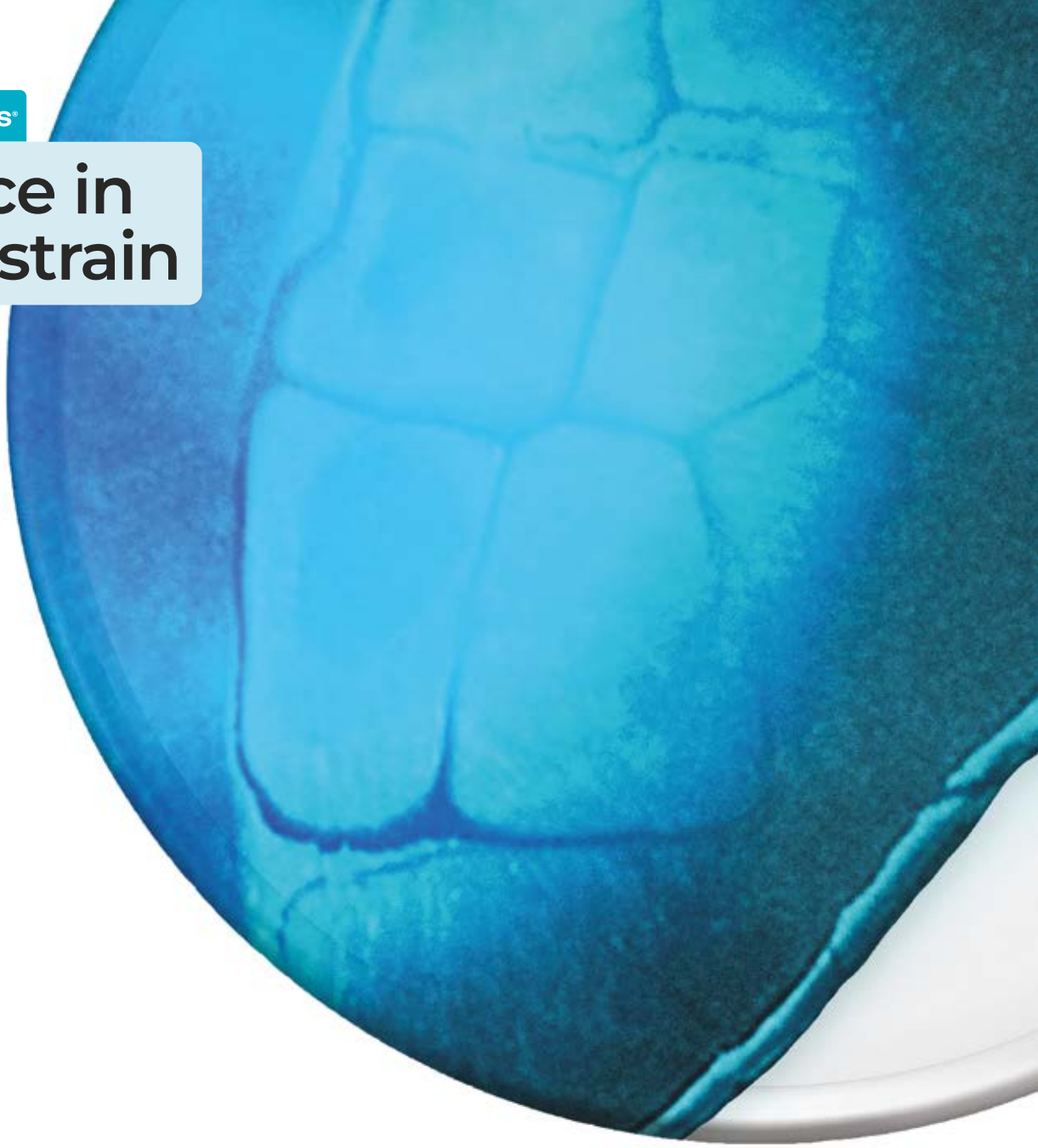
PrecisionBiotics®

Science in every strain



Clinical evidence summary

Gastrointestinal health

Bifidobacterium longum **35624™**

Scientific information. For healthcare professionals only

Contents

* In the following text, *Bifidobacterium longum* 35624™ will be referred to as *B. longum* 35624™

Science in every strain

At PrecisionBiotics, we believe that gastrointestinal health is the cornerstone of whole body health, and we are dedicated to unlocking its potential through targeted, evidence-based science. For the past 25 years, we have been at the forefront of microbiome research, isolating, testing and cultivating unique strains with the potential to deliver important health benefits. Each strain in our formulations is backed by extensive data from clinical trials, and real-world observational studies to lend further weight to the evidence behind our products.

