

Dawson G., Rogers S., Munson J., Smith M., Winter J., Greenson J., Donaldson A., and Varley J.

**Randomized, Controlled Trial of an Intervention for Toddlers With Autism: The Early Start Denver Model**

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**Abstract:** Objective: To conduct a randomized, controlled trial to evaluate the efficacy of the Early Start Denver Model (ESDM), a comprehensive developmental behavioral intervention, for improving outcomes of toddlers diagnosed with autism spectrum disorder (ASD). Methods: Forty-eight children diagnosed with ASD between 18 and 30 months of age were randomly assigned to 1 of 2 groups: (1) ESDM intervention, which is based on developmental and applied behavioral analytic principles and delivered by trained therapists and parents for 2 years; or (2) referral to community providers for intervention commonly available in the community. Results: Compared with children who received community-intervention, children who received ESDM showed significant improvements in IQ, adaptive behavior, and autism diagnosis. Two years after entering intervention, the ESDM group on average improved 17.6 standard score points (1 SD: 15 points) compared with 7.0 points in the comparison group relative to baseline scores. The ESDM group maintained its rate of growth in adaptive behavior compared with a normative sample of typically developing children. In contrast, over the 2-year span, the comparison group showed greater delays in adaptive behavior. Children who received ESDM also were more likely to experience a change in diagnosis from autism to pervasive developmental disorder, not otherwise specified, than the comparison group. Conclusions: This is the first randomized, controlled trial to demonstrate the efficacy of a comprehensive developmental behavioral intervention for toddlers with ASD for improving cognitive and adaptive behavior and reducing severity of ASD diagnosis. Results of this study underscore the importance of early detection of and intervention in autism. *Pediatrics* 2010;125:e17–e23.