



## Assessing Complementary and Controversial Interventions — CHADD Fact Sheet #6

In the past decade, there has been a tremendous upsurge of scientific and public interest in attention-deficit/hyperactivity disorder (AD/HD). This interest is reflected not only in the number of scientific articles, but also in the explosion of books and articles for parents and teachers. Great strides have been made in the understanding and management of this disorder. Children with AD/HD who would have gone unrecognized and untreated only a few short years ago are now being helped, sometimes with dramatic results.

There are still many questions to be answered concerning the developmental course, outcome and treatment of AD/HD. Although there are several effective treatments, they are not equally effective for all children with AD/HD. Among the most effective methods to date is the judicious use of medication and behavior management, referred to in the scientific literature as multimodal treatment. Multimodal treatment for children and adolescents with AD/HD consists of parent and child education about diagnosis and treatment, specific behavior management techniques, stimulant medication, and appropriate school programming and supports. Treatment should be tailored to the unique needs of each child and family.

In an effort to seek effective help for AD/HD, however, many people turn to treatments that claim to be useful but have not been shown to be truly effective, in agreement with standards held by the scientific community.

The following terms are important in understanding treatment interventions:

1. **Medical/medication management** of AD/HD refers to the treatment of AD/HD using medication, under the supervision of a medical professional. See CHADD Fact Sheet #3, “Evidence-based Medication Management for Children and Adolescents with AD/HD,” for more information.
2. **Psychosocial treatment** of AD/HD refers to treatment that targets the psychological and social aspects of AD/HD. See CHADD Fact Sheet #9, “Evidence-based Psychosocial Treatment for Children and Adolescents with AD/HD,” for more information.
3. **Alternative treatment** is any treatment — other than prescription medication or standard psychosocial/behavioral treatments — that claims to treat the symptoms of AD/HD with an equally or more effective outcome. Prescription medication and standard psychosocial/behavioral treatments have been “extensively and well reviewed in the extant literature, with undoubted efficacy.”<sup>1</sup>
4. **Complementary interventions** are not alternatives to multimodal treatment, but have been found by some families to improve the treatment of AD/HD symptoms or related symptoms.

5. **Controversial treatments** are interventions with no known published science supporting them and no legitimate claim to effectiveness.

Before actually using any of these interventions, families and individuals are encouraged to consult with their medical doctors. Some of these interventions are targeted to children with very discrete medical problems. A good medical history and a thorough physical examination should check for signs and symptoms of such conditions as thyroid dysfunction, allergic history, food intolerance, dietary imbalance and deficiency, and general medical problems that may mimic symptoms of AD/HD.

### **How are Treatments Evaluated?**

There are two ways that treatments may be evaluated: (1) standard scientific procedure or (2) limited case studies or testimonials. The scientific approach involves testing a treatment in carefully controlled conditions, with enough subjects to allow researchers to be comfortable with the “strength” of their findings. These studies are repeated a number of times by various research teams before arriving at a conclusion that a particular treatment helps a particular problem.

The studies need to include techniques that decrease the chance of reaching incorrect conclusions. These techniques include comparing the particular treatment to placebo or other treatments, assigning people to the particular treatment or the comparison treatment in a random fashion, and when possible, not letting families or researchers know which treatment the person is receiving until the study is finished, or at least having people evaluate the outcomes of the study who are not associated with the study and are unaware of what each person received. It is also important that the people in the study have the same diagnosis, which is obtained using a clearly defined process, and that sound scientific measures are used to assess outcomes.

Good scientific studies are often published in scientific journals, and must go through a peer review before they are published. Peer review is the analysis of research by a group of professionals with expertise in a specific scientific or medical field. Findings are not considered substantive until additional studies have been conducted to reaffirm (or refute) the findings.

In the second method of evaluation, conclusions are drawn from a limited number of patients and are often based solely on testimonials from doctors or patients. A treatment that is evaluated only in this manner is not necessarily a harmful or ineffective treatment. However, the lack of standard scientific evaluation raises questions about the effectiveness and safety of a treatment.

### **How Do I Assess Alternative Treatments?**

Alternative treatment approaches are usually publicized in books or journals that do not require independent review of the material by recognized experts in the field. Often, in fact, the advocate of a particular treatment approach publishes the work himself. Measurement techniques and statistical means of evaluation are usually not present, and “proof” of the effectiveness of the treatment often comes in the form of single case studies or descriptions of the author’s clinical experience with a large number of patients.

