

Efficacy of psychosocial interventions for children with ADHD and emotion dysregulation: a  
systematic review

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## 1. Introduction:

Attention-Deficit Hyperactivity Disorder (ADHD) is a complex neurodevelopmental disorder associated with significant social, academic and family functioning impairment (Verret et al., 2016). ADHD is the most prevalent psychiatric disorder in childhood and one of the first reasons for referral. The worldwide prevalence is stable, and is estimated at 5.3% (Polanzcyk et al., 2007; Banaschewski et al., 2017). In France, ADHD prevalence ranges between 3.5 and 5.6% in school-age children, and the male to female ratio is 2-3 to 1 (Lecendreux et al., 2011). According to the DSM-V, ADHD is characterized by a triad of symptoms (inattention, hyperactivity, impulsivity) (American Psychiatry Association, 2013) with long-lasting effects on the life of the children and their family. Children with ADHD are more likely to have poor quality of life (Peasgood et al., 2016), to experience social difficulties with peers (Verret et al., 2016) and to have poor academic performance in mathematics and reading (Efron et al., 2014). They are also at higher risk of comorbid psychiatric disorders (Yoshimasu et al., 2012).

Irritability, low frustration tolerance, and affective instability are frequently observed in children with ADHD (Sobanski et al., 2010) and have been related to chronic emotional regulation dysfunction (D'Ambrogio and Speranza, 2012). Some authors consider emotional dysregulation (ED) as an important ADHD feature that significantly contributes to the observed functional impairments (social, family, academic, cognitive functioning) (Bunford et al., 2015). Emotion regulation is defined as a set of processes by which an individual assesses, inhibits, maintains, or modifies the intensity, frequency or duration of emotional reactions in order to have the appropriate social behavior or to achieve goals (Thompson, 1991). Bunford et al. (2015) described ED as "an individual's inability to exercise any or all aspects of the modulatory processes involved in emotion regulation, to such a degree that the inability results in the individual functioning meaningfully below his or her baseline". According to Shaw et al. (2014), ED includes: a) excessive and inappropriate emotional reactions and experiences in relation to social norms; b) uncontrolled and rapid shifts in emotions, and c) the abnormal allocation of attention to emotional stimuli. ED definitions tend to focus mainly on negative emotions; however, Sjöwall et al. (2013) suggested that children with ADHD can experience difficulties also in regulating positive emotions. In both cases, the quality of the child's social response is affected (Bunford et al., 2015). Children with ADHD and ED show more negative responses during a difficult task (Shaw et al., 2014) and more intense emotion in response to a frustrating task (Maedgen and Carlson, 2000).

A study on 1186 participants with combined type ADHD showed that 75% of children had at least some ED symptoms and 25% had severe ED (Sobanski et al., 2010). ED tends to be more frequent in patients with ADHD characterized by significant hyperactivity/impulsivity (Semrud-Clikeman et al., 2010). However, ED is not a specific ADHD feature, and can be found in other disorders, such as oppositional defiant disorder (ODD), anxiety disorder, mood disorder, and bipolar disorder (Bunford et al., 2015).

In 2003, to facilitate research on non-episodic severe irritability in children, Leibenluft and colleagues defined a clinical syndrome called "Severe Mood Dysregulation" (SMD). This childhood condition is characterized by chronic abnormal levels of anger and sadness, hyperarousal symptoms, and heightened verbal or physical reactivity. This new entity should help to differentiate children with chronic irritability from those with pediatric bipolar disorder (Brotman et al., 2006). In view of improving the specific management of children with chronic irritability and ED, a new diagnosis was introduced in the DSM-V (APA, 2013): Disruptive Mood Dysregulation Disorder (DMDD) (Rao, 2014). DMDD criteria are: a) severe and recurrent temper outbursts that are disproportionate to the situation and inconsistent with the developmental level. These temper outbursts are present at least three times per week; b) between temper outbursts, the mood is persistently irritable or angry most of the day and nearly every day; c) symptoms must be present for  $\geq 12$  months, with no symptom-free interval longer than 3 months; d) symptoms must be present at least in two areas; e) diagnosis should not be made before 6 years or after 18 years of age; and f) symptom onset before the age of 10 years (APA, 2013). The DMDD and SMD criteria are relatively similar, but SMD includes also hyperarousal symptoms (Miller et al., 2018).

It has been shown that patients with ADHD and ED are more likely to present a complex and severe symptomatology (Reimherr et al., 2010), with higher risk of comorbidities (Anastopoulos et al., 2011). Indeed, in children with ADHD, ED has been associated with various impairments, including difficulties with peers, poorer academic performance, and more familial conflicts (Wehmeier et al., 2010; Qian et al., 2016). Longitudinal studies reported ED persistence during childhood and the increased risk of negative developmental trajectories. A study on 2076 children followed for 14 years showed that ED (measured with the Child Behavior Checklist-Dysregulation Profile during childhood) was associated with higher frequency of anxiety disorders, mood disorders, disruptive disorders and substance abuse in adulthood (Althoff et al., 2010). These findings indicate that ED should be regularly monitored in children with ADHD and should be managed with targeted therapeutic interventions.

In recent years, many studies have focused on the treatment of children with ADHD and ED because the overall functioning is more affected by emotional problems than by the ADHD core symptoms (Anastopoulos & al., 2011). Drugs, such as methylphenidate (MPH) (Lenzi & al., 2013; Fernandez de la Cruz & al., 2015; Kultu & al., 2017; Winters & al., 2018) and lisdexamfetamine dimesylate (Childress & al., 2014), improve ED in ADHD. However, drugs are not sufficient to reduce ED impact on the overall functioning of children with ED (Baweja & al., 2016), and non-pharmacological strategies may also be needed to better control ED.

