A Randomised, Double-blind, Placebo-Controlled Trial: The effects of a multi-strain probiotic, in Adults with diarrhoea-predominant IBS

Question:

Is a multi-strain probiotic more effective than placebo at reducing GI symptoms and improving QoL in patients with IBS-D?

Methods:

360 out of 400 participants diagnosed with moderate-to-severe symptomatic diarrhoea-predominant IBS (IBS-D), in accordance with Rome III criteria, completed a trial to receive probiotic (14 bacteria strains; 8 billion CFU per day) or placebo capsules for 16 weeks. IBS symptoms (e.g abdominal pain and frequency, measured by the IBS-SSS questionnaire) and quality of life (measured by the 34-item IBS-QoL questionnaire) were assessed monthly for 5 months. No change in lifestyle/diet was introduced.

Results:

181 patients received probiotic and 179 received placebo. At month 5, abdominal pain level had decreased significantly more in the probiotic group than in the placebo group (58.5 ± 11.1 to 18.1 ± 15.2 vs. 57.2 ± 10.6 to 30.2 ± 19.9; p<0.001).

The number of bowel motions/day was significantly reduced from month 2 onwards in the probiotic group, compared with the placebo group.

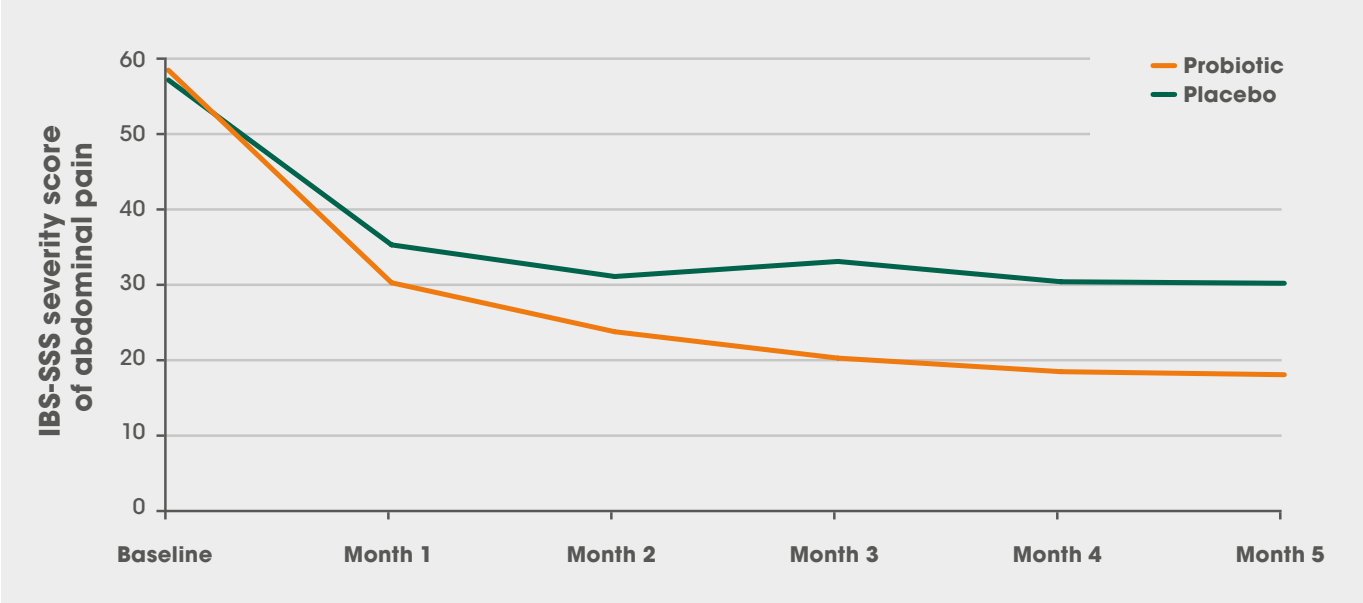
At baseline, all patients rated their symptoms as moderate to severe while at the end of the trial, this was reduced to 13.8% in the probiotic group compared with 48.0% in the placebo group (p<0.001). No serious adverse events were reported.

Conclusions:

The multi-strain probiotic was associated with a statistically significant consistent improvement in overall symptom severity in patients with IBS-D, and was well tolerated.

