

A 1.5-Year Follow-Up of Parent Training and Atomoxetine for Attention-Deficit/Hyperactivity Disorder Symptoms and Noncompliant/Disruptive Behavior in Autism.

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Abstract

OBJECTIVE:

To examine status of children with autism spectrum disorder (ASD) 10 months after a 34-week clinical trial of atomoxetine (ATX) and parent training (PT).

METHODS:

In a 2×2 design, 128 children with ASD and attention-deficit/hyperactivity disorder (ADHD) were randomly assigned ATX, PT+placebo, PT+ATX, or placebo alone. PT was weekly for 10 weeks, and then monthly. ATX/placebo was titrated over 6 weeks [≤ 1.8 mg/kg/d], and then maintained until week 10. Responders continued to week 34 or nonresponse. Placebo nonresponders had a 10-week ATX open trial; ATX nonresponders were treated clinically. All continued to week 34. With no further treatment from the study, all were invited to follow-up (FU) at 1.5 years postbaseline; 94 (73%) participated. Changes from Week 34 to FU and from baseline to FU were tested by one-way analysis of variance or chi-squared test. PT versus no PT was tested by chi-squared test, Fisher's exact test, Welch's t-test, Student's t-test, and Mann-Whitney's U test.

RESULTS:

For the whole sample, the primary outcomes (parent-rated ADHD on the Swanson, Nolan, and Pelham [SNAP] scale and noncompliance on the Home Situations Questionnaire [HSQ]) deteriorated mildly from week 34 to FU, but were still substantially better than baseline (SNAP: $t = 12.177$, $df = 93$, $p < 0.001$; HSQ: $t = 8.999$, $df = 93$, $p < 0.001$). On the SNAP, 61% improved $\geq 30\%$ from baseline (67% did at week 34); on noncompliance, 56% improved $\geq 30\%$ from baseline (77% did at week 34). Outcomes with PT were not significantly better than without PT (SNAP $p = 0.30$; HSQ $p = 0.27$). Originally assigned treatment groups did not differ significantly. Only 34% still took ATX; 27% were taking stimulants; and 25% took no medication.

CONCLUSIONS:

The majority retained their 34-week end-of-study improvement 10 months later, even though most participants stopped ATX. For some children, ATX continuation may not be necessary for continued benefit or other drugs may be necessary. Cautious individual clinical experimentation may be justified. Twelve sessions of PT made little long-term difference. ClinicalTrials.gov Identifier: Atomoxetine, Placebo and Parent Management Training in Autism (Strattera) (NCT00844753).