The objectives and underlying mechanisms of psychosocial interventions and pharmacotherapy are different. Drugs reduce symptoms through their neurobiological effects, while psychosocial interventions help to develop cognitive and behavioral strategies that are supposed to limit ED by improving emotion management and conflict solving and by developing socio-emotional skills. These skills are particularly important in children with ADHD and ED who experience social difficulties with peers (Lee & al., 2018) and lack strategies to regulate their emotions to adapt to their environment (Braet & al., 2014).

In ADHD with ED, psychosocial interventions have been less studied than pharmacological treatments. Previous meta-analyses have examined the effects of psychotherapeutic interventions for emotional problems in children with severe mood dysregulation or DMDD (Benarous & al., 2017), and for ED in children with externalizing disorders (Battagliese & al., 2015). However, none focused specifically on ED in ADHD. One study compared psychosocial intervention and pharmacological treatment (Fernandez de la Cruz & al., 2016), but ED evaluation was not accurate.

The primary objective of this systematic review was to examine the effects of psychosocial interventions in children and adolescent with ADHD and ED, by focusing on their efficacy for ED management. The second objective was to discuss the strengths and limitations of different research strategies to study children with ADHD and ED in order to improve their design.

## **2. Method:**

This systematic literature search followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines (Liberati et al., 2009).

### *2.1 Search procedure and data sources*

Two investigators (AG and CV) carried out the literature research independently and screened the titles and abstracts to check the eligibility of the identified articles. They read the full text of the selected studies and extracted data for descriptive and statistical analyses.

The PsycInfo-Esbco (PsycInfo, ERIC, PsycArticles, Psychology, and Behavioral Sciences Collection), PubMed, Web of Science databases and Science Direct article collections were searched to identify relevant research articles. The reference lists of the selected articles were inspected to identify other eligible studies.

The WHO International Clinical Trials Registry Platform that includes international trials registries, such as Clinicaltrial.gov (2016), was also searched to retrieve relevant unpublished studies. When an article was not available, the authors were contacted by e-mail.

The used search terms were: “ADHD” AND “Child” OR “Adolescent” AND “Psychotherapy” OR “Treatment” OR “Intervention” AND “Mood dysregulation” OR “Anger” OR “Irritability” OR “Frustration” OR “Emotion Regulation”. This algorithm was used in the following search sections: “Abstract” for PsychInfo-Esbco and for PubMed, “Topic” for Web of Science, and “Title, abstract and keywords” for Science Direct.

Only articles published after year 2000 and up to May 2018 (revised in June 2019) were considered.

## *2.2 Selection criteria*

Articles were included only if they met the following criteria: a) study carried out in children and adolescents younger than 18 years of age; b) on the effects of psychosocial treatments on ED in children and adolescents with ADHD; c) randomized controlled trial (RCT), quasi-experimental study, or open-label uncontrolled study design; d) used standardized measures; e) in English or French; and e) ADHD diagnosis according to internationally recognized criteria (DSM-IV, -IV-TR, -V, or ICD-10).

## *2.3 Data selection and data extraction*

The retrieved articles were independently screened for relevance by two authors (AG and CV). In case of disagreement, consensus was reached by discussion. If needed, the authors were contacted to obtain missing data and/or additional information. Reasons for excluding a study included: a) not meeting the inclusion criteria; b) sample including adults; c) other language than French or English; and d) duplicate publications.

When several publications concerned the same group of participants, they were included and counted as one unit of analysis.

The following data were extracted by AG and CV: a) authors and year of publication; b) sample characteristics (age, sex, ethnic composition); c) diagnoses; d) intervention type; e) intervention duration; f) measures; g) intervention target, and h) intervention outcomes.

## *2.4 Assessment of the risk of bias*

The risk of bias in each study was assessed with the Risk of Bias In Non-randomized Studies - of interventions tool (ROBINS-I) (Sterne et al., 2016). This tool is based on the Cochrane Bias tool for RCTs. As most of the identified studies had a single-arm design, the main specific bias of this review was the lack of well-designed RCTs.

