT s for the network meta-analysis by Cortese et al. were double-blind RCTs, either parallel-group or crossover, lasting at least one-week, enrolling children (≥5 to <12 years), adolescents (≥12 to <18 years), or adults (≥18 years) with a primary ADHD diagnosis based on DSM-III to DSM-5 or ICD-9/10. There were no restrictions on ADHD subtype, gender, Intelligence Quotient (IQ), socioeconomic status, or comorbidities unless requiring additional medication. Eligible studies assessed oral monotherapy with amphetamines (including lisdexamfetamine), atomoxetine, bupropion, clonidine, guanfacine, methylphenidate (including dexmethylphenidate), and modafinil (reflection FDA approved or commonly used medications for ADHD) comparing them against each other or placebo. Trials using enrichment designs —such as those selecting only participants who responded to the medication after an initial trial phase, which could overestimate efficacy and tolerability, were excluded. Details about inclusions and exclusion criteria are reported in supplemental material 2.

The 2018 network meta-analysis by Cortese et al, included a total of 133 RCTs meeting inclusion criteria. Since then, the database has been updated on a yearly basis, using the same search strategy, syntax, and terms. Additionally, viloxazine was added as an eligible medication in the 2022 update, reflecting the FDA's approval of this drug for ADHD in April 2021. The most recent version of the database, based on an update on 17 January 2025, incudes 167 RCTs (supplemental material 3). For each trial, MED-ADHD includes the main published report, as well as any other related reports (secondary or post hoc analyses, conference proceeding data from clinicaltrials.gov, and unpublished data provided by manufacturers/study authors). MED-ADHD also includes a list of excluded RCTs, with reasons for exclusion (supplemental material 4).

For the present review, we examined each RCT in MED-ADHD – including all the available sources of information for any given trial (main reports, reports of secondary analyses, and unpublished information/data) – to determine whether, for each RCT, an outcome related to treatment response was present, and, if so, which threshold (in terms of percentage reduction or cut off) was used, in any rating scale of ADHD symptoms severity, to define response. We also collected information included study details (authors, title, year, primary vs. secondary analysis), design (parallel or crossover RCT, case-control), participant age, ADHD subtype, medication type, and the rating scale used to measure core ADHD symptom severity before, after, and/or during follow-up.

**RESULTS**

From the 167 trials screened, 88 RCTs provided a definition of response based on a specific percentage reduction or improvement in ADHD core symptom severity, measured using standardized ADHD rating scales. Some studies (n=3) also reported a cutoff score (rather than a percentage) on these scales to define treatment response.

The ADHD rating scales identified in these 88 RCTs included the Attention Deficit/Hyperactivity Disorder Rating Scale (ADHD-RS), Conner’s Parent Rating Scale (CPRS), Conner’s Teacher Rating Scale (CTRS), Conner’s Adult ADHD Rating Scale (CAARS), Swanson, Kotkin, Atkins, M-Flynn, Pelham Scale (SNAP), Adult ADHD Investigator Rating Scale (AISRS), and Wender-Reimherr Adult Attention Deficit Disorder Scale (WRAADS).

Among the 88 studies that defined treatment response in relation to a percentage decrease of symptoms severity, the response threshold varied as follows: 39 studies considered at least a 30% reduction, 13 studies used a 25% threshold, 5 studies used 40%, 10 studies used 50%, and 5 studies used 20% or more reduction in ADHD symptom severity as the definition of treatment response. Additionally, three studies considered more than a 30% improvement as their response criterion. For additional details on these studies, see supplemental material 5.

Some studies used multiple thresholds: five studies applied both a ≥25% and ≥40% reduction, two studies considered at least 25%, 30%, and 40% improvement, two studies applied both ≥30% and ≥50%, and another study used both >25% and ≥50% improvement as response definitions (supplemental material 5 for details of these studies).

