# Review

Eduardo Serrano-Troncoso<sup>1</sup> Monica Guidi<sup>2</sup> José Ángel Alda-Díez<sup>1</sup> Is psychological treatment efficacious for attention deficit hyperactivity disorder (ADHD)? Review of nonpharmacological treatments in children and adolescents with ADHD

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Introduction: Attention deficit hyperactivity disorder (ADHD) is the most prevalent psychiatric disorder in children and adolescents, and has a great impact on the psychological development of affected patients. Even though its efficacy is proven, the use of medication for ADHD has several limitations, and non-pharmacological interventions are considered a necessary component of treatment.

**Methodology:** This work is a review of evidence-based non-pharmacological treatments with demonstrated efficacy for ADHD in children and adolescents, analyzed by age groups.

**Results:** Non-pharmacological treatments that have shown scientific evidence of efficacy are psychological and psychoeducational interventions. Psychological interventions include behavioral therapy, parent training (PT) and social skills training. Psychoeducational interventions include a set of practices to improve learning and are carried out in the school setting. Scientific evidence of efficacy in preschool children is limited to PT, while different psychological and psychoeducational interventions have been shown to be beneficial in school-age children. The available evidence for non-pharmacological treatment in adolescence is so far insufficient.

**Conclusions:** Though more randomized controlled trials are necessary for non-pharmacological interventions to become established practices, there are clear indications of their efficacy. For more severe cases of ADHD, a combination of non-pharmacological and pharmacological treatment is recommended.

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# ¿Es el tratamiento psicológico eficaz para el trastorno por déficit de atención con hiperactividad (TDAH)? Revisión sobre los tratamientos no farmacológicos en niños y adolescentes con TDAH

Introducción: El trastorno por déficit de atención con hiperactividad (TDAH) es el trastorno psiquiátrico más prevalente en la edad infanto-juvenil, y tiene un gran impacto sobre el desarrollo psicológico de los niños afectados. Aunque su eficacia está comprobada, el uso de la medicación para el TDAH tiene varias limitaciones, y las intervenciones no farmacológicas se consideran un componente necesario del tratamiento.

Metodología: El presente trabajo es una revisión de los tratamientos no farmacológicos basados en la evidencia que han demostrado eficacia para el TDAH en niños y adolescentes, analizados por grupos de edad.

**Resultados:** Los tratamientos no farmacológicos que han mostrado evidencia científica de su eficacia son las intervenciones psicológicas y psicopedagógicas. Las intervenciones psicológicas incluyen la terapia de conducta, el entrenamiento para padres (EP) y el entrenamiento en habilidades sociales. Las intervenciones psicopedagógicas incluyen un conjunto de prácticas para mejorar el aprendizaje que se realizan en el contexto escolar. La evidencia científica de eficacia para niños de edad preescolar se circunscribe al EP, mientras que diferentes intervenciones psicológicas y psicopedagógicas han demostrado ser beneficiosas para los niños de edad escolar. La evidencia disponible sobre el tratamiento no farmacológico en la adolescencia es todavía insuficiente. Eduardo Serrano-Troncoso, et al.

**Conclusiones:** Aunque son necesarios más ensayos controlados aleatorizados para que las intervenciones no farmacológicas se conviertan en prácticas establecidas, existen indicaciones claras de su eficacia. En los casos más graves de TDAH se recomienda el tratamiento no farmacológico combinado con la medicación.

Palabras clave: Trastorno por déficit de atención con hiperactividad, Tratamiento psicológico, Eficacia, Tratamientos basados en la evidencia, Preescolares, Niños y adolescentes

#### INTRODUCTION

Attention deficit hyperactivity disorder (ADHD) is the most prevalent psychiatric disorder in childhood and adolescence. It represents one of the most common reasons for referring children to a specialist.<sup>1</sup> It has been calculated that the prevalence of ADHD worldwide is over 5%.<sup>2</sup> Equally, in Spain, the most recent estimate indicates a prevalence of 1.2–4.6%, depending on the diagnostic criteria used.<sup>3</sup> ADHD has a significant impact on the psychological development of affected children. It interferes in their social, emotional and cognitive functioning, and may affect their quality of life.<sup>4</sup> ADHD symptoms may persist into adult age, causing serious difficulties in daily life activities and an increased risk of substance abuse,<sup>5,6</sup> depression and anxiety disorders.<sup>7,8</sup>

