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A double-blind randomized placebo-controlled trial on 4 to 6-year-olds with attention-deficit/hyperactivity disorder: probiotics as adjuvant therapy to Ritalin

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Child Psychiatrist

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No conflict of interest

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Abstract Text

Objectives

Stimulants are the standard of care for ADHD, however possible side-effects have prompted many to seek alternate treatments; probiotics are among the most promising candidates. This study evaluated the efficacy and safety of probiotics+ Ritalin compared to placebo+ Ritalin on ADHD symptoms in preschoolers.

Methods

Forty 4-6 year-olds with ADHD were recruited among the referrals to a child psychiatric outpatient clinic. The Diagnostic Infant and Preschool Assessment was used to confirm the diagnosis and evaluate the co morbid disorders. The participants were randomly assigned to either control (Ritalin + placebo) or investigation (Ritalin + probiotic) group. The severity of symptoms was assessed using the Conner's Parent Rating Scale and the Clinical Global Impression- Severity Scale at baseline, week 4 and week 8. Medications' adverse effects were checked after 4- and 8- week intervals.

Results

There were not any significant differences between the two groups at pre- treatment based on the gender, age, intellectual ability, and severity of the ADHD symptoms. In both groups, the ADHD indices decreased significantly from week 0 to week 8, however comparing data for different time-points among both groups revealed no significant differences. The adverse effects of the two regimens were not significantly different, however, the investigation group showed less decreased appetite.

Conclusions

The probiotics were safe and well-tolerated in preschoolers. Although the findings of this study did not support their efficacy on ADHD improvement, probiotics may be used to increase the appetite in children receiving the stimulants. Further studies with larger sample sizes and longer follow-ups are suggested.