

## Treatment Intervention Advisory Committee Review and Determination

**Date:** October 30, 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)

**RE:** Determination of Mendability 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 1/31/14.

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### Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Mendability 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

Mendability (the copyrighted name of the treatment package) is described by its developers as sensory enrichment therapy. The website is at: <https://www.mendability.com> and makes scientific claims but does not provide any references or links to research. The authors of the single peer reviewed article documenting its effectiveness described it as “daily exposure to multiple sensorimotor stimuli, distributed throughout the day.” Parents of the children in the study received a kit that include scented oils, a variety of textures, manipulatives, pictures of a variety of paintings and objects, music/CD player, water bowls, and Play-Doh. Parents were also given a list of other materials to provide such as a wooden plank for a walking exercise, soap and oils, a bowl, metal spoons, ice, blindfold, noise maker, picture book, cookie sheet, oven dish, mirror, ball, pill, markers and music with matching pictures. The children received stimulation with the materials in a very scripted fashion throughout the day each day (e.g., fragrance exposure four times a day as well as at night, classical music once a day, 4-7 additional sensorimotor enrichment exercises twice a day).

#### Synopsis of review

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

- The study listed below was the only research article found specific to the practice titled, “Mendability.” The authors of this research (and creators of the Mendability program) include in the article’s reference list and on the Mendability website many references to research and other publications that are not specific to the practice as defined. Many of these sources refer to rodent studies, other treatments specific to ASD, and descriptions of the types and possible causes of ASD and while perused to determine appropriateness for inclusion in this review, were deemed unacceptable so are not included here.
- Woo and Leon (2013) found that the systematic application of sensory enrichment therapy (i.e., Mendability) over a six-month period resulted in significantly greater improvement, or gains, in both Childhood Autism Rating Scale scores and Leiter-R Visualization and Reasoning scores compared to the standard care group (controlling for pre-intervention, or baseline, scores). Additionally, more parents in the intervention group than in the control group reported seeing improvement in their children over the course of the study. Study participants included 28 male children between the ages of 3 and 12 years with a diagnosis of autism. Participants were divided into two groups, one group of 15 receiving standard care (including ABA; speech, occupational, physical and/or social skill therapy, and adaptive physical education) as the control group, and the second group of 13 receiving standard care with the addition of sensory enrichment therapy. The researchers controlled for the effects of medication and other or recently introduced therapies/treatments. Children were matched for age and severity of diagnosis across both groups. Concerns regarding the rigor of this study related to validity of parent provided data as parents were part of both treatment and data reporting. Further concerns relate to the size of the group (28) and power of findings.
- Neither the National Standards Project’s 2009 report or the National Professional Development Center on Autism Spectrum Disorders initial review in 2009 found any evidence to support the use of a Sensory Integration Treatment Package. Recently the National Professional Development Center on Autism Spectrum Disorders published a follow up review, dated 2014, in which they identified two sensory-based treatments as having some support in the research literature, but still considered as insufficient evidence. These practices are Sensory Diet and Sensory Integration and Fine Motor Intervention.
- Finally, the most recent search of Ebscohost and other academic search engines revealed only two press releases; one detailing that the organization had earned The Joint Commission’s Gold Seal of Approval for Behavioral Health Care, and another that they had released a new version of their program at the 2015 Autism Society of America Conference.

These recent findings were also taken into consideration as part of this determination recommendation.

The committee’s conclusions regarding Mendability:

- There are limited data available to draw meaningful conclusions about its efficacy with only one research study (Woo & Leon, 2013).
- To date, no authoritative bodies have recognized this as having an evidence base.

- The majority of the research articles referenced by the developers of Mendability summarized research done with rats rather than with people.

In sum, it is the decision of the committee that Mendability meets criteria for Level 4, insufficient evidence (DHS 107 – 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: Craniosacral Therapy

#### 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

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Date: October 30, 2015

Committee Members Completing Initial Review of Research Base: Lana Collet-Klingenberg, Jenny Asmus

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**

Woo, C.C., & Leon, M. (2013). *Environmental enrichment as an effective treatment for autism: A randomized controlled trial*. Behavioral Neuroscience, 127(4), 487-497.