According to the principal international classification systems, that is, the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)<sup>9</sup> and the International Classification of Diseases (ICD-10),10 ADHD is defined by three main categories of symptoms. These categories make up the so-called core symptoms: inattention, hyperactivity and impulsivity. Furthermore, ADHD is frequently associated with other psychiatric disorders.<sup>11</sup> According to a study conducted in Sweden, up to 87% of school-age children who fulfill the ADHD criteria have at least one comorbid disorder.<sup>12</sup> Among the most frequent comorbidities are oppositional defiant disorder, learning disorders, tics and anxiety disorders. Patients with ADHD who have comorbid disorders have greater difficulties at the social, emotional and psychological level. This affects clinical presentation, prognosis, therapeutic plan and response to treatment.<sup>1</sup>

ADHD is a heterogeneous disorder. Its etiopathogeny involves the interaction of multiple genetic and environmental factors. Heritability is high (76%),<sup>13</sup> and although the origin of the disorder is still unknown, it seems to be related to a dysfunction of the prefrontal cortex, possibly caused by a delay in cortical maturation, and of frontal-subcortical pathways. Developmental changes are observed in ADHD symptoms, and both the clinical manifestations and the needs of the patients vary according to age. Hyperactivity and impulsivity symptoms tend to appear earlier (at 3–4 years of age) while inattention becomes evident upon starting school (5–7 years).<sup>16</sup> Furthermore, hyperactivity and impulsivity decline more than inattention during childhood. In adolescence, hyperactivity decreases, with predominance of a sensation of subjective restlessness. Inattention generally persists, remaining until adult age. Impulsivity is shown by a greater conflict with adults and a tendency to increased risk behaviors.<sup>1</sup> These developmental differences are important for the choice of treatment, which must be adjusted to the needs and symptoms of each patient and should be modified according to the different stages, taking into account the developmental level characterizing each phase.<sup>17</sup>

For decades, ADHD has been mainly treated with stimulants, particularly methylphenidate and amphetamines. Their beneficial effect has been known for more than 70 years. In most cases, these drugs lead to a rapid and considerable improvement in the patient's core symptoms and behavior.<sup>18</sup> In Spain, immediate-release methylphenidate has been on the market since 1981. In recent years, the introduction of extended-release formulations and nonstimulant medications such as atomoxetine - a norepinephrine reuptake selective inhibitor<sup>19</sup> - have significantly extended the choice of available strategies for pharmacological treatment.<sup>1</sup> In spite of its efficacy, pharmacological treatment has some limitations, such as possible adverse effects and uncertainty on the risk-benefit balance in less studied groups of patients like preschool children.<sup>20</sup> In Spain, both methylphenidate and atomoxetine are indicated for the treatment of ADHD from 6 years of age, as part of a complete treatment that includes psychological, educational and social treatments, and when non-pharmacological measures are not sufficient by themselves.

Several clinical practice guidelines (CPG), including those of the *National Institute for Health and Clinical Excellence* (NICE) in the United Kingdom,<sup>20</sup> have concluded that non-pharmacological interventions are a necessary component of the treatment of ADHD for all patients. In general, physicians acknowledge that more than just a prescription is necessary for the management of this disease.<sup>21</sup> This review presents a general overview of evidence-based non-pharmacological treatments that have been shown to be effective for ADHD in children and adolescents. The different intervention programs and their application are analyzed by age groups (preschool children, school children and adolescents), and their possible combination with pharmacological treatment is considered.

#### METHODOLOGY

The current work is a review of the available literature published between 1995 and 2010 on non-pharmacological treatment of ADHD. National and international CPGs on ADHD were also reviewed. The following databases were used for the review of the literature: Pubmed/Medline, Psycinfo and Web of Knowledge. In the case of preschool children, for the literature published up to October 2009, this review was based on the articles cited in the CPG for ADHD of the Scottish Intercollegiate Guidelines Network

(SIGN).<sup>22</sup> In the case of school-age children and adolescents, for the literature published up to March 2009, this review is based on the articles cited in the Spanish CPG on ADHD.<sup>1</sup> For the literature published after March 2009, searches were made for the different non-pharmacological interventions using the following criteria: ADHD + parent training (PT), cognitive-behavioral therapy (CBT), social skills training (SST), school-based interventions, academic interventions and multimodal treatment. Inclusion criteria were language (articles published in English, Spanish and French) and age group (preschool, school and adolescents). These searches identified 609 articles. The final selection of the literature was made according to the levels of evidence described in the CPG of the SIGN<sup>16</sup> and included systematic reviews, metaanalysis and controlled clinical trials. A final number of 12 articles published after March 2009 was included.

