

Treatment Intervention Advisory Committee Review and Determination

Date: January 29, 2016

To: DHS/DLTC

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

RE: Determination of the Brain Balance Program[®] 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 April 12, 2012

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views the Brain Balance Program[®] 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

From their website: “The Brain Balance Program[®] is the most comprehensive approach to overcoming the symptoms of ADHD, learning disabilities, processing disorders, Asperger syndrome, and a host of other related childhood learning and developmental issues. Our cutting-edge, integrated approach combines three core modalities into one program. Each child’s program includes sensory motor training and stimulation and cognitive and academic activity plans coupled with nutritional testing and easy-to-follow dietary guidelines.”

Synopsis of review

In the case of the Brain Balance Program[®], please refer to the attached reference list that details the reviewed research. The committee’s conclusions regarding Brain Balance include that there continues to be limited experimental research documenting either its use or effectiveness. In the previous reviews of this therapy, it was determined that there did not exist a sufficient evidence base to be considered a proven and effective treatment. We did not identify any additional research published at the time of this review; therefore, there continues to be insufficient evidence to consider the Brain Balance Program[®] a proven and effective treatment.

In sum, it is the decision of the committee that the Brain Balance Program[®] retain a Level 4 efficacy rating (Insufficient evidence) as no new research has been found to support the therapy since the last review.

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: Brain Balance Program®

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: January 29, 2016

Committee Members Completing Initial Review of Research Base: Jeffrey Tiger, Shannon Stuart

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:

- 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

Merillo, R. (2009). *Disconnected kids*. Perigee/Penguin: New York, New York.

Leisman, G., & Merillo, R. (no date). *Functional disconnectivities in autism*. Unpublished manuscript.

Melillo, R., & Leisman, G. (no date). *Autism spectrum disorders as a functional disconnection syndrome*. Unpublished manuscript.

Leisman, G., Melillo, R., Thum, S., Ransom, M.A., Orlando, M., Tice, C., & Carrick, F.R. (2010). The effect of hemisphere specific remediation strategies on the academic performance outcome of children with ADD/ADHD. *International Journal of Adolescent Medicine and Health*, 22 (2), 273-281.