

Efficacy of *Bifidobacterium breve* CECT7263 for infantile colic treatment: an open-label, parallel, randomised, controlled trial

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Table S1. Parameters related with intestinal function and behavior of infants.^{1,2}

		Simethicone Group (n=44)	Bb + Lf Group (n=57)	Bb (n=49)	Group
Faecal depositions per week					
≤7 times	Baseline, %	22.5	27.8	38.1	
	4 Week, %	33.3	28.9	33.3	
8 to 21 times	Baseline, %	37.5	37	28.6	
	4 Week, %	46.2	48.9	38.5	
>21 times	Baseline, %	40	35.2	33.3	
	4 Week, %	20.5	22.2	28.2	
Improve at 4-week	No, %	86.5	67.4	76.3	
	Yes, %	13.5	32.6*	23.7	
Stool consistency					
Hard or very hard	Baseline, %	7	9.1	4.3	
	4 Week, %	10	4.3	4.9	
Soft	Baseline, %	46.5	49.1	55.3	
	4 Week, %	65	67.4	70.7	
Mushy or watery	Baseline, %	46.5	41.8	40.4	
	4 Week, %	25	28.3	24.4	
Improve at 4-week	No, %	85	83	88.1	
	Yes, %	15	17	11.9	
Flatulency					
Never or sometimes	Baseline, %	7.1	1.8	4.3	
	4 Week, %	75	76.1	70.7	
Frequently	Baseline, %	66.7	56.4	61.7	
	4 Week, %	20	19.6	26.8	
Very frequently	Baseline, %	26.2	41.8	34	
	4 Week, %	5	4.3	2.4	
Improve at 4-week	No, %	5.1	0	0	
	Yes, %	94.9	100	100	
Stomachache					
Never or sometimes	Baseline, %	9.3	1.9	6.5	
	4 Week, %	80	78.3	85.4	
Frequently	Baseline, %	6.1	51.9	54.3	

	4 Week, %	15	19.6	14.6
Very frequently	Baseline, %	25.6	46.3	39.1
	4 Week, %	5	2.2	0
Improve at 4-week	No, %	5	0	4.9
	Yes, %	95	100	95.1
Sleeping hours during night per day				
< 6 hours	Baseline, %	35.7	41.8	31.9
	4 Week, %	7.7	6.5	5
6 to 8 hours	Baseline, %	54.8	49.1	55.3
	4 Week, %	51.3	43.5	45
>8 hours	Baseline, %	9.5	9.1	12.8
	4 Week, %	41	50	50
Improve at 4-week	No, %	21.1	25.5	22.5
	Yes, %	78.9	74.5	77.5
Total sleeping hours per day				
< 11 hours	Baseline, %	50	40.7	45.8
	4 Week, %	12.8	20	14.6
11 to 14 hours	Baseline, %	36.4	44.4	39.6
	4 Week, %	61.5	55.6	47.5
>14 hours	Baseline, %	13.6	14.8	22.5
	4 Week, %	25.6	24.4	30
Improve at 4-week	No, %	35	44.4	36.6
	Yes, %	65	55.6	63.4

¹ Values indicated the % of infants at each group for every category. * Indicates $P < 0.05$ Simethicone vs Bb+Lf.

² Lf = *Lactobacillus fermentum* CECT5716; Bb = *Bifidobacterium breve* CECT7263.

Table S2. Parameters related with the parents' mood during intervention.^{1,2}

		Simethicone Group (n=44)	Bb + Lf Group (n=57)	Bb (n=49)	Group
Disappointed	Baseline, %	70.5	66.7	75	
	4 Week, %	12.5	8.7	2.4	
Normal	Baseline, %	20.5	18.5	18.8	
	4 Week, %	7.5	21.7	24.4	
Satisfied	Baseline, %	9.1	14.8	6.2	
	4 Week, %	80	69.6	73.2	
Improve at 1- week	No, %	34.1	47.2	27.3	
	Yes, %	65.9	52.8	72.7*	
Improve at 2- week	No, %	21.4	22	23.8	
	Yes, %	78.6	78	76.2	
Improve at 3- week	No, %	12.2	19.1	7.1	
	Yes, %	87.8	80.9	92.9	
Improve at 4- week	No, %	7.3	14.9	0	
	Yes, %	92.7	85.1	100 [¥]	

¹ Values indicated the % of the parents at each group for every category. * Indicates $P < 0.05$ Bb vs Bb+Lf; [¥] indicates $P < 0.05$ Bb vs Bb+Lf vs Simethicone.

² Lf = *Lactobacillus fermentum* CECT5716; Bb = *Bifidobacterium breve* CECT7263.