### **Questions to Ask Alternative Health Care Providers**

The following questions should be asked of health care providers regarding any intervention being considered. Negative or incomplete answers to these questions should be a cause for concern because it suggests the absence of adequate research on the intervention.

- Have clinical trials (scientific tests of the effectiveness and safety of a treatment using consenting human subjects) been conducted regarding your approach? Do you have information regarding the results?
- Can the public obtain information about your alternative approach from the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health? (The NCCAM supports research on complementary and alternative medicine, trains researchers, and disseminates information to increase public understanding of complementary and alternative medicine.) The office can be reached toll free at 888-644-6226 or through its Web site (<http://nccam.nih.gov>).
- Is there a national organization of practitioners? Are there state licensing and accreditation requirements for practitioners of this treatment?
- Is your alternative treatment reimbursed by health insurance?

### **Checklist for Spotting Unproven Remedies**

This list has been adapted from *Unproven Remedies*, Arthritis Foundation, 1987.

#### **1. Is it likely to work for me?** Suspect an unproven remedy if it:

- claims to work for everyone with AD/HD and other health problems. No treatment works for everyone.
- uses only case histories or testimonials as proof. It is essential that promising reports from individuals using a treatment be confirmed with systematic, controlled research.
- cites only one study as proof. One can have far more confidence in a treatment when positive results have been obtained in multiple studies.
- cites a study without a control (comparison) group. Testing a treatment without a control group is a necessary first step in investigating a new treatment, but subsequent studies with appropriate control groups are needed to clearly establish the effectiveness of the intervention.

#### **2. How safe is it?** Suspect an unproven remedy if it:

- comes without directions for proper use;
- does not list contents;
- has no information or warnings about side effects; and
- is described as harmless or natural. Remember, most medication is developed from “natural” sources, and that “natural” does not necessarily mean harmless.

#### **3. How is it promoted?** Suspect an unproven remedy if it:

- claims to be based on a secret formula;
- claims to work immediately and permanently for everyone with AD/HD;
- is described as “astonishing,” “miraculous,” or an “amazing breakthrough;”
- claims to cure AD/HD;
- is available from only one source;
- is promoted only through infomercials, self-promoting books, or by mail order; and
- claims that the particular treatment is being suppressed or unfairly attacked by the medical community.

### **Evaluating Media Reports**

Develop a healthy skepticism and be sure to watch for red flags when evaluating media reports of medical advances. When evaluating reports of health care options, consider the following questions:

**1. What is the source of the information?** Good sources of information include medical schools, government agencies (such as the National Institutes of Health and the National Institute of Mental Health), professional medical associations, and national disorder/disease-specific organizations (such as CHADD). Information from studies in reputable, peer-reviewed medical journals is more credible than popular media reports.

**2. Who is the authority?** The affiliations and relevant credentials of “experts” should be provided, though initials behind a name do not always mean that the person is an authority. Reputable medical journals now require researchers to reveal possible conflicts of interest, such as when a researcher conducting a study also owns a company marketing the treatment being studied or has any other potential conflict of interest.

**3. Who funded the research?** It may be important to also know who funded a particular research project.

**4. Is the finding preliminary or confirmed?** Unfortunately, a preliminary finding is often reported in the media as a “breakthrough” result. An “interesting preliminary finding” is a more realistic appraisal of what often appears in headlines as an “exciting new breakthrough.” You should track results over time and seek out the original source, such as a professional scientific publication, to get a fuller understanding of the research findings.

### **Tips for Negotiating the World Wide Web**

The good news is that the Internet is becoming an excellent source of medical information. The bad news is that with its low cost and global entry, the Web is also home to a great deal of unreliable health information.

In addition to the tips cited earlier, Web surfing requires special considerations:

- **Know the source.** The domain name (e.g., www.chadd.org) tells you the source of information on the Web site, and the last part of the domain name tells you about the source (e.g., .edu = university/educational, .biz/.com = company/commercial, .org = non-profit organization, .gov = government agency).
- **Obtain a “second opinion” regarding information on the Web.** Pick a key phrase or name and run it through a search engine to find other discussions of the topic or talk to your health care professional.

### **Financial Resources Required by Families**

Families need to be aware of the financial implications of any treatment. Ask the following questions to determine the financial impact of a treatment:

1. Is the treatment covered by health insurance?
2. What out-of-pocket financial obligation will the family have?
3. How long will this out-of-pocket financial obligation be?

