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Herbal Medicine for Diarrhoea-Predominant IBS: A Randomised Controlled Clinical Study.

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Abstract

Irritable Bowel Syndrome with Diarrhoea (IBS-D) is a chronic functional gastrointestinal disorder involving altered gut motility, visceral hypersensitivity, gut–brain axis dysregulation, and microbiota imbalance. Conventional therapies often provide incomplete relief, necessitating multi-target therapeutic strategies. IBS-Sure Plus is a polyherbal formulation developed to address multiple pathophysiological pathways underlying IBS-D. This study evaluates the efficacy of IBS-Sure Plus compared with mesalamine and placebo in patients with IBS-D. In this prospective, randomised, three-arm, open-label, parallel-group study, 60 adults diagnosed with IBS-D (Rome IV criteria) were randomised (1:1:1) to receive IBS-Sure Plus, mesalamine, or placebo (n=20 per group) for 3 weeks. Primary outcomes included bowel movement frequency and stool consistency assessed using the Bristol Stool Scale (BSS). Secondary outcomes included complete spontaneous bowel movements (CSBM), symptom severity, effect size (ES), standardised response mean (SRM), and treatment satisfaction. Baseline characteristics were comparable across groups. IBS-Sure Plus demonstrated large to very large effect sizes (0.90–3.59) across symptom domains, exceeding mesalamine (0.65–2.31), while placebo showed negligible effects. SRM values indicated consistent responsiveness with IBS-Sure Plus (0.43–0.48). CSBM increased from 30% at baseline to 100% at Week 3 with IBS-Sure Plus, compared with 80% for mesalamine and 25% for placebo. Stool consistency normalised (BSS Types 3–4) predominantly in the IBS-Sure Plus group. Treatment satisfaction differed significantly among groups ($p < 0.0001$). IBS-Sure Plus demonstrated superior short-term efficacy compared with mesalamine and placebo, supporting its potential as a multi-target therapeutic option for IBS-D. Larger, blinded studies are warranted.

Trial registration number: CTRI/2022/04/041561 (Clinical Trial Registry of India) Date: April 1, 2022.

Keywords: Irritable Bowel Syndrome with Diarrhoea (IBS-D); Polyherbal Formulation; Abdominal Pain; Bloating; Acidity; Appetite Loss

1. Introduction

Irritable Bowel Syndrome (IBS) is a chronic functional gastrointestinal disorder characterised by recurrent abdominal pain associated with altered bowel habits in the absence of identifiable structural abnormalities. The pathophysiology of IBS involves a complex interplay between altered gut motility, visceral hypersensitivity, gut microbiota imbalance, and dysregulation of the gut–brain axis [1, 2]. Although IBS was historically considered a stress-related disorder, contemporary evidence suggests that it is a multifactorial condition influenced by neuromuscular dysfunction, microbial dysbiosis, immune activation, and genetic susceptibility [3]. Recent advances in microbiome research have demonstrated significant alterations in the gut microbial composition of patients with IBS, indicating that dysbiosis may

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play a key role in symptom generation and disease progression. Furthermore, emerging genomic studies have identified genetic markers associated with increased susceptibility to IBS, highlighting the potential for targeted and personalised management strategies [4,5].

Globally, IBS affects approximately 4% of the population and is associated with a substantial reduction in quality of life due to symptoms such as abdominal pain, bloating, altered bowel habits, and gastrointestinal discomfort [5]. Among its clinical subtypes, IBS with diarrhoea (IBS-D) poses particular therapeutic challenges because of frequent bowel movements, urgency, and symptom exacerbation during periods of psychological stress or anxiety [6]. The cyclical association between psychological distress and gastrointestinal symptoms further complicates food intake patterns, with many patients developing meal-related anxiety, appetite loss, and fear of symptom exacerbation [7-9]. Over time, this may contribute to inadequate dietary intake, weight loss, and nutritional deficiencies.

Managing IBS-D requires an integrative approach that considers dietary modification, pharmacologic therapy, stress management, and microbiota-directed interventions. Commonly recommended strategies include low-FODMAP diets, small, frequent meals, and avoidance of known triggers [10-12]. Pharmacological options such as antispasmodics, antidiarrheal agents, acid-suppressive medications, fibre supplements, and probiotics are frequently used but often provide incomplete or temporary relief [13-16]. Moreover, long-term dependence on these therapies may raise concerns regarding safety and tolerability [17, 18].

Acidity and dyspeptic symptoms frequently coexist with IBS and may further aggravate abdominal discomfort, bloating, and diarrhoeal episodes through increased gastric secretions and altered gastrointestinal motility [19]. Therefore, effective management strategies should ideally address both intestinal and gastric components of the disorder to achieve comprehensive symptom control.

From an Ayurvedic perspective, the clinical manifestations of IBS resemble conditions described under Grahani and Atisara, which arise due to impairment of Agni (digestive fire) and imbalance of Vata and Pitta doshas. Disturbances in digestive function lead to improper digestion and absorption, resulting in symptoms such as diarrhoea, abdominal discomfort, bloating, and loss of appetite [20]. Ayurvedic management, therefore, focuses on restoring digestive balance, improving gut function, and strengthening Agni through the use of herbal formulations possessing Deepana, Pachana, and Grahi properties [21].