#### RESULTS

#### Non-pharmacological treatment of ADHD

Although historically the management of ADHD has been mainly pharmacological, non-pharmacological interventions have aroused interest among clinicians and researchers. This is due to issues such as the need to deal with ADHD-related problems that may worsen the core symptoms and that do not improve with medication, patients who do not respond to or have low response to drugs, and possible adverse effects. Other factors are the reluctance of some families to use medication and the need to treat children under 6 years for whom drugs are not recommended (only dexamphetamine is approved in the United Kingdom from 3 years of age).<sup>20</sup>

Non-pharmacological interventions that have shown scientific evidence of efficacy can be divided essentially into two groups: psychological and psychoeducational interventions.<sup>1</sup> Psychological interventions are based on the principles of CBT and include behavioral therapy, PT, cognitive therapy with the child and SST. Psychoeducational interventions include a group of practices within the school setting related with learning. They are divided into academic interventions focused on the child and schoolbased interventions carried out through teacher training.

#### Psychological interventions

#### Behavioral therapy

Behavioral therapy involves the use of rewards and positive reinforcement to encourage the patient to put certain changes into practice in their behavior and to improve control of motor activity, impulsivity or attention.<sup>1,20</sup> Through a functional analysis of the child's behavior that allows identification of those factors that are maintaining the inadequate conduct, the behaviors that need changing are defined. The existing contingencies are analyzed and a new contingency system is constructed in accordance with the objectives proposed, planning a reinforcement program. Positive reinforcement may include praise, positive attention, rewards and privileges. Techniques are also used to reduce undesired behaviors through negative consequences. These include response cost (for example the loss of a positive reinforcement), time out or isolation and overcorrection (to compensate the consequences of the undesired behavior). Another behavior modification technique is token economy, which combines positive reinforcement and response cost. Many of the non-pharmacological treatments for ADHD (PT, CBT, SST and psychoeducational interventions) are based on the principles of behavioral therapy. The efficacy of their application has been recently corroborated by a metaanalysis of 174 studies.23

## Parent training (PT)

ADHD is often associated with poor familial functioning, elevated stress levels and conflictive relationships between parents and children.<sup>24</sup> PT is a treatment program whose objective is to inform the parents about ADHD and to teach them how to use behavioral therapy techniques to improve the management of their children, increase the confidence of the parents and improve the parent-child relationship through better communication and attention to the child's development. The programs are structured, developed in a specific number of sessions and generally done in a group. Some examples are the programs *New Forest Parenting Programme* (NFPP),<sup>25</sup> Triple P<sup>26</sup> and *The Incredible Years* (IY).<sup>27</sup>

## Cognitive therapy

The purpose of cognitive therapy is to help the child develop more planned and reflexive ways of thinking and behaving, identifying the maladaptive cognitions and stressing their impact on behavior and emotions in order to replace them with other, more adequate, cognitions. Patients learn to adopt a more systematic and productive attitude towards tasks and problem solving, using different procedures, in particular self-instruction and self-control techniques.<sup>1,20</sup>

## Social skills training (SST)

Children and adolescents with ADHD often have relationship problems with their peers, and a deficit is observed in social skills. Children without ADHD describe those with ADHD as unpredictable, problematic and aggressive, which often leads to social rejection.<sup>28</sup> The objective of SST is to develop the necessary behaviors and abilities to establish and maintain constructive social relationships. This is done, for example, by teaching patients how to make visual contact, smile, and maintain an appropriate body posture. It uses CBT techniques and is usually performed in group format. Although SST has demonstrated efficacy in children with ADHD, it is necessary to define a well-established standard intervention program and also to determine exactly what the necessary components are for it to be effective.<sup>29</sup>

## **Psychoeducational interventions**

## Academic interventions

School results of children and adolescents with ADHD are insufficient or lower than expected for their intellectual capacity. The objective of academic interventions is to improve school functioning and performance through specific sessions teaching academic competences. Similarly, adaptations of tasks and expectations can be designed in accordance with the characteristics of the child, for example simplifying the instructions given in the class, adapting school materials and in some cases the physical environment in which the child works in the classroom. The information available in the literature on the efficacy of these interventions is very limited, although there are studies that indicate that they may be effective.<sup>17</sup>