### **Forewarned is Forearmed**

Get into the habit of actively seeking out information about AD/HD and every prescribed medication and intervention that is proposed for you or your child. If you use alternative medicines, don't forget that they, too, are drugs. To prevent harmful interactions with prescribed medications, inform your health care provider of any alternative medication used. Before actually beginning an intervention, check with your medical doctor.

## **Overview of Alternative, Complementary, and Controversial Treatments for AD/HD**

This information is provided for educational purposes only. Because not every treatment for every individual is effective, CHADD encourages additional research on all complementary interventions that demonstrate some potential.

### **Dietary Intervention**

Dietary interventions (as contrasted with dietary supplements) are based on the concept of elimination, that one or more foods are eliminated from one's diet.

The most publicized of these diet elimination approaches is the Feingold Diet.<sup>2</sup> This diet is based on the theory that many children are sensitive to dietary salicylates and artificially added colors, flavors, and preservatives, and that eliminating the offending substances from the diet could improve learning and behavioral problems, including AD/HD. Despite a few positive studies, most controlled studies do not support this hypothesis.<sup>1</sup> At least eight controlled studies since 1982, the latest being 1997, have found validity to elimination diets in only a small subset of children "with sensitivity to foods."<sup>1</sup> While the proportion of children with AD/HD who have food sensitivities has not been empirically established, experts believe that the percentage is small.<sup>1,3,4</sup> Parents who are concerned about diet sensitivity should have their children examined by a medical doctor for food allergies.

Research has also shown that the simple elimination of sugar or candy does not affect AD/HD symptoms, despite a few encouraging reports.<sup>1,5</sup>

### **Nutritional Supplements**

Nutritional supplementation is the opposite of the dietary elimination approach. While the elimination diet assumes that something is unhealthy and should be removed from the diet, supplementation is based on the assumption that something is missing in the diet in an optimal amount and should be added. Parents who are concerned about possible missing nutrients should have their children examined by a medical doctor.

While the Food and Drug Administration (FDA) regulates the sale of prescription medication, the FDA does not strictly regulate the ingredients or the manufacturer claims about dietary supplements. Go to the FDA Web site (<http://www.fda.gov>) to learn about existing regulations.

AD/HD is a brain-based disorder where the chemistry of the brain (neurotransmitters) is not functioning as it should. Nerve cell membranes are composed of phospholipids containing large amounts of polyunsaturated fatty acids (omega-3 and omega-6). Studies have been conducted to examine the impact of omega-3 and omega-6 deficiency and the possible impact of fatty acid supplementation. Further controlled studies are needed.<sup>1</sup>

Recently, organizations exclusively promoting glyconutritional supplements have come into business and are widely publicizing their products. Glyconutritional supplements contain basic saccharides necessary for cell communication and formation of glycoproteins and glycolipids. These saccharides are glucose,

galactose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, and xylose. Two small studies showed a reduction in inattention and hyperactivity symptoms after a program of glyconutritional supplements,<sup>6,7</sup> but a third study found no impact of the supplements on symptoms.<sup>1</sup>

The following conclusions regarding various supplements are based on an extensive review of the scientific literature:<sup>1</sup>

1. Treatments with supplements that “are neither proven nor found lacking in definitive controlled trials” include essential fatty acid supplementation, glyconutritional supplementation, recommended daily allowance (RDA) vitamins, single-vitamin megadosage, and herbals.
2. Megadose multivitamins (as opposed to RDA multivitamins) “have been demonstrated to be probably ineffective or possibly dangerous,” and “have not only failed to show benefit in controlled studies, but also carry a mild risk of hepatotoxicity and peripheral neuropathy.”
3. “For children with demonstrated deficiencies of any nutrient (e.g., zinc, iron, magnesium, vitamins), correction of that deficiency is the logical first-line treatment. It is not clear what proportion of children have such a nutritional deficiency.” The deficiency as a cause of AD/HD without other symptoms has not been demonstrated.
4. Amino acid supplementation does not appear to be “a promising area for further exploration.”
5. “No systematic data regarding AD/HD efficacy could be found for hypericum, Ginkgo biloba, Calmplex, Defendol, or pycnogenol.”

### **Interactive Metronome Training**

Interactive Metronome Training is a relatively new intervention for individuals with AD/HD. The Interactive Metronome (IM) is a computerized version of a simple metronome — i.e. what musicians use to “keep the beat” — and produces a rhythmic beat that individuals attempt to match with hand or foot tapping. Auditory feedback is provided, which indicates how well the individual is matching the beat. It is suggested that improvement in matching the beat over repeated sessions reflects gains in motor planning and timing skills.