Given the limitations of existing therapies, there is increasing interest in polyherbal formulations rooted in traditional medicine systems such as Ayurveda. Herbal formulations offer multi-targeted mechanisms, better tolerability, and promising therapeutic potential for chronic gastrointestinal conditions [22-25]. The IBS Sure Plus Tablet is a specifically designed polyherbal formulation incorporating botanicals such as Musta (*Cyperus rotundus* L.), Ativisha (*Aconitum heterophyllum* Wall.), and Sunthi (*Zingiber officinale* Roscoe), each known in Ayurveda for their digestive, antidiarrheal, carminative, anti-inflammatory, and gut-modulatory properties [26-29]. This unique phytochemical combination is hypothesised not only to alleviate hallmark symptoms of IBS-D, such as diarrhoea, abdominal cramps, and bloating, but also to support appetite regulation and mitigate gastric acidity. Therefore, the present study was undertaken to evaluate the efficacy and safety of IBS Sure Plus Tablet in patients with IBS-D through a structured clinical investigation aimed at generating reliable and reproducible clinical evidence.

2. Material and Methods

2.1. Study Design

This study was conducted as a prospective, randomised, three-arm, parallel-group, open-label, placebo- and active-controlled clinical trial with an allocation ratio of 1:1:1. The trial was carried out at Healing Hands Clinic, Pune, India; www.healinghandsclinic.co.in. The participants were recruited from April 2022 to June 2022. Each participant was followed for a total duration of three weeks, with four scheduled visits (baseline and three follow-up visits). Randomisation was performed using a computer-generated random sequence. Allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes prepared by independent personnel not involved in recruitment or outcome assessment.

Due to practical limitations in matching the polyherbal formulation in taste, colour, and odour, the study was conducted in an open-label manner. However, standardised and validated outcome measures were used to reduce assessment bias.

Ethical approval was obtained from the Independent Ethics Committee of Healing Hands Clinic (Approval No.: HHCRS/IBS Sure Plus/005/2022). The trial was prospectively registered with the Clinical Trial Registry of India (CTRI/2022/04/041561). Written informed consent was obtained from all participants prior to enrolment.

2.2. Study Drug

IBS Sure Plus™ tablets are an Ayurvedic polyherbal preparation manufactured by Healing Hands & Herbs Pvt. Ltd., India. Each tablet comprises standardised herbal extracts, including Musta (*Cyperus rotundus* L.) 100 mg, Ativisha (*Aconitum heterophyllum* Wall.) 50 mg, and Sunthi (*Zingiber officinale* Roscoe) 100 mg.

For the control arm, Glucovita tablets were administered as the placebo intervention, while mesalamine tablets served as the active comparator and were procured from the pharmacy at Healing Hands Clinic. Although Glucovita does not represent a completely inert placebo, it was selected due to its comparable tablet formulation, acceptable taste, established safety record, and broad availability. These characteristics facilitated consistent dosing, handling, and administration procedures across all study groups.

2.3. Dose and Population

2.3.1. Dose

Participants assigned to the intervention arm received IBS Sure Plus™ tablets at a dose of two tablets twice daily, administered before breakfast and before dinner with water. Those in the placebo arm were given Glucovita tablets following the same dosing schedule—two tablets prior to breakfast and two tablets prior to dinner with water. Similarly, the reference treatment group received mesalamine tablets at a dosage of two tablets twice daily, taken before breakfast and before dinner with water, thereby ensuring uniformity in administration frequency and mode across all study groups. Medication adherence was assessed at each follow-up visit through tablet counts and patient self-reporting.

2.3.2. Population

A total of 60 participants were enrolled and randomised equally into three groups (n = 20 per group).

2.3.3. Inclusion Criteria

Participants were considered eligible if they met all of the following criteria:

- Male or female subjects aged ≥18 years.
- Diagnosis of Irritable Bowel Syndrome with Diarrhoea (IBS-D) according to Rome IV diagnostic criteria.
- Negative serum pregnancy test at screening for women of childbearing potential.
- No use of medications known to influence bowel function within one week prior to study initiation.
- Willingness to participate in the study and provide written informed consent.

2.3.4. Exclusion Criteria

Participants were excluded if they met any of the following criteria:

- Known hypersensitivity or allergy to any component of the study medications.
- Presence of significant uncontrolled systemic illness, including uncontrolled diabetes mellitus, renal dysfunction, hepatic disease, hyperthyroidism, or hypothyroidism.
- Use of probiotic therapy within the preceding three months.
- Confirmed or suspected pregnancy at screening.
- History of prior gastrointestinal surgery.

2.3.5. Study Procedure

Following screening and confirmation of eligibility, participants were randomly assigned to one of the three treatment arms. At Visit 1 (baseline), a detailed medical history was obtained, and a comprehensive physical examination was performed. Baseline assessments included evaluation of IBS-D symptom severity, documentation of bowel movement frequency, and assessment of stool consistency using the Bristol Stool Scale (BSS). The presence and frequency of complete spontaneous bowel movements (CSBM) were also recorded prior to initiation of treatment.

Participants returned for two interim follow-up visits (Visits 2 and 3), during which symptom severity was reassessed and stool consistency was again evaluated using the BSS. The frequency of CSBM was documented at each visit. In

addition, medication adherence was reviewed, and participants were monitored for any adverse events or treatment-related complications.

