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# Efficacy and Safety of a Mool Health's Personalized Ayurvedic Gut Health Regimen in Management of Functional Constipation (FC) and irritable bowel syndrome with constipation (IBS-C): A Clinical Evaluation

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**Abstract**

Functional constipation (FC) and irritable bowel syndrome with constipation (IBS-C) are common gastrointestinal disorders that significantly impair quality of life. This study evaluated the efficacy and safety of a personalized Ayurvedic gut health regimen developed by Mool Health in adults with FC or IBS-C. A 28-day clinical trial was conducted at Tulsi Multispecialty Hospital, Delhi, India, involving 40 adult Participants aged 18–60 years. Participants received individualized Ayurvedic therapy tailored according to baseline symptom severity determined through an online diagnostic assessment. Efficacy was evaluated using a Visual Analog Scale (VAS), Patient Assessment of Constipation-Symptoms (PAC-SYM), and the Bristol Stool Form Scale, while safety was monitored through adverse event reporting and vital sign assessment.

All participants (FC: 24; IBS-C: 16) completed the 28-day study with no dropouts. Based on Clinical response rate of the participants of VAS score assessment at the end of the study, (95%) reported reduction in constipation, (90.5%) in acidity, (77.7%) in bloating, (89.2%) in gas, (90%) in stress, and (70%) in Sleeplessness symptoms. PAC-SYM scores demonstrated significant reductions in abdominal discomfort (-80.4%), rectal burning (-76.2%), and hard stools (-78.9%). Stool frequency was lowered from $2.53 \pm 0.43$ to $1.38 \pm 0.27$ movements/day signifying the improvement in gut health. All participants had transitioned from constipated stool types (Types 1–2) to normal forms (Types 3–4) by day 28. Subgroup analysis revealed that FC participants had a higher frequency of Type 4 stools (66.7%), whereas the IBS-C group showed greater improvement in bloating (-83.33%) and acidity (-83.93%). No serious adverse events were observed.

These findings from this explorative study suggest that Mool Health's personalized regimen is a safe and holistic intervention in management of FC and IBS-C.

**Keywords:** functional constipation, IBS-C, Ayurvedic intervention, Probiotic, gut health, clinical trial, personalized therapy

## Introduction

Constipation represents one of the most widespread functional gastrointestinal disorders, with a global burden that spans all age groups and substantially impairs health-related quality of life. In India, the prevalence and clinical presentation of functional constipation (FC) and IBS-C vary significantly across demographic and socio-economic groups. A study reported that 75.6% of Indian patients with chronic constipation were diagnosed with FC, while 24.4% had IBS-C, highlighting the predominance of FC and the clinical heterogeneity within this population.[1]

Clinically, Functional constipation (FC) is defined by reduced bowel movement frequency, excessive straining, hard or fragmented stools, and a persistent sensation of incomplete rectal evacuation. In irritable bowel syndrome with constipation (IBS-C), these symptoms are typically accompanied by recurrent abdominal pain or discomfort, which is characteristically relieved following defecation.[2]

From an Ayurvedic perspective, constipation is attributed to an imbalance in the Pitta and Vata doshas, along with the accumulation of Ama (toxins), which collectively disrupt normal digestive processes and bowel elimination.[3]

Although the market offers a wide range of laxatives and dietary interventions, their long-term effectiveness remains questionable. Prolonged use of certain laxatives can lead to dependency and adverse side effects, while many patients report persistent symptoms and dissatisfaction despite these conventional treatments.[4] This highlights a critical gap in sustainable, patient-centered care for constipation management.

This underscores an urgent unmet need for better, sustainable, and comprehensive treatment modalities. Recent research highlights the crucial role of gut microbiota in maintaining digestive function, with disruptions in microbial balance increasingly linked to constipation and other gastrointestinal disorders.[5] Symptoms such as bloating, gas, and acidity often accompany constipation, reflecting impaired motility and fermentation imbalances.[6] Ayurvedic remedies like Triphala,[7] Isabgol,[8] and Ashwagandha[9] have been traditionally used as mild, plant-based laxatives to promote gut health and restore microbial homeostasis. However, prolonged or unsupervised use of such agents may result in physiological dependence and diminished natural bowel motility. Moreover, modern lifestyle factors—including chronic stress, inadequate sleep, irregular dietary habits [10] and physical inactivity are increasingly recognized as key contributors to constipation. These findings highlight the need for comprehensive and sustainable therapeutic strategies that not only provide symptomatic relief but also target the underlying causes.

Thus, an exploratory clinical trial was conducted to evaluate the efficacy and safety of a Mool Health's personalized gut health regimen in adult patients diagnosed with functional constipation (FC) and irritable bowel syndrome with constipation (IBS-C). Key outcome measures included changes in constipation severity, bowel movement frequency, stool consistency, and associated gastrointestinal symptoms. The regimen's safety was systematically assessed throughout the intervention period.

## Materials and methods

### Study design and population:

This exploratory clinical trial was conducted at Tulsi Multi speciality Hospital, Delhi, India, according to the guidelines of the Declaration of Helsinki, and ICH-GCP. Study was approved by the Central Independent Ethics Committee of the hospital and is registered with the Clinical Trials Registry of India (CTRI/2024/12/077721). Total 40 eligible participants were enrolled based on clinical evaluation and

assessment of stool samples using Bristol Stool Form Scale assessment [23,24]. An informed consent was obtained from all subjects involved in the study before enrolment by the investigator.

**Patient recruitment:**

Participants were recruited through referrals and outpatient clinics. Screening included medical history, physical exam, compliance to inclusion and exclusion criteria and standardized assessment of GI symptoms by the investigator.

**Inclusion criteria**: comprised adults (18–60 years) both male and females; clinically diagnosed with mild to severe FC or IBS-C.

**Exclusion criteria:** Patients with gastrointestinal disorders such as irritable bowel syndrome with Diarrhea (IBS-D), irritable bowel syndrome with Mixed Bowel Habits (IBS-M), inflammatory bowel disease, recent GI surgery, hepatic or immunocompromising conditions, recent antibiotic use (within two weeks), and pregnancy or lactation.