The rationale behind IM training is that motor planning and timing deficits are common in children with AD/HD and are related to problems with behavioral inhibition that some experts believe are critical to understanding the disorder. In addition, these deficits are alleviated by stimulant medication treatment. Thus, it is plausible that interventions to improve motor timing and planning abilities directly, such as IM training, could also be helpful to children with AD/HD. There is no evidence that motor in-coordination is related to behavioral inhibition.

To date, there has been a single study of IM training for boys with AD/HD.<sup>8</sup> This was a well-conducted study with appropriate control groups, and the results indicated that boys who received IM training showed improvements in a wide range of areas. Thus, this intervention appears to be promising.

Additional research using IM training in individuals with AD/HD is necessary, however, before the value of this approach can be known with greater certainty.

### **Sensory Integration Training**

Sensory integration (SI) therapy, which is delivered by occupational therapists, is not a treatment for AD/HD. It is an intervention for SI dysfunction, a condition in which the brain is overloaded by too many sensory messages and cannot normally respond to the sensory messages it receives. The theory behind SI therapy is that through structured and constant movement, the brain learns to better react and integrate the

various sensory messages it is receiving.<sup>9,10</sup> SI therapy attempts to treat developmental coordination problems.<sup>11</sup>

Some pediatricians and occupational therapists acknowledge that SI dysfunction is a possible associated finding or disorder in some children with AD/HD, but it is not universally recognized and diagnostic criteria are not well established. There is practically no published clinical research on SI therapy. There is considerable anecdotal support for its value in treating SI dysfunction, particularly children with tactile hypersensitivity.<sup>12</sup>

Recent meta-analyses of SI training for various disabled children have not found it to be superior to other treatments, and several studies found that its contribution was not significant at all.<sup>13,14</sup> AD/HD was not examined in these studies. SI therapy is not a treatment for AD/HD but some children with AD/HD may have SI dysfunction.

### **Antimotion Sickness Medication**

The theory behind this approach is that there is a relationship between AD/HD and problems with the inner ear system, which plays a major role in balance and coordination.<sup>15</sup> Advocates of this approach recommend a mixed array of medications, including antimotion sickness medication, usually meclizine and cyclizine, and sometimes in combination with stimulant medications. The only controlled, blinded study that examined this treatment found the theory not valid.<sup>16</sup>

This approach is not consistent in any way with what is currently known about AD/HD, and is not supported by research findings. Anatomically and physiologically, there is no reason to believe that the inner ear system is involved in attention and impulse control other than in marginal ways.

### **Candida Yeast**

Candida is a type of yeast that lives in the human body. Normally, yeast growth is kept in check by a strong immune system and by “friendly” bacteria, but when the immune system is weakened or friendly bacteria are killed by antibiotics, candida can overgrow. Some believe that toxins produced by the yeast overgrowth weaken the immune system and make the body susceptible to AD/HD and other psychiatric disorders.<sup>17,18,19</sup> They tout the use of antifungal agents, such as nystatin, in combination with sugar restriction. There is no “systematic prospective trial data” to support this hypothesis.<sup>1</sup>

### **EEG Biofeedback**

EEG biofeedback — also referred to as neurofeedback — is an intervention for AD/HD that is based on findings that many individuals with AD/HD show low levels of arousal in frontal brain areas. The basic understanding is that the brain emits various brainwaves that are indicative of the electrical activity of the brain and that different types of brainwaves are emitted depending on whether the person is in a focused and attentive state or a drowsy/day dreaming state.

In neurofeedback treatment, individuals with AD/HD are taught to increase arousal levels in these regions so that they are more similar to those found in individuals without AD/HD. When this has been learned, it is expected that improvements in attention and reductions in hyperactive/impulsive behavior will result.

Recent research suggests that the theory underlying EEG biofeedback treatment is consistent with what is known about differences in brain activity between individuals with and without AD/HD.<sup>20,21,22</sup> This treatment has been used for over 25 years<sup>23</sup> and there are many parents who report that it has been

extremely helpful for their child. There have also been several published studies of neurofeedback treatment that have reported encouraging results.<sup>24,25,26,27</sup>

It is important to emphasize, however, that although several studies of neurofeedback have yielded promising results, this treatment has not yet been tested in the rigorous manner that is required to make a clear conclusion about its effectiveness for AD/HD.<sup>28</sup> “The aforementioned studies can not be considered to have produced persuasive scientific evidence concerning the effectiveness of EEG biofeedback for ADHD.”<sup>23</sup> Controlled randomized trials are required before conclusions can be reached.<sup>29</sup>

Until then, buyers should beware of the limitations in the published science. Parents are advised to proceed cautiously as it can be expensive — a typical course of neurofeedback treatment may require 40 or more sessions — and because other AD/HD treatments (i.e., multi-modal treatment) currently enjoy substantially greater research support. (See CHADD Fact Sheets #8 and #9.)

