

## Treatment Intervention Advisory Committee Review and Determination

**Date:** January 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) 107

**RE:** Determination of the PLAY Project 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 August 17, 2012

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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 the PLAY Project 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

From the PLAY Project website ([www.playproject.org/about](http://www.playproject.org/about)): the "PLAY Project is an evidenced-based parent-mediated autism intervention model that can be learned and delivered by experts in child development. PLAY Project offers a certification training and supervision combination that prepares trainees to deliver the intervention with fidelity (in accordance with the research)... Richard Solomon, M.D., a developmental and behavioral pediatrician, developed this program in response to the lack of availability of intensive early intervention services for children with ASD. He designed the PLAY Project early intervention program as a cost effective, practical approach. PLAY has been implemented as a primary intervention for ASD in early intervention settings and often supplements existing services (e.g. special education, language and occupational therapies, and/or ABA/behavioral interventions)... The principles, methods and techniques of the PLAY Project emphasize the child's readiness or following the child's lead as a means for improving social impairment, a core deficit of autism spectrum disorder. Professionals coach parents to build a joyous, engaged relationship with their child with autism spectrum disorder... The PLAY Project's mission is to train a global network of pediatric professionals to deliver an evidence-based, low-cost, intensive developmental intervention to families of young children with autism spectrum disorders."

The intervention is based on Greenspan's Functional Developmental Levels and emphasizes quality of social reciprocity, specifically length of joint engagement, initiations, and reciprocal social exchanges.

Parents are trained by certified consultants, and parents are asked to play with their child and use the techniques taught for at least 2 hours per day.

### Synopsis of review

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

Since the last review in July 2014, one additional peer-reviewed, published study was found and reviewed (Solomon et al., 2014). Additionally, there is one other experimental, group study on the PLAY Project (Solomon et al., 2007). Both studies were done by the PLAY Project developers. The 2007 study did not include any control group, and thus it is unclear whether changes attributed to the PLAY Project were actually due to the treatment or were due to general development. The 2014 study, in contrast, was a very high quality randomized controlled study done over multiple sites, with a large number of children, with high fidelity and reliability of measures. The 2014 study showed significant improvements in both parent and child social behaviors, and in parent depression, vs. a community control group. Additionally, children in the PLAY Project group were 2.39 times more likely to move up an ADOS diagnostic category, over one year, than the control group, a significant difference. It is particularly important that the 2014 study showed gains in social-emotional domains, which are areas that are exceedingly relevant for very young children. This 2014 study, overall, is an important contribution in regards to the PLAY Project as a complementary treatment for ASD.

However, the standards given here require that, to be classified as a Level 3 or higher treatment, the study must be high quality: defined as being conducted by someone other than the developer of the treatment, and as being recognized by other authoritative bodies as being an effective treatment for ASD. The peer-reviewed PLAY Project studies (2007 and 2014) were both done by the PLAY Project developer. Also, although the National Professional Development Center lists Parent-Implemented Intervention (PII) as an Evidence-Based Practice, the PLAY Project is not listed as one of the packages providing evidence for PII (see EBP fact sheet [HERE](#)). The PLAY Project is also not listed by the National Standards Project as an EBP, or on the American Speech and Hearing Association (ASHA) ASD treatments site as an EBP. Therefore, the PLAY Project has yet to attain recognition by other authoritative bodies as an Evidence-Based Practice for ASD.

In sum, it is the decision of the committee that the PLAY Project has insufficient evidence of effectiveness, and should remain as considered: Level 4- Insufficient Evidence (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: The PLAY Project

#### 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: January 30, 2015

Committee Members Completing Initial Review of Research Base: Roger Bass, PhD, Amy Vaughan Van Hecke, PhD

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

The PLAY Project (2011). Scientific Evidence for Intensive Developmental Interventions (IDI). Unpublished reference list.

The PLAY Project (2011) Randomized controlled trial of the P.L.A.Y. Project intervention model for autism: Abstract (no date), Unpublished grant proposal abstract.

Solomon, R., Necheles, J., Ferch, C., & Bruckman, D. (2007). Pilot study of a treatment program for young children with autism: The P.L.A.Y. project home consultation program. *Autism, 11*(3), 205-224.

Solomon, R. (2008). Play based intervention for very young children with autism: The PLAY Project. In *Play Therapy for Very Young Kids* (Eds. Kelly-Zion, S., Schaefer, C., McCormick, J., & Ohnoqi, A.). Maryland: Jason Aronson

Solomon, R. (2008). Play therapy for very young children: The PLAY project. In *Play Therapy for Very Young Children* (Ed. Charles Schaefer). Rowman and Littlefield.