Key findings:

1. **Abdominal pain** level had **decreased by almost 70%** in the intervention group vs 47% in the placebo at follow-up;
2. IBS **pain frequency** decreased by **>70%** (7.7 per 10 days to 2.2 at month 5)
3. All dimensions of QoL showed **significantly greater and consistent improvement** in the intervention group than in the placebo group;
4. **At the end** of the trial **34% of patients** in the intervention group vs 13% in placebo group were **symptom-free**



Ishaque SM, Khosruzzaman SM, Ahmed DS, Sah MP. A randomized placebo-controlled clinical trial of a multi-strain probiotic formulation (Bio-Kult®) in the management of diarrhea-predominant irritable bowel syndrome. *BMC Gastroenterol* 2018;**18**(1):71.

Probiotic Supplement used = Bio-Kult Advanced (Ingredients - Bulking agent: microcrystalline cellulose, *Bacillus subtilis* PXN® 21™, *Bifidobacterium bifidum* PXN® 23™, *Bifidobacterium breve* PXN® 25™, *Bifidobacterium infantis* PXN® 27™, *Bifidobacterium longum* PXN® 30™, *Lactobacillus acidophilus* PXN® 35™, *Lactobacillus delbrueckii* ssp. *bulgaricus* PXN® 39™, *Lactobacillus casei* PXN® 37™, *Lactobacillus plantarum* PXN® 47™, *Lactobacillus rhamnosus* PXN® 54™, *Lactobacillus helveticus* PXN® 45™, *Lactobacillus salivarius* PXN® 57™, *Lactococcus lactis* ssp. *lactis* PXN® 63™, *Streptococcus thermophilus* PXN® 66™, (milk, soya), vegetable capsule (hydroxypropyl methylcellulose).)

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Research Study

THE BACKGROUND:

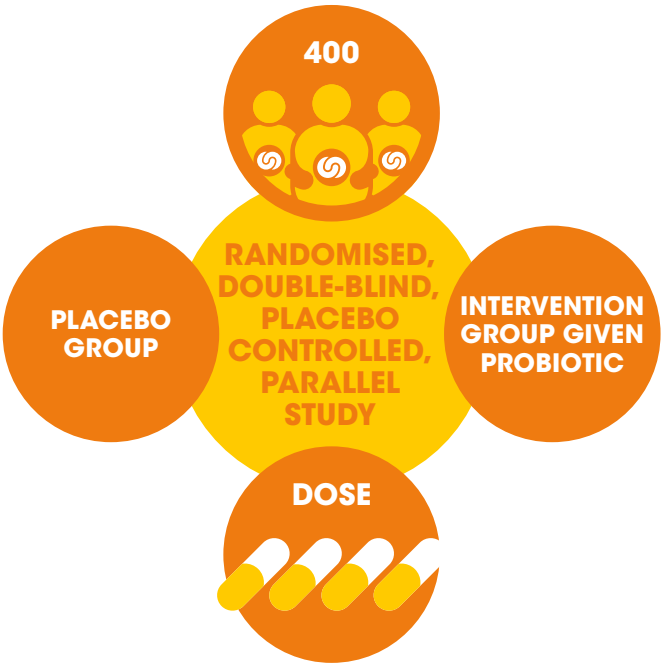
What is IBS?

- ongoing/regular abdominal pain
- troublesome defaecation (constipation or diarrhoea)
- abdominal distension

REDUCED QUALITY OF LIFE

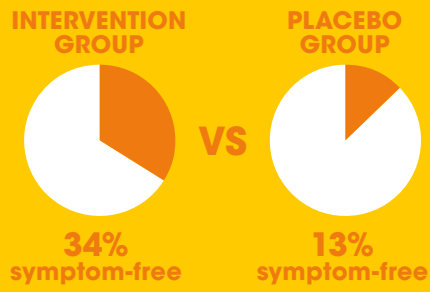
£ 166M / PA NHS MEDICATION COST

THE STUDY:

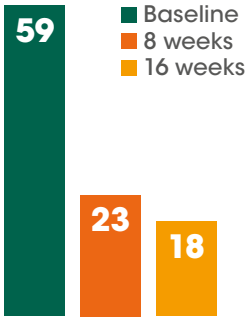


THE RESULTS:

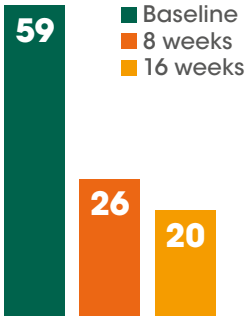
1) All dimensions of QoL showed **significantly greater and consistent improvement** in the intervention group than in the placebo group;
2) **At the end** of the trial **34% of patients** in the intervention group vs 13% in placebo group were **symptom-free**



PAIN SCORE



ABDOMINAL DISTENTION



BOWEL MOVEMENTS PER DAY

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