

Effect of multi-strain probiotics (multi-strain microbial cell preparation) on glycaemic control and other diabetes-related outcomes in people with type 2 diabetes: a randomized controlled trial

ABSTRACT

Aim: Evidence of a possible connection between gut microbiota and several physiological processes linked to type 2 diabetes is increasing. However, the effect of multi-strain probiotics in people with type 2 diabetes remains unclear. This study investigated the effect of multi-strain microbial cell preparation ~~み~~ also refers to multi-strain probiotics ~~み~~ on glycaemic control and other diabetes-related outcomes in people with type 2 diabetes. **Design:** A randomized, double-blind, parallel-group, controlled clinical trial. **Setting:** Diabetes clinic of a teaching hospital in Kuala Lumpur, Malaysia. **Participants:** A total of 136 participants with type 2 diabetes, aged 30 ~~歳~~ 70 years, were recruited and randomly assigned to receive either probiotics (n = 68) or placebo (n = 68) for 12 weeks. **Outcomes:** Primary outcomes were glycaemic control-related parameters, and secondary outcomes were anthropomorphic variables, lipid profile, blood pressure and high-sensitivity C-reactive protein. The Lactobacillus and Bifidobacterium quantities were measured before and after intervention as an indicator of successful passage of the supplement through gastrointestinal tract. **Statistical analysis:** Intention-to-treat (ITT) analysis was performed on all participants, while per-protocol (PP) analysis was performed on those participants who had successfully completed the trial with good compliance rate. **Results:** With respect to primary outcomes, glycated hemoglobin decreased by 0.14 % in the probiotics and increased by 0.02 % in the placebo group in PP analysis (p < 0.05, small effect size of 0.050), while these changes were not significant in ITT analysis. Fasting insulin increased by 1.8 µU/mL in placebo group and decreased by 2.9 µU/mL in probiotics group in PP analysis. These changes were significant between groups at both analyses (p < 0.05, medium effect size of 0.062 in PP analysis and small effect size of 0.033 in ITT analysis). Secondary outcomes did not change significantly. Probiotics successfully passed through the gastrointestinal tract. **Conclusion:** Probiotics modestly improved HbA1c and fasting insulin in people with type 2 diabetes.

Keyword: Blood pressure; Glycated hemoglobin; Glycaemic control; High-sensitivity C-reactive protein; Homeostasis model assessment-estimated insulin resistance; Lipid profile; Type 2 diabetes mellitus