The gut microbiome – a target in the management of IBS

The importance of the gut microbiome in human health and disease is well established and our knowledge of its complex composition and potential is growing. The gut microbiome influences human physiology, immune function, metabolism and nutrition. Evidence is also emerging of an underlying link between the pathophysiology of functional gastrointestinal disorders (FGID) such as IBS and the gut microbiome.[1,2]

The gut microbiome in health

The gut microbiome plays a key role in the regulation of many functions in the body, including:[3]

- Maintenance of normal gut physiology and health
- Protection against pathogens
- Support of the immune system, digestion, metabolism, insulin sensitivity and secretion
- Modulation of gut-brain communication

The gut microbiome in illness

An imbalanced gut microbiome has been shown to upregulate inflammatory cytokine release in the gut (see page 4, Figure 1a.) and is associated with a number of conditions, including IBS:[1,2,4]

Randomised, placebo-controlled trials have demonstrated that targeting the gut microbiota, for example by supplementation with certain probiotic strains, can alleviate symptoms of IBS.[1] This has led to FGID such as IBS being re-defined as disorders of the gut-brain-axis.[1,2]

Strategies for helping manage symptoms of IBS: diet and probiotics

- Long-term and consistent dietary changes may have a positive effect on the composition of the gut microbiome.[5]
  - In some cases, a low FODMAP (fermentable oligo-, di-, mono-saccharides and polyols) diet or an elimination diet may be advised, but only under the care of a specialist dietitian[6]
- Supplementation of the gut microbiome with specific probiotics has been shown to have a number of strain-specific health benefits.[7]

There is increasing interest in the evidence for probiotics in the management of IBS[1-3]

Introducing *B. longum* 35624™ – a probiotic strain discovered and researched by PrecisionBiotics

B. longum 35624™ is part of the genus of bacteria called *Bifidobacterium*. Bifidobacteria are among the first types of bacteria to colonise the gut after birth. They are considered to be well adapted to the human gastrointestinal (GI) tract.[8]

Mechanism of action

B. longum 35624™ has a surface covering called exopolysaccharide (EPS), which has a unique structure.[9,10]

- EPS is important for the viability of *B. longum* 35624™ in the gut[11,12]
- EPS is also responsible for some of the anti-inflammatory effects of *B. longum* 35624™[9,10]

Animal models and human clinical trials provide evidence for the immunoregulatory mechanisms of *B. longum* 35624™.[13,14] Some bacteria have proinflammatory effects, but *B. longum* 35624™ has been shown to engage with dendritic cells, resulting in an anti-inflammatory pathway, as illustrated in Figures 1a and 1b.[12-14] The introduction of *B. longum* 35624™ into an imbalanced gut microbiome leads to:[12-14]

1. Downregulation of proinflammatory cytokines (e.g. IL-12 and TNF-α)
2. Upregulation of anti-inflammatory cytokines (e.g. IL-10, TGF-β)
3. Activation of regulatory T-cells

Figure 1a. Imbalanced gut microbiome

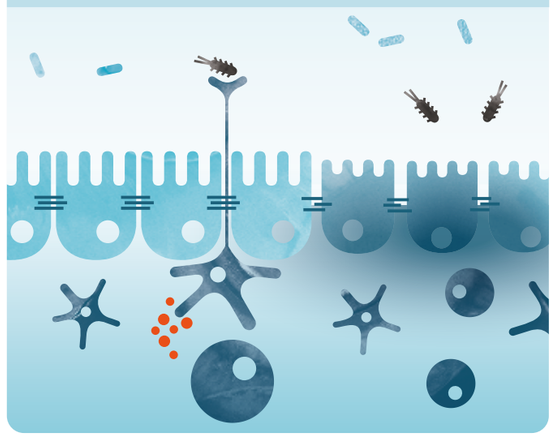
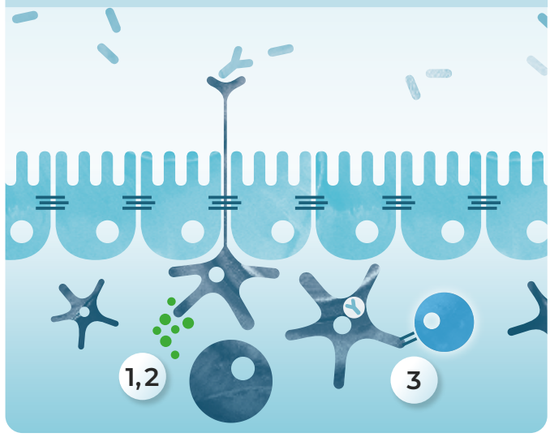