**Study intervention:**

Following informed consent and eligibility confirmation, 40 participants were enrolled and assigned to symptom-tailored interventions. Participants received a personalized gut health regimen based on baseline gastrointestinal symptoms and severity. Treatment allocation was guided by a predefined symptom-based algorithm, with participants receiving one or more study formulations according to their predominant symptom profile. The products, indications, and dosing schedules are summarized in Table 1.

**Table 1: Study Treatment Intervention**

| Products and Probiotics | Dosages (or as prescribed by PI) |
|---|---|
| Consti Free & Gut Bliss | Take 2 tablet at bedtime with water &<br>Take 1 tablet twice a day after meals with water |
| Acid Soothe | Take 1 tablet twice a day after meals with water |
| Digest Ease | Take 1 tablet twice a day after meals with water |
| Consti Care (For Mild)<br>Consti Free (For Severe) | Take 1 tablet at bedtime with water<br>Take 2 tablet at bedtime with water |
| Stress Less | Take 2 tablet at bedtime with water |
| Probiotic (*B. coagulance* + Inulin fiber) | Take 1 tablet at bedtime with water |

The intervention included specific combinations of herbal supplements, probiotics, and adjunct therapies targeting constipation, bloating, gas, acidity, stress, and sleep disturbances. Participant anonymity was maintained throughout, with data recorded under coded identifiers. All investigational products used in this trial were manufactured under good manufacturing practice (GMP) standards by Tatvartha Health Private Limited. Although the intervention period allowed for a 28-day extension in non-responders, no extensions were necessary. Participants were instructed to record daily intake in subject diaries. Compliance was assessed via pill counts and diary reviews at follow-up visits.

**Outcome measures**

**Efficacy assessments:** Primary efficacy endpoints Included changes in constipation severity and stool consistency from baseline to day 28 using Visual analogue scale (VAS) score analysis.

Secondary endpoints included changes in bowel movement frequency, improvements in stool consistency, and symptom relief related to straining, bloating, incomplete evacuation, and abdominal discomfort.

**Safety assessments:** The safety of the investigational products was evaluated by monitoring all adverse and serious adverse events, including their incidence, severity, and relation to the intervention. Vital signs (heart rate, blood pressure, respiratory rate, temperature) and physical exams were performed at baseline and day 28. No major health problems occurred during the trial, and the researchers used simple summaries to monitor any possible safety concerns.

**Statistical analysis**

Demographic and baseline characteristics were summarized using descriptive statistics. Continuous variables were reported as mean ± SD, and categorical variables as frequencies and percentages. Vital signs and physical exam findings were summarized descriptively.

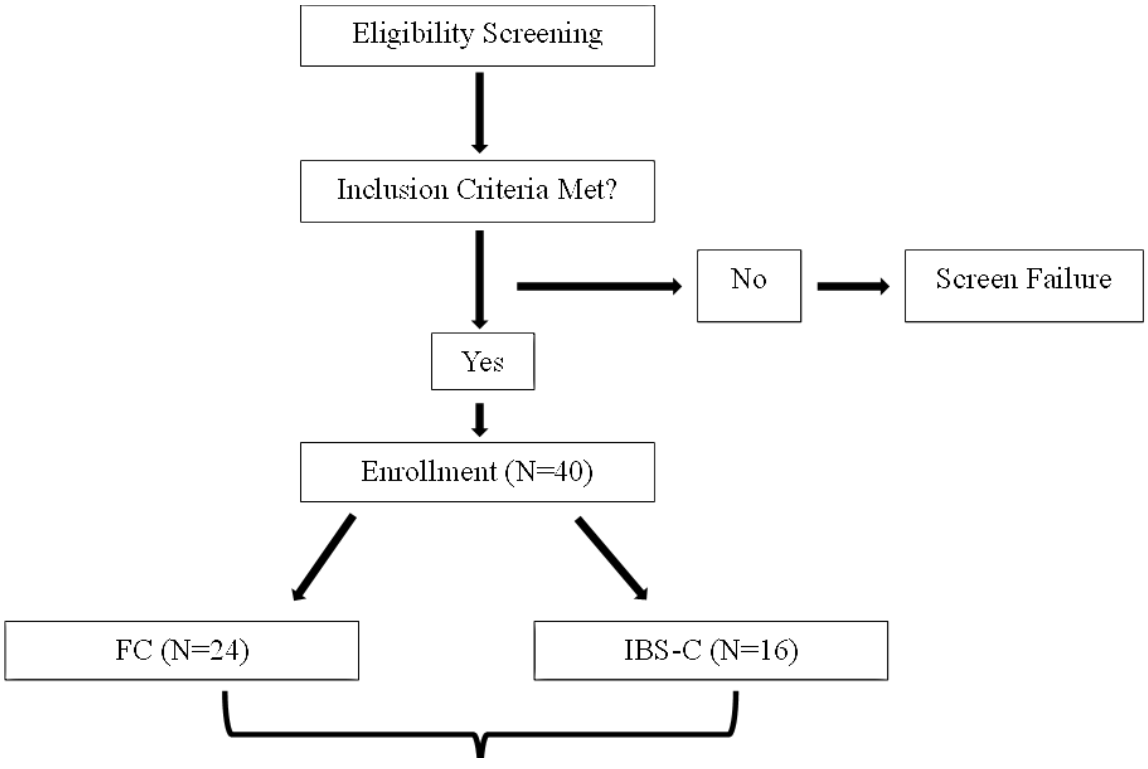
Analyses were conducted using:

Safety Analysis Set (SAF): All participants who received at least one dose

Full Analysis Set (FAS): Participants with at least one post-baseline assessment and no major protocol deviations

Per Protocol Set (PPS): Participants who completed the study per protocol with complete baseline and day 28 data

Primary and secondary endpoints were analyzed using the FAS population under the intention-to-treat principle. Statistical tests were two-sided with a 5% significance level. Data was analyzed using validated software R (version 4.6; R Foundation for Statistical Computing, Vienna, Austria) in compliance with Good Clinical Practice (GCP). Figure 1 summarises overview of study design, screening, intervention allocation, and follow-up.



