

Treatment Intervention Advisory Committee Review and Determination

Date: February 23, 2018

To: Wisconsin Department of Health Services

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

RE: Determination of Early Start Denver Model (ESDM) as a proven and effective treatment for children and adults

This is an initial review

This is a re-review. Previously reviewed (rated) on February 8, 2013 (2), April 2014 (2), July 2015 (2), and October 26, 2016 (2).

No new research located; determination from month, year stands (details below)

Section One: Overview and Determination

Please find below a statement of our [determination](#) as to whether or not the committee views Early Start Denver Model (ESDM) 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

The Early Start Denver Model is a comprehensive early intervention program for toddlers and pre-school-aged children, ages 12-48 months, with Autism Spectrum Disorders (ASD). ESDM was developed in 2003, by Sally Rogers and Geri Dawson, as early-age extension of the Denver Model. ESDM utilizes developmental, relationship-based, and behavioral approaches (i.e., applied behavior analysis) during play-based interactions to increase communication, imitation, sharing, joint attention, and play.

The key characteristics of ESDM include the following:

- Naturalistic applied behavioral analytic strategies
- Sensitive to normal developmental sequence
- Deep parental involvement
- Focus on interpersonal exchange and positive affect
- Shared engagement with joint activities
- Language and communication taught inside a positive, affect-based relationship

ESDM is usually provided in various natural settings such as the home or the daycare/preschool by an ESDM therapist. An ESDM therapist who is trained and certified in ESDM may be a qualified health

professional such as a psychologist, behaviorist, occupational therapist, speech and language pathologist, early intervention specialist or developmental pediatrician

Synopsis of current review (February 2018)

Committee members completing current review of research base: Tia Schultz and Jenny Asmus

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

A search of the literature from 2016-2017, yielded 11 potential articles. Ten of these articles did not meet criteria for review for the following reasons: 1 was published in Chinese, 1 was published in French, 2 assessed the cost-effectiveness of ESDM, 1 assessed the social validity of ESDM, 2 assessed a gaming platform using components of ESDM, 1 assessed a hybrid model of ESDM, and 2 were evaluations that utilized pre/post research methods. The pre/post designs did not meet criteria for review because neither included a comparison group. An additional article was published in December 2017, but could not be screened or reviewed because it was not yet available. Therefore, it is recommended that ESDM remains at a rating of Level 2-Established or Moderate Evidence.

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 ESDM remain at a rating of Level 2-Established or Moderate Evidence.

Review history (October 2016)

A literature search was conducted for years 2015 and 2016 in order to find updates on empirical evidence on the ESDM published since the last review. There has been one peer-reviewed, experimental study found since the last review of the ESDM.

One article (Estes, A., Munson, J., Rogers, S.J., Greenson, J., Winter, J., and Dawson, G., 2016) found for the current review cycle was a long-term follow-up study of 39 children with ASD who previously participated in a randomized clinical trial of ESDM. In that study, ESDM showed efficacy for immediate post-treatment results. The follow-up study assessed the same group of children 2 years following their involvement in ESDM and found that the children had maintained gains in the following areas: overall intellectual ability, adaptive behavior, symptom severity, and challenging behavior. Interestingly, while the control group and intervention group in the original study showed no differences in autism symptoms following treatment, this follow-up study demonstrated improved core autism symptoms and adaptive behavior when compared with the control group. A notable finding was that the ESDM group received fewer hours of intervention during the follow-up period, than did the control group (community intervention as usual). It should be noted that this study, like the others comprising the evidence-base for ESDM also included the Model's creator, Sally Rogers

After reviewing the research and applying the criteria from the Treatment Review Checklist, it is the decision of the committee that ESDM remain at a rating of Level 2-Established or Moderate Evidence based on lack of research conducted by those other than the Model's creators to examine the efficacy of ESDM for children with ASD.

(July 2015)

A literature search was conducted for years 2013 through 2015 in order to find updates on empirical evidence on the ESDM published since the last review. There have been two peer-reviewed experimental studies since the last review of the ESDM.

The previous review found the efficacy of ESDM was studied in a NIH-funded, randomized controlled trial (Dawson, 2010) showing that children who received ESDM therapy for 20 hours a week (15 hours by trained therapists, 5 hours by parents) over two years demonstrated improvement in cognitive skills, language skills, and adaptive behavior along with fewer autism symptoms than children referred for interventions not involving ESDM.

There have been two peer-reviewed studies since the last review of ESDM. One study (Vivanti et al, 2014) examined whether delivering ESDM in a group day care setting would be feasible and effective. In Australia, 27 preschoolers with ASD received from 15 to 25 hours of ESDM per week for a year in a group setting. Their results were compared with a similar group of children with ASD who received a combined educational and therapy program at another day care center. At the end of a year, improvement in adaptive, cognitive, and social skills were seen in both groups. Greater gains in receptive language and developmental rate were made by children in the ESDM group (Vivanti et al, 2014).

Another study (Vivanti, 2013) investigated learning profiles associated with response to the Early Start Denver Model delivered in a group setting. Preliminary results from 21 preschool children with ASD aged 2 to 5 years suggest that the children with more advanced skills in functional use of objects, goal understanding and imitation made the best developmental gains after 1 year of treatment. Cognitive abilities, social attention, intensity of the treatment and chronological age were not associated with treatment gains (Vivanti, 2013).