Figure 1b. Impact of *B. longum* 35624™ on gut microbiome



Dendritic cell · T cell · Regulatory T cell · Harmful bacteria · *B. longum* 35624™ · Other gut bacteria · Proinflammatory cytokines · Anti-inflammatory cytokines

***B. longum* 35624™ has been shown to reduce inflammation, and can help manage IBS symptoms, including abdominal pain, bloating, bowel straining and gas[2,3,15-18]**

Guidelines and expert opinion on *B. longum* 35624™

Globally recognised to help manage IBS symptoms

International clinical guidelines have recognised the potential of specific probiotic strains, including *B. longum* 35624™, in the management of IBS symptoms.[19]

The 2024 World Gastroenterology Organisation (WGO) guidelines on probiotics and prebiotics have stated that *B. longum* 35624™ is effective in managing IBS.[19] The WGO also stressed the importance of evidence from human studies when recommending any probiotic in clinical practice.[19]

The 2018 European Society for Primary Care Gastroenterology (ESPCG) consensus outlined that *B. longum* 35624™ helps to:[20]

- Relieve overall symptom burden in some patients with IBS
  (Evidence grade: High; Agreement: 100%)
- Relieve overall symptom burden in some patients with diarrhoea-predominant IBS (IBS-D)
  (Evidence grade: Low; Agreement: 100%)
- Reduce abdominal pain in some patients with IBS
  (Evidence grade: High; Agreement: 100%)
- Reduce bloating/distension in some patients with IBS
  (Evidence grade: Moderate; Agreement: 75%)
- Improve frequency and/or consistency of bowel movements in some IBS patients
  (Evidence grade: Moderate; Agreement: 100%)

High evidence:
Probiotics with supportive evidence for benefit should be tried.

Moderate evidence:
Probiotics with supportive evidence for benefit could be tried.

Clinical evidence for *B. longum* 35624™ in helping manage IBS symptoms

Backed by decades of clinical research: With more than 25 scientific publications on gastrointestinal health and 13 on IBS specifically (see table below), including double-blind, placebo-controlled randomised trials, there is a wealth of clinical evidence demonstrating the efficacy of *B. longum* 35624™ in helping to manage IBS symptoms.[15-18,21-29]