At Visit 4 (Week 3), a final evaluation of all primary and secondary outcomes was conducted. Primary outcomes included the change in bowel movement frequency from baseline to Week 3 and the change in stool consistency as measured by the BSS. Secondary outcomes comprised the proportion of participants achieving CSBM, changes in individual symptom domains (abdominal pain, degree of straining, abdominal discomfort, bloating, acidity, and loss of appetite), and calculation of effect size (Cohen's d) and Standardised Response Mean (SRM) to determine the magnitude and responsiveness of treatment effects. Treatment satisfaction was assessed at the final visit using a five-point Likert scale.

2.4. Statistical Analysis

The collected data was analysed using PAST 4.03(PAST version 4.03 (Hammer, Ø., Harper, D.A.T., Ryan, P.D., Natural History Museum, University of Oslo), Microsoft Office Excel 2021 software [Microsoft® Excel® 2021 MSO (Version 2501 Build 16.0.18429.20132)] and R-studio (RStudio/2023.06.0+421© 2009-2023). Statistical significance was set at 5 % (α=0.05). Participant demographics and baseline characteristics were summarised using mean, SD, and range for continuous variables and frequencies and percentages for categorical variables. Categorical outcomes, including Bristol Stool Chart classifications and complete spontaneous bowel movements, were analysed using frequencies and percentages. The Kruskal–Wallis H test was used to analyse treatment satisfaction scores between groups. When a statistically significant overall difference was observed, post-hoc pairwise comparisons were performed using Dunn's test. Effect size and Standardised Response Mean (SRM) were calculated to determine the magnitude and responsiveness of treatment effects across symptom domains.

3. Result

3.1. Baseline Demographic and Anthropometric Characteristics

The demographic and baseline anthropometric profile of the study population indicates that the three treatment groups were well balanced and comparable at baseline. Both male and female participants were represented across all arms, with a slightly higher proportion of female participants overall, which is consistent with the known epidemiology of IBS-D.

Participants in all three groups were similar in age distribution, ensuring that treatment outcomes were not confounded by age-related physiological differences. Likewise, body weight, height, and body mass index (BMI) were comparable between groups, suggesting a broadly homogeneous population with no clinically meaningful baseline imbalance in body composition or nutritional status. The BMI values across groups were within a range consistent with a mixed population of normal-weight and overweight individuals, reflecting a real-world IBS-D population rather than a narrowly selected cohort. Importantly, no group demonstrated extreme deviations in anthropometric parameters that could bias gastrointestinal motility, drug response, or symptom perception.