The three RCTs defined treatment response using rating scale score cutoffs. One study set the SNAP-IV (ADHD subscale) score threshold at ≤1 to classify participants as responders. Another study considered an AISRS score of <18 as the response threshold, while the third study required a minimum decrease of 10 points (equivalent to one standard deviation) from baseline on the CPRS and CTRS scores (supplemental material 5).

The table summarizing the number of studies that defined treatment response, and the respective thresholds used (Table 1) and the table presenting the ADHD rating scales and the thresholds applied across studies (Table 2) are included.

**DISCUSSION**

To our knowledge, this is the first report to quantitatively assess the definition of response, and the various thresholds quantified in different trials in terms of the percentage/cutoff decrease in ADHD core symptom severity using standardized rating scales across available RCTs of ADHD medications. This review helps identify inconsistencies and underscores the urgent need for a consensus on a universal definition of treatment response in the field of pharmacological treatment in ADHD.

Our analysis revealed that 52.7% of the RCTs eligible for our analysis explicitly defined treatment response using a percentage decrease in ADHD rating scale scores, albeit with variable definitions. The most commonly used threshold was a ≥30% reduction from baseline in ADHD-RS scores, followed by ≥25%, ≥40%, and ≥50%. Some studies also reported response thresholds using other scales such as CAARS, SNAP-IV, AISRS, and WRAADS, often adopting similar cutoff values. However, a significant proportion of studies (47.3%) did not specify any threshold to define response, highlighting the inconsistency in defining treatment success across ADHD trials.

The absence of an established definition for ADHD medication response is not unique to ADHD research. Similar challenges have been reported in other psychiatric disorders. For example, in first-episode psychosis (FEP), there has been a push to establish clear clinical outcome definitions to improve consistency in research (Lee et al., 2020). Likewise, in treatment-resistant anxiety disorders (TR-AD), a lack of standardized response criteria has for a long time hindered the development of effective interventions, despite the availability of first-line treatments such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), and cognitive behavioral therapy (CBT) (Bandelow et al., 2023, Bystritsky, 2006, Loerinc et al., 2015, Sanderson and Bruce, 2007). Additionally, the absence of a consensus definition on treatment-resistant depression (TRD) has for a long time hampered progress in prevalence estimates, risk factor identification, and treatment innovation (McIntyre et al., 2023).

To address the lack of a standardized definition for treatment response in ADHD medication trials, future research in the field of ADHD could prioritize two key approaches. First, individual patient data (IPD) meta-analyses could be conducted to examine the relationship between ADHD core symptom severity rating scales and clinical global impression (CGI) scores. This method has been successfully employed in obsessive-compulsive disorder (OCD) research to establish treatment response thresholds via equipercentile linking (Farhat et al., 2022). While the CGI has not been consistently used across trials of ADHD (in our dataset, about 80.4% of RCTs reported the use of CGI), access to individual participant data from a subgroup of RCTs would enable this analytic approach.

Second, a Delphi method-based consensus approach could be undertaken to achieve an established definition agreement on treatment response criteria for ADHD medications. Similar efforts have been made in anxiety disorders and depression, where after summarizing the current state of knowledge based on international guidelines and a systematic review, surveys were conducted to collect free-text responses covering key aspects of TR-AD (Domschke et al., 2024) and TRD (Sforzini et al., 2022). This was followed by an online consensus meeting, where a panel of multidisciplinary international experts and stakeholders anonymously voted on written statements across three survey rounds. As a result this helped in obtaining systematic and clinically useful operational definitions and guideline to support the design of future mechanistic studies and streamline clinical trials for regulatory approval (Domschke et al., 2024, Sforzini et al., 2022). We plan to undertake an effort with representatives from the major scientific ADHD organizations worldwide (American Professional Society of ADHD and Related Disorders [APSARD], European Network for Hyperkinetic Disorders [Eunethydis], Canadian ADHD Resource Alliance [CADDRA], and the World Federation of ADHD), alongside input from associations of people with lived experience (Children and Adults with Attention-Deficit/Hyperactivity Disorder [CHADD] and ADHD Europe).