		Reported significant improvements in outcomes						
Reference		**Overall IBS symptom severity**	**Abdominal pain**	**Abdominal distension**	**Bowel movement**	**Passage of gas**	**Quality of life**	**Additional outcomes**
O'Mahony *et al.* 2005[15]	**Double blind, placebo-controlled RCT*** - 1 x 10^{10} CFU/day, 8 weeks, Ireland - 77 adults, IBS (Rome II), all sub-types	✓	✓		✓			Improvement in inflammatory biomarkers (IL10:IL12 ratio)
Whorwell *et al.* 2006[16]	**Double blind, placebo-controlled RCT*** - 1 x 10^{8} CFU/day, 4 weeks, UK - 362 adults, IBS (Rome II), all sub-types	✓	✓	✓	✓	✓		
Charbonneau *et al.* 2013[21]	**Double blind, placebo-controlled RCT*** - 1 x 10^{10} CFU/day, 12 weeks - 159 adults, IBS							Modification of microbiome colonisation
Ünsal *et al.* 2024[22]	**RCT*** - 1 x 10^{8} CFU/day, 8 weeks, Turkey - 60 adults, IBS							Increased plasma zonulin levels (marker for intestinal integrity)
Emmanuel *et al.* 2019[23]	**Real-world, open-label study**** - 1 x 10^{10} CFU/day, 8 weeks, France - 43 adults, IBS-D (Rome IV), failed to respond to low-FODMAP diet	✓	✓		✓			Improvement in anxiety and depression scores
Arriaza Peso *et al.* 2022[24]	**Real-world, prospective open-label observational study**** - 1 x 10^{9} CFU/day, 90 days, Spain - 110 adults, IBS (Rome IV), all sub-types	✓	✓	✓	✓			
Sabaté and Iglicki 2022[17]	**Real-world, prospective open-label observational study**** - 1 x 10^{9} CFU/day, 30 days, France - 233 adults, IBS (Rome IV), all sub-types	✓	✓	✓	✓		✓	
Skrypnyk *et al.* 2022[25]	**Real-world, prospective open-label study**** - 1 x 10^{10} CFU/day, 8 weeks, Ukraine - 1,260 adults, IBS	✓	✓		✓		✓	
Lenoir *et al.* 2023[18]	**Real-world, open-label, observational study**** - 1 x 10^{9} CFU/day, 8 weeks, Germany - 37 adults, IBS (Rome IV), all sub-types	✓	✓	✓	✓	✓		
Kinnear *et al.* 2023[26]	**Real-world, retrospective online survey**** - 1 x 10^{10} CFU/day, 3 months, UK - 34 HCPs, 34 adults, IBS	✓	✓	✓	✓		✓	
Sorensen K, *et al.* 2024[27]	**Real-world, open-label study**** - 1 x 10^{9} CFU/day, 12 weeks, China - 305 adults, IBS	✓	✓	✓	✓		✓	
Cruchet Muñoz *et al.* 2024[28]	**Paediatric, open-label observational study**** - 1 x 10^{9} CFU/day, 12 weeks, Chile - 64 children and adolescents (8-18y), IBS (Rome IV)	✓	✓	✓	✓		✓	
Sorensen K, *et al.* 2025[29]	**Real-world, open-label study**** - 1 x 10^{8} CFU/day, 8 weeks, China - 220 children, IBS	✓	✓		✓		✓	

The safety of *B. longum* 35624™ is well documented in human clinical studies, including post-marketing surveillance.[30-32]

CFU, colony forming unit; FODMAP, fermentable oligo-, di-, mono-saccharides and polyols; HCP, healthcare professional; IBS, irritable bowel syndrome; IBS-D, diarrhoea-predominant IBS; RCT, randomised controlled trial.

* Comparison vs. placebo. ** Comparison vs. baseline.

p≤0.05
p<0.001

1. Randomised controlled trial | O'Mahony *et al.* 2005

B. longum 35624™ can alleviate overall IBS symptoms and help manage every cardinal symptom[15]

Study aim:

To compare the IBS symptom response and cytokine ratios of probiotic preparations containing either *B. longum* 35624™ or another strain.

Study method:

- Randomised, double-blind, placebo-controlled study of 77 IBS patients.
- Participants were randomised to receive either *B. longum* 35624™ at 1 x 10^{10} (one billion) colony forming units (CFU), *Lactobacillus salivarius* UCC4331, or a placebo, each daily for 8 weeks, followed by a 4-week washout period.
- The cardinal symptoms of IBS (abdominal pain or discomfort, bloating or distention, and bowel movement difficulty) were recorded daily and assessed each week, and assessment of quality of life and stool microbiology were performed at baseline and at the end of the intervention phase.

Results:

IBS symptoms significantly improved vs. placebo

- Both composite and individual scores for abdominal pain/discomfort, bloating/distention and bowel movement difficulty were significantly ($p<0.05$) lower vs. placebo for those randomised to receive *B. longum* 35624™ strain for 7 out of 8 weeks of the supplementation period. This was not observed in those who received *L. salivarius* UCC4331 (Table 1).

Effect sustained for a further two weeks

- During the post-supplementation follow-up washout period, those taking *B. longum* 35624™ continued to report symptom improvement for a further 2 weeks, unlike those who received *L. salivarius* UCC4331 (Table 1).