## School-based interventions (teacher training)

In a similar way to PT, school-based interventions focus on teachers in order to provide them with the necessary knowledge about ADHD and prepare them to put into practice specific behavioral techniques in the classroom. These include establishing effective rules and giving orders. positive reinforcement, time out or more extensive contingency management programs, both at the individual level and with the whole class.<sup>17</sup>

# Non-pharmacological interventions based on scientific evidence: analysis by age groups

# Preschool children (3–5 years)

There is a consensus that ADHD also affects preschool children, and in recent years the number of cases in this age group has increased considerably.<sup>30</sup> Symptoms, associated problems and comorbidities are very similar to those observed in school-age children. They generally persist over time and continue in subsequent developmental stages. Furthermore, the early onset of symptoms seems to be associated with a more serious course of the disorder. This emphasizes the importance of detecting and treating ADHD in this patient population.<sup>17</sup>

Few studies have evaluated the efficacy of psychological treatment in preschool children with ADHD. Scientific evidence is limited to PT<sup>22</sup> specifically to three intervention programs: NFPP, Triple P and IY.30 NFPP consists of 8 individual sessions led by a specially trained therapist. The sessions focus on psychoeducation of ADHD, parent-child relationship, behavioral therapy to help the parents establish limits, and attention training. Triple P has two versions, one standard and one extended. Both include 10 individual sessions with the therapist, in which parents are taught strategies to stimulate the skills and development of the child, and to establish effective limits and manage problematic behaviors. The extended version also includes strategies for couple support and coping with problems, although no significant differences have been observed between the two versions with regard to efficacy.<sup>31</sup> IY is an intervention performed in a group. It is conducted in 12 sessions of 2.5 hours each, in which parents are taught to establish a positive relationship with the children through playing, to use praise, rewards and incentives as positive reinforcements, to establish effective limits and give instructions, and to manage disobedience. The efficacy of these programs has been verified in three randomized controlled trials (RCTs). These trials have demonstrated significant improvements in the core symptoms of ADHD and in associated behavior problems.<sup>25,27,31</sup> The effect size in the case of the NFPP is comparable with that observed with stimulants in older children.<sup>30,32</sup> IY and Triple P have been evaluated in long-term follow-ups, showing that the beneficial effects are maintained after the intervention for at least one year.<sup>31,33</sup> A low response to IY is associated with internalizing problems and aggressive behavior prior to the onset of treatment.<sup>34</sup> Furthermore, ADHD or depression symptoms in the mother also seem to reduce the efficacy of these types of intervention, while the severity of ADHD symptoms in children is associated with a better response to treatment.<sup>30</sup> Currently, there are no studies that compare efficacy among the three intervention programs.

# School-age children (6-12 years)

Due to comorbid conduct, emotional and social relationship problems in school-age children with ADHD, the interventions used most for this age group are PT, SST and school-based and academic interventions.<sup>17</sup>

The nature of psychological treatment for school-age children is more complex than for preschool children, as different types of intervention are used at the same time that involve parents, children, and teachers. This makes it difficult to determine which components have greater impact on efficacy, whether it is one of them or their combination.<sup>1,20</sup> NICE carried out a meta-analysis of psychological interventions for ADHD.<sup>20</sup> They found 8 RCTs published between 1997 and 2007 that investigated the

treatment of school-age children and fulfilled the inclusion and quality criteria established. Of these, the studies that included children with a mean age under 8 years focused on PT, used as single treatment<sup>35</sup> or as coadjuvant to routine community care.<sup>36</sup> The studies that included participants with a mean age over 8 years considered PT together with interventions that involved the children or family (cognitivebehavioral intervention<sup>37,38</sup> and SST<sup>39,40</sup>), or interventions only on the children (SST<sup>41</sup> and a stress management program<sup>42</sup>). The results of this meta-analysis indicated moderate beneficial effects of psychological interventions in the evaluations of ADHD symptoms and conduct problems by parents. These effects were maintained at least up to 3-6 months after completing the treatment. The evidence is not sufficient or it is limited regarding the beneficial effects of psychological interventions in teacher assessments (ADHD symptoms and behavioral problems). Similarly, there is limited scientific evidence regarding the benefits of psychological therapy on social skills and academic functioning.