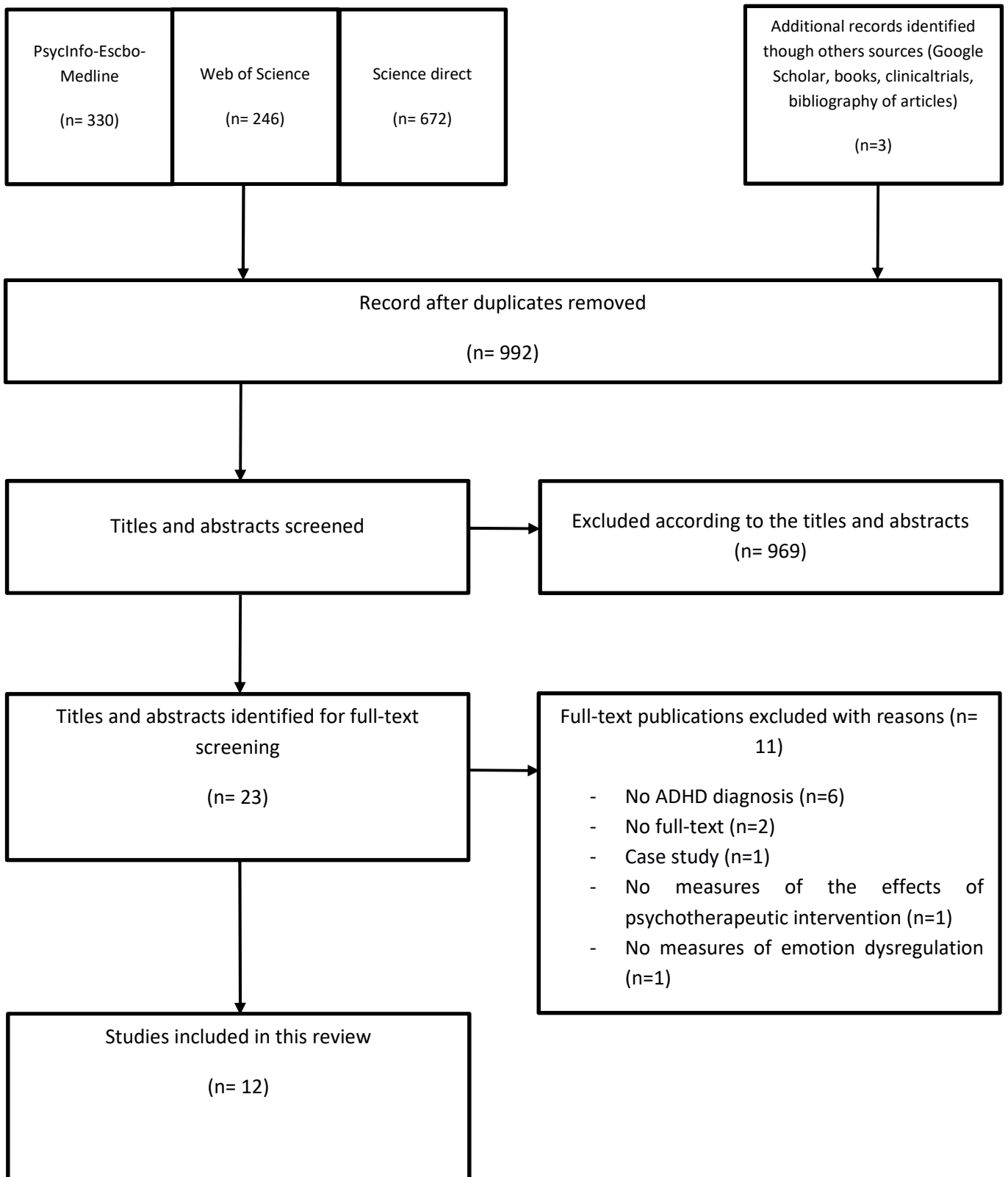


Fig.1 PRISMA diagram of the screening process and study selection

### 3. Results:

#### 3.1 Description of the included studies

The study selection flowchart is shown in Figure 1. In total, 992 articles were identified. After screening the titles and abstracts, 23 studies were selected, but only 12 studies met the selection criteria for this review: five RCTs, one quasi-experimental study, four open-label uncontrolled studies, and two ongoing studies. The other articles were excluded for several reasons: a) no ADHD diagnosis; b) full-text not available (paid articles, authors unreachable, or authors did not reply to our enquiry), c) the effect of psychological treatment was not measured, d) only pharmacologic treatment of ED, and e) studies on ED without psychosocial interventions.

### *3.2 Randomized Controlled Trials*

Five RCTs were included in this review.

Hannesdottir et al., (2017) examined the efficacy of the OutSMARTers program in 8-10-year-old children with ADHD (n = 41). Children were assigned randomly to the OutSMARTers program group or Waitlist group. Both groups were compared with a Parent training group that was not randomized due to practical constraints. In the OutSMARTers program group, participants were taught techniques to identify facial expressions, to develop coping strategies for problem solving, and to improve executive functions. In the Waitlist group, participants started the OutSMARTers program later. In the Parent group, training sessions were based on Barkley's program (Barkley, 1997). Results indicated that in the OutSMARTers program and Parents groups, emotional symptoms were reduced and emotion regulation was improved compared with the Waitlist group. There was no difference between treatment groups, and the positive effects were maintained at the 3 month follow-up.

Waxmonsky et al. (2016) assessed an integrative group therapy in 7-12 year-old children with ADHD and SMD (n = 52). Children were assigned to the experimental therapy (AIM) or to the community psychosocial treatment (CC) group. Before starting treatment, ADHD symptoms were stabilized with psychostimulant drugs in all participants to confirm that mood symptoms were not caused by a non-optimal ADHD treatment. The two therapeutic programs were based on techniques employed in multifamily psychoeducation groups (Fristad et al., 1998), the Community Parent Education program (COPE, Cunningham et al., 1998), and the Coping Power program (Lochman et al., 2008). In the AIM group, the program focused on the management of emotions and the development of coping strategies. For parents, sessions were focused on psychoeducation, identification of triggers that reinforced negative moods, and management of inappropriate behaviors using problem-solving techniques. In the CC group, participants did not receive any treatment, but families were encouraged to contact local psychosocial providers. The Mood Severity Index scores (tool to assess mood symptoms) decreased over time, but without significant differences between groups at the end of the study. Moreover, the integrative psychosocial treatment was associated with a significantly greater improvement in parent-rated irritability (effect size, ES= 0.63) particularly the "often angry" item of the Disruptive Behavior Disorders Structured Parent Interview (DBD-I). Other mood symptoms and hyperarousal also were moderately reduced in children in the AIM group.

