

Treatment Intervention Advisory Committee Review and Determination

Date: April 24, 2015

To: DHS/DLTC

From: Wisconsin Department of Health Services Autism and other Developmental Disabilities
Treatment Intervention Advisory Committee: Lana Collet-Klingenberg, Ph.D. (chairperson) ACK

RE: Determination of Auditory Integration Therapy as a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities

This is an initial review

This is a re-review. The initial review was in April 2014

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Auditory Integration Therapy (AIT) as a proven and effective treatment for children with autism spectrum disorder and/or other developmental disabilities. In subsequent sections you will find documentation of our review process including a description of the proposed treatment, a synopsis of review findings, the treatment review evidence checklist, and a listing of the literature considered. In reviewing treatments presented to us by DHS/DLTC, we implement a review process that carefully and fully considers all available information regarding a proposed treatment. Our determination is limited to a statement regarding how established a practice is in regard to quality research. We do not make funding decisions.

Description of proposed treatment

According to a position paper by the American Speech-Language-Hearing Association (ASHA), Auditory Integration Therapy (AIT) is described as follows:

"Dr. Guy Berard, an otolaryngologist in France, developed a method of AIT based on the premise that certain people have hypersensitive hearing at selected frequencies and that this can cause agitation, pain, and interference with learning. Berard has explained that even in the absence of hypersensitive hearing, people can present with audiograms that have "peaks" and "valleys," that is, thresholds for adjacent audiometric frequencies that differ by 5 dB or more and result in atypical perception of sounds. In his book, *Hearing Equals Behavior*, Berard (1993) theorizes that these auditory distortions may result in such behavioral disturbances as autism spectrum disorders, learning disabilities, depression, and aggressiveness. Berard suggests that AIT treats these distortions by exercising the middle ear muscles and auditory nervous system in much the same way that muscles are retrained in physical therapy for an injured elbow (Berard, 1993, pp. 78–80). An audiogram, frequently the first step in the Berard method of AIT, is believed to help identify the presence of the auditory "abnormalities" (Berard, 1993, pp. 61–76) and is used to monitor possible changes as a result of treatment. Berard claims that following AIT, children's audiograms that previously had peaks and valleys, demonstrating areas of hyper- and hyposensitivity, are "flattened," reflecting the elimination of auditory distortions and, subsequently, an improvement in behavioral abnormalities. The validity of defining these "peaks and valleys" as auditory abnormalities has been questioned elsewhere (Gravel, 1994; Miller & Lucker, 1997; Tharpe, 1998, 1999)."

Synopsis of review

In the case of AIT, please refer to the attached reference listing that details the reviewed research. The committee's conclusions regarding AIT include summaries of previous reviews.

This is the second review of Auditory Integration Therapy. Below is information regarding the initial review followed by the current re-review.

The initial review of Auditory Integration Training in 2014 concluded that

1. Traditionally, AIT has been conducted with a device Berard designed called the Ears Education and Retraining System (EERS). This device was banned from importation by the Food and Drug Administration (FDA) in the United States as it lacked evidence of medical benefit. No AIT device has been approved by the FDA for marketing as a medical device in the U.S. This means that a manufacturer cannot promote AIT equipment as a device that is intended for the cure, mitigation, or treatment of a disease or a condition such as autism, attention deficit disorder, or other physical or mental condition.
2. Rankovic, Rabinowitz, and Lof (1996) examined the output of the EERS and found that the average output levels at the eardrum were 110 dB when employed by a trained AIT practitioner and 118 dB at the maximum setting of the device. Of note is that children's eardrums are smaller therefore these levels are most likely an underestimate of what would be delivered to a child. The Occupational Safety and Health Administration (U.S. Department of Labor, 1983) warns that adults who are exposed to noise levels at or above 85 dBA for an 8-hour time-weighted average are at risk for noise-induced hearing loss; the acceptable exposure time decreases dramatically as the intensity of the sound increases. For example, the maximum allowable exposure levels for occupational noise are 90 dBA for 8 hours, 110 dBA for 30 minutes, and 125 dBA for less than 4 minutes (ASHA, 1991). With the program requirements for AIT this data make it clear there is potential for harm to a child's hearing.
3. Numerous professional organizations do not support AIT, many have position papers against AIT, and all have deemed AIT experimental. These include the American Academy of Pediatrics, the New York State Department of Health, the USFDA, the American Speech-Language-Hearing Association, the Educational Audiology Association, and the American Audiology Association.
4. Regarding studies reviewed, their limitations included:
 - ~ lack of control groups/placebo (majority of studies did not include)
 - ~ historical factors (3 month follow-up maximum; not clear gains at follow-up were related to AIT)
 - ~ data collection procedures (no direct dependent variables measured; primary data reported was parent collected), and
 - ~ lack of a cause and effect attributable to AIT.

