

## Homeopathy for Childhood and Adolescence Ailments: Systematic Review of Randomized Clinical Trials

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**OBJECTIVE:** To assess the evidence of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments.

**METHODS:** Systematic literature searches were conducted through January 2006 in MEDLINE, EMBASE, AMED, CINAHL, Cochrane Central, British Homeopathic Library, ClinicalTrials.gov, and the UK National Research Register. Bibliographies were checked for further relevant publications. Studies were selected according to predefined inclusion and exclusion criteria. All double-blind, placebo-controlled randomized clinical trials of any homeopathic intervention for preventing or treating childhood and adolescence ailments were included. According to the classification of the World Health Organization, the age range defined for inclusion was 0 to 19 years. Study selection, data extraction, and assessment of methodological quality were performed independently by 2 reviewers.

**RESULTS:** A total of 326 articles were identified, 91 of which were retrieved for detailed evaluation. Sixteen trials that assessed 9 different conditions were included in the study. With the exception of attention-deficit/hyperactivity disorder and acute childhood diarrhea (each tested in 3 trials), no condition was assessed in more than 2 double-blind randomized clinical trials. The evidence for attention-deficit/hyperactivity disorder and acute childhood diarrhea is mixed, showing both positive and negative results for their respective main outcome measures. For adenoid vegetation, asthma, and upper respiratory tract infection each, 2 trials are available that suggest no difference compared with placebo. For 4 conditions, only single trials are available.

**CONCLUSION:** The evidence from rigorous clinical trials of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments is not convincing enough for recommendations in any condition.

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ADHD = attention-deficit/hyperactivity disorder; CAM = complementary and alternative medicine; RCT = randomized clinical trial

Parents increasingly use complementary and alternative medicine (CAM) for their children's ailments.<sup>1-9</sup> Among CAM treatments, homeopathy is one of the most popular options.<sup>10-14</sup> However, homeopathy continues to be one of the most controversial CAM practices for children or indeed any other patient group. Administering homeopathic substances is based on the proposed law of similars that

suggests that "like cures like."<sup>15</sup> In homeopathy, the process of diluting and shaking is believed to impart additional potency to solutions. However, for substances so highly diluted that they cannot be measured, no plausible mode of action exists. Nevertheless, parents often perceive homeopathy as effective, natural, and therefore risk free.<sup>16,17</sup> Homeopaths believe that children in particular are good responders to such remedies,<sup>18,19</sup> and some observational studies seem to confirm this notion.<sup>20</sup> This systematic review aims to assess the evidence from rigorous clinical trials of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments.

### METHODS

#### SEARCH STRATEGY

Systematic literature searches were conducted to identify all randomized clinical trials (RCTs) of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments. The following databases were searched from their respective inception to January 2006: MEDLINE (from 1951), EMBASE (from 1974), AMED (from 1985), CINAHL (from 1982), Cochrane Central (issue 4, 2005), British Homeopathic Library, ClinicalTrials.gov, and the UK National Research Register. Search terms, including wildcards (\$), were as follows: *homeopath\$, homoeopath\$, homöopath\$, homéopath\$, pediatr\$, paediatr\$, pädiatr\$, pédiatr\$, child\$, kinder\$, enfant\$, newborn, neonat\$, infant\$, adolescen\$, and random\$*. The strategy was refined after preliminary searches on MEDLINE of more than 3000 potentially relevant titles using the term *homeopathy* (U.A.). To identify additional published or unpublished studies, we conducted hand searches in our extensive departmental files, conference proceedings (Focus on Alternative and Complementary Therapies 1996 to 2006), and relevant medical journals (*Phytomedicine* 1994-2006, *Alternative and Complementary Therapies* 1995-2006, *Forschende Komplementärmedizin Klassische Naturheilkunde* 1994-2006, and *Homeopathy*, formerly *British Homeopathic Journal*, 1995-2006). Hand searches also included the bibliographies of all retrieved articles and contact with experts. No language restrictions were imposed.

