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A Multisite Randomized Controlled Two-Phase Trial of the Early Start Denver Model Compared to Treatment as Usual

Objective: This single-blind, randomized, multisite, intent-to-treat study was designed to replicate and extend Dawson et al.'s (Pediatrics. 2010;125: e17-e23) randomized controlled trial testing the effects of the Early Start Denver Model (ESDM), an intensive play- and routines-based intervention delivered in natural settings.

Method: A randomized controlled trial was conducted at 3 universities. One hundred eighteen children 14 to 24 months old with autism spectrum disorder were enrolled and randomly assigned to ESDM or community interventions for 27 months. Eighty-one children completed the full treatment course and all assessments; data from all 118 children were used in analyses. Children assigned to the ESDM intervention received 3 months of weekly parent coaching followed by 24 months of 15 hour per week (on average) 1:1 treatment weekly on average in homes or daycare settings from supervised therapy assistants while parents received coaching 4 hours monthly from a certified ESDM therapist.

Results: For the primary analyses, there were time-by-group and time-by-group-by-site interactions for language outcome. In the significant 3-way interaction involving site, 2 sites showed a significant ESDM advantage and the third site showed no significant group differences. In the planned 2-way analysis that pooled data across all 3 sites, there was a significant advantage found for the ESDM group. For the secondary analyses, there were no significant differences between the ESDM and community groups involving developmental quotient, autism severity, or adaptive behavior. The treatment effect of group on language outcomes was not moderated by baseline developmental quotient, autism severity, or language.

Conclusion: Results of the primary analysis provide a partial replication of Dawson et al.'s 2010 language findings.

Clinical trial registration information: Intensive Intervention for Toddlers with Autism; [https://clinicaltrials.gov/; NCT00698997](https://clinicaltrials.gov/;NCT00698997). **Key words:** autism spectrum disorder, early intervention, toddlers, Early Start Denver Model (ESDM), developmental quotient (DQ) *J Am Acad Child Adolesc Psychiatry* 2019;58(9):853–865.