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
       Treatment Intervention Advisory Committee: Lana Collet-Klingenberg, Ph.D. (chairperson)

RE: Determination of Craniosacral Therapy 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 January 30, 2015

Section One: Overview and Determination

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

Craniosacral Therapy is a form of bodywork focused primarily on the concept of primary respiration and regulating the flow of cerebrospinal fluid by using therapeutic touch to manipulate the synarthrodial joints of the cranium. To do this, a practitioner will apply light touches to a patient’s skull, face, spine, and pelvis. John Upledger (cited below) describes it as “a gentle, hands-on method of whole-body evaluation and treatment that may have a positive impact on many systems of the body,” and that it “helps normalize the environment of the craniosacral system, a core physiological body system . . . extends from the skull, face, and mouth down to the sacrum and coccyx . . . consist of a compartment formed by the dura mater membrane, the cerebrospinal fluid contained within, the systems that regulate the fluid flow, the bones that attach to the membranes, and the joints and sutures that interconnect these bones.” He goes on to describe the procedure as “using about 5 g of pressure, roughly the weight of a nickel, the CST practitioner evaluates the system by testing for ease of motion and the rhythm of cerebrospinal fluid pusing within the membranes. Specific treatment techniques are then used to release restrictions in sutures, fasciae, membranes, and any other tissues that may influence the craniosacral system. The result is an improved internal environment that frees the central nervous system to return to its optimal levels of health and performance.”
Synopsis of review
In the case of Craniosacral Therapy, please refer to the attached reference listing that details the reviewed research. The committee’s conclusions regarding Craniosacral Therapy include the following findings:

- There are no randomized, blinded, and placebo-controlled published outcome studies.
- There is little science in any aspect of Craniosacral Therapy.
- There is no scientific support for major elements of the therapy. The only publication purporting to show diagnostic reliability with sufficient detail to permit evaluation (Upledger, 1977) is deeply flawed.
- There is no scientific evidence of effective treatment.

For this review, a 1994 article disputing the use of craniosacral motion as evidence of therapeutic effect was reviewed. The authors reported that their investigation could not relate measures of craniosacral motions to those of heart and respiratory rates and that, more importantly, the therapists involved were not able to reliably measure it. The authors concluded that as there are physical therapists trained in craniosacral therapy and currently using it, it is imperative for additional research to determine the existence of craniosacral motion, reliability in measuring it, and evidence that it is an effective tool for therapy.

In sum, it is the decision of the committee that Craniosacral Therapy continues to meet the criteria for a Level 4 treatment (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: 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

Date: January 29, 2016

Committee Members Completing Initial Review of Research Base: Lana Collet-Klingenberg, Jeffrey Tiger

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