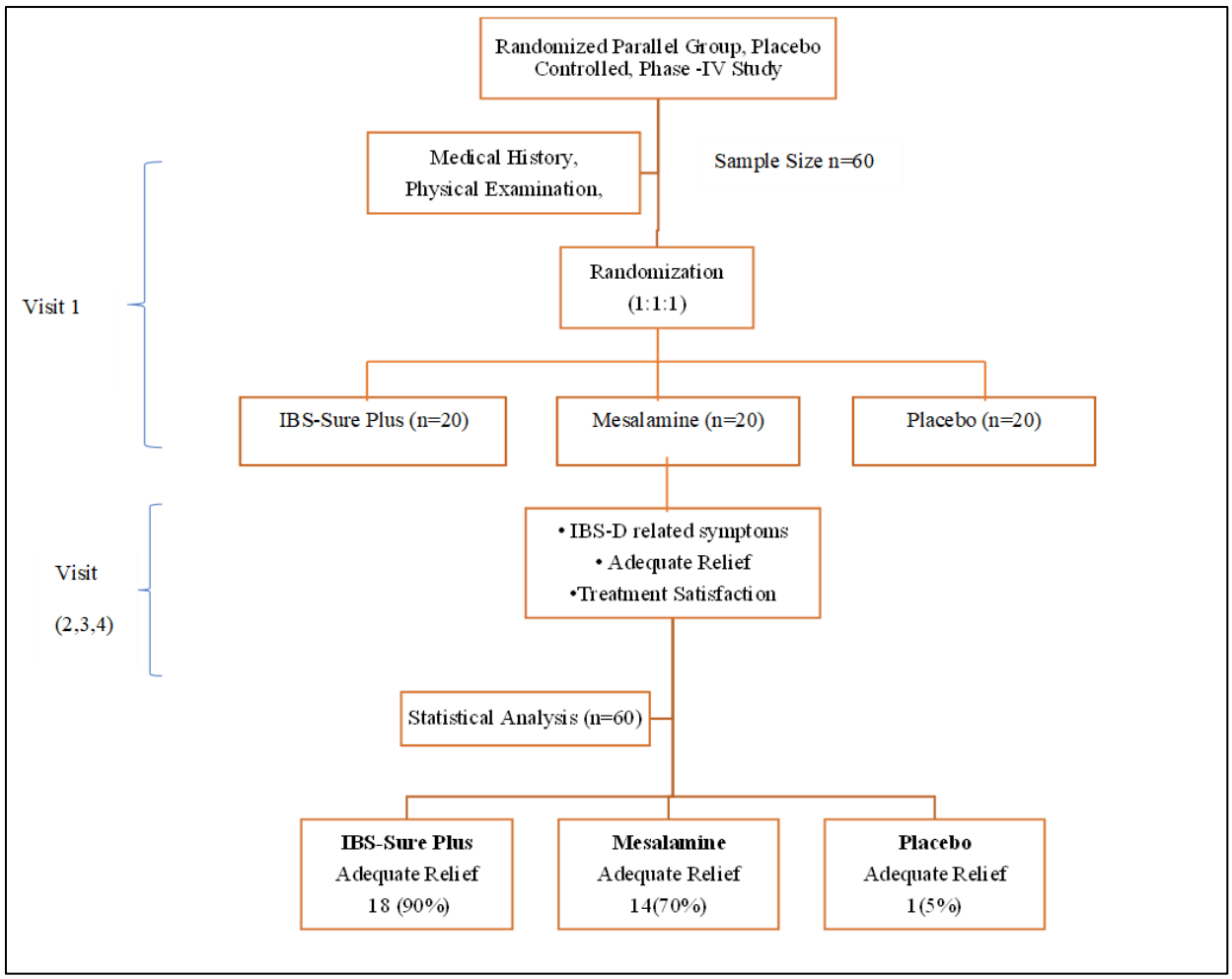

Figure 1 Participant flow chart

Table 1 Demographic Details

	IBS-SURE Plus	Mesalamine	Placebo	Total
Gender n (%)				
Male	9(45%)	11(55%)	6(30%)	26(43.33%)
Female	11(55%)	9(45%)	14(70%)	34(56.67%)
Age (yr.)				
Mean (SD)	47.05(14.63)	47.15(15.36)	52.15(13.86)	48.78(14.58)
Range	54	45	62	65
Weight (kg)				
Mean (SD)	63.75(11.14)	65.85(11.13)	63.65(11.70)	64.42(11.18)
Range	35	46	40	49
Height (cm)				
Mean (SD)	165.66(9.95)	167.49(9.35)	167.18(8.05)	166.78(9.03)
Range	30.48	30.48	30.48	30.48
Body Mass Index (BMI) (Kg/m^2)				

Mean (SD)	23.115(2.68)	23.49(3.62)	24.83(10.02)	23.81(6.28)
Range	10.9	15.3	47.1	47.1

3.2. Effect Size and Standardised Response Mean Analysis

The magnitude of treatment effect across six key IBS-D symptoms (abdominal pain, straining, abdominal discomfort, loss of appetite, acidity, and bloating) was assessed using Effect Size (ES) and Standardised Response Mean (SRM) for the IBS-Sure Plus, Mesalamine, and Placebo groups (Table 2).

IBS-Sure Plus demonstrated consistently large to very large effect sizes across all symptoms (ES range: ~0.9 to 3.6), indicating substantial clinical improvement from baseline. The largest effects were observed for abdominal pain, abdominal discomfort, acidity, and bloating, reflecting strong symptom control within 3 weeks of treatment. Mesalamine showed moderate to large effects across most domains (ES range: ~0.7 to 2.3), confirming therapeutic benefit but of a lower magnitude compared with IBS-Sure Plus. Improvements were particularly notable for abdominal pain and abdominal discomfort, though less pronounced than those seen with IBS-SURE Plus. In contrast, the placebo group showed negligible or negative effect sizes (ES range approximately −0.11 to 0.14), indicating minimal improvement or worsening of symptoms over time, confirming the absence of a clinically meaningful placebo response.

The Standardised Response Mean (SRM) analysis, which reflects the sensitivity to change, showed a similar pattern. IBS-Sure Plus produced consistently high SRM values (approximately 0.43–0.48), demonstrating strong and uniform responsiveness across all symptom domains. Mesalamine produced moderate SRMs (~0.42–0.48), while the placebo showed very low or negative SRMs, indicating poor symptom improvement (Figure 2).

Table 2 Effect Size (ES) and Standardised Response Mean (SRM) Analysis

Symptoms	Measure	IBS-Sure Plus	Mesalamine	Placebo
Abdominal Pain	ES	3.5940	2.3170	0.1442
	SRM	0.4822	0.4791	0.1274
Degree of Straining	ES	1.1428	0.9047	- 0.1442
	SRM	0.4652	0.4655	- 0.2032
Abdominal Discomfort	ES	2.6831	1.3430	- 0.1143
	SRM	0.4805	0.4799	- 0.1228
Loss of Appetite	ES	0.9021	0.6561	0.0405
	SRM	0.4311	0.4216	0.0720
Acidity	ES	3.5485	1.8439	- 0.0624
	SRM	0.4791	0.4434	- 0.0815
Abdominal Bloating	ES	2.3106	1.3141	- 0.0994
	SRM	0.4740	0.4729	- 0.1486