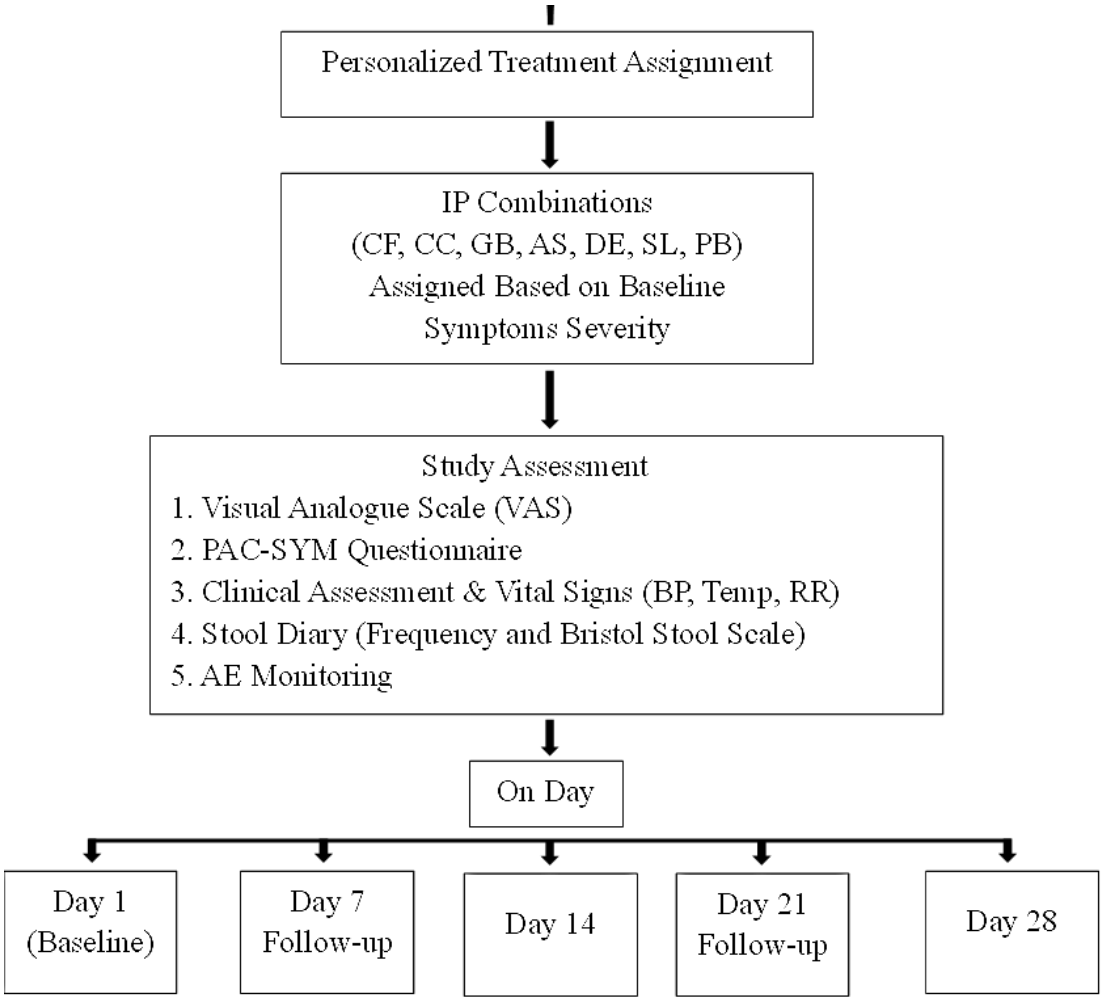



**Figure 1.** Overview of Study Design, Screening, Intervention Allocation, and Follow-Up
**VAS**-Visual Analogue Scale | **AE**-Adverse Event | **CF**-Consti Free | **CC**-Consti Care | **GB**-Gut Bliss | **AS**-Acid Soothe | **DE**-Digest Ease | **SL**-Stress Less | **BP**-Probiotic (IBS-C)

Dietary compliance was calculated as the percentage of days participants adhered to prescribed dietary recommendations divided by total study days, based on participant self-reported adherence logs.

## Results

The study was conducted from December 2024 to February 2025 at a single center in Delhi, India, involving 40 adults with functional constipation (n = 24) or IBS-C (n = 16). All participants completed five clinic visits (days 1, 7, 14, 21, and 28) as instructed to them till day 28 of intervention treatment with no dropouts or major protocol deviations. A total of eight minor protocol deviations were reported, including three cases of re-consenting and re-enrollment due to an administrative delay in treatment assignment and five cases in which the final study visit was conducted one day later than scheduled. These deviations were considered minor and had no impact on participant safety, study conduct, data integrity, or study outcomes.

The mean age of participants in the trial was 31.8 ± 8.58 years; baseline demographics (age, BMI, gender) were comparable between groups. Vital signs and physical exams were found stable throught

the study. No serious adverse events were recorded throughout the study, few associated GI issues found at baseline were found to be resolved by day 28 in few cases as mentioned in fig/table. Mild events (cold, cough, fever, headache) were seen in 9 participants (22.5%) and deemed unrelated to the regimen. All subjects were included in the final analyses.

**VAS score analysis**

Symptom severity for acidity, bloating, constipation, gas, sleep disturbances, and stress was evaluated using a Visual Analogue Scale (VAS) on days 1, 14, and 28. VAS score 1-3, 4-7 & 8-10 was defined as mild, moderate and severe respectively [25].

**Clinical response rate of the participants**

Cases reporting moderate to severe symptoms were only considered for the assessment. To guarantee a robust therapeutic effect clearing any potential subjective measurement error, a strict clinical responder cutoff was established as an absolute reduction of > 3.0 points on the 0–10 VAS was considered as clinically meaningful improvement [26]. As described in table 1, (95%) reported reduction in constipation, (90.5%) in acidity, (77.7%) in bloating, (89.2%) in gas, (90%) in stress, and (70%) in Sleeplessness symptoms.

**Table 2. Clinical response rate of the participants**

| Symptoms | No. of participants with moderate to severe symptoms at baseline (n=40) | No of participants reported reduction in symptoms at last visit (Day 28) (reduction of more than 3 points in VAS score) | Percent reduction |
|---|---|---|---|
| Constipation | 40 | 38 | 95% |
| Acidity | 21 | 19 | 90.5% |
| Bloating | 18 | 14 | 77.7% |
| Gas | 37 | 33 | 89.2% |
| Stress | 20 | 18 | 90% |
| Sleeplessness | 20 | 14 | 70% |

**Symptom severity assessment**

Symptom severity for acidity, bloating, constipation, gas, sleep disturbances, and stress was evaluated using a Visual Analogue Scale (VAS) on days 1, 14, and 28. Table 1 summarizes the mean percentage changes and corresponding *p*-values for all 40 participants (N = 40). Significant improvements were observed in all symptoms, with the highest reduction noted in constipation severity (83.19%), followed by gas (83.09%), stress (82.72%), acidity (79.22%), sleep disturbance (77.14%), and bloating (75.51%). All changes were highly significant on day 14 and 28 ($p < 0.0001$). Figure 2 illustrates the consistent decline in symptom severity over time.

