



VOICE OF PRIMARY CARE GASTROENTEROLOGY

ISSUE 16, 2023 - NO 1

THE DIGEST

Has
the NHS got
the guts for
the environmental
challenge?



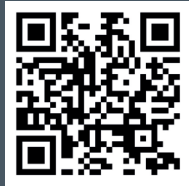
The Primary Care Society
for Gastroenterology

75
2

Real-world experience from a survey of UK-based users of the prebiotic B-GOS

Authors

Dr Marion Sloan[✉], Dr Kevin Barrett,
Dr Sophie Nelson, Laura Tilt



Abstract

Prebiotics are substrates that are selectively utilised by commensal microorganisms, modulating the composition of microbiota to confer a health benefit. Controlled clinical trials in selected patients have reported improved gastrointestinal (GI) symptoms and sleep after consumption of prebiotics. Bimuno®, also referred to as B-GOS, is the most widely studied, commercially available galactooligosaccharide (GOS) prebiotic. We conducted a retrospective, non-interventional, assessment of self-reported experiences following B-GOS supplementation. An internet-based questionnaire was completed by 1,171 UK-based adult users of B-GOS to determine the key motivations for taking the product and to assess their symptom. Responses were collected electronically using an online platform hosted by the Primary Care Society of Gastroenterology (PCSG) Secretariat. Over one in three respondents had diagnosed or self-diagnosed irritable bowel syndrome (IBS), a similar number suffered sleep disturbances and a quarter experienced chronic pain. The most common reasons for B-GOS supplementation included: promotion of healthy digestion, bloating or stomach discomfort and sleep disturbance. Among individuals who were motivated to use B-GOS for GI problems, chronic pain and sleep, there was marked self-reported improvement in quality of life. Before using B-GOS, 29% (340/1,171) reported the impact of their condition on quality of life as 'significant' (5 on a 5-point scale where 1= 'no impact' and 5= 'significant impact'). 67% reported a score of 4 or 5. Following use of B-GOS, these numbers fell to one in five (223/1,171, 19%) and almost one in two respectively (562/1,171, 48%). The majority (691/1,171, 59%) of these users rated the usefulness of B-GOS in improving their condition as 4 or 5 out of 5. Our analysis adds substantial real-world evidence (RWE) to existing clinical study data on B-GOS and suggests that further investigation is warranted to explore the benefits of prebiotics on the conditions reported.

Acknowledgements

We gratefully acknowledge the feedback from all participating Bimuno® users.

Funding

This work was financially supported by an unrestricted educational grant from Clasado Biosciences Ltd. Funding went to the Primary Care Society for Gastroenterology and Satellite PR who carried out the research and collated the results for the project.

The author(s) received no financial support for the research, authorship and/or publication of this article.

Disorders of gut-brain interaction (DGBI) are defined by several variable combinations of chronic or recurrent gastrointestinal symptoms that do not have an identified underlying pathophysiology, the most common example being IBS.¹ Rome IV elaborates: “[DGBI are] a group of disorders classified by GI symptoms related to any combination of the following: motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and altered central nervous processing.” DGBI have been linked to altered sleep quality and chronic pain, both of which can have considerable negative impact on patient quality of life.

According to NICE, the prevalence of IBS in the general population is estimated to be between 10% and 20%, although the true prevalence may be higher as it is thought that many people with IBS symptoms do not seek medical advice. IBS is twice as common in women than men and there is also a significant prevalence of IBS in older people. Each year, approximately 10% of the population will experience IBS symptoms and up to half will seek medical advice from primary care clinicians.²

Around a third of adults in Western countries experience sleep problems at least once a week, with 6-10% fulfilling the criteria for insomnia disorder. The prevalence of insomnia is 1.5 – 2 times higher in females than males. It can occur at any age but is most common in older adults. The prevalence of insomnia is higher in people with comorbid conditions, including chronic pain and psychiatric conditions.³

The concept of prebiotics was introduced by Gibson and Roberfroid in 1995.⁴ Prebiotics are not digestible but modulate the microbiota with a positive effect on microbes that are beneficial to gut health. Prebiotics have been shown to have beneficial effects that extend beyond the gut.