A key strength of our review is the utilization of the MED-ADHD database, which provides the most comprehensive and up-to-date information on industry- and academic-sponsored ADHD RCTs. By systematically identifying the variability in response thresholds, our study serves as an initial step toward establishing a more consistent framework for defining ADHD medication efficacy.

However, some limitations should be acknowledged. First, despite the comprehensive nature of the MED-ADHD database, we cannot rule out that some relevant studies may have not been missed. Second, we were not able to systematically retrieve unpublished data for each RCT, which could have provided additional insights into the definition of response in some RCTs. Third, MED-ADHD focuses on a selected list of medications that were either approved by the FDA or more commonly used off-label; it does not cover all the medications tested in RCTs of ADHD medications.

Despite these limitations, this study highlights the need to reach a standardized definition of ADHD treatment response for each rating scale, which would improve the comparability of clinical trials, enhance regulatory decision-making, and ultimately optimize treatment strategies for individuals with ADHD. Future research efforts should focus on establishing these criteria to ensure consistency in ADHD medication trials.

**CONCLUSIONS**

This review highlights that nearly half of the RCTs investigating ADHD pharmacological treatment efficacy in children and adults, identified through electronic databases, do not define or report treatment response based on reductions in ADHD symptom severity measured by standardized rating scales. Among the studies that do provide a definition, the criteria vary across trials and rating scales, underscoring the need for a universal standard. We encourage future research to work towards establishing a universally accepted treatment response criterion for ADHD medications for each rating scale. This would enhance comparability across trials.

**Clinical significance**

A standardized treatment response threshold for each rating scale would enhance trial comparability and the evaluation of different ADHD medications and formulations. Additionally, it could aid in developing a prediction model to classify individuals as responders or non-responders, improving personalized treatment by predicting medication efficacy based on universal thresholds.

**Author’s contribution**

Conceptualization, S.C.; Methodology, S.C., E.M., M.G.P.; Data curation, S.R., G.C., G.F., F.T.; Writing – original draft preparation, S.R.; Writing – review and editing, S.C., G.C., F.T.; Supervision, S.C., E.M., M.G.P. All authors have read and agreed to the published version of the manuscript.

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**Table 1**: **Number of studies defining treatment response and thresholds used to define treatment response.**

|  |  |
| --- | --- |
| **% improvement/reduction in ADHD symptom severity as the ADHD medication response definition** | **No. of studies** |
| Response definition stated | 88 |
| ≥30% | 39 |
| ≥25% | 13 |
| ≥50% | 10 |
| ≥40% | 5 |
| ≥20% | 5 |
| >30% | 3 |
| ≥25%&≥40% | 5 |
| ≥25%**,** ≥30% &≥40% | 2 |
| ≥30%&≥50% | 2 |
| >25% & ≥50% | 1 |
| **ADHD rating scale score cutoff** | **No. of studies** |
| SNAP-IV Score ≤1 | 1 |
| AISRS score <18 | 1 |
| CPRS; CTRS score ≥10 points(1SD) decrease | 1 |
| No response definition stated | 79 |

**Table 2: ADHD rating scales and the thresholds applied across RCTs**

|  |  |  |
| --- | --- | --- |
| **ADHD rating scale** | **% of studies out of the 88 RCTs** | **% reduction in ADHD symptom severity rating scale as the response definition** |
| ADHD-RS-IV | 36% | ≥30% |
| 15.1% | ≥25% |
| 8.1% | ≥40% |
| 8.1% | ≥50% |
| 3.4% | ≥20% |
| 1.2% | >30% |
| 1.2% | >25% |
| CAARS | 4.7% | ≥30% |
| 5.8% | ≥25% |
| 4.7% | ≥40% |
| 1.2% | ≥50% |
| 2.3% | ≥20% |
| SNAP-IV | 1.2% | ≥30% |
| 1.2% | ≥25% |
| 1.2% | ≥40% |
| AISRS | 6.8% | ≥30% |
| 2.3% | >30% |
| 2.3% | ≥50% |
| WRAADS | 1.2% | ≥30% |
| 3.5% | ≥50% |