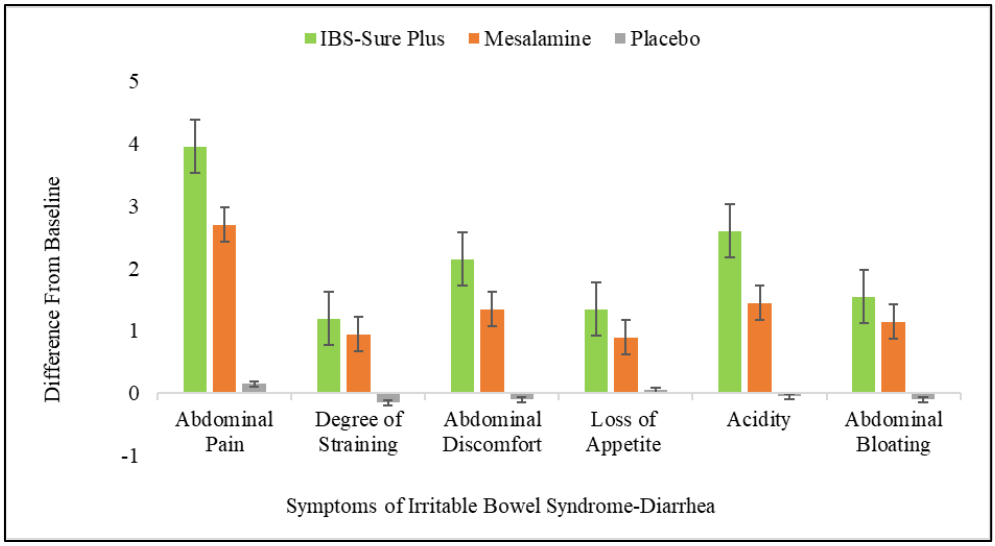

Figure 2 Graphical representation of symptoms of irritable bowel syndrome in IBS-D patients

3.3. Complete spontaneous bowel movement:

Table 3 Change in the complete Spontaneous Bowel Movement in irritable bowel syndrome (Diarrhoea) (IBS-D) patients from baseline to 3 weeks

Visit	IBS Sure Plus	Mesalamine	Placebo
Visit 1	6 (30%)	5 (25%)	5(25%)
Visit 2	12(60%)	9(45%)	4(20%)
Visit 3	17(85%)	12(60%)	5(25%)
Visit 4	20 (100%)	16(80%)	5(25%)

The proportion of patients reporting complete spontaneous bowel movements (CSBM) increased progressively in the IBS-Sure Plus and mesalamine groups over the 3-week treatment period, while no meaningful improvement was observed in the placebo group.

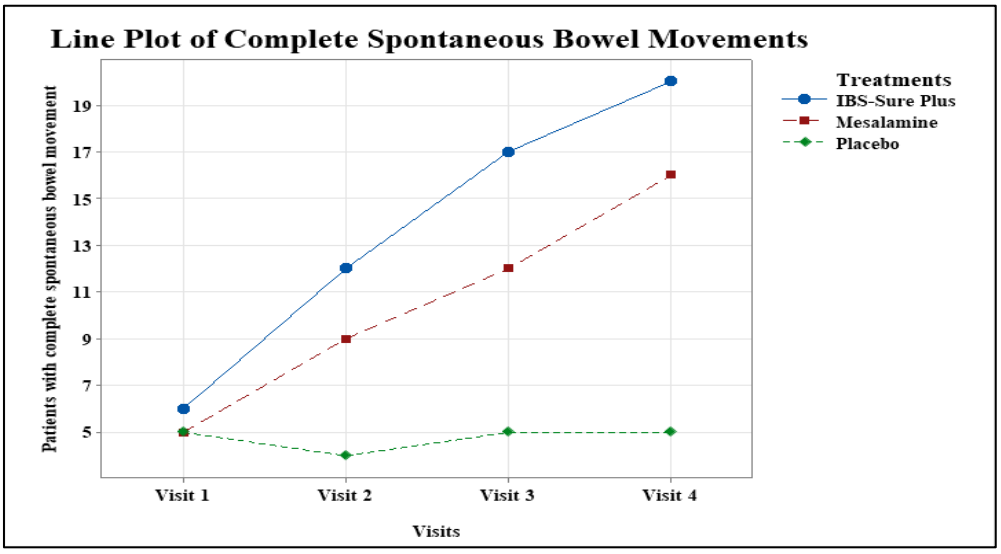

Figure 3 Graphical representation of Complete spontaneous bowel movements

At baseline (Visit 1), only 25–30% of patients across all groups reported CSBM. By Visit 4, 100% of patients in the IBS-Sure Plus group achieved CSBM, compared with 80% in the mesalamine group and 25% in the placebo group. The improvement with IBS-Sure Plus was both faster and greater than with mesalamine, indicating superior restoration of bowel completeness. The placebo group showed no sustained change from baseline (Table 3 and Figure 3).

3.4. Change in Stool Form (Bristol Stool Scale)

Stool consistency was assessed using the Bristol Stool Scale (BSS) across all study visits. At baseline, the majority of patients in all three groups had loose stools consistent with IBS-D, with mean BSS values predominantly in the diarrhoeal range (Types 6–7).

Over the 3-week treatment period, the IBS-Sure Plus group showed a marked shift toward normal stool consistency. By Visit 4, most patients in this group achieved BSS Types 3–4, indicating well-formed, normal stools. The mesalamine group also demonstrated improvement, with stool consistency moving toward Types 4–5, although the magnitude of normalisation was less pronounced than with IBS-Sure Plus. In contrast, the placebo group showed minimal change across visits, with stool forms remaining largely within the diarrhoeal range (Types 6–7) throughout the study (Table 4 and Figure 4).