Fernandez de la Cruz et al. (2015) assessed whether ADHD treatment could decrease irritability in 7-9 year-old children with ADHD (n = 579). Children were assigned to one of the following four groups: Medication management (MedMgt), Behavioral treatment (Beh), Combined treatment (Comb), and standard Community Care (CC). In the MedMgt group, participants received a stimulant or another drug if MPH was not tolerated. Beh included multi-component individual and group parent training (35 sessions), teacher consultations (10 sessions and phone contacts), an intervention by a behavioral specialist in the classroom (12 weeks), and a summer treatment program (STP) for children. Comb combined the Beh and MedMgt strategies. The CC group (control) involved a community treatment chosen by parents from a list of community mental health resources. In this group, 67.4% of children received a pharmacological treatment. The Swanson, Nolan and Pelham (SNAP) rating scale score for irritability decreased in all groups after 14 months of treatment. The highest effect size value was observed in the Comb group (ES=0.82), followed by the MedMgt (ES=0.63), CC (ES=0.48) and Beh (ES=0.42) groups. Effects sizes were more modest among treatments. This study showed that MedMgt effect on irritability was superior than that of Beh, but not of CC. Comb was better than CC and Beh



alone, but not of MedMgt alone. Standard pharmacologic ADHD treatments efficiently reduced irritability in children with ADHD.

Herbert et al., (2013) examined the efficacy of a parent training and emotion socialization program for parents of preschool-aged children with ADHD (n = 31). Families were assigned to the parent training (PT) or waitlist group. In the PT group, the program was based on the Parenting Your Hyperactive Preschooler Program (Harvey et al., 2010). Parents were taught traditional parenting strategies to manage child behavior, and emotion socialization strategies to help children to improve their emotion regulation. Parents in the PT group reported that emotional lability was decreased and emotion socialization was improved in their children.

Miranda and Presentacion (2000) examined the efficacy of cognitive behavioral therapy (CBT) in 9-12-year-old children with ADHD (n=32), with (n=16) and without aggressiveness (n=16). Participants were assigned to the self-control program (SC; based on The “Stop and Think” program of Kendall et al., 1980) group or to the SC plus Anger Control Training (SC+ACT) group. Each group included eight children with ADHD and aggressiveness and eight children with ADHD without aggressiveness. The SC program comprised sessions where participants were taught cognitive and behavioral techniques (self-instruction, modeling...) for problem solving. ACT was used to teach children how to control their anger (relaxation, role-playing exercise...). ADHD symptoms and antisocial behaviors were reduced and social adjustment was improved in both groups. According to the parents, these improvements were superior in children with ADHD and aggressiveness who were in the SC+ACT group. In children without aggressiveness, parents observed improvements in both treatment groups, but to a lower extent compared with children with aggressiveness. The therapeutic benefit was maintained in both groups for 2 months after the intervention.

**Table 1:** Randomized controlled trials that evaluated the benefit of psychosocial interventions for children with ADHD and emotion dysregulation

Authors (year)	Sample characteristics: number, age range (mean), sex, ethnic composition	Diagnosis	Intervention and control condition	Study duration	Measures	Receivers of the intervention	Outcomes
Hannesdottir, Ingvarsdottir and Bjornsson (2017)	N= 41 Age range 8-10 years 70.7% boys	ADHD 100%	OutSMARTers program (10 sessions for 5 weeks) vs Waitlist vs Parent training program	5 - 7 weeks Follow-up: 3 months only for the parent training and OutSMARTers groups	WISC-IV ADHD-RS SSRS ERC SDQ Luminosity assessment task	Children Parents	-Reduction of inattention and hyperactivity/impulsivity symptoms and emotional symptoms in the OutSMARTers and Parent training groups; -No difference between the OutSMARTers and Parent training group; -Beneficial effects present at the 3 month follow-up visit in the OutSMARTers an Parent training groups
Waxmonsky, Waschbusch, Belin, Li, Babocsai, Humphrey, Pariseau, Babinski, Hoffman, Haak, Mazzant, Fabiano, Petit, Fallahazad and Pelham (2016)	N = 56 Age range = 7-12 69.4% boys	ADHD 100% ODD 94.6% CD 8.9% AD 35.7% SMD 100%	Experimental therapy (AIM) (11 sessions of 105 minutes) vs Community psychosocial care Medication before starting treatment	17 weeks No follow-up	DBD-I DBD-RS WASH-U-KSADS SCQ BDI-II ASRS CDRS-R YMRS	Children, Parents	-Improvement in the parent-rated irritability score in the AIM group -No difference in mood symptoms (MSI) between groups; - Little effect on ADHD symptoms in both groups
Fernandez de la Cruz, Simonoff, McGough, Halperin, Arnold and Stringaris (2015)	N = 579 Age range = 7-10 (8.5) 80.3% boys Ethnic composition: 60.8% White, 19.9% African American, and 19.3% Hispanic	ADHD 100%	Behavioral treatment (Beh; parent training group, school intervention, summer camp program for children) vs Medication management (MedMgt) vs Combined treatment (Comb) vs Treatment-as-usual in the community (CC)	14 months	SNAP CBCL CISP Conners Scales	Children, Parents, Teachers	- Reduction of irritability scores after treatment in all groups; - MedMgt superior to Beh for reducing irritability, but not to CC; - Comb better than CC and Beh, but not MedMgt; - Effectiveness of standard ADHD treatments for reducing irritability
Herbert, Harvey, Roberts, Wichowski and Lugo-Candelas (2013)	N= 31 Age range 8-10 74.2% boys Ethnic composition: 83.9% European-American, 6.4% African American, 3.2% Hispanic, and	ADHD 100%	Parent training and emotion socialization program (14 sessions of 90 minutes) vs Waitlist	14 weeks No follow-up	BASC 2-PRS DISC-IV DBRS ERC CCNES Audiotaped assessment of parent-child interactions	Parents	-Reduction of ADHD and ODD symptoms in the Parent training group; - Decreased emotional lability in children; -Improved emotion socialization in parents