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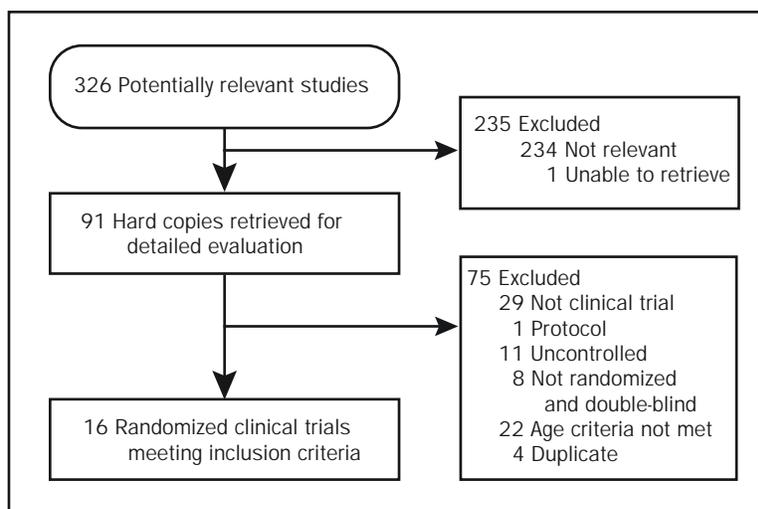


FIGURE 1. Flowchart of trial selection process.

**STUDY SELECTION**

Titles and abstracts of identified articles were assessed, and hard copies of potentially relevant articles were obtained. All double-blind, placebo-controlled RCTs that assessed children or adolescents were included. According to the classification of the World Health Organization, the age range defined for inclusion was 0 to 19 years. Studies that assessed patients older than 19 years were excluded.

**VALIDITY ASSESSMENT**

Methodological quality was independently assessed by 2 authors (U.A., M.H.P.) using the system developed by Jadad et al,<sup>21</sup> which quantifies the likelihood of bias inherent in trials based on the description of randomization, blinding, and withdrawals.

**DATA ABSTRACTION**

Data on study design, study quality, population, intervention, outcomes, and adverse events were extracted from included trials using a specifically designed data extraction sheet. Study selection and data extraction were performed independently by 2 authors (U.A., M.H.P.) and discussed and validated by the third author (E.E.). Disagreements were discussed and resolved.

**RESULTS**

The literature searches identified 326 articles (Figure 1). After assessing titles and abstracts, 234 articles were found to be irrelevant. An additional article, which was a protocol of a double-blind RCT for autism,<sup>22</sup> could not be retrieved despite attempts to contact the author. Of 91 articles that

were retrieved as hard copies for detailed evaluation, 75 were excluded for the following reasons: not a clinical trial, not randomized and double blind, duplicate publication, protocol without results, or not within age limits. Sixteen trials met the inclusion criteria and were reviewed.<sup>23-38</sup> In these trials, individualized or standardized homeopathic agents were tested in 9 different conditions, using different routes of administration and doses either with or without concomitant treatments. Key information is provided in Tables 1 and 2.

**ADENOID VEGETATIONS**

Two RCTs<sup>23,24</sup> with a total patient sample of 137 and a score of 4 and 5 for methodological quality reported that homeopathic treatments were not effective for reducing the size of adenoid vegetations and preventing the need for adenoidectomy (Table 1).

**ATTENTION-DEFICIT/HYPERACTIVITY DISORDER**

Three RCTs<sup>25-27</sup> tested homeopathic interventions for patients with attention-deficit/hyperactivity disorder (ADHD). Two trials<sup>25,27</sup> (N=20 and 62, respectively) reported effects in favor of homeopathy for their respective main outcome measures, Conners' Parent Symptom Questionnaire and Conners' Global Index-Parent compared with placebo (Table 1). Another RCT<sup>26</sup> (N=43) reported no intergroup differences for Conners' Global Index-Parent.