Table 4 Change in Stool Form

Group	Visit	Type 3	Type 4	Type 5	Type 6	Type 7
IBS-Sure Plus	Visit 1	0 (0%)	0 (0%)	4 (20%)	7 (35%)	9 (45%)
	Visit 2	0 (0%)	2 (10%)	8 (40%)	9 (45%)	1 (5%)
	Visit 3	0 (0%)	10 (50%)	9 (45%)	1 (5%)	0 (0%)
	Visit 4	3 (15%)	16 (80%)	1 (5%)	0 (0%)	0 (0%)
Mesalamine	Visit 1	0 (0%)	0 (0%)	5 (25%)	10 (50%)	5 (25%)
	Visit 2	0 (0%)	1 (5%)	11 (55%)	6 (30%)	2 (10%)
	Visit 3	0 (0%)	6 (30%)	11 (55%)	3 (15%)	0 (0%)
	Visit 4	2 (15%)	12 (60%)	5 (25%)	1 (5%)	0 (0%)
Placebo	Visit 1	0 (0%)	0 (0%)	6 (30%)	7 (35%)	7 (35%)
	Visit 2	0 (0%)	1 (5%)	8 (40%)	9 (45%)	2 (15%)
	Visit 3	0 (0%)	2 (10%)	6 (30%)	6 (30%)	6 (30%)
	Visit 4	0 (0%)	2 (15%)	4 (20%)	5 (25%)	9 (45%)

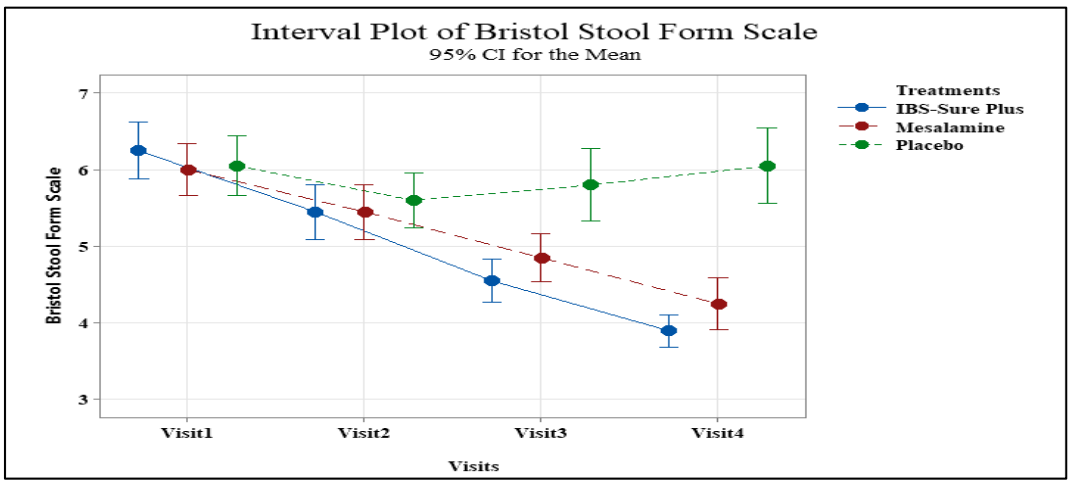

Figure 4 Graphical representation of the Bristol Stool Scale in IBS-D patients having different treatments

3.5. Treatment Satisfaction Assessment

Treatment satisfaction was evaluated at the end of the 3-week therapy using a five-point Likert scale ranging from "Not at all satisfied" to "Very satisfied." Differences among treatment groups were analysed using the Kruskal–Wallis H test at a 5% level of significance.

A statistically significant difference in treatment satisfaction was observed among the three groups at the final visit ($p < 0.0001$), indicating that at least one group median differed significantly from the others. Post-hoc analysis using Dunn's test demonstrated that all pairwise comparisons were statistically significant ($p < 0.05$).

Table 5 Analysis of treatment satisfaction assessment

Sr No.	Factor	n	Average rank	Significantly Different (P<0.05) from Factor
1.	IBS-Sure Plus	20	47.08	(2)(3)
2.	Mesalamine	20	32.13	(1)(3)
3.	Placebo	20	12.3	(1)(2)

The mean rank scores were highest for the IBS-Sure Plus group (47.08), followed by the Mesalamine group (32.13), and lowest for the Placebo group (12.30). These findings indicate significantly greater patient satisfaction with IBS-Sure Plus compared to both Mesalamine and Placebo (Table 5).

4. Discussion

The present randomised, three-arm, open-label clinical study evaluated the therapeutic efficacy of IBS-Sure Plus in comparison with mesalamine and placebo in patients with IBS-D. The findings demonstrate that IBS-Sure Plus produced clinically meaningful and statistically significant improvements across multiple symptom domains, including abdominal pain, straining, abdominal discomfort, bloating, acidity, appetite loss, stool consistency, and complete spontaneous bowel movements (CSBM). Overall, the magnitude and consistency of improvement were greater in the IBS-Sure Plus group compared with both mesalamine and placebo.

Baseline demographic and anthropometric characteristics were comparable across all three groups, with no clinically relevant imbalances in age, gender distribution, body weight, height, or BMI. This homogeneity strengthens the internal validity of the study and supports that observed differences in outcomes are likely attributable to the interventions rather than baseline confounders.

