Treatment Intervention Advisory Committee Review and Determination

Date: 4-28-2017
To: DHS/DLTC
From: Wisconsin Department of Health Services Autism and other Developmental Disabilities Treatment Intervention Advisory Committee: Lana Collet-Klingenberg, Ph.D. (chairperson)
RE: Determination of Tomatis 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 November 2013

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Tomatis 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
The Tomatis Method is based on the work of Dr. Alfred Tomatis who developed a method of auditory stimulation, which has been proposed to lead to accelerated development of language and communication skills. Specifically, the Tomatis Method involves the presentation of musical recordings through a device that electronically modulates the acoustical signals. The device (called an “Electronic Ear”) was designed by Dr. Tomatis to attenuate low-frequency sounds while amplifying high-frequency sounds. The theory behind the Tomatis Method is that by listening to modulated auditory input, children gradually are able to focus their listening on language frequencies. Administration of the Tomatis Method requires a trained Tomatis practitioner and the use of the Electronic Ear device.

Synopsis of review
In the case of Tomatis Method, please refer to the attached reference listing that details the reviewed research. The committee’s conclusions regarding Tomatis Method include

Review summary of October 30, 2015
In the case of the Tomatis Method, please refer to the attached reference listing that details the reviewed research. The committee’s conclusions regarding the Tomatis Method include that there have not been any additional, peer-reviewed, experimental studies since the last review in 2014. The previous review found only one published, peer-reviewed, experimental study (Corbett, Shickman, & Ferrer, 2008) evaluating the Tomatis Method of auditory stimulation with children having ASD.
diagnoses. The results of this study indicate that the Tomatis Method had no effect on children’s receptive and expressive language; that is, children made similar language gains across placebo and Tomatis conditions.

In sum, it is the decision of the committee that Tomatis Therapy, based on the findings of this study as well as the lack of other well-controlled studies in peer-reviewed journals examining the efficacy of the Tomatis Method for children with ASD, it is the committee’s conclusion that the Tomatis Method has a Level 4 rating: Insufficient Evidence (Experimental Treatment).

Review summary of 4-27-2017:
One research study was located:

This study demonstrated what previous TIAC reviews have found and what those reviewing the Tomatis Literature echo: the research methodology is inadequate to make a positive case for the use of this method. As noted in the review form: the statistical procedure was nor appropriate for ordinal data, the parents' reports (by the authors' admission) was erratic and perhaps of questionable validity, a lack of baselines does not allow us to evaluate whether the children involved were improving independent of the Tomatis procedure, the Ancova data analysis procedure by design is intended to control statistically what is not controlled empirically i.e., in fact.

Several earlier works reviewed large bodies of AIT data and found that research design issues do not justify recommendations. For example, Mumford, Cross, Cullen, Reeves, Gould, and Douglas (2000) found that none of 16 children treated with AIT. Again in 2011, Sinha, Silove, Hayen, and Williams reviewed RCTs of AIT including the Tomatis method and found that "There is no evidence that auditory integration therapy or other sound therapies are effective as treatments for autism spectrum disorders."

In sum, it is the decision of the committee that the Tomatis Method remain at a level 4 - Insufficient Evidence.
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.


Section Three: DLTC-TIAC Treatment Review Evidence Checklist

Name of Treatment: Tomatis Method

**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: At this level, please specify if the treatment is reported to be potentially harmful, providing documentation

Date: April 28, 2017

Committee Members Completing Initial Review of Research Base: Roger Bass, Julie LaBerge

Committee Decision on Level of Evidence to Suggest the Proposed Treatment is Proven and Effective:
Level 4 - Insufficient Evidence (Experimental Treatment)

References Supporting Identification of Evidence Levels:


Section Four: Literature Review
From the October 30, 2015 review:

For the current review:

*Cite all literature reviewed here and note month of most recent article reviewed for future reviewers.