The prebiotic, B-GOS, comprises two structurally different β -galactooligosaccharides: β -1,3 galactooligosaccharides and β -1,4 and/or 1,6 galactooligosaccharides. One of the structures in B-GOS is 3-galactosyl-lactose, which is known as a human milk oligosaccharide (HMO), a substrate utilised by bifidobacteria.

Many controlled studies have been conducted in patients with functional symptoms of IBS, fibromyalgia and sleep disturbance. However, while prospective, randomised, controlled trials are essential for providing the robust scientific evidence on which to base clinical recommendations, their outcomes may not be representative of the effects that can be expected in a real-world setting.

Our study aimed to add to the body of evidence from controlled clinical trials by evaluating the self-reported experiences of individuals who use prebiotics such as B-GOS outside the clinical trial conditions.

Methods

Data collection

The study recruited 1,171 consumers from 30 September 2021 using an internet-based questionnaire developed by the study sponsor (Clasado Biosciences Ltd., Reading, UK) in collaboration with a Delphi-style panel of experts from the UK PCSG. Study participants provided consent via an online platform with the knowledge that their anonymised data would be collected, analysed, interpreted and potentially used for commercial reasons. B-GOS is a food supplement which is not under the remit of ethics or regulatory bodies for healthcare legislation that would normally apply to a medicine or medical device. At no time was it suggested that the product had therapeutic properties or could take the place of conventional medical management.

In addition to customers recruited via the Bimuno® customer database, an external control group of 50 participants was recruited to compare responses with the main cohort. This group was taken from among people who use, or had used, B-GOS in the real world but did not receive any communication from the Bimuno® team and did not buy directly from them. As an incentive, participants were invited to participate in a prize draw on completion of the study. There were no exclusions and use of other medications, products and diets was permitted.

Demographic evaluation

Primary consumers of B-GOS were asked about their prior and current health, including conditions suffered and main symptoms, their B-GOS usage and other lifestyle interventions. Respondents were asked to compare their experiences before and after B-GOS supplementation.

Responses were collected electronically via the survey interface, using a mixture of binary questions, rating scales, visual analogue scales and quality of life questions. Data from the study were compiled by the interface software into descriptive statistics, anonymised and encrypted. The sponsor and affiliated parties did not observe or have access to any personal data. Respondents were only permitted to answer the questions once in order to progress to the next stage of the questionnaire and were not able to enter the survey more than once from the same IP address. Attempting to make multiple entries from different computers was strongly discouraged.

Of the 1,171 individuals recruited and screened, 831 (71%) were female. The majority of respondents did not live with any dependent children (82%), were based in the South East of the UK (21%), were aged between 55-64 (29%) and had an annual household income of between £20,000 and £50,000.

Results

Existing conditions

Participants were asked if they had been diagnosed or believed that they suffered a range of common complaints, specifically ones that often motivate people to take pre- and probiotics (Fig. 1). Irritable bowel syndrome (IBS), sleep disturbances and chronic pain emerged as the three most common health conditions suffered by respondents. 36% reported diagnosed or self-diagnosed IBS and 35% reported sleep disturbances.

Do you have any of the following conditions?

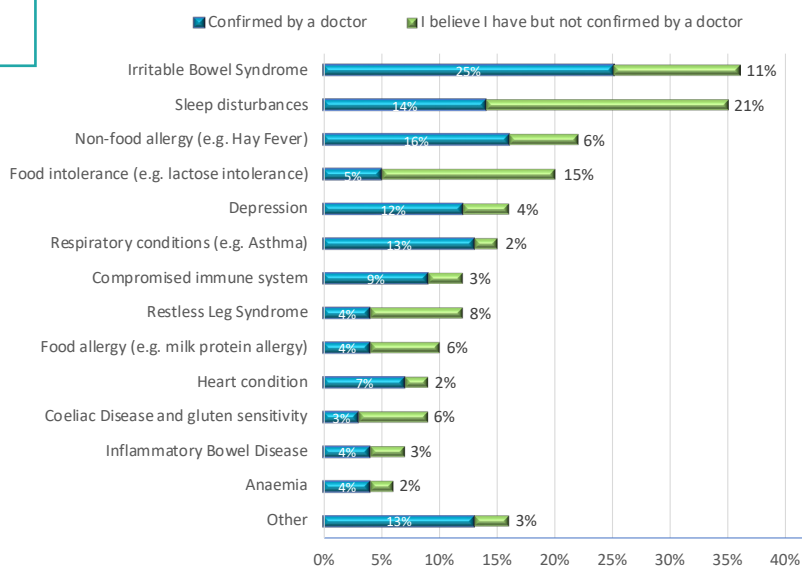


Figure 1
N = 1,171

Do you suffer from chronic pain?