With regard to other variables such as internalizing symptoms and self-efficacy, there is insufficient evidence of the beneficial effects of psychological therapy.<sup>1,20</sup> On the other hand, another meta-analysis performed by NICE in children with conduct disorders indicates that there is strong evidence that PT is effective in this population, which includes patients with ADHD. On this basis, NICE considers that PT has a high likelihood of being effective in children with ADHD up to 12–13 years of age.<sup>43</sup>

More recent studies also support the efficacy of psychological interventions in school-age children. One pilot study conducted in 21 children, aged 7-10 years, examined the effectiveness of a new 10-week intervention program (Family STARS) that combines behavioral activation (a type of third-generation behavioral therapy developed for anxiety and depression<sup>44</sup>) with PT, detecting a decrease in behavioral problems below the clinical significance level.45 Another study (n=74) evaluated the efficacy of a program specifically designed for fathers (Coaching Our Acting-Out Children: Heightening Essential Skills [COACHES]) that combines PT with training in sports skills for children and parents in order to improve father-child interactions using the context of a football match.<sup>46</sup> Compared with PT alone, although no significant differences were detected in ADHD symptoms, it was observed that parents became more involved in the process, with increased participation in the sessions, compliance with tasks and satisfaction with treatment. Furthermore, parent assessments of their child's improvements were more positive. An extended PT program has also been developed (Strategies to Enhance Positive Parenting [STEPP]) to cope with the specific needs of single mothers, with which, compared to a traditional program, better participation in the treatment was demonstrated (n=120).47 Another training program (Parental Friendship *Coaching* [PFC]) designed to teach parents to facilitate the social relationships of their children has demonstrated improvement in social skills, quality of friendships and acceptance by peers.<sup>48</sup>

Regarding psychoeducational interventions, a metaanalysis conducted in 1997 indicated that, in the school setting, contingency management strategies and academic interventions are more effective for behavioral change than cognitive-behavioral strategies.49 Likewise, the SIGN quidelines<sup>22</sup> indicate that children with ADHD need an individualized school intervention program including both academic and behavioral components. As explained in the Spanish CPG on ADHD<sup>1</sup>, there are multimodal interventions that go from individual intervention with the child up to parent and teacher training, such as the Irvine Paraprofessional Program,<sup>50</sup> and other more specific ones that have the advantage of being easier and simpler to implement. Individualized treatments to teach academic skills and competencies seem to be producing promising results. This is the case of an individual intervention program on organizational skills,<sup>51</sup> which has demonstrated beneficial effects on the capacity to complete homework and general academic performance. Other interventions are conducted from the school and require the participation of teachers in order to put behavioral modification techniques and educational adaptations into practice in the classroom.<sup>1</sup> According to a meta-analysis conducted by NICE<sup>20</sup> only one study has compared teacher-mediated intervention versus no intervention,52 demonstrating a strong reduction of conduct problems. However, both the Spanish CPG and NICE recommend adaptations in the school setting. In order to be able to put this into practice, teachers must receive the necessary training on ADHD and the educational and behavioral modification techniques that have to be used. This is generally done through informative material and specific training programs.<sup>1,20</sup>

In addition to the previously described interventions, there are multimodal programs that include both psychological and psychoeducational components. One example is the Summer Treatment Program (STP).50,53 This is an intensive 8-week program, conducted in a context similar to a school or summer camp, that was used in the collaborative multimodal treatment study of children with ADHD (MTA study).<sup>50</sup> Although considerable effects have been described on different behavioral aspects and the severity of symptoms, the complexity of this program and the resources needed for its application greatly limit its use in clinical practice.<sup>17</sup> Preliminary results on a program derived from the STP specific for younger children (4-6 years) indicate that it has beneficial effects at least in the short term,<sup>54</sup> providing another possible option for the treatment of preschool children.