**ASTHMA**

In 2 RCTs, the effectiveness of standardized<sup>28</sup> (N=86) and individualized<sup>29</sup> (N=93) homeopathy was assessed in patients with asthma. Both RCTs reported no differences compared with placebo on several outcome measures, in-

TABLE 1. Double-Blind, Placebo-Controlled Randomized Clinical Trials of Homeopathy for Childhood and Adolescence Ailments\*

Reference	Patient conditions	Design (Jadad score, maximum of 5)	Total sample size, mean age (H/P <sup>†</sup> ), sex	Intervention, <sup>‡</sup> potencies, <sup>§</sup> duration	Main outcome measures	Main results	Main adverse events
Feuchter et al, <sup>23</sup> 2001	Adenoid vegetation	Parallel (5)	97, 6/6 y, 65% male	Standardized, material, 3 mo	Need for adenoidectomy after 3-mo treatment	No intergroup difference	Acute inflammation of the middle ear (5 H; 6 P), influenza (4 both), acute tonsillitis (3 H; 5 P), cough (5 H; none P), scarlet fever (2 both), rhinitis (2 both), digestive complaints (1 both)
Furuta et al, <sup>24</sup> 2003	Adenoid vegetation	Parallel (4)	40, 3-7 y, 57% male	Standardized and individualized, material, 4 mo	Size of adenoid vegetation, symptom questionnaire	No intergroup differences	None
Strauss, <sup>25</sup> 2000	ADHD	Parallel (2)	20, "children," 90% male	Standardized, material, 2 mo	PSQ, CCT	Intergroup differences for PSQ ( $P=.01$ ) and improvement compared with baseline for CCT ( $P$ value not reported)	Not reported
Jacobs et al, <sup>26</sup> 2005	ADHD	Parallel (5)	43, 9.5/9 y, 77% male	Individualized, not reported, 18 wk	CGI-P	No intergroup difference	None
Frei et al, <sup>27</sup> 2005	ADHD	Crossover (5)	62, 10/10 y, 89% male	Individualized, material, 6 wk	CGI-P	Intergroup difference ( $P=.048$ )	Adverse events causing withdrawal: 1 increasing tics, 2 behavioral disorders, 1 reactive depression
Freitas et al, <sup>28</sup> 1995	Asthma	Parallel (4)	86, 1-12 y, 51% male	Standardized, material, 6 mo	Intensity, frequency, duration of asthma attacks	No intergroup differences	Not reported
White et al, <sup>29</sup> 2003	Asthma	Parallel (5)	93, 5-15 y, 54% male	Individualized, not reported, 1 y	Active quality of living subscale of the Childhood Asthma Questionnaire	No intergroup difference	Homeopathy: exacerbation of eczema (4 H; 2 P) and asthma (3 both), headache (3 H), fever (1 H), sickness (1 H), rash (1 P), depression and irritability (3 P), sleeping difficulties (2P); 1 patient was withdrawn because of adverse events (cough, behavior, and sleeping disorders)
Jacobs et al, <sup>30</sup> 2001	Acute otitis media	Parallel (5)	75, 3.5/3.1 y, 41% male	Individualized, nonmaterial, 5 d or until improvement	Symptom scores, treatment failures, presence of middle ear effusion	Intergroup differences for symptom scores ( $P<.05$ ), no intergroup differences for treatment failures, ear effusion	None
Mokkapatti, <sup>31</sup> 1992	Conjunctivitis	Parallel (2)	1306, 4-15 y, not reported	Standardized, nonmaterial, 3 d	Overall conjunctivitis severity score	No intergroup difference	Not reported
Jacobs et al, <sup>32</sup> 1993	Diarrhea	Parallel (5)	34, 6 mo-5 y, not reported	Individualized, nonmaterial, 3 d or until improvement	No. of days with diarrhea, No. of daily stools	No intergroup differences	Not reported
Jacobs et al, <sup>33</sup> 1994	Diarrhea	Parallel (5)	92, 1.6/1.5 y, not reported	Individualized, nonmaterial, 5 d	No. of days with diarrhea, No. of daily stools	Intergroup differences for both outcome measures ( $P=.048$ and $P<.05$ , respectively)	None