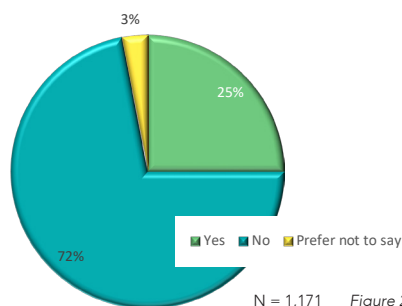


Figure 2
N = 1,171

Chronic pain

A quarter of respondents reported suffering from chronic pain (Fig. 2). The study defined chronic pain as: "Pain that has carried on for 12 weeks or more, despite treatment. This could be pain relating to a specific injury or condition, or pain that has come on without an immediate, specific cause." Those who suffered from chronic pain were not asked if this had been diagnosed by a GP or other healthcare professional.

Reasons for using B-GOS

Reported reasons for using B-GOS varied, but problems with indigestion and general stomach discomfort emerged as the most cited reason (33%). Other reasons included IBS and 'to improve gut health' and 26% reported using the product for reasons relating to sleep (Fig. 3).

Some respondents gave more than one reason when answering, including 'having seen a TV Doctor recommend' prebiotics for help with sleep (10%). The most common sleep issue was waking in the night and not being able to get back to sleep. Of those who reported using B-GOS for sleep improvement, 80% had not received a diagnosis.

Why do you use Bimuno?

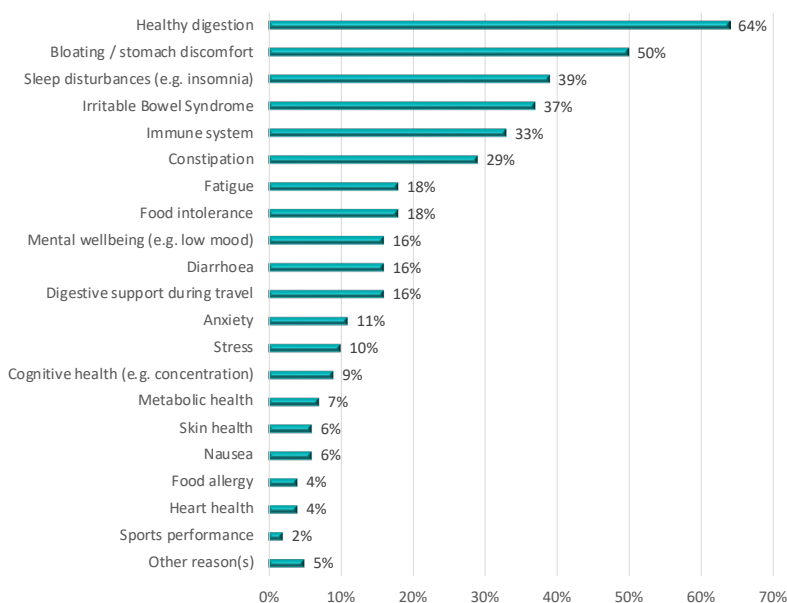


Figure 3
N = 1,171

Reported impact on QoL

On the 1-5 scale for impact on QoL, 67% rated the impact as 4 or 5 before using B-GOS and 48% rated the impact as 4 or 5 after using B-GOS. 59% rated the usefulness of B-GOS as 4 or 5 (top 2 scores). The biggest relative improvement pre- and post-B-GOS use was found in those who gave sleep problems as a reason for taking the prebiotic. However, only 53% of these individuals strongly felt this effect was attributable to B-GOS. By contrast, of those who gave bloating/stomach as reasons for use, 64% strongly felt that B-GOS was useful for their condition. The reported top 2 score for impact of IBS on QoL fell from 74% to 52%, with 62% rating B-GOS as positively useful in this condition (Table 1).

