

Probiotics' effects on perception of health and bowel frequency: a double-blind, randomised, placebo-controlled clinical trial

Authors: Ayman S Bannaga,^{A,B} Monika M Widlak,^{A,B} Nadeem Tehami,^A Sudheer Vinnamala,^A Nidhi Sagar,^{A,B} Ella Mozdiak,^{AB} Nicola O'Connell,^A Leighanne Burns,^A Khalifa Elmusharaf^C and Ramesh P Arasaradnam^D

Table 1. Comparison between the components of EQ-5D in each visit

	Visit 1			Visit 2			Visit 3		
	Placebo	V3P	p-value	Placebo	V3P	p-value	Placebo	V3P	p-value
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Mobility	1.00	1.00	1	1.03	1.03	0.90	1.03	1.04	0.80
Self-care	1.00	1.00	1	1.03	1.00	0.40	1.03	1.00	0.40
Usual activities	1.00	1.00	1	1.03	1.00	0.40	1.05	1.00	0.20
Pain	1.02	1.00	0.3	1.05	1.00	0.20	1.05	1.04	0.80
Anxiety	1.02	1.05	0.5	1.03	1.09	0.20	1.03	1.07	0.40
EQ-5D	5.05 (0.2)	5.05 (0.2)	0.96	5.16 (0.6)	5.13 (0.3)	0.78	5.18 (0.6)	5.14 (0.4)	0.78
Health today	88.5 (9.8)	85.4 (11.8)	0.2	88.1 (10.7)	84.1 (19.3)	0.3	88.6 (15.6)	85.1 (19.4)	0.4

Aims

To evaluate the effects of probiotics on individuals' perception of health and bowel frequency.

Methods

The VSL#3 Probiotic (V3P; Visbiome in USA; Vivomixx in EU) contains eight strains of live, freeze-dried lactic acid bacteria. It has some therapeutic potential in ulcerative colitis and pouchitis. Healthy volunteers of age 18 years and above were invited to join the study. Excluded were individuals who had antibiotics 6 weeks or probiotics 4 weeks prior to recruitment and those with chronic gastrointestinal diseases except for irritable bowel syndrome. 83 individuals were recruited and randomised blindly, 42 to the V3P group and 41 to the placebo group. Each individual was given either placebo or probiotics to be taken twice daily for 4 weeks.

One individual assigned to the V3P group did not attend any visit following the start of the trial. Individuals' perception of health and bowel frequency was assessed during three visits (week 0, week 4 and week 8). Individuals' perception of health was assessed using EQ-5D, which is a standardised tool that provides a simple descriptive profile and a single index value for health status. The analysis was done using SPSS version 23. Intention to treat analysis was used; we compared mean scores of EQ-5D between the two groups using an independent t-test in each visit. A p-value was considered significant if less than 0.05.

Results

Mean age was 28.8 years (placebo) vs 27.4 years (V3P), body mass index (BMI) 24.4 vs 25.3 kg/m², smoking 0.73 vs 1.71 cigarettes per week, alcohol consumption 6.24 vs 4.56 units per week, males 16 vs 15, females 25 vs 26. There were no significant differences in participant characteristics between the two groups. There was no statistically significant difference when comparing components of the EQ-5D: mobility, self-care, usual activities, pain and anxiety between the two groups (Table 1). Comparing the health score in the two groups, there was no statistically significant difference during all visits: week 0 (88.5 vs 85, p=0.2), week 4 (85.4 vs 88.1, p=0.3) and week 8 (88.6 vs 85.1, p=0.4). There was no statistically significant difference between mean bowel frequency comparing

Authors: ^ADepartment of Gastroenterology, University Hospitals Coventry and Warwickshire NHS Trust, UK; ^BWarwick Medical School, University of Warwick, UK; ^CGraduate Entry Medical School, University of Limerick, Ireland; ^DApplied Biological and Experimental Sciences, University of Coventry, UK

placebo and V3P groups: visit 1 (7.83±SD 3.41 vs 6.5±SD 3.19), visit 2 (7.54±SD 3.35 vs 6.83±SD 3.42) and visit 3 (7.7±SD 3.04 vs 6.59±SD 3.46).

Conclusions

V3P did not cause any significant change in individuals' perception of health or bowel frequency compared with placebo over 8 weeks. ■

Conflict of interest statement

No conflicts of interest.