Table 1. Improvements in composite and individual symptom scores for *B. longum* 35624™ and *L. salivarius* UCC4331 vs. placebo

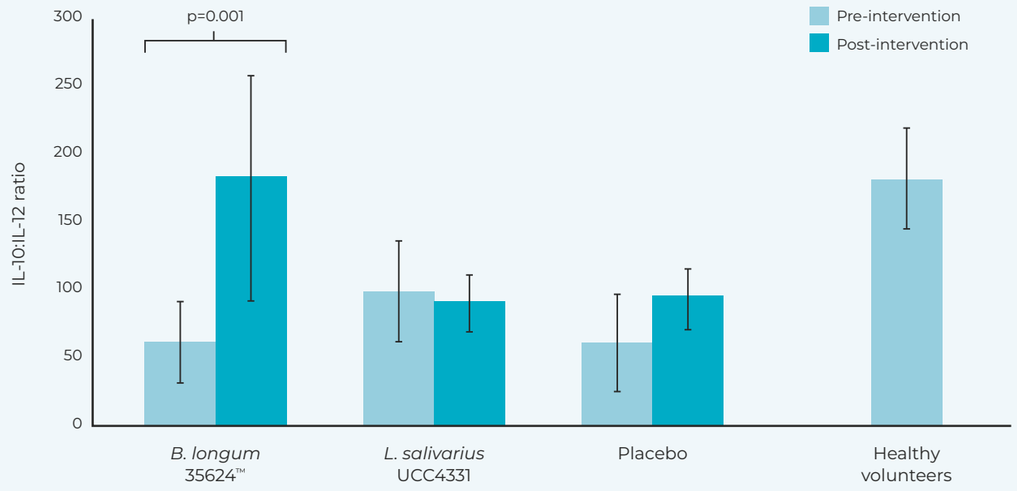
	Supplementation period (weeks)								Follow-up (weeks) *No probiotic supplement*			
	1	2	3	4	5	6	7	8	9	10	11	12
B. longum 35624™	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✗
L. salivarius UCC4331	✗	✓	✗	✗	✗	✗	✗	✗	✗	✗	✗	✗

Adapted from O'Mahony *et al.* 2005[15]

Production of proinflammatory cytokines was normalised

At baseline, individuals with IBS had a significantly lower IL-10:IL-12 ratio vs. healthy volunteers, indicating a proinflammatory state. After taking *B. longum* 35624™, *in vitro* analysis showed the cytokine ratio in the group with IBS was normalised and became comparable with healthy volunteers (Figure 2). This was not observed in those who received *L. salivarius* UCC4331 or placebo.

Figure 2. Comparison of IL-10:IL-12 ratio pre- and post-intervention period



Adapted from O'Mahony *et al.* 2005[15]

Conclusions:

B. longum 35624™ was shown to alleviate overall IBS symptoms and help manage every individual cardinal symptom: abdominal pain/discomfort, bloating/distention, and bowel movement difficulty.

As well as symptomatic improvement in IBS, *B. longum* 35624™ achieved normalisation of the IL-10:IL-12 cytokine ratio, indicating an immunoregulatory response.

These positive outcomes were not observed with the other probiotic strain, highlighting the strain-specific effects of *B. longum* 35624™.

B. longum 35624™ was effective in reducing symptoms of IBS within 4 weeks[16]

Study aim:

In a primary care setting, to evaluate the efficacy of different levels of *B. longum* 35624™ in managing IBS symptoms in adult female subjects.

Study method:

