

Probiotic Compared with Standard Milk for High-caries Children: A Cluster Randomized Trial

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Abstract

The aim of this study was to compare milk supplemented with probiotic lactobacilli with standard milk for the increment of caries in preschool children after 10 mo of intervention. The study was a triple-blind, placebo-controlled randomized trial. Participants were children aged 2 and 3 y ($n = 261$) attending 16 nursery schools in a metropolitan region in Chile. Nursery schools were randomly assigned to 2 parallel groups: children in the intervention group were given 150 mL of milk supplemented with *Lactobacillus rhamnosus* SP1 (10^7 CFU/mL), while children in the control group were given standard milk. Interventions took place on weekdays for 10 mo. Data were collected through a clinical examination of participants. The primary outcome measure was the increment of caries in preschool children. This was assessed using the International Caries Detection and Assessment System (ICDAS). The dropout rate was 21%. No differences in caries prevalence were detected between the groups at baseline ($P = 0.68$). After 10 mo of probiotic intake, the caries prevalence was 54.4% in the probiotic group and 65.8% in the control group. The percentage of new individuals who developed cavitated lesions (ICDAS 5-6) in the control group (24.3%) was significantly higher than that in the probiotic group (9.7%). The increment of dental caries showed an odds ratio of 0.35 ($P < 0.05$) in favor of the probiotic group. At the cavitated lesion level, the increment of new caries lesions within the groups showed 1.13 new lesions per child in the probiotic group compared with 1.75 lesions in the control group ($P < 0.05$). The probiotic group showed an increment of 0.58 ± 1.17 new lesions compared with 1.08 ± 1.70 new lesions observed in the control group. The difference in caries increment was significant at the cavitated lesion level ($P < 0.01$). In conclusion, the regular long-term intake of probiotic-supplemented milk may reduce caries development in high-caries preschool children (ClinicalTrials.gov: NCT01648075).