Abstract

OBJECTIVE: To evaluate the effectiveness of guanfacine extended-release (GXR) versus placebo as adjunct therapy to usual care stimulant therapy in improving executive function in children aged 6 to 12 years diagnosed with ADHD.

METHOD: In this single center, double-blind placebo-controlled crossover trial, subjects continued to take their psychostimulant and were randomly assigned at baseline to receive active treatment or placebo first. Efficacy measures included Behavioural Rating Inventory of Executive Function (BRIEF-P), ADHD Rating Scale IV (ADHD-RS IV), and Clinical Global Impressions of Severity of Illness (CGI-S) and Improvement (CGI-I) scales. Safety measures included adverse events and vital signs.

RESULTS: Significant benefits of GXR plus psychostimulant were observed on BRIEF-P (p value = .0392), ADHD-RS-IV (p < .0001), CGI-S (p = .0007), and CGI-I (p = .003). There were no serious adverse events and no new safety signals.

CONCLUSION: Use of GXR as adjunctive therapy to stimulant therapy significantly improves executive function in children with ADHD.