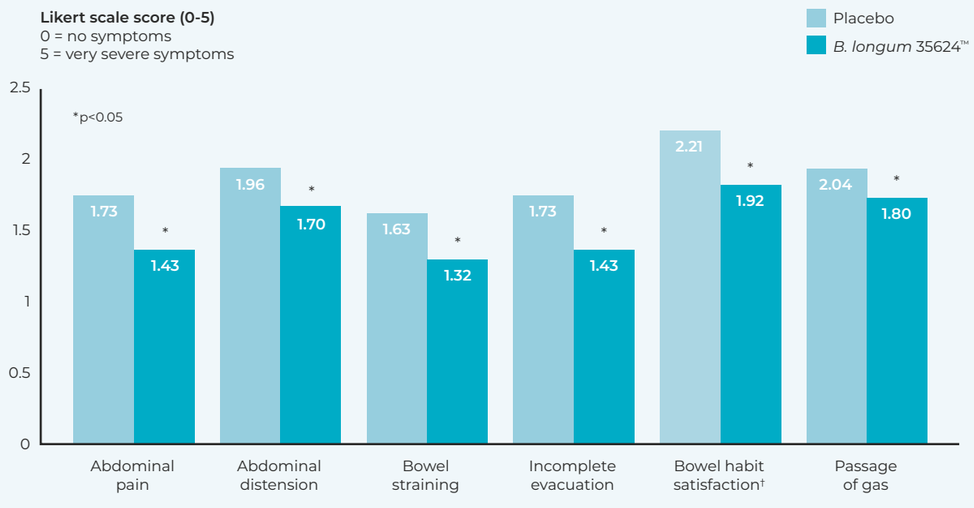
- Double-blind, placebo-controlled, multi-centre (20 centres) study of 362 IBS patients.
- Following a 2 week baseline assessment, participants were randomised to receive either placebo or *B. longum* 35624™ at 1 x 10^6, 1 x 10^8 or 1 x 10^{10} colony forming units (CFU) daily for 4 weeks.
- IBS symptoms were monitored daily and scored on a 6-point Likert scale with primary outcome being abdominal pain or discomfort.
- Other outcome measures included composite IBS symptom score, subjects' global assessment of IBS symptom relief, and quality of life scores.

Results:

IBS symptoms significantly improved vs. placebo

After 4 weeks of supplementation with *B. longum* 35624™ at 1 x 10^8 CFU per day, significant reduction from baseline was observed vs. placebo for the primary outcome of abdominal pain (-0.89 vs -0.58; p=0.023). Additionally, bloating/distension, sense of incomplete evacuation, passage of gas, straining, and bowel habit satisfaction were all significantly improved vs. placebo (Figure 3).

Figure 3. Changes in IBS symptom scores from baseline after 4 weeks of daily supplementation



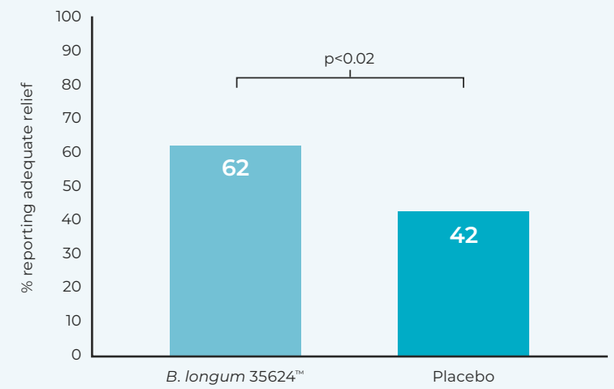
Adapted from Whorwell *et al.* 2006[16]

†**Likert scale used for this outcome was different:**
0 = very satisfied and 5 = very dissatisfied

Participants reported significant improvements in IBS symptoms

After 4 weeks of supplementation with *B. longum* 35624™ at 1 x 10^8 CFU, 62% of participants reported an improvement in their IBS symptoms, compared with 42% in the placebo group (p<0.02) (Figure 4).

Figure 4. Global assessment of IBS symptoms after 4 weeks of daily supplementation with *B. longum* 35624™ or placebo



Adapted from Whorwell *et al.* 2006[16]

Conclusions:

B. longum 35624™ (1 x 10^8 CFU daily) was shown to be well tolerated and effective in managing the symptoms of IBS within 4 weeks across all subjects, irrespective of bowel habit subtype.

B. longum 35624™ was associated with clinically significant reduction in IBS symptom severity after 30-day supplementation[17]

Study aim:

To assess the effect of *B. longum* 35624™ on IBS severity and quality of life in a real-life setting in France.

Study method:

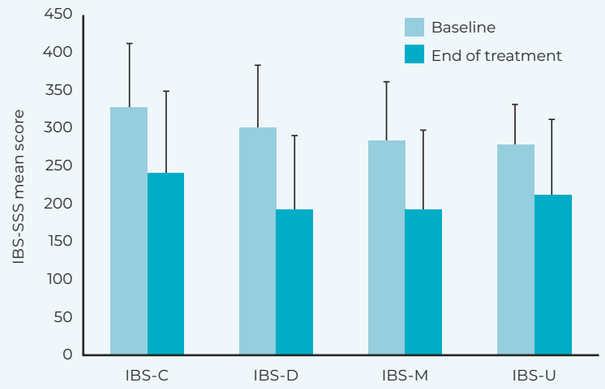
- Prospective, open-label, multi-centre, observational study of 233 subjects with IBS symptoms, according to Rome IV criteria.
- Participants received 1 capsule of *B. longum* 35624™ at 1 x 10^9 CFU daily for 30 days.