Effect size (ES) and Standardised Response Mean (SRM) analyses further substantiate the clinical relevance of the findings. IBS-Sure Plus demonstrated large to very large effect sizes across all evaluated symptoms, particularly for abdominal pain, abdominal discomfort, acidity, and bloating. These large ES values indicate substantial improvement from baseline within a relatively short treatment duration of three weeks. In comparison, mesalamine produced moderate to large effects, confirming therapeutic benefit but with a lower magnitude than IBS-Sure Plus. The placebo group demonstrated negligible or negative effect sizes, indicating minimal spontaneous improvement and reinforcing the true pharmacological effect of the investigational product. The SRM results mirrored this pattern, demonstrating strong responsiveness and consistency of symptom change with IBS-Sure Plus.

Restoration of bowel function is a key therapeutic goal in IBS-D management. The proportion of patients achieving CSBM increased progressively in the IBS-Sure Plus group, reaching 100% by Week 3. This improvement was both faster and greater than that observed with mesalamine (80%) and markedly superior to placebo (25%). The ability of IBS-Sure Plus to normalize bowel completeness suggests a meaningful impact on intestinal motility regulation and coordinated bowel evacuation.

Similarly, stool form assessment using the Bristol Stool Scale revealed a clear shift from diarrhoeal stool types (Types 6–7) toward normal stool consistency (Types 3–4) in the IBS-Sure Plus group. Although mesalamine demonstrated improvement toward Types 4–5, normalisation was less pronounced. The placebo group showed minimal sustained change. Normalisation of stool form is clinically significant, as it reflects improved intestinal transit and better symptom control.

Patient-reported treatment satisfaction further supports the clinical findings. The Kruskal–Wallis H test demonstrated a statistically significant difference among groups ($p < 0.0001$), and Dunn's post-hoc analysis confirmed that all pairwise comparisons were significant. The highest mean rank for satisfaction was observed in the IBS-Sure Plus group, followed by mesalamine and placebo. These results indicate that patients perceived greater overall benefit with IBS-Sure Plus, aligning with objective improvements in symptom scores and bowel parameters.

The superior performance of IBS-Sure Plus may be attributed to its polyherbal composition, which is designed to exert multi-targeted effects. IBS-D is a multifactorial disorder involving altered motility, visceral hypersensitivity, gut microbiota imbalance, mucosal inflammation, and stress-related dysregulation of the gut–brain axis [29,30]. A multi-component herbal formulation may address several of these pathophysiological pathways simultaneously, potentially explaining the broader and more consistent therapeutic response observed in this study. Additionally, improvement in acidity and appetite loss suggests a dual gastric and intestinal modulatory action, supporting holistic symptom control.

The study has several strengths, including randomised allocation, the inclusion of both placebo and active comparator arms, predefined outcome measures, and the use of validated assessment tools such as the Bristol Stool Scale. However, certain limitations must be acknowledged. The open-label design introduces the possibility of performance and detection bias, although standardised outcome assessments and independent randomisation procedures were implemented to mitigate this risk. The relatively short duration of follow-up (three weeks) limits conclusions regarding long-term efficacy and safety. Furthermore, as a single-centre study with a modest sample size, external generalizability may be limited.

Future multicenter, double-blind studies with larger sample sizes and longer follow-up periods are warranted to confirm these findings and evaluate the long-term sustainability of the response. Additional mechanistic studies exploring microbiota modulation, inflammatory biomarkers, and gut–brain axis parameters would further clarify the underlying therapeutic mechanisms of IBS-Sure Plus.

5. Conclusion

In conclusion, IBS-Sure Plus demonstrated superior efficacy compared with mesalamine and placebo in improving global IBS-D symptoms, restoring bowel function, normalising stool consistency, reducing acidity, and enhancing patient satisfaction within three weeks of therapy. These findings suggest that IBS-Sure Plus may represent a promising multi-target therapeutic option for the management of IBS-D.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of ethical approval

The study was conducted only after getting approval from a Healing Hands independent ethics committee.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

[1] Tang HY, Jiang AJ, Wang XY, et al. Uncovering the pathophysiology of irritable bowel syndrome by exploring the gut-brain axis: a narrative review. Annals of Translational Medicine. 2021;9(14).

[2] Porwal A, Bhagwat G, Kamble P, et al. The Irritable Bowel Syndrome (IBS): Understanding its types, prevalence, and treatment options. World Journal of Advanced Research and Reviews. 2024;22(01):720-728.

[3] Qin HY, Cheng CW, Tang XD, et al. Impact of psychological stress on irritable bowel syndrome. World journal of gastroenterology: WJG. 2014;20(39):14126.

[4] Labus JS, Hollister EB, Jacobs J, et al. Differences in gut microbial composition correlate with regional brain volumes in irritable bowel syndrome. Microbiome. 2017;5:1-7.

[5] Colomier E, Algera J, Melchior C. Pharmacological therapies and their clinical targets in irritable bowel syndrome with diarrhea. Frontiers in Pharmacology. 2021;11:629026.

[6] El-Serag HB, Olden K, Bjorkman D. Health-related quality of life among persons with irritable bowel syndrome: a systematic review. Alimentary pharmacology & therapeutics. 2002;16(6):1171-85.