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TABLE 1. Continued\*

Reference	Patient conditions	Design (Jadad score, maximum of 5)	Total sample size, mean age (H/P†), sex	Intervention,‡ potencies,§ duration	Main outcome measures	Main results	Main adverse events
Jacobs et al, <sup>34</sup> 2000	Diarrhea	Parallel (5)	126, 1.7/1.4 y, 67.5% male	Individualized, nonmaterial, 5 d	No. of days with diarrhea, No. of daily stools	Intergroup differences for both outcome measures ( $P=.04$ and $P=.02$ , respectively)	Not reported
Alibeu & Jobert, <sup>35</sup> 1990	Postop pain-agitation syndrome	Parallel (2)	50, 6 mo-14 y, 72% male	Standardized, not reported, postop period	Sedation of agitation 15 min after operation	Intergroup difference ( $P<.05$ )	Not reported
de Lange de Klerk et al, <sup>36</sup> 1994	Recurrent URTI	Parallel (3)	170, 4.2/3.6 y, 56% male	Individualized, material, 1 y	Daily symptom scores, No. of antibiotic treatment courses, adenoidectomies, and tonsillectomies after 1-y follow-up	No intergroup difference for any main outcome measure	Not reported
Steinsbekk et al, <sup>37</sup> 2005	URTI	Parallel (5)	251, 3.6/3.2 y, 41% male	Standardized, nonmaterial, 12 wk	Total daily symptom score	No intergroup difference	"Mild and transient" adverse events (4 P; 9 H); no dropouts due to adverse effects
Kainz et al, <sup>38</sup> 1996	Warts	Parallel (4)	60, 8/9 y, not reported	Individualized, material, 8 wk	No. of responders (50% reduction in warts area)	No intergroup difference	Thrombosis of a capillary hemangioma (1 P), exacerbation (1 both)

\*ADHD = attention-deficit/hyperactivity disorder; CCT = Children's Checking Task; CGI-P = Conners' Global Index-Parent; H = homeopathy; P = placebo; postop = postoperative; PSQ = Conners' Parent Symptom Questionnaire; URTI = upper respiratory tract infection.

†Unless otherwise indicated.

‡Standardized homeopathy indicates same remedies for all patients; individualized homeopathy indicates remedies that best match the symptom picture of a patient.

§Material potencies are dilutions above Avogadro's number; nonmaterial potencies are dilutions below Avogadro's number.

cluding the intensity, frequency, and duration of asthma attacks (Table 1).

#### ACUTE OTITIS MEDIA

A single RCT<sup>30</sup> (N=75) assessed patients with acute otitis media and reported a decrease in symptom scores compared with placebo as recorded by parent diaries. These data require independent replication.

#### CONJUNCTIVITIS

Another single RCT<sup>31</sup> (N=1306) conducted during a viral conjunctivitis epidemic assessed schoolchildren who were treated with Euphrasia 30C for 3 days. No significant difference was found in favor of homeopathy compared with placebo for preventing viral conjunctivitis.

#### DIARRHEA

Three RCTs,<sup>32-34</sup> which were similar in design and from the same research group, tested individualized homeopathy in acute childhood diarrhea. Two RCTs<sup>33,34</sup> (N=92 and 126, respectively) reported effects in favor of homeopathy for the duration of diarrhea and the number of unformed stools, whereas another RCT<sup>32</sup> (N=34) failed to show intergroup differences for these outcome measures in its main analysis.

#### POSTOPERATIVE PAIN-AGITATION SYNDROME

Patients were treated with standardized homeopathy as an adjunct to conventional premedication during surgical operations. This single RCT<sup>35</sup> (N=50) reported beneficial effects for postoperative agitation in children compared with placebo. These data require independent replication.

#### UPPER RESPIRATORY TRACT INFECTION

Two double-blind RCTs<sup>36,37</sup> (N=170 and 251, respectively) included patients aged 3 to 4 years. Neither of the studies reported significant differences compared with placebo for the main outcome measures (Table 1).

#### WARTS

A single RCT<sup>38</sup> (N=60) was identified for treating warts. It failed to demonstrate the effectiveness of individualized homeopathic treatment for reducing the size of warts.