# Adolescents (13–18 years)

Approximately 50% of children with ADHD continue to fulfill the diagnostic criteria during adolescence,<sup>17</sup> although, as previously mentioned, symptoms change. Research on ADHD in adolescents has focused on the use of medication, this being the treatment used most.<sup>17</sup> According to NICE, none of the studies included in the meta-analysis of psychological interventions for ADHD provide evidence of what an effective intervention for adolescents would be. However, it is considered likely that the interventions that function with older children can also be applied to this age group.<sup>20</sup> Our search of the literature has not revealed any recent article published between March 2009 and 2010 on non-pharmacological treatment of adolescents with ADHD. A good analysis of the previous literature can be found in the review by Young and Amarasinghe.<sup>17</sup>

# **Combined treatment**

Although a comprehensive analysis of combined treatment of ADHD is beyond the objectives of this review, it is useful to mention some essential points. As described in the introduction, in spite of its proven efficacy, medication is not considered as first-line treatment for all children with ADHD. Pharmacological treatment is recommended only from 6 years of age, in patients who have severe symptoms of ADHD or who have moderate symptoms but do not sufficiently respond to non-pharmacological interventions.<sup>1,20</sup>

The most important study that has evaluated the effects of combined treatment compared to medication alone is undoubtedly the MTA study,<sup>55,56</sup> the largest RCTs of combined treatment for ADHD conducted to date. In this study, four types of intervention were compared: pharmacological treatment (methylphenidate), nonpharmacological treatment (an intervention that included PT, STP and adaptation in the school<sup>50</sup>), a combination of the two previous ones, and routine community care (in most cases medication). According to the results, the effects of methylphenidate are equivalent to those of combined treatment, although in the combined group similar improvements were achieved with a significantly lower medication dose. A small beneficial effect of combined treatment over medication alone was observed for parentrated scores on behavioral problems. However, it must be considered that medication is less effective in routine clinical practice than in the context of an RCT, where treatment conditions are much more controlled than in real life. In fact, in the MTA study, both medication and combined treatment were superior to routine treatment. This suggests that psychological intervention is effective as a coadjuvant to routine medication, as has also been demonstrated in other studies.36

On the basis of these results and the rest of the information available in the literature, the CPGs<sup>1,20</sup> consider that there are different reasons why non-pharmacological treatment can be combined with pharmacological treatment. Medication acts on the core symptoms of ADHD, while nonpharmacological treatment is more aimed at the secondary problems and comorbidities associated with the disorder. In severe cases, it may be convenient to initiate pharmacological treatment together with non-pharmacological therapy in order to obtain more immediate improvements. This can be especially important if there is a marked social dysfunction, great family pressure, or if the child is facing imminent expulsion from school. Equally, even when psychological intervention is the preferred option of the child or their family, this may not be feasible due to the severity of symptoms. In these cases, medication has the potential to facilitate rapid initial improvement during the first weeks and can help to benefit from the psychological techniques later on. This is because behavioral learning during psychological treatment can be favored by the combined use of pharmacological treatment. Finally, combining pharmacological treatment with psychological intervention can lead to a reduction of drug doses, decreasing adverse effects and concerns about the use of medication.<sup>1,20</sup>

# CONCLUSIONS

The results of the current review indicate that there is clear scientific evidence of the efficacy of non-pharmacological treatment for ADHD. PT is the recommended intervention for preschool children, and three programs in particular have demonstrated validity in the context of RCTs: NFPP, Triple P and IY.<sup>30</sup>

The situation is more complex for school-age children. In these children, interventions normally include more than one setting simultaneously (family and school) and they have both psychological and psychoeducational components, including individual sessions with the children, training for parents and teachers, and adaptations in the school.<sup>1,20</sup>

Although the beneficial effects of these interventions are proven, data in the literature are still limited, in particular in the case of adolescents where very few studies have been conducted. In order for non-pharmacological interventions to become an established practice, more RCTs need to be conducted to directly compare the different intervention programs and exactly define which components are needed for them to be effective. At the same time, mental health teams should be trained in these types of nonpharmacological techniques. Furthermore, the data available are, in general, insufficient to carry out sub-analyses and identify which subgroups of patients can benefit the most from non-pharmacological treatment.<sup>20</sup> Is psychological treatment efficacious for attention deficit hyperactivity disorder (ADHD)? Review of non-pharmacological treatments in children and adolescents with ADHD

#### CONFLICTS OF INTEREST

Eduardo Serrano-Troncoso and José Ángel Alda-Díez have no conflicts of interest related to this article. Monica Guidi is a professional medical writer employed by Caudex Medical, UK whose contribution to this manuscript was funded by Shire Development LLC, USA.

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