Solomon, R. (2012). The PLAY project: A train-the-trainer model for young children with autism. In *Play Based Interventions for Children and Adolescents with Autism Spectrum Disorders* (Eds. Loretta Gallo- Lopez and Larry Rubin). Routledge Press.

Solomon, R., Van Egeren, L., Mahoney, G., Quon-Huber, M., & Zimmerman, P. (2014). PLAY Project home consultation intervention program for young children with Autism Spectrum Disorders: A Randomized controlled trial. *Journal of Developmental and Behavioral Pediatrics, 35*(8): 475-485. Reviewed January 9, 2015.

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Article Reference:	Solomon, R., Van Egeren, L., Mahoney, G., Quon-Huber, M., & Zimmerman, P. (2014). PLAY Project home consultation intervention program for young children with Autism Spectrum Disorders: A Randomized controlled trial. <i>J Dev Beh Pediatr</i> , 35(8): 475-485
IV Description	Parent-training, community-based intervention. Certified and trained PLAY consultants coached parents via in-person, videotape, and written feedback once monthly for 3 hours, for 1 yr. Pre-post design. Randomized into either PLAY group or Community Services comparison group (CS: Treatment as usual, included speech, OT, and special education). All children were not receiving more than 2 hrs/wk of any other intensive interventions during the study, but nearly all were enrolled in preschool.
DV	Parent-child interactions (Maternal and Child Behavior Rating Scales: MBRS, CBRS; Functional Emotional Assessment Scale: FEAS), language and development (MCDI and Mullen), ASD diagnosis/symptoms (ADOS and SCQ), parent stress and depression (PSI, CES-D).
# in study	128 children from 5 disability services agencies (Easter Seals) in 4 states, randomized in 2, 1-yr cohorts
Age ranges	2 y 8 mo – 5 yr 11 mo
Diagnoses	DSM-IV autism, PDD-NOS, community prior diagnosis; meet criteria for ASD or Autism on the ADOS and SCQ (examiners were blinded to group)
Study Results	The PLAY group alone was more likely to improve on ADOS classification- 2.39 times more likely than CS controls to move up a category into “less severe” autism. Significant time/group interactions on MBRS (Responsiveness/Child Oriented and Affect/Animation scales) indicated improvements in parents’ interaction behaviors, CBRS (Attention and Initiation) improvements in PLAY group indicating improvements in child social behavior, and FEAS, with PLAY showing more improvement in Greenspan’s developmental levels of social-emotional reciprocity: all of these showing good improvements in parent and child social behavior. PLAY parents were also less likely to be classified as depressed over time and did not differ in stress levels to CS parents. PLAY Consultants at the Easter Seals sites had high fidelity with the developers.
Reviewer Comments	Study done by intervention developer. Gains were shown in social-emotional/relational domains in both parents and children. This is important because these are the areas other accepted interventions (e.g., ABA) do not do well at. Overall: this is a <b>high quality and important study</b> , and merits a closer look at PLAY as complementary to other approaches, especially as regards social-emotional areas in very young children.

## Group Design EBP Inclusion Criteria Checklist

Instructions: Read each item and check the appropriate box. If you check “NO” at any time, the article can be discarded as it will not be included as evidence for a practice.

Item	YES	NO	Rationale
Does the study have experimental and control/comparative groups?	x		
Were appropriate procedures used to increase the likelihood that relevant characteristic of	x		
Was their evidence for adequate reliability for the key outcome measures? And/or when relevant, was inter-observer reliability assessed and reported to be at an acceptable level?	x		One scale on the MBRS (parent-child interaction coding scale) had low alpha reliability (Achievement Orientation- .22 at pretest and .58 at post), but all other scales, questionnaires, and measures had acceptable validity, test-retest and inter-rater reliability. 2 of the inter-rater values for the MBRS were in the .60's range.
Were outcomes for capturing the intervention's effect measured at appropriate times	x		
Was the intervention described and specified clearly enough that critical aspects could be	x		
Was the control/comparison condition(s) described?	x		
Were data analysis techniques appropriately linked to key research questions and	x		
Was attrition NOT a significant threat to internal validity?	x		
Does the research report statistically significant effects of the practice for individuals with ASD for at least one outcome variable?	x		PLAY group more likely to improve on ADOS classification- 2.39 times more likely than CS; significant time/group interactions on MBRS (Responsiveness/Child Oriented and Affect/Animation scales), CBRS (Attention and Initiation), and FEAS, with PLAY showing more improvement; PLAY parents less likely to be classified as depressed over time
Were the measures of effect attributed to the intervention? (no obvious unaccounted confounding factors)	x		Although the CS group had other treatments (speech), these did not exceed 2 hrs/week plus community special education/preschool/kindergarten, and the PLAY group received these services as well. Because both groups received these services, but only the PLAY group received PLAY, any differences in the PLAY group's outcomes could be attributed to PLAY participation.