Results:

Improvements in IBS symptoms

- After a 30-day supplementation period with *B. longum* 35624™, significant decrease from baseline in IBS severity was observed (mean ± SD IBS symptom severity score (IBS-SSS) scores: 208 ± 104 vs. 303 ± 81, p>0.001), representing a 31% reduction from baseline in mean IBS-SSS score (Figure 5).

Figure 5. Mean IBS-SSS score before and after 30-day supplementation period



Adapted from Sabaté and Iglicki 2022[17]

IBS-C, constipation-predominant IBS; IBS-D, diarrhoea-predominant IBS; IBS-M, mixed IBS; IBS-U, unidentified subtype IBS.

- After 30 days, significant (p<0.001) reductions vs. baseline were also seen for a range of individual outcomes:
  - ✓ Severity of abdominal pain
  - ✓ Presence and severity of abdominal distension
  - ✓ Bowel habit dissatisfaction
  - ✓ Interference with everyday life
  - ✓ Quality of life (IBS-QoL)

Conclusions:

In adults with IBS defined according to Rome IV criteria, 30-day supplementation with *B. longum* 35624™ was associated with clinically significant reduction in IBS symptoms across all levels of symptom severity vs. baseline in a real-world setting.

B. longum 35624™ is associated with significant and meaningful reductions in symptom severity across all IBS subtypes[18]

Study aim:

To assess the effectiveness, safety and tolerability of *B. longum* 35624™ in adults with IBS in Germany in a real-life setting.

Study method:

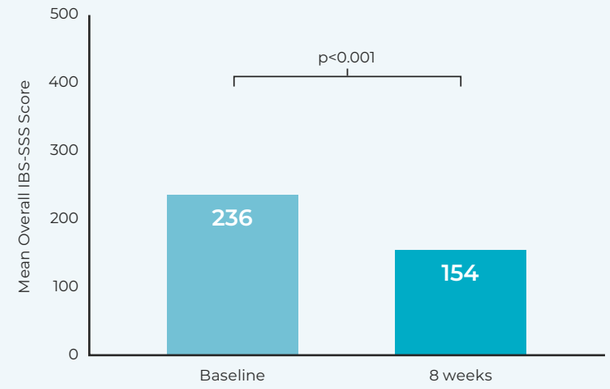
- Prospective, open-label, multi-centre, observational study of 37 adults diagnosed with IBS according to Rome IV criteria.
- Participants received 1 capsule of *B. longum* 35624™ at 1 x 10^9 CFU daily for 8 weeks.

Results

Significant IBS symptom improvement

- Significant decrease in IBS severity was observed vs. baseline (mean total IBS symptom score (TISS) scores: 6.97 vs. 12.3, p<0.0001; mean ± SD IBS-SSS scores: 154 ± 110 vs. 236 ± 102, p<0.001, Figure 6).

Figure 6. Mean IBS-SSS score before and after an 8-week supplementation period[18]



Adapted from Lenoir *et al.* 2023[18]

- *B. longum* 35624™ was associated with significant improvements from baseline in bloating, passage of gas, diarrhoea (p<0.0001 for all), and abdominal pain (p<0.001).

Positive results for quality of life and tolerability

- Quality of life was also improved after 8 weeks vs. baseline (p<0.0032), and over 60% of patients reported they felt adequate relief.
- No serious adverse events were reported and tolerability was rated “very good” or “good” by 89% of participants.

Conclusions:

In adults with IBS, 8-week supplementation with *B. longum* 35624™ in a real-world setting was associated with significant and clinically meaningful reductions in symptom severity vs. baseline across all IBS subtypes.

