

Treatment Intervention Advisory Committee Review and Determination

Date: July 31, 2015

To: DHS/DLTC

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

RE: Determination of BrainBeat 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

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views BrainBeat 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 www.brainbeat.com, "BrainBeat improves brain timing and rhythm through real-time, millisecond feedback. By training the brain to focus solely on a target tone in frequent, intense timeframes, BrainBeat forces the neurons on both sides of the brain to talk to each other more efficiently. With practice, the areas of the brain that control functions such as attention and learning, become more synchronized like the gears of a clock. In short, the brain learns to focus on demand."

However, the specific characteristics of BrainBeat intervention are unclear. The website did say BrainBeat is based on Interactive Metronome (IM), which is an intervention used by occupational therapists and other professionals to improve rhythmicity. The website states, "The proven and often profound benefits of IM were apparent. But there was one limitation. IM was only available through healthcare professionals. Believing everyone can benefit from better focus, company leaders Matt Wukasch and Robert Ryan came together with a shared vision: to make IM available to consumers as a cognitive trainer for human performance called BrainBeat. They decided to focus their initial efforts on the developing minds of grade school kids." The website did not provide information on the extent to which it is based on IM.

Synopsis of review

In the case of BrainBeat, please refer to the attached reference listing that details the reviewed research. The committee's conclusions regarding BrainBeat include the following findings:

- The BrainBeat website provided 5 articles supporting its claim that BrainBeat has a decade of research supporting its effectiveness. However, 2 articles were not published in peer-reviewed journals. The other 3 articles focused on IM (1 of which was a theoretical piece).
- Though the BrainBeat website states that BrainBeat is based on IM, it is unclear to what degree BrainBeat adheres to IM procedures. Without knowing how similar or dissimilar BrainBeat is to IM procedures outlined in other studies, it is not possible to use IM research as a basis for support of BrainBeat. No peer-reviewed studies were found on BrainBeat specifically.
- Further, IM procedures are typically carried out by professionals (such as Occupational Therapists, Speech Therapists, or School Psychologists) for individuals who have an identified "need" for IM programming. BrainBeat can be obtained by anyone, regardless of diagnosis or confirmed areas of challenge and implemented without professional guidance.

In sum, it is the decision of the committee that BrainBeat meets criteria for a Level 5 – Untested/Experimental Treatment.

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: BrainBeat

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: July 31, 2015

Committee Members Completing Initial Review of Research Base: Tia Schultz, Amy Van Hecke

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

The following peer-reviewed journal articles were provided on www.brainbeat.com. However, all three focus on Interactive Metronome; none of them evaluate BrainBeats. Therefore, a full review of these articles was not warranted.

Koomar, J., Burpee, J. D., DeJean, V., Frick, S., Kavar, M. J., Fischer, D. M. (2001). Theoretical and clinical perspectives on the Interactive Metronome: A view from Occupational Therapy practice. *The American Journal of Occupational Therapy*, 55(2), 163-166. (theoretical/case illustration article)

Ritter, M., Colson, K. A., & Park, J. (2013). Reading intervention using Interactive Metronome in children with language and reading impairment: A preliminary investigation. *Communication Disorders Quarterly*, 34, 106-119. doi:10.1177/1525740112456422

Taub, G. E., McGrew, K. S., & Keith, T. Z. (2007). Improvements in interval time tracking and effects on reading achievement. *Psychology in the Schools*, 44(8), 849- 863. doi: 10.1002/pits.20270