

Research article

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## Hyperbaric treatment for children with autism: a multicenter, randomized, double-blind, controlled trial

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### Abstract

**Background:** Several uncontrolled studies of hyperbaric treatment in children with autism have reported clinical improvements; however, this treatment has not been evaluated to date with a controlled study. We performed a multicenter, randomized, double-blind, controlled trial to assess the efficacy of hyperbaric treatment in children with autism.

**Methods:** 62 children with autism recruited from 6 centers, ages 2–7 years (mean  $4.92 \pm 1.21$ ), were randomly assigned to 40 hourly treatments of either hyperbaric treatment at 1.3 atmosphere (atm) and 24% oxygen ("treatment group",  $n = 33$ ) or slightly pressurized room air at 1.03 atm and 21% oxygen ("control group",  $n = 29$ ). Outcome measures included Clinical Global Impression (CGI) scale, Aberrant Behavior Checklist (ABC), and Autism Treatment Evaluation Checklist (ATEC).

**Results:** After 40 sessions, mean physician CGI scores significantly improved in the treatment group compared to controls in overall functioning ( $p = 0.0008$ ), receptive language ( $p < 0.0001$ ), social interaction ( $p = 0.0473$ ), and eye contact ( $p = 0.0102$ ); 9/30 children (30%) in the treatment group were rated as "very much improved" or "much improved" compared to 2/26 (8%) of controls ( $p = 0.0471$ ); 24/30 (80%) in the treatment group improved compared to 10/26 (38%) of controls ( $p = 0.0024$ ). Mean parental CGI scores significantly improved in the treatment group compared to controls in overall functioning ( $p = 0.0336$ ), receptive language ( $p = 0.0168$ ), and eye contact ( $p = 0.0322$ ). On the ABC, significant improvements were observed in the treatment group in total score, irritability, stereotypy, hyperactivity, and speech ( $p < 0.03$  for each), but not in the control group. In the treatment group compared to the control group, mean changes on the ABC total score and subscales were similar except a greater number of children improved in irritability ( $p = 0.0311$ ). On the ATEC, sensory/cognitive awareness significantly improved ( $p = 0.0367$ ) in the treatment group compared to the control group. Post-hoc analysis indicated that children over age