	6.4% multiethnic N = 32 Age range = 9-12 (9.7) 78.1% boys	ADHD 100%	22 1-hour sessions of cognitive behavioral therapy ("Stop and Think" program for children) + ACT (anger management techniques) vs Cognitive behavioral therapy alone	3 months Follow-up: 2 months	Conners Scales HQ EPC IOWA PIS SCRS SSAQ	Children	- Improvements of several measures for all groups: reduction of ADHD symptoms and antisocial behavior and greater social adjustment, but higher effect of the combined treatment; - No difference between interventions for children with ADHD with/without aggressiveness
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Abbreviations: **ADHD**: Attention Deficit with Hyperactivity Disorder; **ODD**: Oppositional Defiant Disorder; **CD**: Conduct Disorder; **SMD**: Severe Mood Dysregulation; **AD**: Anxiety Disorder; **RCT**: Randomized Controlled Trial; **BMOD**: Behavior Modification Therapy; **CC**: Standard Community Care; **MedMgt**: Medication management; **Beh**: Behavioral Treatment; **Comb**: combination of treatments; **AIM**: Experimental therapy; **ACT**: Anger Control Training; **CBT**: Cognitive-Behavioral Therapy; **ERC**: Emotion Regulation Scale for Children; **SDQ**: Strength and Difficulties Questionnaire; **CBCL**: Child Behavior Checklist; **YMRS**: The Young Mania Rating Scale; **CDRS-R**: The Children's Depression Rating Scale Revised; **DBD-RS**: Disruptive Behavior Disorders Rating Scale; **DBD-I**: Disruptive Behavior Disorders Structured Parent Interview; **WASH-U-KSADS**: The Washington University in St.Louis Kiddie Schedule for Affective Disorders and Schizophrenia; **SSRS**: Social Skills Rating Scale; **ARI**: Affective Reactive Index ; **CGI-I**: Clinical Global Impression-Improvement Score; **MASC**: Multidimensional Anxiety Scale for Children; **WIAT**: Wechsler Individual Achievement Test; **ABS**: Antisocial Behavior Scale; **OAS**: Overt Aggression Scale; **BAS**: Barnes Akathisia Scale; **SARS**: Simpson-Angus Rating Scale; **BASC 2-PRS**: Behavior Assessment System for Children 2-Parent Report Scale; **DISC-IV**: Diagnostic Interview Schedule of Children, 4<sup>th</sup> Edition; **DBRS**: Behavior Rating Scales; **CCNES**: The Coping With Children's Negative Emotion Scale; **AIMS**: Abnormal Involuntary Movement Scale; **CISP**: Columbia Impairment Scale-Parent Version; **SNAP**: Swanson, Nolan and Pelham Rating Scale; **BDI-II**: Beck Depression Inventory; **ASRS**: Adult ADHD Self-Report Scale; **SCQ**: Social Communication Questionnaire; **HQ**: Hyperactivity Questionnaire; **EPC**: Scale of Behavioral Problems; **SCRS**: Self-Control Rating Scale; **SSAQ**: Social Skills Assessment Questionnaire, **PIS**: Problems Inventory in the School.

### 3.3 Quasi-experimental studies

Only one quasi-experimental study was eligible. Waxmonsky et al. (2008) evaluated the efficacy of MPH and behavior modification therapy (BMOD) in 5-12-year-old children with ADHD with/without SMD. Children (n=101) were separated in two groups: children with SMD and high Young Mania Rating Scale score (YMRS; Young et al., 1978) (SMD group; n=33) and children with ADHD but without SMD (control group; n=68). All participants received MPH and BMOD for 9 weeks during a STP. BMOD intensity (no, low, and high) varied each 3 weeks and MPH doses (placebo, 0.15, 0.3 and 0.6mg/kg) varied daily. The BMOD program included social skill training and a reward system when children adopted the desired behavior. BMOD session frequency varied according to its intensity: no session, weekly sessions (low intensity), or daily sessions (high intensity). After 9 weeks, the YMRS score was reduced by 34% in the SMD group compared to baseline. Multimodal treatment was effective for children with ADHD with a reduction of externalizing symptoms and improved depression and mania.

### 3.4 Open-label uncontrolled studies

Four open-label uncontrolled studies and two ongoing studies were eligible.

One open-label uncontrolled study included 9-11-year-old children with ADHD and deficient emotion regulation enrolled to participate in the Managing Frustration for Children (MFC) program (n=52) (Rosen et al., 2018). This group intervention included eleven sessions for children and one information session for parents. First, participants learnt how to develop effective emotional and behavioral coping strategies. Then, they learnt how to identify common cognitive biases and to modify them. Participants were helped to analyze contextual clues, triggers of emotional distress and behaviors in other people in order to understand factors that contribute to frustration and deficient emotion regulation. The intervention significantly reduced the Emotion Regulation Checklist score from 2.79 (baseline) to 2.22 (post-intervention). The MFC program also significantly reduced the Child Behavior Checklist (CBCL)-Externalizing and CBCL-Internalizing scores. The authors suggested that interventions focused on deficient emotion regulation could improve emotion regulation and emotional functioning in children with ADHD and ED.