(April 2014)

No new research located; determination from February 2013 stands

(February 2013)

A search using terms such as ASD, Autism, Early Start Denver Model, ESDM, early intervention, and parent interventions, along with a request from Dr. Sally Rogers for additional works resulted in six articles that were subsequently reviewed. Two of the articles were reports on different aspects of the same study. Thus two of the studies were experimental group designs, two were experimental single-subject designs, and one was a non-experimental case study. Participant ages ranged from 18 to 65 months across the studies with the majority of participants being Caucasian. Outcomes assessed included: IQ, Language/Communication, Adaptive Behavior, Social Behavior, EEG Activity, Diagnoses, Attention, Imitation and Play. In all of the studies, training parents to utilize procedures was a big component, as well as assessing parent fidelity of implementation. In the two group studies, participants were randomly assigned to one of two treatment groups. Outcomes were compared between groups and also to typical peers (via normed assessments, e.g., ADOS). In those two studies all participants showed gains, but those in the ESDM group generally showed greater improvement (though not in all cases). Results were varied, but often showed statistical as well as clinical significance.

In sum, in the case of ESDM, there exists some well-designed research with a mix of both group and single subject design experimental studies. However, to date, all of the research has been conducted within research groups of which the practice's creators, Dr. Sally Rogers & Dr. Geraldine Dawson, have been a part. The ESDM has only been verified with very young populations (ages 10 – 36 months) having ASD diagnoses. It is notable that this comprehensive treatment package has been well documented with a treatment manual, training conditions, and assessment of fidelity in all related studies. Finally, it is noted that parent training and intervention are an important part of this practice. It is the committee's conclusion that ESDM has achieved a Level two rating: Established or Moderate Evidence (DHS 7 – Proven & Effective 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: TIAC Treatment Review Evidence Checklist

Name of Treatment: **ESDM**

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:

- Participants ranged from 10 – 65 months (18-60 months for recent literature review) with diagnoses on the ASD spectrum
- Dependent variables included IQ, Language/Communication, Adaptive Behavior, EEG Activity, Social Behavior, Change in Diagnosis, Attention, Imitation, Play.
- Studies include three group studies, two single subject studies, and one case study. One of the group studies, Rogers, Estes, et al. (2012) had questionable results. This model has a parent implementation component, which is notable, as it increases the likelihood of follow through in the home setting.

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

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:

Dawson, G., Rogers, S.J., Munson, J., Smith, M., Winter, J., Greenson, J., Donaldson, A., & Varley, J. (2010). Randomized, controlled trial of an intervention for toddlers with autism: The Early Start Denver Model. *Pediatrics*, 125, e17-e23

Dawson, G., Jones, E.J.H., Merkle, K., Venema, K., Lowy, R., Faja, S., Kamara, D., Murias, M., Greenson, J., Winter, J., Smith, M., Rogers, S.J., & Webb, S.J. (in press). Early behavioral intervention is associated with normalized brain activity in young children with autism. *Journal of the American Academy of Child & Adolescent Psychiatry*.

Dawson, G., Rogers, S.J., Munson, J., Smith, M., Winter, J., Greenson, J., Donaldson, A., Varley, J. (2010). Randomized, controlled trial of an intervention for toddlers with autism: The early start Denver model. *Pediatrics* 125(1), p. e16-e23.

Estes, A., Munson, J., Rogers, S.J., Greenson, J., Winter, J., and Dawson, G. (2016). Long-term outcomes of early intervention in 6-year-old children with autism spectrum disorder. *Journal of the American Academy of Child & Adolescent Psychiatry*, 54(7), 580-587.

Rogers, S.J., Estes, A., Lord, C., Vismara, L., Winter, J., Fitzpatrick, A., Guo, M., & Dawson, G. (2012). Effects of a brief early start Denver model (ESDM)-based parent intervention on toddlers at risk for autism spectrum disorders: A randomized controlled trial. *Journal of the American Academy of Child & Adolescent Psychiatry*, 51(10), p. 1052-1065.

Rogers, S., Hayden, D., Hepburn, S., Charlifue-Smith, R., Hall, T., Hayes, A. (2006). Teaching young nonverbal children with autism useful speech: A pilot study of the denver model and PROMPT interventions. *Journal of Autism & Developmental Disorders* 36(8), p. 1007-1024.

Vismara L., Colombi C., Rogers S. (2009). Can one hour per week of therapy lead to lasting changes in young children with autism? *The National Autistic Society* 13(1), p. 93-115.

Vismara, L., Rogers, S. (2008). The early start Denver Model: A case study of an innovative practice. *Journal of Early Intervention* 31(1), p. 91-108.

Vismara, L.A., Young, G.S., & Rogers, S.J. (2011). Community dissemination of the Early Start Denver Model: Implications for science and practice. *Topics in Early Childhood Special Education*. doi: 10.1177/02711214114092

Vivanti G, Dissanayake C, Zierhut C, Rogers SJ, Victorian ASELCC Team.(2013). Brief report: predictors of outcomes in the Early Start Denver Model delivered in a group setting. *Journal of Autism and Developmental Disorders*, 43(7):1717–24.

Vivanti, G., Paynter, J., Duncan, E., Fothergill, H., Dissanayake, C., Roger, S.J, & the Victorian ASELCC Team.(2014). Effectiveness and Feasibility of the Early Start Denver Model Implemented in a Group-Based Community Childcare Setting. *Journal of Autism and Developmental Disorders*. DOI: 10.1007/s10803-014-2168-9