## DISCUSSION

Parents often perceive homeopathic remedies as effective, natural, and risk free and therefore well suited for their children's ailments. Also, many homeopaths believe that children are particularly good responders to homeopathic remedies. However, the best evidence from double-blind

TABLE 2. Characteristics of Homeopathic and Concomitant Treatments of Included Studies\*

Reference	Homeopathic remedies†	Regimen	Concomitant treatment
Feuchter et al, <sup>23</sup> 2001	Nux vomica D200 potency, Okoubaka D3 potency, Tuberculinum D200 potency, Barium iodatum D4 and D6 potencies	Nux vomica, 5 globules once at the start of the study; Okoubaka, 15 globules daily before meals from the first day for 4 wk; Tuberculinum, 5 globules once 4 wk after the start of the study; Barium iodatum D4 potency, 3 tablets daily before meals from wk 4 to 8; Barium iodatum D6 potency, 3 tablets daily for 4 wk from wk 8 to 12	Acute intercurrent diseases were treated homeopathically if possible so as not to compromise the effect of homeopathic remedies
Furuta et al, <sup>24</sup> 2003	Agraphis nutans 6C potency, Thuya 6C potency, Adenoid 21C potency in addition to individualized remedies	Not reported	Not reported
Strauss, <sup>25</sup> 2000	Selenium-Homaccord (selenium in varying potencies of 10X, 15X, 30X, and 200X and potassium phosphate in varying potencies of 2X, 10X, 30X, and 200X)	Not reported	Methylphenidate (Ritalin in 10 patients)
Jacobs et al, <sup>26</sup> 2005	41 different remedies prescribed: Medorrhinum, Saccharum officinalis, Calcarea carbonica, Calcarea phosphorica, China officinalis, stramonium	Homeopathic remedies prescribed with no limit. Doses and potencies not reported	Stimulant medications (5 H; 4 P)
Frei et al, <sup>27</sup> 2005	17 different remedies prescribed, potencies between Q3 and Q42: Calcarea carbonica, sulfur, Chamomilla, Lycopodium, silica, Hepar-sulph., Nux vomica, China, Ignatia, Mercurius, Capsicum, Causticum, Hyoscyamus, phosphorus, phosphoric acid, sepia, Staphysagria	Not reported	Not reported
Freitas et al, <sup>28</sup> 1995	Blatta orientalis 6C potency	Two globules delivered 3 times daily	Conventional asthma medicines (for prevention or crisis)
White et al, <sup>29</sup> 2003	Various remedies in different potencies (no details reported)	Homeopaths were free to practice in their usual way, combining homeopathic prescriptions with lifestyle suggestions and other advice	β-Adrenergic inhalers (all patients), inhaled steroids (33 H; 36 P), sodium cromoglycate (6 H; 2 P), salbutamol nebulas (1 H)
Jacobs et al, <sup>30</sup> 2001	8 different remedies in C30 potency; 4 most commonly used were Pulsatilla nigrans, Chamomilla, sulfur, Calcarea carbonica	3 to 5 pellets 3 times daily	Analgesics (10 P; 5 H)
Mokkapatti, <sup>31</sup> 1992	Euphrasia 30C potency	A total amount of 5 to 6 pills	Not reported
Jacobs et al, <sup>32</sup> 1993	Various remedies in 30C potency (no details reported)	2 pills daily	Oral rehydration therapy, normal feeding; standard antiparasitic medication at the end of intervention if needed
Jacobs et al, <sup>33</sup> 1994	18 different remedies in 30C potency: Podophyllum, Chamomilla, Arsenicum album, Calcarea carbonica, sulfur, Mercurius vivus, Pulsatilla, phosphorus, China, Gambogia, Aethusia, aloe, belladonna, Bryonia, Colchicum, Croton tiglium, Dulcamara, Nux vomica	One dose after every unformed stool	Oral rehydration therapy, normal feeding; standard antiparasitic medication at the end of intervention if needed; 11 children were given antidiarrheal medication by their parents (6 P; 5 H)
Jacobs et al, <sup>34</sup> 2000	19 different remedies in 30C potency; 5 most commonly listed: Podophyllum, sulfur, Arsenicum album, Calcarea carbonica, Chamomilla	One dose after every unformed stool	Oral rehydration therapy, normal feeding; standard antiparasitic medication at the end of intervention, if needed
Alibeu & Jobert, <sup>35</sup> 1990	Aconite (potency not reported)	Dose not reported, administered at least once, to be repeated as many times as necessary	Halothane (1.5%), nitric oxide, Alimemazine (1 mg/kg), methohexital (25 mg/kg intrarectally)
de Lange de Klerk et al, <sup>36</sup> 1994	Remedies in various potencies, mainly D6, D30, and D200 (remedies not reported)	Homeopathic medicines and follow-up prescriptions were based on the clinical course	Adequate nutrition advice, antibiotics, adenolectomy, tonsillectomy if needed
Steinsbekk et al, <sup>37</sup> 2005	Calcarea carbonica, Pulsatilla, sulfur in C30 potency	2 pills 2 d/wk. In addition, 1 pill up to once every hour if the child had an acute episode of URTI but reduce the intake if the URTI was mild or when there was an improvement	Antibiotics, painkiller/antipyretic drugs if needed
Kainz et al, <sup>38</sup> 1996	10 different remedies were preselected: sulfur 12X potency, Calcium carbonicum 30X potency, Natrium muriaticum 30X potency, sepia 12X potency, Causticum 12X potency, Staphysagria 12X potency, Thuja 12X potency	Globuli 12X potency were administered once a day; globuli 30X potency every other day	None