Symptom severity and usefulness of B-GOS

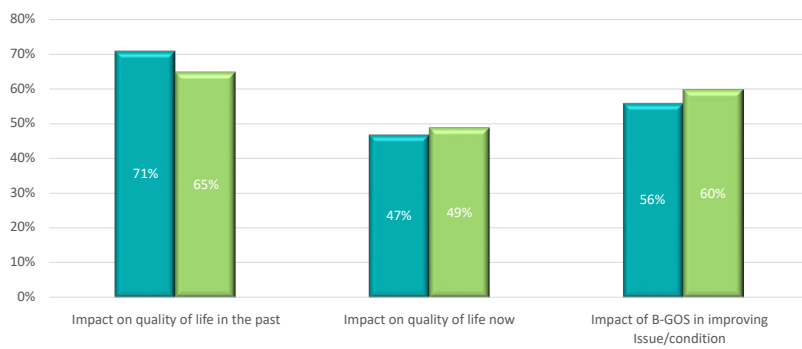
	Pre-B-GOS Top 2* scores	Post-B-GOS Top 2 scores	Usefulness of B-GOS Top 2 scores
Total Sample (1,171)	(67%)	(48%)	(59%)
Prompted reason			
Healthy digestion (753)	70%	50%	61%
Bloating / stomach (582)	74%	53%	64%
Sleep (455)	66%	45%	53%
IBS (437)	74%	52%	62%
Immune system (388)	68%	53%	61%
Constipation (341)	72%	55%	62%

■ > 5% above total sample
■ > 5% below total sample

* Scores of 4 or 5 out of 5

Table 1

Perceived positive impact of B-GOS on QoL for those suffering from chronic pain



*N = 297 **N = 841

Figure 4

Of the total 297 participants who reported suffering from chronic pain, 71% selected 4 or 5 when rating its impact on their QoL. This percentage dropped to only 47% following B-GOS use and 56% believed that B-GOS had contributed to this recovery.

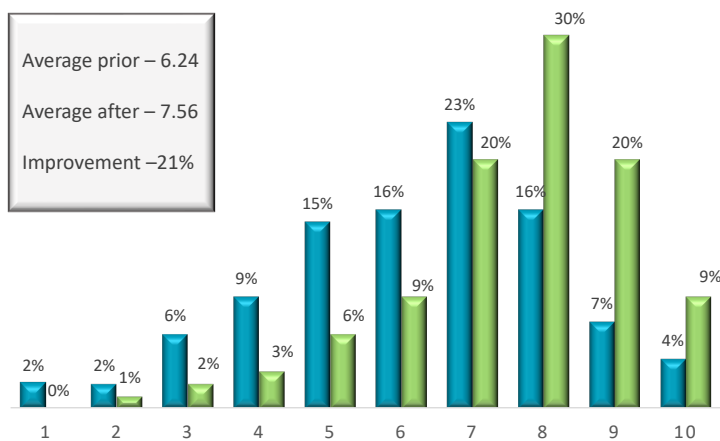
Although the group suffering from chronic pain experienced a greater improvement to their QoL post-B-GOS than those not suffering chronic pain, a smaller number attributed these improvements to use of the product (Fig. 4).

126 respondents who reported using B-GOS for sleep issues also suffered from chronic pain. 71% of these selected rating of 4 or 5 for impact of their condition on their QoL pre-B-GOS in contrast to 47% post-B-GOS – a greater rate of improvement than many other conditions cited by respondents as reasons for product usage. 51% believed that B-GOS had contributed to this recovery.

For the whole group completing the questionnaire, there was a marked improvement in overall reported health and wellbeing following B-GOS supplementation, with more reporting good health and fewer reporting poor health (Fig. 5).

Health and wellbeing before and after B-GOS

■ Immediately prior to taking B-GOS ■ Since taking B-GOS



Average prior – 6.24
 Average after – 7.56
 Improvement –21%

N = 1,171

Figure 5



Discussion

Controlled clinical trials are a vital part of the evidence base for a treatment and will remain the gold standard to guide recommendations. However, they represent a snapshot in time in a highly selected population, often treated for short durations which do not represent the real-life situation. While the positive effects in our study may be entirely expected in self-motivated consumers, it is reassuring that the benefits of B-GOS can also be observed in a large, real-world sample of individuals, exposed to the confounding factors of ongoing, everyday life.