Waxmonsky et al. (2013) carried out a pilot study in seven children with ADHD and SMD (age: 7-12 years) to assess the feasibility and the potential efficacy of a psychosocial program that included a parent training intervention and CBT for children. All participants were treated and stabilized with psychostimulants. Six weeks after the intervention end, mood symptoms were improved, according to the Children's Depression Rating Scale, Revised (CDRS-R) and YMRS scores. This study showed



that multimodal interventions improve emotional regulation in children with ADHD and SMD. In 2016, Waxmonsky et al. started a RCT with a larger sample to confirm their results.

Blader et al., (2016) examined the effects of the combination of treatments with stimulants and family-based behavioral therapy on persistent mood symptoms in 6-13-year-old children with ADHD and disruptive behavior disorder (n=156). All participants were taking pharmacological treatments for ADHD and their parents participated in group training based on the COPE program (Cunningham et al., 1998). Aggressive behavior and periodic rage outbursts were remitted in 51% of participants with ADHD and disruptive behavior disorder. This was associated with a decrease in the irritability and depression ratings.

Sanchez et al., (2019) examined the efficacy of an emotion regulation intervention in 8-14-year-old children with ADHD (n=41). In this intervention, children were taught strategies to control and regulate negative emotions and to identify and express emotions (n=10 sessions). At the end of each session, their parents received guidelines to help their child to use such techniques in daily life. According to the parents, children had fewer emotional problems, and fewer difficulties in emotional regulation, and better anger management after the intervention.

One ongoing open-label uncontrolled study (NCT0251893) is recruiting 8-17-year-old children with DMDD and behavioral disorders (ADHD or ODD). The aim of this study is to compare three treatments: CBT, Interpretation Bias Training (IBT), and their combination. IBT is a computer-based training program that focuses on impairments in socio-emotional information processing. Irritability, anxiety, depression and functional impairment will be monitored during the study. Children can participate in one or both programs, as they wish. Currently, no result is available. Expected outcomes are an improvement in the Clinical Global Impression-Improvement score and a reduction of the Affective Reactivity Index (Stringaris et al., 2012). The primary completion date is planned in December 2022.

Another ongoing open-label trial (NCT03733548) recruited 11-16-year-old children with ADHD and poor emotion regulation with the aim of assessing the impact of the Regulating Emotions Like An eXpert (RELAX) intervention on emotion regulation in adolescents. In this program, adolescents learnt skills to manage emotion regulation and conflicts, and parents received information on how to help their child to use such techniques in daily life. Emotion regulation, family conflict and respiratory sinus arrhythmia were monitored during the study. Expected outcomes were a better emotion regulation and a reduction of family conflicts. Currently, no result is available. The primary completion date of this study was July 2019.

**Table 2: Quasi-Experimental Trial and Open-label Uncontrolled Trial evaluating the benefit of psychosocial interventions for children with ADHD and emotion dysregulation**

Authors (year)	Sample characteristics: number, age range (mean), sex, ethnic composition	Diagnosis	Intervention and control condition	Study duration	Measures	Receivers of the intervention	Outcomes
Waxmonsky, Pelham, Gnagy, Cummings & al. (2008)	N = 101 Age range = 5-12 years 33 subjects in SMD group (mean age: 8) 68 subjects in no SMD group (mean age: 8.7) 81% boys	ADHD 100% ODD 54% CD 12% SMD 55%	Behavior Modification Therapy (BMOD): 3 weeks each session (no, low intensity and high intensity) Medication during STP (variation of doses everyday)	9 weeks No follow-up	YMRS CDRS-R IRS PSERS CGI-I DBD DISC	Children	For SMD group: - Reduction of 34% in YMRS score; - Reduction of 31% in CDRS-R score; - Improvement in externalizing symptoms; - Improvement in all impairment
Rosen, Leaberry, Slaughter, Flogleman, Walerius, Loren & Epstein (2018)	N= 52 Age range = 9-11 (9.84) 80.8% boys	ADHD 100% AD 30.8% BD 28.8% MD 25% LD 19.2%	12 sessions per week (90 min) of the Managing Frustration for Children (MFC) : 11 sessions for children and 1 session for parents (information about children's program)	12 weeks No follow-up	VARs ERC CBCL CDI MASC	Children Parents	- Improvement of ERC scores after intervention; - Significant effect of the MFC on CBCL-Externalizing scores; - Significant decrease on Internalizing-CBCL scores after intervention; - Improvement of depressive symptoms and negative emotion by child-reported
Waxmonsky, Wymbs, Pariseau, Waschbusch & al. (2013)	N= 7 Age range = 7-12 (mean age:	ADHD 100% SAD 28.6%	Behavioral parent training (COPE), summer camp	9 weeks	WASH-U-KSADS DBD	Children Parents	- Large effects on CDRS-R and YMRS ratings; - Small effects on parental ratings

