

Effect of Family Navigation on Diagnostic Ascertainment Among Children at Risk for Autism: A Randomized Clinical Trial From DBPNet

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IMPORTANCE: Early identification of autism spectrum disorder (ASD) is associated with improved cognitive and behavioral outcomes. Targeted strategies are needed to support equitable access to diagnostic services to ensure that children from low-income and racial/ethnic minority families receive the benefits of early ASD identification and treatment. **OBJECTIVE:** To test the efficacy of family navigation (FN), an individually tailored, culturally informed care management strategy, to increase the likelihood of achieving diagnostic ascertainment among young children at risk for ASD. **DESIGN, SETTING, AND PARTICIPANTS:** This randomized clinical trial of 249 families of children aged 15 to 27 months who had positive screening results for possible ASD was conducted in 11 urban primary care sites in 3 cities. Data collection occurred from February 24, 2015, through November 5, 2018. Statistical analysis was performed on an intent-to-treat basis from November 5, 2018, to July 27, 2020. **INTERVENTIONS:** Families were randomized to FN or conventional care management (CCM). Families receiving FN were assigned a navigator who conducted community-based outreach to families to address structural barriers to care and support engagement in recommended services. Families receiving CCM were assigned to a care manager, who did limited telephone outreach. Families received FN or CCM after positive initial screening results and for 100 days after diagnostic ascertainment. **MAIN OUTCOMES AND MEASURES:** The primary outcome, diagnostic ascertainment, was measured as the number of days from randomization to completion of the child's clinical developmental evaluation, when a diagnosis of ASD or other developmental disorder was determined. **RESULTS:** Among 250 families randomized, 249 were included in the primary analysis (174 boys [69.9%]; mean [SD] age, 22.0 [3.5] months; 205 [82.3%] publicly insured; 233 [93.6%] non-White). Children who received FN had a greater likelihood of reaching diagnostic ascertainment over the course of 1 year (FN, 108 of 126 [85.7%]; CCM, 94 of 123 [76.4%]; unadjusted hazard ratio [HR], 1.39 [95% CI, 1.05-1.84]). Site (Boston, New Haven, and Philadelphia) and ethnicity (Hispanic vs non-Hispanic) moderated the effect of FN (treatment × site interaction; $P = .03$; Boston: HR, 2.07 [95% CI, 1.31-3.26]; New Haven: HR, 1.91 [95% CI, 0.94-3.89]; and Philadelphia: HR, 0.91 [95% CI, 0.60-1.37]) (treatment × ethnicity interaction; $P < .001$; Hispanic families: HR, 2.81 [95% CI, 2.23-3.54] vs non-Hispanic families: HR, 1.49 [95% CI, 1.45-1.53]). The magnitude of FN's effect was significantly greater among Hispanic families than among non-Hispanic families (diagnostic ascertainment among Hispanic families: FN, 90.9% [30 of 33], and CCM, 53.3% [16 of 30]; vs non-Hispanic families: FN, 89.7% [35 of 39], and CCM, 77.5% [31 of 40]). **CONCLUSIONS AND RELEVANCE:** Family navigation improved the likelihood of diagnostic ascertainment among children from racial/ethnic minority, low-income families who were detected as at risk for ASD in primary care. Results suggest differential effects of FN by site and ethnicity.

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