- Format: Abstract

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An open-label pilot study of a formulation containing the anti-inflammatory flavonoid luteolin and its effects on behavior in children with autism spectrum disorders.

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Abstract

BACKGROUND:
Accumulating evidence suggests an association between autism spectrum disorders (ASD) and inflammation in brain regions related to cognitive function. The natural flavonoid luteolin has antioxidant, anti-inflammatory, mast cell-blocking, and neuroprotective effects. It was shown to improve cognitive performance in a mouse model of ASD, but its effect in humans has not been adequately studied.

OBJECTIVES:
The goal of this study was to assess the effectiveness and tolerability in white children with ASD of a dietary supplement containing 2 flavonoids (>95% pure), luteolin (100 mg/capsule, from chamomile) and quercetin (70 mg/capsule), and the quercetin glycoside rutin (30 mg/capsule) from the Sophora japonica leaf, formulated in olive kernel oil to increase oral absorption.

METHODS:
Fifty children (4-10 years old; 42 boys and 8 girls) with ASD were enrolled in a 26-week, prospective, open-label trial at the 2nd University Department of Psychiatry at "Attikon" General Hospital, Athens, Greece. Children were referred for the study by their respective physicians or came from the practice of the senior author. ASD diagnosis by clinical assessment was based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, symptom list and corroborated by using the Autism Diagnostic Observation Schedule. The dose of the study formulation used was 1 capsule per 10 kg weight per day with food. The primary outcome measures were the age-equivalent scores in the Vineland Adaptive Behavior Scales domains. Secondary outcomes included the Aberrant Behavior Checklist, the Autism Treatment Evaluation Checklist, and the Clinical Global Impression-Improvement score. Data were measured at baseline, week 18, and week 26. Parents were interviewed for any possible improvements they noticed and instructed to report any unusual adverse events.

RESULTS:
A total of 40 children completed the protocol. There was a significant improvement in adaptive functioning as measured by using the VABS age-equivalent scores (8.43 months in the communication domain, 7.17 months in daily living skills, and 8 months in the social domain; $P < 0.005$), as well as in overall behavior as indicated by the reduction (26.6%-34.8%) in Aberrant Behavior Checklist subscale scores. Age, sex, and history of allergies had no effect on the results, whereas the initial level of functioning or difficulty did predict the final outcome in most of the measures used. There was a transient (1-8 weeks) increased irritability in 27 of the 50 participants.

CONCLUSIONS:
These results are encouraging in that the combination of the flavonoids luteolin and quercetin seemed to be effective in reducing ASD symptoms, with no major adverse effects. ClinicalTrials.gov identifier: NCT01847521.

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