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The effect of phosphatidylserine containing Omega3 fatty-acids on attention-deficit hyperactivity disorder symptoms in children: a double-blind placebo-controlled trial, followed by an open-label extension.

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Source

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Abstract

OBJECTIVE:

To study the efficacy and safety of phosphatidylserine (PS) containing Omega3 long-chain polyunsaturated fatty acids attached to its backbone (PS-Omega3) in reducing attention-deficit/hyperactivity disorder (ADHD) symptoms in children.

METHOD:

A 15-week, double-blind, placebo-controlled phase followed by an open-label extension of additional 15 weeks. Two hundred ADHD children were randomized to receive either PS-Omega3 or placebo, out of them, 150 children continued into the extension. Efficacy was assessed using Conners' parent and teacher rating scales (CRS-P,T), Strengths and Difficulties Questionnaire (SDQ), and Child Health Questionnaire (CHQ). Safety evaluation included adverse events monitoring.

RESULTS:

The key finding of the double-blind phase was the significant reduction in the Global:Restless/impulsive subscale of CRS-P and the significant improvement in Parent impact-emotional (PE) subscale of the CHQ, both in the PS-Omega3 group. Exploratory subgroup analysis of children with a more pronounced hyperactive/impulsive behavior, as well as mood and behavior-dysregulation, revealed a significant reduction in the ADHD-Index and hyperactive components. Data from the open-label extension indicated sustained efficacy for children who continued to receive PS-Omega3. Children that switched to PS-Omega3 treatment from placebo showed a significant reduction in subscales scores of both CRS-P and the CRS-T, as compare to baseline scores. The treatment was well tolerated.

CONCLUSIONS:

The results of this 30-week study suggest that PS-Omega3 may reduce ADHD symptoms in children. Preliminary analysis suggests that this treatment may be especially effective in a subgroup of hyperactive-impulsive, emotionally and behaviorally-dysregulated ADHD children.

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