**Table 3. Changes in symptom severity as measured by VAS scores over 28 days (n=40)**

| Symptoms | Day 1 | Day 14 | Day 28 | % Change in Mean Score | p-value |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Acidity** | 3.85 ± 1.86 | 1.60 ± 0.96 | 0.80 ± 0.52 | -79.22 % | <0.0001 |
| **Bloating** | 2.45 ± 2.31 | 1.00 ± 0.88 | 0.60 ± 0.55 | -75.51 % | <0.0001 |
| **Constipation** | 5.95 ± 0.75 | 3.10 ± 1.19 | 1.00 ± 0.55 | -83.19 % | <0.0001 |
| **Gas** | 5.50 ± 1.68 | 2.55 ± 1.36 | 0.93 ± 0.69 | -83.09 % | <0.0001 |
| **Sleep Disturbances** | 3.85 ± 1.72 | 1.93 ± 0.89 | 0.88 ± 0.61 | -77.14 % | <0.0001 |
| **Stress** | 4.05 ± 1.91 | 1.75 ± 0.81 | 0.70 ± 0.65 | -82.72 % | <0.0001 |

*Values expressed as Mean ± SD
*Reduction (-) in mean % change indicates improvement in symptoms from baseline
*p-value < 0.05 indicates statistical significance (the effect is likely real, not due to chance)

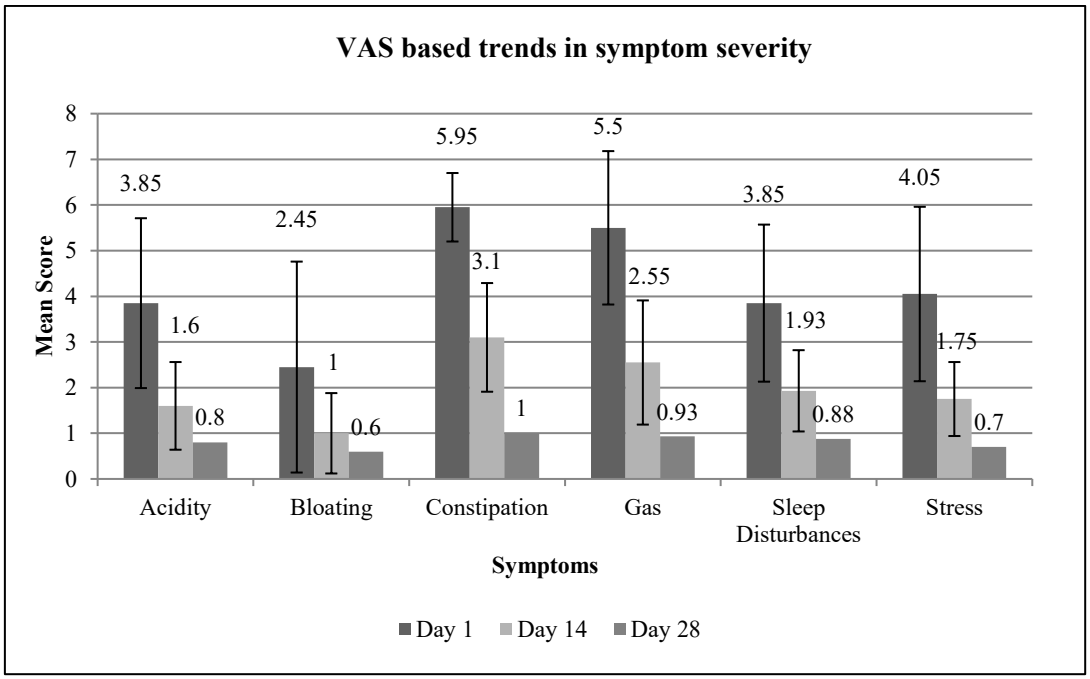



**Figure 2.VAS-based trends in symptom severity**

**PAC-SYM score analysis**

Constipation-related symptoms were assessed using the PAC-SYM questionnaire on days 1, 14, and 28. Table 2 and Figure 3 show significant improvements across all domains -abdominal, rectal, and stool symptoms. The percentage change in mean score on day 28 shows reductions in abdominal discomfort (–78.75%), pain in abdomen (–76.67%), bloating (–76.19%), and rectal symptoms such as stomach cramp (–75.11%), painful bowel movements (–73.64%), rectal burning (–72.91%), and stool-related issues such as hard bowel movements (–75.63%), small bowel movement (–71.10%), straining to pass bowel movements (–72.97%), and urgency to pass bowel (–75.00%) with high significance ($p < 0.0001$), highlighting the regimen's efficacy.