Summary

A targeted approach that's globally recognised to help manage IBS symptoms

- Clinical guidelines highlight the potential strain-specific benefit of *B. longum* 35624™ for managing the symptoms of IBS.[19,20]
- Animal models and human clinical trials support the anti-inflammatory and immunoregulatory mechanisms of action of *B. longum* 35624™.[12-14]

Backed by decades of clinical research with more than 25 publications on gastrointestinal health:[15-18,21-29]

- Randomised controlled trials provide robust evidence that *B. longum* 35624™ significantly helps manage IBS symptoms vs. placebo in:[15,16,21,22]
  - ✓ Symptom scores for all IBS symptoms
  - ✓ Abdominal pain/discomfort
  - ✓ Bloating/distension
  - ✓ Bowel habit satisfaction
  - ✓ Inflammatory biomarkers
- Real-world, prospective observational cohort studies provide real-world evidence that taking *B. longum* 35624™ delivers significant improvements from baseline in:[17,18,21-29]
  - ✓ Overall IBS symptom severity scores
  - ✓ Abdominal pain, abdominal distension, bowel habit satisfaction and interference with everyday life
  - ✓ Quality of life and overall wellbeing
- The safety of *B. longum* 35624™ is well documented in human clinical studies, including post-marketing surveillance.[30-32]
- *B. longum* 35624™ has been carefully selected for its safety and efficacy by PrecisionBiotics.

Abbreviations:

B, bifidobacterium; CFU, colony forming unit; EPS, exopolysaccharide; ESPCG, European Society for Primary Care Gastroenterology; FGID, functional gastrointestinal disorder; FODMAP, fermentable oligo-, di-, mono-saccharides and polyols; GI, gastrointestinal; HCP, healthcare professional; IBS, irritable bowel syndrome; IBS-C, constipation-predominant IBS; IBS-D, diarrhoea-predominant IBS; IBS-M, mixed IBS; IBS-U, unidentified subtype IBS; IBS-SSS, IBS severity scoring system; IL, interleukin; QoL, quality of life; RCT, randomised controlled trial; SD, standard deviation; TGF, transforming growth factor; TISS, total IBS symptom score system; TNF, tumour necrosis factor; WGO, World Gastroenterology Organisation.

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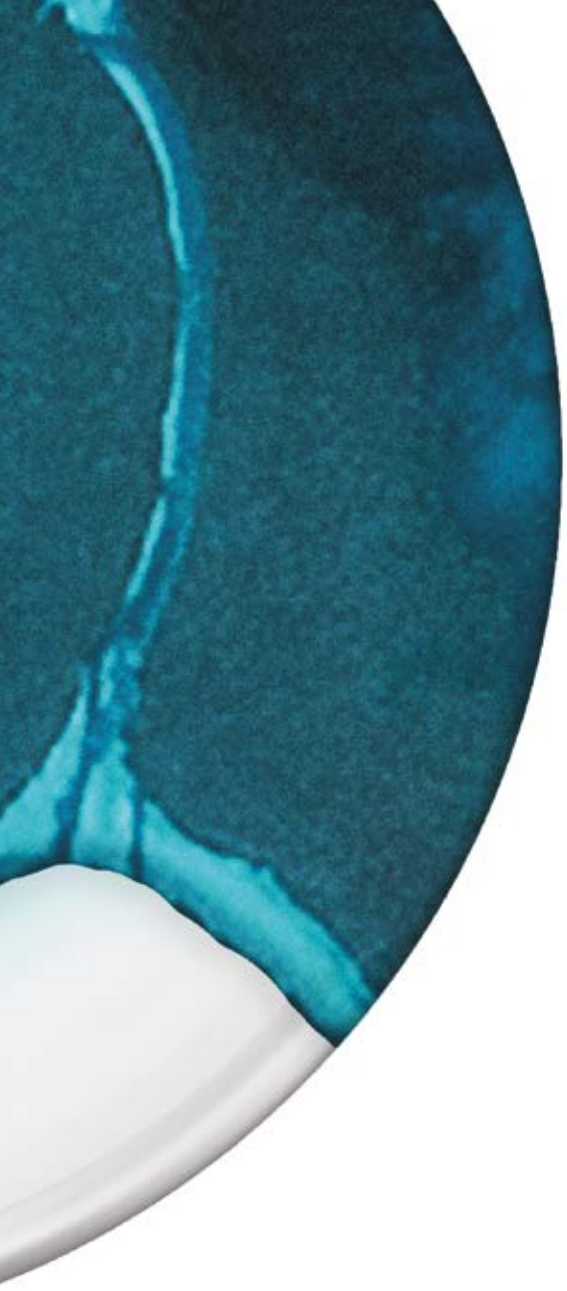

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