\*H = homeopathy; P = placebo; URTI = upper respiratory tract infection.

†Shown are the reported remedies with potencies, if present.

RCTs shows no compelling data for any therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments.

In this systematic review, 16 double-blind RCTs that assessed 9 different conditions could be included. Most of these trials suggest that homeopathic remedies were not associated with effects that significantly differed from placebo. With the exception of ADHD and acute childhood diarrhea (each tested in 3 trials), no condition was assessed in more than 2 double-blind RCTs. In fact, for 4 conditions only single RCTs are available (Table 1). The evidence for ADHD and acute childhood diarrhea is mixed, showing both positive and negative results for their respective main outcome measures. Also, the trials of acute childhood diarrhea were all conducted by the same research group and therefore require replication in independent rigorous trials. One way of producing an indication of the weight of the evidence for a particular indication is to combine the quality of the evidence with the level of evidence (eg, RCT with a Jadad score of 5) and the volume of evidence. Thus, even if quality and level are high (ie, rigorous RCT), weight can only be considered low for a particular indication if the volume is small (eg, a single trial).

Children are less likely than adults to have had drug treatment, believed by homeopaths to hinder the success of their remedies. Studies of homeopathy, including data of adult populations, concluded that studies with better methodological quality tend to yield less positive results.<sup>39-41</sup> Our systematic review of double-blind, placebo-controlled RCTs that assessed only children and adolescents also does not show convincing evidence of effectiveness and therefore does not allow any recommendations. Other reviews of homeopathy for pediatric populations have reached more favorable conclusions.<sup>16,42,43</sup> However, these reviews were not systematic and therefore are open to bias.

Homeopathic remedies are generally regarded as safe.<sup>44</sup> Only a few mild adverse events were reported in the reviewed RCTs (Table 1). This finding is supported by several postmarketing surveillance studies, which reported only a few adverse events.<sup>45,46</sup> However, homeopathy is not totally devoid of risks. According to homeopathic beliefs, aggravations of symptoms occur in approximately 20% of patients.<sup>47</sup> Also, it may delay effective treatment or diagnosis.<sup>48,49</sup> One example for this is the reluctance of some homeopaths to recommended immunizations.<sup>50,51</sup>

Limitations of our systematic review, and indeed systematic reviews in general, pertain to the potential incompleteness of the reviewed evidence. We aimed to identify all RCTs on the topic. The distorting effects on systematic reviews arising from publication bias and location bias are well documented. For this study, we searched databases

with a focus on the American and European literature and those that specialize in complementary medicine and included hand searches. The search was not restricted in terms of publication language, and the appraisal of the clinical evidence was performed independently by 2 reviewers. Therefore, we are confident that our search strategy has located all relevant data on the subject.

## CONCLUSION

The evidence from rigorous clinical trials of any type of therapeutic or preventive intervention testing homeopathy for childhood and adolescence ailments is not convincing enough for recommendations in any condition.

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