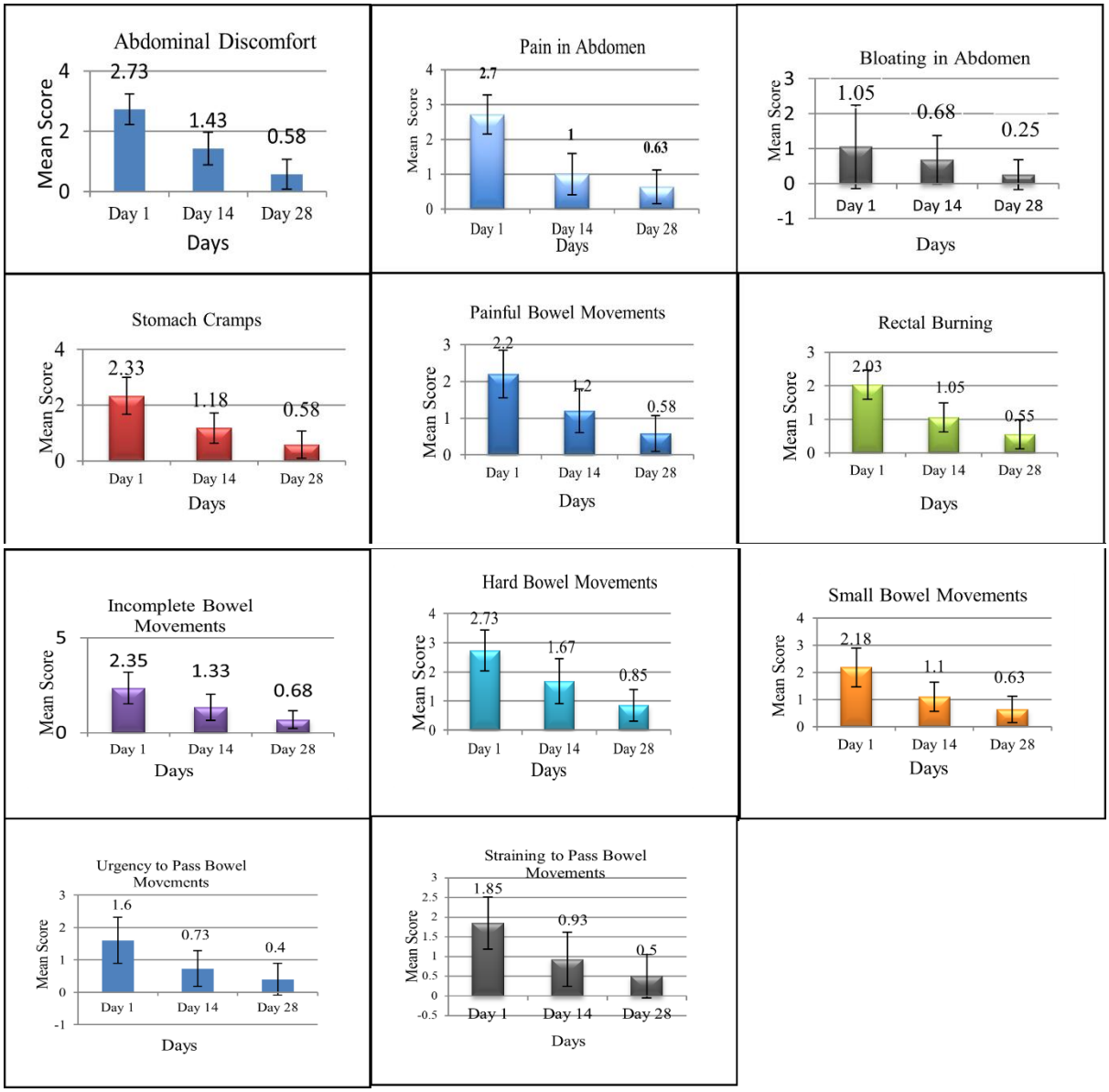



**Figure 3. PAC-SYM-based symptom improvement trends over 28 days of intervention**

**Table 4. Changes in symptom severity based on PAC-SYM scores over 28 days (n=40)**

| Symptoms | Day 1 | Day 14 | Day 28 | % Change in Mean score | p-value |
|---|---|---|---|---|---|
| **Abdominal Discomfort** | 2.73 ± 0.51 | 1.43 ± 0.54 | 0.58 ± 0.49 | -78.75 % | <0.0001 |
| **Pain in Abdomen** | 2.70 ± 0.56 | 1.00 ± 0.59 | 0.63 ± 0.48 | -76.67 % | <0.0001 |
| **Bloating Abdomen** | 1.05 ± 1.20 | 0.68 ± 0.69 | 0.25 ± 0.43 | -76.19 % | <0.0001 |
| **Stomach Cramps** | 2.33 ± 0.66 | 1.18 ± 0.54 | 0.58 ± 0.49 | -75.11 % | <0.0001 |
| **Painful Bowel Movements** | 2.20 ± 0.65 | 1.20 ± 0.60 | 0.58 ± 0.49 | -73.64 % | <0.0001 |

| | | | | | |
|---|---|---|---|---|---|
| **Rectal Burning** | 2.03 ± 0.66 | 1.05 ± 0.63 | 0.55 ± 0.50 | -72.91 % | <0.0001 |
| **Incomplete Bowel Movements** | 2.35 ± 0.83 | 1.33 ± 0.69 | 0.68 ± 0.47 | -71.06 % | <0.0001 |
| **Hard Bowel Movements** | 2.38 ± 0.70 | 1.28 ± 0.77 | 0.58 ± 0.54 | -75.63 % | <0.0001 |
| **Small Bowel Movements** | 2.18 ± 0.71 | 1.10 ± 0.54 | 0.63 ± 0.48 | -71.10 % | <0.0001 |
| **Straining to Pass Bowel Movements** | 1.85 ± 0.66 | 0.93 ± 0.69 | 0.50 ± 0.55 | -72.97 % | <0.0001 |
| **Urgency to Pass Bowel Movements** | 1.60 ± 0.71 | 0.73 ± 0.55 | 0.40 ± 0.49 | -75.00 % | <0.0001 |

*Values expressed as Mean ± SD

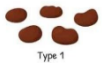
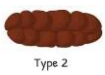
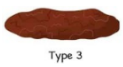
* Reduction (-) in mean % change indicates improvement in symptoms from baseline

*p-value < 0.05 indicates statistical significance (the effect is likely real, not due to chance)

**Stool consistency and frequency**

Improvement in stool consistency was observed over the study period, assessed using the Bristol Stool Form Scale as shown in Table 3. At baseline visit, 17 subjects (42.5%) had Type 1 stools (hard), and 23 (57.5%) had Type 2 stools (lumpy). On second visit, 6 subjects (15%) had Type 2 stools, 24 subjects (60%) had Type 3, and 10 subjects (25%) had Type 4 stools. By day 28, 17 subjects transitioned to Type 3 (sausage with cracks), and all 23 shifted to Type 4 (smooth and soft), indicating normalization of stool form.