Our real-world study included a heterogeneous group of individuals who were self-motivated purchasers and consumers of Bimuno®. 67% of respondents reported using B-GOS regularly and had done so in the last 2 weeks. 12% reported occasional use in the last 3 months. 19% said they had not taken B-GOS for 3 months or more but would consider reuse and 2% said they would not consider reuse. Of those taking B-GOS regularly or occasionally within the last 3 months, 84% did so on a daily basis.

In the small control group of B-GOS users (N=50), more reported that the improvement in health and wellbeing was not related, or only slightly related, to B-GOS (rating 1 or 2), with 42% rating at that level in the control compared to just 22% in the main sample. However, the shift was largely from mid-ratings of 3 and not a marked difference in numbers saying that the improvements were strongly related to B-GOS.

The use of the Bimuno® database as a means of collecting real-world evidence is associated with some obvious limitations and should only be considered as an insight into the pattern of real-world use. Our study was driven entirely by participant responses, with no objective measures. The age and regional spread of the study population was not nationally representative and only internet-users could participate. The use of an online questionnaire may also be confounded by recall bias.

The subjects had variable underlying GI symptoms and health conditions, which means that no conclusive associations between benefits and specific symptoms can be drawn. It should also be noted that 70% (820/1,171) of respondents were using

other products and medication in conjunction with B-GOS, either for the issues stated or for other unconnected reasons. Furthermore, around two-thirds of respondents had made at least one lifestyle change – dietary change and increased exercise being the most significant.

Although it was not possible to implement any quality assurance process or to eliminate delinquent responders, the algorithms in the software did prevent the accumulation of multiple responses and responses that were not logical.

For the reasons given above, only limited and cautious inferences can be drawn from the study results and they should be considered only as an adjunct to the existing controlled clinical trial data.

The fact that most B-GOS use was associated with gastrointestinal issues – mostly undiagnosed – was not surprising and neither was the large number who wanted simply to improve their gut health. The relatively high percentage reporting use of B-GOS for chronic pain was an unexpected observation. These results suggest that further investigation into the benefits of prebiotics is warranted.

Conclusions

Our study results add real-world evidence to the general body of clinical study evidence that supports B-GOS supplementation to promote GI health benefits in individuals affected by IBS and its related symptoms.

Among individuals who were motivated to use B-GOS for GI problems, chronic pain or sleep disturbance, there was marked self-reported improvement in quality of life. Most users attributed much of this improvement to the use of B-GOS supplementation.

© The Author(s) 2023

References

1. <https://www.karger.com/Article/FullText/505287>
2. <https://www.nice.org.uk/guidance/qs114/documents/irritable-bowel-syndrome-in-adults-qs-briefing-paper2>
3. <https://cks.nice.org.uk/topics/insomnia/background-information/prevalence/>
4. Gibson GR, Roberfroid MB. Dietary modulation of the human colonic microbiota: introducing the concept of prebiotics. J Nutr. 1995 Jun;125(6):1401–12.

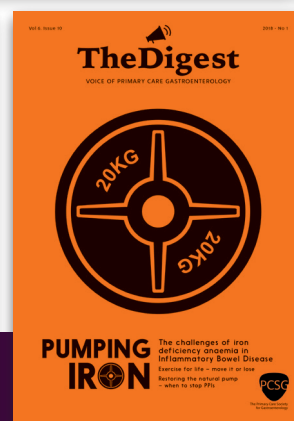
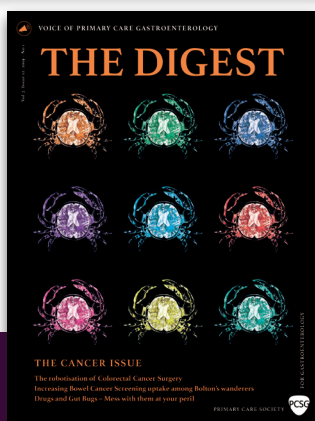
PCSG MEMBER BENEFITS CONCERNING THE DIGEST:

- ✓ Automatic subscription to The PCSG Digest eMagazine
- ✓ Access to view previous copies
- ✓ Access to The PCSG Newsletter The Digestif



ALL AVAILABLE
ONLINE

pcsg.org.uk/the-digest/



Send in your letters for publication and suggestions
for editorial contributions to editor@pcsg.org.uk