	8.7) 100% boys		program (Coping power program) and parents-child meetings. Medication before starting treatment		YMRS CDRS-R CGAS APQ WASI		of ADHD, ODD and CD symptoms; -Improvement in CGAS scores; -Small effect on increasing parental involvement with their child
Blader, Pliszka, Kafantaris & al. (2016)	N= 156 Age range = 6-13 (mean age: 9.28) 78.8% boys	ADHD 100% ODD 90.32% CD 9.68%	Group Parent Training (COPE) Medication treatment (STIM)	No durations indicated	K-SADS R-MOAS ConnGI-P ERC CDRS-R CBCL	Children Parents	- 51% of participants remitted aggressive and periodic rageful outbursts; - Improvement of mood symptoms with decreased aggression
Sanchez, Lavigne, Romero & Elosegui (2019)	N= 64 Age range: 8-14 years 81.3% boys	ADHD 100%	Emotion Regulation intervention : 10 session for children	No duration indicated	Nepsy-II SENA	Children Parents	-Reduction of emotional problems after intervention; -Better regulation of negative emotions; -Improvement of anger control and emotional regulation; -Improvement of emotional adaptation
<a href="http://www.clinicaltrials.gov/NCT02531893">http://www.clinicaltrials.gov/NCT02531893</a>	N= 200 Age range = 8-17 years	ADHD - NA DMDD 100% ODD - NA	Cognitive Behavioral Therapy (CBT) vs Interpretation Bias Training (IBT) vs Combined treatment (IBT and CBT)	12-16 weeks for CBT 10 weeks for IBT (14 sessions) No Follow-up	ARI CGI-I	Children Parents	Study in progress (results in 2020)
<a href="http://www.clinicaltrials.gov/NCT03733548">http://www.clinicaltrials.gov/NCT03733548</a>	N= 20 Age range = 11-16 years	ADHD 100%	Regulating Emotions Like An eXpert (RELAX) : 8 session for adolescent and 1 booster session	8 weeks Follow-up: 8 weeks	DERS CBQ EKG	Children Parents	Study in progress (results in 2019)

**ADHD:** Attention Deficit with Hyperactivity Disorder; **ODD:** Oppositional Defiant Disorder; **CD:** Conduct Disorder; **AD:** Anxiety Disorder; **SAD:** Separation Anxiety Disorder; **SMD:** Severe Mood Dysregulation **SMD:** Severe Mood Dysregulation; **BD:** Behavior Disorder; **MD:** Mood Disorder; **LD:** Learning Disorder; **DMDD:** Disruptive Mood Dysregulation Disorder; **MFC:** Managing Frustration for Children; **STIM:** Stimulant Treatment; **CBT:** Cognitive-Behavioral Therapy; **IBT:** Interpretation Bias Training; **BMOD:** Behavior Modification Therapy; **STP:** Summer Treatment Program; **VARS:** Vanderbilt ADHD Rating Scale; **CBCL:** Child Behavior Checklist; **MASC:** Multidimensional Anxiety Scale for Children; **CDI:** Children's Depression Inventory; **ERC:** Emotion Regulation Scale for Children; **YMRS:** The Young Mania Rating Scale; **CDRS-R:** The Children's Depression Rating Scale Revised; **DBD:** Disruptive Behavior Disorders Rating Scale; **R-MOAS:** Retrospective – Modified Overt Aggression Scale; **ConnGI-P:** Connors Global Index; **WASH-U-KSADS:** The Washington University in St.Louis Kiddie Schedule for Affective Disorders and Schizophrenia; **APQ:** Alabama Parenting Questionnaire; **WASI:** Wechsler Abbreviated Scale of Intelligence; **CGAS:** Children's Global Assessment Scale; **NEPSY-II:** Neuropsychological Battery, **SENA:** Spanish Assessment System for Children and Adolescents; **PSERS:** Pittsburgh Side Effect Rating Scale, **ARI:** Affective Reactivity Index; **CGI-I:** Clinical Global Impression; **IRS:** Impairment Rating Scale; **DISC:** Diagnostic Interview Schedule for Children; **DERS:** Difficulties in Emotion Regulation Scale; **CBQ:** Conflict Behavior Questionnaire; **EKG:** Electrocardiography.

#### 4. Discussion:

The aim of this systematic review was to evaluate the efficacy of psychosocial interventions for ED in children and adolescents with ADHD.

The results of the included RCTs (Fernandez de la Cruz et al., 2015; Waxmonsky et al., 2013, 2016) show that multimodal interventions (behavioral therapy or CBT associated with parental training) have beneficial effects on the overall functioning of children with ADHD and ED and reduce emotional symptoms, such as irritability and depression.

Two studies on children with ADHD and ED showed beneficial effects. Miranda and Presentacion (2000) reported that the combination of SC and ACT is beneficial in children with ADHD and aggressiveness. The effects were maintained for 2 months after the intervention end. Rosen et al. (2018) demonstrated the positive impact of the MFC program on emotion regulation and overall functioning in children with ADHD.

Three studies (Herbert et al., 2013; Hannesdottir et al., 2017; Sanchez et al., 2019) on emotion regulation in children with ADHD suggested that psychosocial interventions reduce emotional problems, improve the regulation of negative emotions, and decrease emotional symptoms.

Three other studies indicated that the combination of pharmacologic treatment and psychosocial interventions can help to reduce irritability (Fernandez de la Cruz et al., 2015; Waxmonsky et al., 2016), aggressive behaviors and periodic rageful outbursts (Blader et al., 2016). In the study by

Waxmonsky et al (2016), ADHD symptoms had to be pharmacologically stabilized before the psychosocial intervention. In two clinical cases, the combination of medication and psychosocial treatment (Callahan, 2010; Tudor et al., 2016) reduced anger, aggression and irritability. In the study on the MTA program (MTA Cooperative Group, 1999; Fernandez de la Cruz et al., 2015), irritability was more efficiently reduced by ADHD pharmacological management than by the behavioral intervention, but not compared with the standard community care. However, in this study, psychosocial treatment did not directly target ED, while in the other articles, programs were focused on emotional aspects.

Several studies showed a reduction of aggressive behavior, irritability (Waxmonsky et al., 2008), ED (Kultu et al., 2017; Gamli and Tahiroglu, 2018) and standard ADHD symptoms (Boylan and Eppel, 2008) with monotherapy or with the combination of two medications (Gadow et al., 2014).