**Table 5. Stool consistency distribution based on the Bristol Stool Form Scale (n=40)**

| Consistency type recorded by subjects | Baseline | Day 14 | Day 28 | Interpretation |
|---|---|---|---|---|
| **Hard Stool**   | 17 (42.5 %) | 0 | 0 | Reduced to 0 |
| **Lumpy Stool**   | 23 (57 %) | 6 (15 %) | 0 | Reduced to 0 |
| **Sausage with Cracks**   | 0 | 24 (60 %) | 17 (42.5 %) | Increased initially, slight reduction by Day 28 |
| **Smooth, Soft Stool**   | 0 | 10 (25 %) | 23 (57 %) | Progressive increase |

*Values expressed as - n (%)

Stool frequency among participants from baseline to day 28 was assessed via the Bristol Stool Scale. Mean stool frequency decreased from 2.53 movements/day on day 1 to 1.38 movements/day by day 28. Mean stool frequency also decreased progressively, reflecting more regular and normalized bowel movements following the intervention. Figure 4 displays the transition in mean change in stool frequency.

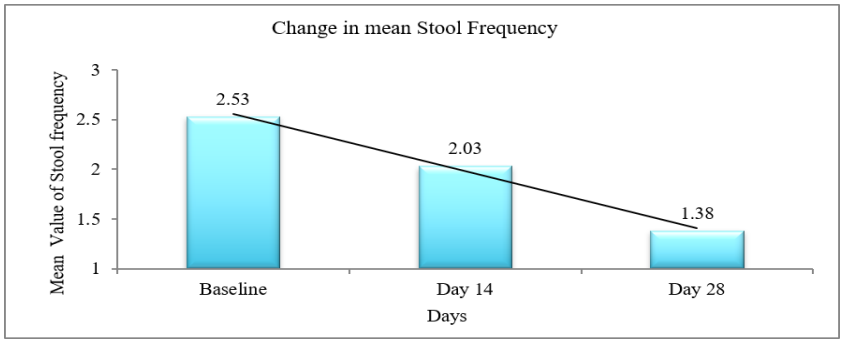



**Figure 4. Change in mean stool frequency from baseline to day 28 of treatment**

Subjects were given a diet chart along with a diary card to record their daily diet on a weekly basis. Diet compliance improved steadily, beginning at 23% on day 1 and increasing to 40% by days 14 and 28, indicating enhanced adherence over time.

**Subgroup analysis: functional constipation and IBS-C**

The evaluation of symptom severity using Visual Analog Scale (VAS) scores revealed significant improvements across multiple gastrointestinal and associated symptoms in both FC and IBS-C groups following 28 days of intervention with Mool Health's personalized gut health regimen. VAS scores indicated acidity scores decreased by 74.07% in the FC group and 83.93% in the IBS-C group ($p < 0.0001$ for both), while gas symptoms showed a similar degree of reduction in both groups (FC: 83.02%, IBS-C: 83.05%; $p < 0.0001$). Constipation severity improved markedly, with reductions of 85.48% in FC and 80.36% in IBS-C participants ($p < 0.0001$). Although bloating improved significantly in the IBS-C group (84.31% reduction; $p < 0.0001$), the change in the FC group was modest and not significant (28.57%; $p = 0.2831$). Sleep disturbances and stress levels also showed significant improvement in both groups, with reductions exceeding 70% ($p < 0.0001$). Overall, FC showed slightly greater relief in constipation and IBS-C showed higher improvements in bloating and acidity, suggesting a potentially enhanced therapeutic response in subgroups (Table 4).

**Table 6. Symptom severity improvement based on VAS scores in functional constipation (FC) and IBS-C subgroups (n=40)**

| Symptoms | Day 1 | | Day 28 | | % Change in Mean score | | p-value | |
|---|---|---|---|---|---|---|---|---|
| | FC | IBS-C | FC | IBS-C | FC | IBS-C | FC | IBS-C |
| **Acidity** | 2.7 ± 1.4 | 5.6 ± 0.8 | 0.7 ± 0.5 | 0.9 ± 0.6 | -74.07 % | -83.93 % | <0.0001 | <0.0001 |
| **Bloating** | 0.7 ± 1.0 | 5.1 ± 0.6 | 0.5 ± 0.5 | 0.8 ± 0.6 | -28.57 % | -84.31 % | 0.2831 | <0.0001 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Constipation** | 6.2 ± 0.7 | 5.6 ± 0.7 | 0.9 ± 0.6 | 1.1 ± 0.5 | -85.48 % | -80.36 % | <0.0001 | <0.0001 |
| **Gas** | 5.3 ± 2.0 | 5.9 ± 1.0 | 0.9 ± 0.6 | 1.0 ± 0.8 | -83.02 % | -83.05 % | <0.0001 | <0.0001 |
| **Sleep Disturbance** | 3.0 ± 1.2 | 5.2 ± 1.6 | 0.8 ± 0.6 | 1.1 ± 0.6 | -73.33 % | -78.85 % | <0.0001 | <0.0001 |
| **Stress** | 3.0 ± 1.2 | 5.6 ± 1.7 | 0.6 ± 0.6 | 0.8 ± 0.8 | -80.00 % | -85.71 % | <0.0001 | <0.0001 |

*Values expressed as Mean ± SD

* Reduction (-) in mean % change indicates improvement in symptoms from baseline.

*p-value < 0.05 indicates statistical significance (the effect is likely real, not due to chance)

**PAC-SYM subgroup analysis**

Symptom assessment using the Patient Assessment of Constipation-Symptom (PAC-SYM) scale showed statistically significant improvement across all evaluated domains in both Functional Constipation (FC) and IBS-C groups by day 28. Abdominal discomfort and constant pain decreased by over 70% in both groups, with the FC group demonstrating slightly higher reductions (80.77% for both symptoms; $p < 0.0001$). Stomach cramps, painful bowel movements, rectal burning, incomplete evacuation, and hardened stools also showed marked symptom relief, with mean percentage improvements ranging from approximately 66% to 78% across both groups ($p < 0.0001$). Straining and small stool volume reduced significantly in both FC and IBS-C groups, with improvements exceeding 68% ($p < 0.0001$). The symptom of inability to evacuate showed the greatest reduction in the IBS-C group (80.95%) compared to 69.23% in FC ($p < 0.0001$). Notably, bloating, though initially minimal in the FC group (0.2 ± 0.5), showed a non-significant change (–50.00%, $p = 0.7540$), while it significantly improved in the IBS-C group by 83.33% ($p < 0.0001$). Overall, both groups benefited significantly from the intervention, with the IBS-C group experiencing more profound improvements in symptoms related to bloating and rectal discomfort (Table 5).