[7] Borghini R, Donato G, Alvaro D, et al. New insights in IBS-like disorders: Pandora's box has been opened; a review. Gastroenterology and Hepatology from bed to bench. 2017;10(2):79.

[8] Konturek PC, Brzozowski T, Konturek SJ. Stress and the gut: pathophysiology, clinical consequences, diagnostic approach and treatment options. J Physiol Pharmacol. 2011;62(6):591-9.

[9] Drossman DA, Chang L, Schneck S, et al. A focus group assessment of patient perspectives on irritable bowel syndrome and illness severity. Digestive diseases and sciences. 2009;54:1532-41.

[10] Wilson B, Cox SR, Whelan K. Challenges of the low FODMAP diet for managing irritable bowel syndrome and approaches to their minimisation and mitigation. Proceedings of the Nutrition Society. 2021;80(1):19-28.

[11] Mansueto P, Seidita A, D'Alcamo A, et al. Role of FODMAPs in patients with irritable bowel syndrome. Nutrition in Clinical Practice. 2015; 30(5): 665-82.

[12] Porwal A, Gandhi P, Kulkarni D. Prospective, Phase IV, Open Label, Non-comparative, Single-arm, Single-centre Pilot Study to evaluate the effectiveness of adding KB01 in participants with IBD, IBS and ODS based on the gut microbiome analysis. wjpps. 2019;8(10):569-578.

[13] Pimentel M. Evidence based management of irritable bowel syndrome with diarrhea. Am J Manag Care. 2018;24(3):S35-46.

[14] Grundmann O, Yoon SL. Irritable bowel syndrome: Epidemiology, diagnosis and treatment: An update for health care practitioners. Journal of gastroenterology and hepatology. 2010; 25(4): 691-9.

[15] Rahimi R, Nikfar S, Rezaie A, et al. Efficacy of tricyclic antidepressants in irritable bowel syndrome: a meta-analysis. World journal of gastroenterology: WJG. 2009; 15(13): 1548.

[16] Camilleri M, Heading RC, Thompson WG. Consensus report: clinical perspectives, mechanisms, diagnosis and management of irritable bowel syndrome. Alimentary pharmacology & therapeutics. 2002; 16(8): 1407-30.

[17] Park J, Floch MH. Prebiotics, probiotics, and dietary fiber in gastrointestinal disease. Gastroenterology Clinics of North America. 2007;36(1):47-63.

[18] D'Silva A, MacQueen G, Nasser Y, et al. Yoga as a therapy for irritable bowel syndrome. Digestive diseases and sciences. 2020;65:2503-14.

[19] Noddin L, Callahan M, Lacy BE. Irritable bowel syndrome and functional dyspepsia: different diseases or a single disorder with different manifestations?. MedGenMed. 2005;7(3):17.

[20] Sharma V, Pathariya S, Lodhi S. Ayurvedic Perspective of Irritable Bowel Syndrome as Grahani - Assessing the Effectiveness of a Holistic Treatment Approach. J Ayurveda Integr Med Sci. 2025;10(6):369-373.

[21] Maurya N, Ram M, Jaiswal RNT, Saxena A. A review article of Grahani Roga and its Ayurvedic management. J Ayurveda Integr Med Sci. 2024;9(7):138-142.

[22] Balkrishna A, Srivastava D, Parveen R, Kukreti A, Sharma N. Herbal Approaches to Gastrointestinal Disorders: Integrating Tradition and Science. J Transl Gastroenterol. 2025;00(00):1-46.

[23] Porwal A, Gandhi P, Kulkarni D, et al. PiloKit: a prospective, open-label clinical study for the management of haemorrhoids, anal fissures, and perineal wounds. Journal of Herbal Medicine. 2026;55:101078.

[24] Porwal A, Kundu GC, Bhagwat G, et al. Polyherbal formulation Anoac-H suppresses the expression of RANTES and VEGF for the management of bleeding hemorrhoids and fistula. Mol Med Rep. 2021;24(4):736.

[25] Porwal A, Kundu GC, Bhagwat G, et al. Herbal medicine AnoSpray suppresses proinflammatory cytokines COX-2 and RANTES in the management of hemorrhoids, acute anal fissures and perineal wounds. Exp Ther Med. 2022;23(1):86.

[26] Nagarajan M, Kuruvilla GR, Kumar KS, et al. Pharmacology of Ativisha, Musta and their substitutes. J Ayurveda Integr Med. 2015;6(2):121-133.

[27] Mao QQ, Xu XY, Cao SY, et al. Bioactive Compounds and Bioactivities of Ginger (Zingiber officinale Roscoe). Foods. 2019;8(6):185.

[28] Porwal A, Gandhi P, Bhagwat G. Efficacy and Safety of polyherbal formulation in acid peptic diseases. wjpmr. 2019;5(7):149-152.

[29] Talreja S, Tiwari S. A comprehensive review of Aconitum heterophyllum. Journal of Ayurveda and Integrated Medical Sciences. 2023;8(10):195-201.

[30] Chey WD, Kurlander J, Eswaran S. Irritable bowel syndrome: a clinical review. JAMA. 2015;313(9):949-958.

[31] Drossman DA. Functional gastrointestinal disorders: history, pathophysiology, clinical features and Rome IV. Gastroenterology. 2016;150(6):1262–1279.e2.