

Treatment Intervention Advisory Committee Review and Determination

Date: June 29, 2018

To: Wisconsin Department of Health Services

From: Wisconsin Department of Health Services Treatment Intervention Advisory Committee:

Lana Collet-Klingenberg, Ph.D. (chairperson) *LCK*

RE: Determination of Brain Balance Program® as a proven and effective treatment for children and adults

- This is an initial review
 - This is a re-review. Previously reviewed (rated) on April 12, 2012 (4), January 29, 2013 (4), January 31, 2014 (4), January 30, 2015 (4), and January 2016 (4).
 - No new research located; determination from January, 2016 (4) stands (details below)
-

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. 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 the Department of Health Services, 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 treatment is with regards to quality research. The committee does not make decisions regarding funding.

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 current review (January 2016)

Committee members completing current review of research base: Jeffrey Tiger and Shannon Stuart

Please refer to the reference list ([Section Four](#)) which 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.

Committee's Determination: After reviewing the research and applying the criteria from the [Treatment Review Evidence Checklist](#), it is the decision of the committee that the Brain Balance Program ® retain an efficacy rating of Level 4 (Insufficient evidence) as no new research has been found to support the therapy since the last review.

Review history

(January 2015)

The committee's conclusions regarding Brain Balance include that there continues to be limited experimental research documenting either its use or effectiveness. Its developer was involved in all of the resources available to the committee for review. In the last review that took place in January, 2014, it was determined that there was a lack of empirical support for Brain Balance, as well as research directly related to Brain Balance as a comprehensive treatment package. It was determined that Brain Balance had insufficient evidence at that time to be considered a proven and effective treatment. While the committee did not believe it was a harmful practice, at that time, the committee considered it an experimental practice. Since there has been no new research since that time, the committee concludes that there continues to be insufficient evidence to consider Brain Balance a proven and effective treatment.

(January 2014)

Endorsed the January 2012 review

(January 2013)

Endorsed the January 2012 review

(January 2012)

In the case of Brain Balance, there is limited experimental research documenting either its use or its effectiveness. Its developer was involved in all of the resources available to the committee for review.

The committee's conclusions regarding Brain Balance:

- There are insufficient data available to draw meaningful conclusions about its efficacy.
- Four of the five references focused more on the idea that there is a need for brain balance (i.e., establishing the theory of dis-connectivity across brain hemispheres) than on the remediation of the condition.

In sum, given the general lack of empirical support for Brain Balance, as well as research directly related to Brain Balance as a comprehensive treatment package, it is our decision that Brain Balance has insufficient evidence at this time to be considered a proven and effective treatment. While we do not believe it is a harmful practice, at this time, this committee considers it an experimental practice.

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: 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: The one quasi-experimental study that was reviewed was focused on ADD/ADHD. Other materials listed ASD, Dyslexia and other neurological disorders as conditions to be treated using this method.

- There are insufficient data available to draw meaningful conclusions about its efficacy.
- Four of the five references focused more on the idea that there is a need for brain balance (i.e., establishing the theory of disconnectivity across brain hemispheres) than on the remediation of the condition.
- It is noted that R. Melillo, the developer of brain balance treatments, was involved in all of the research.

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

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

Literature reviewed for current determination:

No new references for current review

Literature reviewed for previous determinations:

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

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

Melillo, R., & Leisman, G. (2010). *Neurobehavioral disorders of childhood: An evolutionary perspective*. Springer eBooks, online service.

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