**Table 7. PAC-SYM domain-wise symptom changes in FC and IBS-C groups from baseline to day 28 (n=40)**

| **Symptoms** | **Day 1** | | **Day 28** | | **% Change in mean score** | | **p- value** | |
|---|---|---|---|---|---|---|---|---|
| | **FC** | **IBS-C** | **FC** | **IBS-C** | **FC** | **IBS-C** | **FC** | **IBS-C** |
| **Abdominal Discomfort** | 2.6 ± 0.6 | 2.9 ± 0.3 | 0.5 ± 0.5 | 0.8 ± 0.4 | -80.77 % | -72.41 % | <0.0001 | <0.0001 |
| **Constant Pain** | 2.6 ± 0.6 | 2.8 ± 0.5 | 0.5 ± 0.5 | 0.8 ± 0.4 | -80.77 % | -71.43 % | <0.0001 | <0.0001 |
| **Bloating** | 0.2 ± 0.5 | 2.4 ± 0.5 | 0.1 ± 0.3 | 0.4 ± 0.5 | -50.00 % | -83.33 % | 0.7540 | <0.0001 |
| **Stomach Cramps** | 2.0 ± 0.6 | 2.8 ± 0.4 | 0.5 ± 0.5 | 0.6 ± 0.5 | -75.00 % | -78.57 % | <0.0001 | <0.0001 |
| **Painful Bowel Movements** | 2.2 ± 0.7 | 2.2 ± 0.5 | 0.6 ± 0.5 | 0.6 ± 0.5 | -72.73 % | -72.73 % | <0.0001 | <0.0001 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Rectal Burning** | 1.8 ± 0.6 | 2.3 ± 0.7 | 0.6 ± 0.5 | 0.5 ± 0.5 | -66.67 % | -78.26 % | <0.0001 | <0.0001 |
| **Incomplete Bowel Movements** | 2.2 ± 0.8 | 2.6 ± 0.8 | 0.6 ± 0.5 | 0.8 ± 0.4 | -72.73 % | -69.23 % | <0.0001 | <0.0001 |
| **Hardened Stools** | 2.3 ± 0.7 | 2.6 ± 0.6 | 0.5 ± 0.5 | 0.7 ± 0.6 | -78.26 % | -73.08 % | <0.0001 | <0.0001 |
| **Small Stool Volume** | 2.0 ± 0.6 | 2.5 ± 0.8 | 0.6 ± 0.5 | 0.6 ± 0.5 | -70.00 % | -76.00 % | <0.0001 | <0.0001 |
| **Straining** | 1.6 ± 0.7 | 2.2 ± 0.4 | 0.4 ± 0.5 | 0.7 ± 0.6 | -75.00 % | -68.18 % | <0.0001 | <0.0001 |
| **Inability to Evacuate** | 1.3 ± 0.6 | 2.1 ± 0.7 | 0.4 ± 0.5 | 0.4 ± 0.5 | -69.23 % | -80.95 % | <0.0001 | <0.0001 |

*Values expressed as Mean ± SD

* Reduction (-) in mean % change indicates improvement in symptoms from baseline

*p-value < 0.05 indicates statistical significance (the effect is likely real, not due to chance)

**Stool frequency and consistency evaluation**

Stool frequency and consistency, assessed via the Bristol Stool Scale, improved in both FC and IBS-C groups. Mean frequency decreased from 2.54 (FC) and 2.63 (IBS-C) at baseline to 1.42 and 1.31, respectively, by day 28. All participants shifted from hard stools (Type 1 or 2) to normal types, with 66.7% of FC subjects reporting Type 4 and 56.3% of IBS-C reporting Type 3 by day 28. No loose stools (Types 5–7) were observed. FC showed slightly better normalization.

**Discussion**

In this exploratory clinical trial, evaluation of efficacy and safety of Mool Health's personalized gut health regimen for management of functional constipation (FC) and irritable bowel syndrome with constipation (IBS-C) was conducted. In context of traditional Ayurvedic medicine, a variety of herbs have long been utilized to support gastrointestinal homeostasis. Triphala, known for its mild laxative action, along with Senna, Ajwain (carom seeds), and Isabgol (psyllium husk), are frequently prescribed to promote bowel regularity and improve digestive efficacy. Furthermore, Guduchi (Tinospora cordifolia) and Ashwagandha (Withania somnifera) are noted for their immunomodulatory and anti-inflammatory properties, which may contribute to restoring gut integrity and enhancing mucosal immunity.[11] Based on these traditional principles, the present intervention incorporated a personalized combination of herbal supplementation, dietary modifications, and lifestyle interventions aimed at improving overall gut health.

Participants showed significant improvements in constipation severity, stool consistency, bowel movement frequency, and related GI symptoms following the intervention. Core strength of this study was its personalized, multifaceted approach, tailored using validated symptom scales. Unlike conventional treatments that target isolated symptoms, this regimen combined Ayurvedic herbs (Triphala, Ajwain, Ashwagandha, Foeniculum vulgare etc.), fiber-rich diet, and lifestyle modifications to address both symptoms and root causes such as dysbiosis, stress, and sleep disturbances. In line with this holistic approach, improvements were also observed across several associated gastrointestinal and psychosomatic symptoms.

The present study demonstrated a significant reduction in symptoms including acidity, bloating, constipation, gas, sleep disturbances, and stress. Among these, constipation, gas, and stress showed the most noticeable improvements. Even symptoms with lower initial severity, such as sleep issues and bloating, improved markedly. These changes were consistent over time and became evident by the second week of the intervention.