During the current review, no new studies were found. There are no currently available rigorous studies supporting the effectiveness of AIT related to outcomes for individual with ASD, and there is an identified potential for harm.

In sum, it is the decision of the committee that AIT remains a Level 5 therapy (Untested/Experimental Treatment and Potentially Harmful).

Section Two: Rationale for Focus on Research Specific to Comprehensive Treatment Packages (CTP) or Models

In the professional literature, there are two classifications of interventions for individuals with Autism Spectrum Disorder (National Research Council, 2001; Odom et al., 2003; Rogers & Vismara, 2008):

- (a) Focused intervention techniques are individual practices or strategies (such as positive reinforcement) designed to produce a specific behavioral or developmental outcome, and
- (b) Comprehensive treatment models are “packages” or programs that consist of a set of practices or multiple techniques designed to achieve a broader learning or developmental impact.

To determine whether a treatment package is proven and effective, the Treatment Intervention Advisory Committee (TIAC) will adopt the following perspective as recommended by Odom et al. (2010):

The individual, focused intervention techniques that make up a comprehensive treatment model may be evidence-based. The research supporting the effectiveness of separate, individual components, however, does not constitute an evaluation of the comprehensive treatment model or “package.” The TIAC will consider and review only research that has evaluated the efficacy of implementing the comprehensive treatment as a package. Such packages are most often identifiable in the literature by a consistently used name or label.

National Research Council. (2001). *Educating children with autism*. Washington, DC: National Academy Press.

Odom, S. L., Brown, W. H., Frey, T., Karusu, N., Smith-Carter, L., & Strain, P. (2003) Evidence-based practices for young children with autism: *Evidence from single-subject research design. Focus on Autism and Other Developmental Disabilities, 18*, 176-181.

Odom, S. L., Boyd, B. A., Hall, L. J., & Hume, K. (2010). Evaluation of comprehensive treatment models for individuals with Autism Spectrum Disorders. *Journal of Autism and Developmental Disorders, 40*, 425-436.

Rogers, S., & Vismara, L. (2008). Evidence-based comprehensive treatments for early autism. *Journal of Clinical Child and Adolescent Psychology, 37*, 8-38.

Section Three: DLTC-TIAC Treatment Review Evidence Checklist

Name of Treatment: Auditory Integration Training

Level 1- Well Established or Strong Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, National Professional Development Center) have approved of or rated the treatment package as having a strong evidence base; authorities are in agreement about the level of evidence.
- There exist ample high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
 - Minimum of two group studies or five single subject studies or a combination of the two.
 - Studies were conducted across at least two independent research groups.
 - Studies were published in peer reviewed journals.
- There is a published procedures manual for the treatment, or treatment implementation is clearly defined (i.e., replicable) within the studies.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 2 – Established or Moderate Evidence (DHS 107 - Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have approved of or rated the treatment package as having at least a minimal evidence base; authorities may not be in agreement about the level of evidence.
- There exist at least two high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
 - Minimum of one group study or two single subject studies or a combination of the two.
 - Studies were conducted by someone other than the creator/provider of the treatment.
 - Studies were published in peer reviewed journals.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 3 – Emerging Evidence (DHS 107 – Promising as a Proven & Effective Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have recognized the treatment package as having an emerging evidence base; authorities may not be in agreement about the level of evidence.
- There exists at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
 - May be one group study or single subject study.
 - Study was conducted by someone other than the creator/provider of the treatment.
 - Study was published in peer reviewed journal.
- Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 4 – Insufficient Evidence (Experimental Treatment)