It would be now important to assess the association of behavioral therapy and pharmacological treatment in studies in which medication is a prerequisite for starting behavioral therapy or CBT. Indeed, the reduction of standard ADHD symptoms (mainly impulsivity) with drugs might allow children with ADHD and ED to better understand behavioral and/or cognitive techniques to manage their emotions.

#### 4.1 Limitations

Some limitations need to be taken into account when interpreting our findings; they are responsible for the poor knowledge in this domain.

##### 4.1.1 Study design

The methodological quality of the few studies that evaluated the efficacy of psychosocial interventions in children with ADHD and ED was inadequate (lack of randomization, of control group, of information about data collection...). Due to the absence of waitlist group or placebo-attention control condition, the positive results reported by the included open-label studies (Waxmonsky et al., 2013; Blader et al., 2016; Rosen et al., 2018; Sanchez et al., 2019) could be explained by non-specific factors (e.g. regular follow-up, attention given to the children).

In the included RCTs, families were aware of the treatment assignment and most participants received community-based psychosocial treatment (Waxmonsky et al., 2016), pharmacologic treatment (Fernandez de la Cruz et al., 2015), or were on a waiting list (Herbert et al., 2013; Hannesdottir et al., 2017). These study designs do not rule out clinicians and parents' expectancy effects.

The important variability of study duration, from 9 weeks (Waxmonsky et al., 2008) to 14 months (Fernandez de la Cruz et al., 2015), limited the comparability of the treatment effects.

Very few studies assessed whether the intervention efficacy persisted in the medium or long term. Only one study showed that effectiveness was maintained at the 2-month post-intervention visit (Miranda and Presentacion, 2000). Another study (Waxmonsky et al., 2016) reported that the irritability score was decreased at 6-weeks after the intervention end. However, the lack of follow-up data for the community care group did not allow comparing outcomes among treatment groups. No psychosocial program included booster therapy sessions to strengthen the intervention effects over time.

##### 4.1.2 Outcome variables

No study considered ED as the primary outcome variable (Bunford et al., 2015). Some studies included participants with SMD, irritability, aggressiveness, emotional lability, or other emotional problems. The included studies assessed the effects of psychosocial interventions on aggressiveness (Miranda and Presentation, 2000; Blader et al., 2016), irritability (Fernandez de la Cruz et al., 2015; Waxmonsky et al., 2008, 2013, and 2016), or deficient emotional regulation (Herbert et al., 2013;

Hannesdottir et al., 2017; Rosen & al., 2018; Sanchez et al., 2019) in children with ADHD. They mainly focused on one ED component, and did not consider ED as a specific measure. According to Bunford et al. (2015), various measures can be used to evaluate different ED aspects (e.g. rating scales, observation, ecological momentary assessment). Assessing the intervention effects on different ED facets and using a common set of core measures would improve the result comparability across studies.

Future research should include information on ED symptoms from several raters (children, parents, teachers and clinicians) and by using different methods (observation, scales), besides assessing functioning and quality of life.

#### 4.1.3 Samples

Further limitations were related to several characteristics of the samples. In one study, ADHD was diagnosed by school psychologists, and participants were selected after ADHD rating by parents and teachers (Miranda and Presentacion, 2000). Therefore, this sample did not come from a clinical population. In most studies, the sample size was small. Waxmonsky et al. (2016) had unbalanced arms due to a multistage design; therefore, the generalization of their findings is questionable.

Finally, the selected studies involved mostly 6-13-year-old children, and only one ongoing study is focused on adolescents (NCT03733548). Two studies with adolescents were not included in this systematic review because the ADHD diagnosis was not an inclusion criterion (Miller et al., 2018), and participants did not have a formal diagnosis of ADHD, despite the presence ADHD symptoms (Kiani et al., 2017). Specifically, Miller et al. (2018) carried out a pilot study to evaluate the feasibility and efficacy of interpersonal psychotherapy for mood and behavior dysregulation (IPT-MBD) in adolescents with DMDD/SMD (age: 12 to 17 years). The Clinical Global Impression-Severity scale scores were significantly lower in the IPT-MBD group compared with the treatment-as-usual group. Kiani et al. (2017) investigated in 13-15-year-old girls with severe ADHD symptoms the impact of mindfulness meditation training. The ED total scores were significantly decreased in the intervention group compared with the control group (waiting list). However, this study used a non-clinical sample of only girls without formal diagnosis of ADHD. Other studies in children with high ED level (DMDD, SMD) were not included due to lack of information on (Derella et al., 2019) or absence of ADHD diagnosis (Perepletchikova et al., 2017). However, they bring useful information, because severe ED is often comorbid with ADHD (Usami, 2016; Bruno et al., 2019). Moreover, psychosocial interventions for DMDD might also be beneficial for children with ADHD and ED, because of their focus on emotional problems.

#### Conclusion:

Most of the psychosocial treatments evaluated in this review were based on behavioral therapy or CBT and included multimodal interventions for parents and children. All studies showed the beneficial effects of psychosocial interventions on emotional symptoms (irritability, depression), aggressiveness, and overall functioning in children with ADHD and ED. However, the limited number of RCTs, the small sample size and the heterogeneity of measurement tools used to assess ED do not allow drawing any general conclusion.

Future studies should: a) include measures to assess all ED components; b) consider ED as the main variable within a common core of outcome measures; c) use high-quality methodological quality; d) recruit more participants and include also adolescents and their family; and e) determine whether the psychosocial intervention effects are maintained in the medium and long term.

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