The marked reduction in constipation aligns with existing literature emphasizing the role of gut-targeted interventions especially those incorporating dietary fibers, herbal laxatives, and microbiota-modulating agents in restoring bowel regularity. Similarly, the reduction in gas and bloating may reflect improved gut motility and microbial balance, potentially mediated by Ayurvedic herbs like Triphala, Ajwain, and Isabgol, which are known to support digestive function and reduce fermentative symptoms.[12]

The notable decline in stress and sleep disturbances suggests a gut-brain axis involvement, wherein improved gastrointestinal function may have positively influenced neuropsychological wellbeing. This is consistent with emerging evidence that gut health interventions particularly those that reduce inflammation and modulate the gut microbiome can alleviate psychological symptoms such as anxiety and sleep irregularities. [13,14] These findings highlight the potential of individualized, intervative gut heath interventions as efficacious and well-tolerated alternatives to standard pharmacological therapies for Functional Constipation and IBS-C. [15]

Further supporting the effectiveness of the intervention, constipation-specific symptoms assessed using the PAC-SYM questionnaire revealed marked improvement across all domains abdominal, rectal, and stool-related. Participants reported substantial relief from abdominal discomfort, bloating, and pain, which are commonly associated with slow colonic transit and visceral hypersensitivity. Similarly, rectal symptoms such as cramping, painful defecation, and burning sensations were significantly reduced, indicating improved neuromuscular coordination and reduced inflammation in the anorectal region. Stool-related difficulties, including hard stools, straining, incomplete evacuation, and urgency, also showed considerable improvement. These findings suggest enhanced stool consistency and bowel motility, attributable to the synergistic action of dietary fibers, gut motility stimulants, and Ayurvedic powder included in the intervention. The consistency and high significance of these improvements ($p < 0.0001$) further validate the therapeutic potential of this integrative approach.

These results are supported by the reported significant reductions in PAC-SYM scores with psyllium husk supplementation, particularly in abdominal pain, bloating, and straining. Similarly, a study demonstrated that fiber and herb-based laxatives offer multi-symptom relief in chronic constipation, reinforcing the effectiveness of comprehensive, gut-targeted approaches. [16,17]

The intervention also led to notable improvements in stool consistency and bowel movement regularity, as assessed using the Bristol Stool Form Scale. Participants who initially exhibited hard or lumpy stools showed a clear transition toward softer, well-formed stools by the end of the study period. This shift suggests enhanced colonic transit and improved stool hydration, consistent with previous findings by who reported that fiber- and herb-based interventions support normalization of stool form in individuals with chronic constipation.

In parallel, stool frequency gradually adjusted to more regular patterns, reflecting a move toward balanced bowel habits. These results are in line with observations by previous study which emphasized that normalization of bowel frequency rather than just increasing it is an important therapeutic goal in functional constipation, often achieved through dietary and lifestyle modifications.[18]

These symptomatic improvements align with the expanding scientific literature suggesting that modulation of the gut microbiota plays a crucial role in maintaining intestinal function. Prior randomized controlled trials have demonstrated that supplementation with multispecies probiotics significantly alleviates constipation-related symptoms in patients with IBS-C, supporting a potential mechanism of action mediated through microbiota regulation and restoration of microbial balance.[19] Notably, this strategy aligns with emerging evidence that individual responses to probiotics can vary based on baseline microbiome composition and dietary patterns, underscoring the relevance of personalized interventions.

Additionally, progressive improvement in diet compliance throughout the study indicates increased participant engagement with the prescribed dietary regimen. This likely played a role in symptom improvement and bowel normalization. These findings align with previous study who showed that improved adherence to dietary guidance significantly enhances therapeutic outcomes in patients with functional bowel disorders.[20]

Aside from symptomatic effects, the intervention had outstanding safety and tolerability, with no severe adverse events during the study period. This is consistent with existing literature that has shown probiotic-based interventions for gastrointestinal diseases tend to have a good safety profile.[21] Excellent participant compliance also indicates that the regimen was feasible and acceptable, further supporting real-world potential.

Another significant finding from our research was the differential response between functional constipation and IBS-C subgroups. Although both groups showed significant improvements, FC participants showed slightly greater normalization of stool consistency, while IBS-C participants reported greater relief in bloating, acidity, and abdominal pain. These subtle patterns reflect the heterogeneity of chronic constipation syndromes and support the rationale for individualized treatment regimens that address specific symptom clusters.[22]

A major strength of this study is its holistic and individualized therapeutic approach, which proved more effective than conventional single-modality treatments that often target isolated symptoms. By combining multispecies probiotic supplementation, Ayurvedic botanical formulations, personalized dietary guidance, and stress management strategies, the regimen addressed both core gastrointestinal issues such as straining and irregular bowel habits and underlying contributors like stress, poor sleep, and lifestyle imbalances. Each participant's treatment was tailored based on their symptom profile using validated assessment tools, ensuring personalized care. This comprehensive approach led to significant improvements in stool consistency, bowel regularity, and overall digestive health.

While the study demonstrated promising outcomes, certain limitations should be noted. The short duration and single-site design suggest the need for longer, multi-center, multi arm studies.

Despite these limitations, the present findings contribute to the growing body of evidence supporting comprehensive and individualized strategies for managing chronic constipation. By addressing both symptom relief and underlying gut dysfunction, a personalized gut health approach may offer more sustained and holistic benefits compared to other conventional therapies, which often focus narrowly on short-term symptomatic control.

## Conclusion

Mool Health's personalized gut health regimen demonstrated high efficacy and safety in the management of functional constipation and IBS-C, as evidenced by significant improvements in VAS and PAC-SYM

scores over the 28-day intervention period. Participants experienced substantial two- to three-fold reductions in core gastrointestinal symptoms, including bloating, constipation, gas, abdominal discomfort, and straining during bowel movements, along with normalization of stool consistency. Based on Clinical response rate of the participants of VAS score assessment at the end of the study, 95% reported reduction in constipation, 90.5% in acidity, 77.7% in bloating, 89.2% in gas, 90% in stress, and 70% in Sleeplessness symptoms. The PAC-SYM questionnaire further demonstrated a consistent reduction in overall symptom severity from baseline to Day 28. By the end of the study, 97.5% of participants reported improved gastrointestinal function based on clinical examination performed by the investigator. The regimen was well tolerated, with high participant adherence, supporting its potential as a safe and effective personalized therapeutic approach for the management of functional constipation and IBS-C.

**Declarations:**

***Institutional Review Board Statement:*** The study was conducted in accordance with the Declaration of Helsinki and was approved by the Central Independent Ethics Committee. CTRI Registration: CTRI/2024/12/077721

***Informed Consent Statement:*** Informed consent was obtained from all subjects involved in the study.

***Data Availability Statement:*** The data presented in this study are available on request from the corresponding author.

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***Conflicts of Interest:*** Authors, Dr. Dipti Gupta and Dr. Devesh Kumar declare no competing financial or personal interests related to this work. Dr. Khemraj Mourya and Dr. Yash Gangal are employees of the study sponsor, Tatvartha Health Pvt. Ltd. Their involvement was strictly limited to study design and manuscript preparation.

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