Bio-Kult® in Irritable Bowel Syndrome

A Randomized, Double-blind, Placebo-Controlled Trial: The effects of a multi-strain probiotic, Bio-Kult®, in Adults with diarrhea-predominant IBS

Question:

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

Methods:

360 moderate-to-severe symptomatic diarrhea-predominant IBS (IBS-D), diagnosed in accordance with Rome III criteria, completed a trial to receive probiotic Bio-Kult® (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 Bio-Kult® and 179 received placebo. At month 5, abdominal pain level had decreased significantly more in the Bio-Kult® 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 movements/day was significantly reduced from month 2 onwards in the Bio-Kult® group, compared with the placebo group.

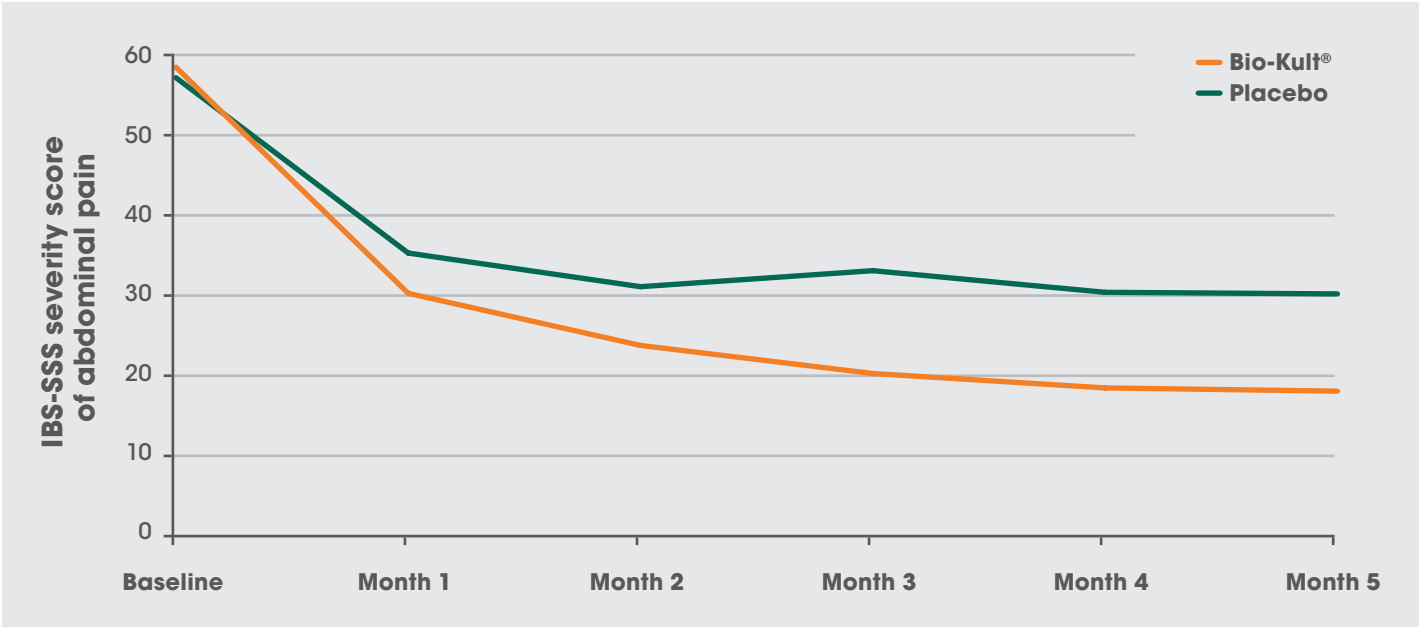
At baseline, all patients rated their symptoms as moderate to severe while at the end of the trial, this was reduced to 13.8% in the Bio-Kult® group compared with 48.0% in the placebo group (p<0.001). No serious adverse events were reported.

Conclusions:

The multi-strain probiotic Bio-Kult® 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**



Bio-Kult®
The experts in probiotics

bio-kult.com

Bio-Kult® in Irritable Bowel Syndrome

THE BACKGROUND:

What is IBS?

- ongoing/regular abdominal pain
- troublesome defecation (constipation or diarrhea)
- abdominal distension

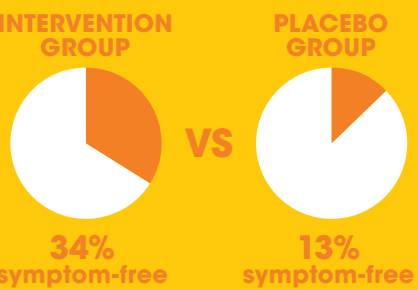
REDUCED QUALITY OF LIFE

£ 166M / PA HOSPITALS MEDICATION COST

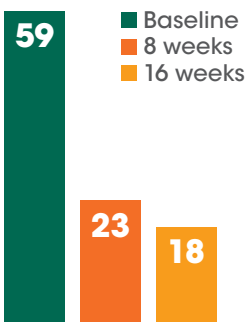
THE STUDY:

THE RESULTS:

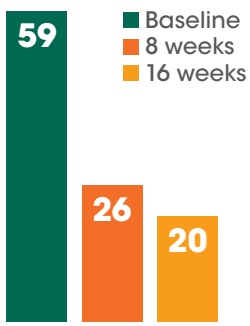
1) All dimensions of QoL showed **significantly greater and consistent improvement** in the intervention group than in the placebo group;
2) **At the end** of the trial **34% of patients** in the intervention group vs 13% in placebo group were **symptom-free**



PAIN SCORE



ABDOMINAL DISTENTION



BOWEL MOVEMENTS PER DAY

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