### **Chiropractic**

Some chiropractors believe that chiropractic medicine is an effective intervention for AD/HD.<sup>30,31,32</sup> Chiropractic is based on the belief that spinal problems are the cause of health problems and that spinal manipulations (“adjustments”) can restore and maintain health. Advocates of this approach believe that imbalance of muscle tone can cause an imbalance of brain activity, and that spinal adjustments as well as other somatosensory stimulation, such as exposure to varying frequencies of light and sound, can effectively treat AD/HD and learning disabilities.<sup>32</sup>

Other chiropractors believe that the skull is an extension of the spine and advocate a method called applied kinesiology, or Neural Organization Technique. The premise behind this approach is that learning disabilities are caused by the misalignment of two specific bones in the skull, which creates unequal pressure on different areas of the brain, leading to brain malfunction.<sup>33</sup> The bones are the phenoid bone at the base of the skull and the temporal bones on the sides of the skull. The theory says that this bone misalignment creates unequal pressure on different areas of the brain. This misalignment is also said to create “ocular lock,” an eye-movement malfunction that contributes to reading problems. The advocates argue that since eye muscles are attached to the skull, if the cranial bones are not in proper position, malfunctions in eye movement (ocular lock) occur. Treatment consists of restoring the cranial bones to the proper position through specific bodily manipulations.

These theories are not consistent with either current knowledge of the causes of learning disabilities or knowledge of human anatomy, as even standard medical textbooks state that cranial bones do not move. No research has been done to support the effectiveness of chiropractic approaches for the treatment of AD/HD.

### **Optometric Vision Training**

Advocates of this approach believe that visual problems — such as faulty eye movements, sensitivity of the eyes to certain light frequencies, and focus problems — cause reading disorders. Treatment programs vary widely, but may include eye exercises and educational and perceptual training.

There is “no systematic data on optometric training for AD/HD despite its widespread use.”<sup>1</sup> In 1972, a joint statement highly critical of this optometric approach was issued by the American Academy of Pediatrics, the then American Academy of Ophthalmology and Otolaryngology, and the American Association of Ophthalmology.

### **Thyroid Treatment**

In children with thyroid dysfunction, the thyroid status seems related to attention and hyper-active-impulsive systems.<sup>34,35</sup> Experts recommend that all children with AD/HD be screened for signs of possible thyroid dysfunction.<sup>36</sup> However, thyroid hormone syndrome appears extremely rare in AD/HD.<sup>37</sup> Thyroid function tests are not recommended unless there are other signs and symptoms to suggest thyroid dysfunction.<sup>38</sup>

## **Lead Treatment**

Hyperactivity in animals is a symptom of lead poisoning<sup>39</sup> and thus chelation therapy<sup>40</sup> is advocated as an approach to lessen lead levels in the blood. Chelation therapy should be considered for children with blood lead elevations. There is significant professional disagreement over how low the lead blood level should be.<sup>1</sup> Consultation with a medical doctor is recommended.

## **Conclusion**

Before actually using any of these interventions, families and individuals are encouraged to consult with their medical doctors. Some of these interventions are targeted to individuals with very discrete medical problems. A good medical history and a thorough physical examination should check for signs of such conditions as thyroid dysfunction, allergic history, food intolerance, dietary imbalance and deficiency, and general medical problems.

Each child and each individual is unique. While multimodal treatment is the gold standard of treatment for AD/HD, not all individuals can tolerate medications, and medications are not always effective. Some individuals experience side effects that are too great. Being an informed consumer about the published science behind an intervention and frequently communicating with your medical doctor are important factors in determining if the interventions identified in this paper should be considered.

CHADD encourages greater independent and objective research on all treatments and interventions.

## **Suggested Reading**

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*This fact sheet was updated in October 2003.*

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**For further information about AD/HD or CHADD, please contact:**

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[www.help4adhd.org](http://www.help4adhd.org)**

**Please also visit the CHADD Web site at [www.chadd.org](http://www.chadd.org).**