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**TITLE:** Probiotics for the management of functional abdominal pain in children: A Cochrane systematic review **AUTHORS (LAST NAME, FIRST NAME):** Gordon, Morris<sup>1, 2</sup>; Stone, Joe<sup>2</sup>; Thomas, Adrian<sup>3</sup>; Akobeng, Anthony<sup>4</sup> **INSTITUTIONS (ALL):** 

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# ABSTRACT BODY:

## Abstract Body: Background

Functional abdominal pain is pain located in the abdomen that cannot be explained by visible or detectable abnormalties. It is hypothesised that the use of probiotics might alter the growth of bacteria in the bowel, promote normal gut physiology and reduce functional symptoms. Given the recent growth in published studies in this area it is necessary to produce a new and focussed synthesis of this evidence by deploying a robust methodology to ensure that there can be a contemporaneous impact on clinical practice.

## Methods

The Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, CINAHL and Cochrane Inflammatory Bowel Disease & Functional Bowel Disorders Group Specialised Trial Register were searched (Inception – July 2015). Manufacturers of probiotics were contacted to identify unpublished trials. References of trials were also searched. Abstracts were considered for inclusion if full details to judge inclusion were offered or available from the authors. Randomised controlled trials (RCTs) that compared probiotics against placebo or any other intervention were eligible for inclusion. Data extraction and assessment of methodological quality of included studies were independently performed by two authors. Analysis was completed in accordance with the intention to treat approach.

## Results

The search yielded 1672 results and nine placebo controlled studies (n = 701) met the inclusion criteria, two as abstracts and seven as published studies. Three studied Lactobacillus GG, three lactobacillus reuteri, one VSL#3, one bacillus coagulans and one bifidobacteria. The studies ranged in length from 4 to 16 weeks. The risk of bias was low for randomisation for seven trials and moderate for two trials. Allocation concealment was low in two studies and unclear in the others. All studies were double blinded, but only four gave details of how this was achieved. The risk of bias was low or unclear in all studies for incomplete outcome data and selective reporting. Meta-analysis of seven studies (n=541) found a statistical significant reduction in the severity of pain using probiotics compared to placebo (MD -0.32; 95% CI -0.38 to -0.25). Meta-analysis of four studies (n=440) found a statistical significant difference in patients reaching treatment success favouring probiotics compared to placebo (OR 1.80; 95% CI 1.20 to 2.69). Meta-analysis of five studies (n=385) found no statistical significant difference in adverse events between probiotics and placebo (OR 0.00; 95% CI -0.07 to 0.06).

## Conclusions

The evidence from the published suggests superior efficacy of probiotics for functional abdominal pain in children when compared with placebo. There is no difference in adverse events, suggesting safety. The evidence base is of moderate quality and relatively small. Further research to investigate the long term impact of probiotic therapy is suggested.

(no table selected)

	Probiotics			Placebo				Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl	
BAUSSERMAN 2005	1.5	0.5	25	1.8	0.7	25	16.7%	-0.30 [-0.64, 0.04]		
Francavilla 2010 1	1.8	0.3	42	3.3	1.5	38	15.3%	-1.50 [-1.99, -1.01]		
Francavilla 2010 2 FAP	2.2	1.2	25	3	1.7	31	12.4%	-0.80 [-1.56, -0.04]		
GAWRONSKA 2006	2.5	1.9	42	2.9	1.5	42	12.7%	-0.40 [-1.13, 0.33]		
hojsak 2015	0.36	0.11	26	0.65	0.14	29	18.2%	-0.29 [-0.36, -0.22]	•	
Saneian 2015	2.1	1.4	59	1.8	1.4	56	15.0%	0.30 [-0.21, 0.81]		
Weizman 2014	4.3	2.1	50	7.2	3.1	51	9.7%	-2.90 [-3.93, -1.87]	+	
Total (95% CI)			269			272	100.0%	-0.72 [-1.19, -0.25]	•	
Heterogeneity: Tau <sup>2</sup> = 0.3										
Test for overall effect: Z =	3.00 (P	= 0.00	3)						-2 -1 U 1 2 Favours (Probiotics) Favours (Placebo)	

Figure 1: Forest plot of severity of pain, Probiotics vs Placebo

	Probiotic	s Plac	Placebo		Risk Difference	Risk Difference		
Study or Subgroup	Events 1	Total Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl		
BAUSSERMAN 2005	7	25 7	25	3.6%	0.00 [-0.25, 0.25]			
Francavilla 2010 1	2	69 2	67	69.4%	-0.00 [-0.06, 0.06]			
GAWRONSKA 2006	9	42 9	42	7.3%	0.00 [-0.18, 0.18]			
hojsak 2015	4	26 5	29	5.9%	-0.02 [-0.21, 0.18]	· · · · · · · · · · · · · · · · · · ·		
Romano 2015	2	32 2	28	13.9%	-0.01 [-0.14, 0.12]	· · · · · · · · · · · · · · · · · · ·		
Total (95% CI)		194	191	100.0%	-0.00 [-0.05, 0.04]	-		
Total events	24	25						
Heterogeneity: Tau <sup>2</sup> = (	0.00; Chi <sup>2</sup> =	0.04, df = 4 (l						
Test for overall effect: Z	Z = 0.12 (P =	= 0.90)	Favours [Probiotics Favours [Placebo					

Forest plot of Adverse events, Probiotics vs Placebo

# **Disclosure Status**

The following authors have completed their 2016 DDW disclosure:: Morris Gordon: Disclosure completed | Joe Stone: No Answer. | Adrian Thomas: No Answer. | Anthony Akobeng: No Answer.