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There is not at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
 - Study was conducted by the creator/provider of the treatment.
 - Study was not published in a peer reviewed journal.
- Participants (i.e., N) are not clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes:

Level 5 – Untested (Experimental Treatment) &/or Potentially Harmful

- Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
- There are no published studies supporting the proposed treatment package.
- There exists evidence that the treatment package is potentially harmful.**
 - Authoritative bodies have expressed concern regarding safety/outcomes.
 - Professional bodies (i.e., organizations or certifying bodies) have created statements regarding safety/outcomes.

Notes:

- ~ United Health Care Policy: “It is unknown if the sound levels used for AIT are harmful to hearing.”
- ~ Training devices are not approved by the USFDA.
- ~ Educational Audiology Association (EAA): “In addition to not being proven effective, AIT's excessive volume levels may harm hearing.”
- ~ ASHA (2003) indicated that practitioners may be in violation of their ethics code if they use AIT.

Date: April 24, 2015

Committee Members Completing Initial Review of Research Base: Jennifer Asmus, Roger Bass

Committee Decision on Level of Evidence to Suggest the Proposed Treatment is Proven and Effective:
Level 5 - Untested (Experimental) Treatment & Potentially Harmful

References Supporting Identification of Evidence Levels:

- Chambless, D.L., Hollon, S.D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology*, 66(1), 7-18.
- Chorpita, B.F. (2003). The frontier of evidence---based practice. In A.E. Kazdin & J.R. Weisz (Eds.). *Evidence-based psychotherapies for children and adolescents* (pp. 42---59). New York: The Guilford Press.
- Odom, S. L., Collet-Klingenberg, L., Rogers, S. J., & Hatton, D. (2010). Evidence-based practices in interventions for children and youth with autism spectrum disorders. *Preventing School Failure*, 54(4), 275-282.

Section Four: Literature Review

Journal articles published since last review:

No new articles found since April 2014.

Journal articles reviewed in the initial review (2014):

Bettison, S. (1996). The long-term effects of auditory training on children with autism. *Journal of Autism and Developmental Disorders*, 26(3), 361–373.

Edelson, S. M., Arin, D., Bauman, M., Lukas, S. E., Rudy, J. H., Sholar, M., & Rimland, B. (1999). Auditory integration training: A double-blind study of behavioral and electrophysiological effects in people with autism. *Focus on Autism and Other Developmental Disabilities*, 14(2), 73–81.

Gee, B.M., Thompson, K., & St. John., H. (2014). Efficacy of a sound-based intervention with a child with an autism spectrum disorder and auditory sensory over-sensitivity. *Occupational Therapy International*, 21, 12-20.

Kershner, J. R., Cummings, R. L., Clarke, K. A., Hadfield, A. J., & Kershner, B. A. (1990). Two-year evaluation of the Tomatis listening training program with learning disabled children. *Learning Disability Quarterly*, 13, 43–53.

Mudford O., Cross B, & Breen S. (2000). Auditory integration training for children with autism: no behavioral benefits detected. *American Journal of Mental Retardation*, 105, 118-129.

Rankovic, C. M., Rabinowitz, W. M., & Lof, G. L. (1996). Maximum output intensity of the audiokinotron. *American Journal of Speech-Language Pathology*, 5(2), 68–72.

Rimland, B., & Edelson, S. M. (1994). The effects of auditory integration training on autism. *American Journal of Speech-Language Pathology*, 3(2), 16–24.

Rimland, B., & Edelson, S.M. (1995). Brief report: A pilot study of auditory integration training in autism. *Journal of Autism and Developmental Disorders*, 25(1), 61–70.

Yencer, K. A. (1998). The effects of auditory integration training for children with central auditory processing disorders. *American Journal of Audiology*, 7(2), 32–44.

Zollweg, W., Palm, D., & Vance, V. (1997). The efficacy of auditory integration training: A double blind study. *American Journal of Audiology*, 6(3), 39–47.