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## Title

The Probiotic BB-12, Are Adverse Events an Issue: Meta-Analysis and Individual Patient-Data Meta-Analysis

Priority 1 (Research Category)

Clinical research (other)

## Presenters

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## Abstract

Context: Probiotics are defined as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host." Bifidobacterium animalis subsp. lactis (BB-12) is the most studied Bifidobacterium in the world and widely used in foods and supplements. Objectives: Our aim was to evaluate adverse events (AEs) in clinical trials of BB-12. Study Design and Analysis: A systematic review following the Cochrane Handbook rules was initially conducted. Two independent reviewers separately searched for articles that qualified based on the following criteria: English language, double-blinded, randomized, and placebo-controlled trial of BB-12. Standard meta-analysis methods were used to examine the pooled data and individual general linear regression modeling was used for the IPDMA. Setting: NA. Population Studied: Individuals in published clinical trials. Interventions: Active treatment with BB-12 and matching placebo. Outcome Measures: Adverse Events. Results: One hundred and seventy-nine studies were identified of which 33 initially gualified for the study. Seventeen of the 33 studies were eligible for the meta analysis, as they had published AE data. All authors of the 33 studies were contacted for the IPDMA and only papers that included full individual and non-zero data were included. Results from nine studies in the MA demonstrated there was no difference in the rates of AE between the placebo and probiotic groups; difference in rates = .02, 95% Cl (-0.01, .04). For the individual presence of AEs in the six studies included in the IPDMA the adjusted OR was 1.39 [.98, 1.97]. Conclusions: The MA and IPDMA found equal AE rates between BB-12 intervention and placebo groups. This is important due to the wide usage of BB12 in foods and supplements. We found that half of the RCTs analyzed for the MA did not report AE data, a major limitation in the probiotic literature.