



Asian Journal of Phytomedicine and Clinical Research

Journal home page: www.ajpcrjournal.com

<https://doi.org/10.36673/AJPCR.2026.v14.i01.A03>



FEASIBILITY AND PRELIMINARY CLINICAL OUTCOMES OF A STANDARDIZED *BOSWELLIA CARTERII* EXTRACT COMBINED WITH STRUCTURED PATIENT EDUCATION IN ADULTS WITH IRRITABLE BOWEL SYNDROME: A PILOT SINGLE- ARM STUDY

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ABSTRACT

Background: Irritable bowel syndrome (IBS) is a common disorder of gut–brain interaction characterized by abdominal pain, bloating, altered bowel habits and impaired quality of life. Complementary approaches targeting both physiological and behavioral aspects of IBS may provide additional benefit. **Objective:** To evaluate the feasibility, safety and preliminary clinical outcomes of a standardized *Boswellia carterii* extract combined with structured patient education in adults with IBS. **Methods:** This pilot single-arm quasi-experimental study enrolled 60 adults with moderate IBS attending outpatient clinics at Mansoura University Hospitals, Egypt. Participants received standardized *Boswellia carterii* extract (500mg capsules standardized to $\geq 65\%$ boswellic acids, twice daily) together with two structured educational sessions focused on IBS self-management. Clinical assessments were performed at baseline, week 1 and month 1. Outcome measures included abdominal pain, bloating severity, bowel habit characteristics, gastrointestinal symptoms and IBS-related quality of life. **Results:** The intervention was feasible and well tolerated. Significant improvements were observed over the study period in abdominal pain, bloating severity, stool frequency and consistency and overall gastrointestinal symptom burden. Quality-of-life scores improved across multiple domains, including physical functioning, health concerns, dietary behavior and social participation. No serious adverse events were reported. **Conclusion:** A multimodal intervention consisting of standardized *Boswellia carterii* extract and structured patient education was feasible, safe and associated with clinically meaningful improvements in IBS symptoms and quality of life. Because of the single-arm design and absence of a control group, these findings should be considered exploratory and hypothesis-generating. Randomized controlled trials are warranted to confirm efficacy.

KEYWORDS

Irritable bowel syndrome, *Boswellia carterii*, Integrative medicine, Patient education and Pilot study.

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INTRODUCTION

Irritable Bowel Syndrome (IBS) is a common condition characterized by symptoms such as abdominal pain and bloating, constipation and diarrhea. IBS occurs without identifiable structural pathology but can significantly affect an

individual's quality of life. The diagnosis of IBS is mostly based on clinical criteria after excluding all other causes of the symptoms experienced. IBS is defined by the presence of abdominal pain or discomfort linked with a change in bowel habits over a period of three months. IBS is among the most common gastrointestinal diseases seen in general practice and secondary care. Recent studies have indicated that IBS should be regarded as a disorder of gut-brain interaction (DGBI). Over 40% of people globally experience at least one DGBI at some point in their lives¹⁻³.

Apart from its high prevalence rate, IBS is also associated with a heavy economic burden on the health care systems around the world, due to high costs related to direct medical expenses and loss of productivity associated with IBS¹.

IBS has a complicated pathophysiological mechanism involving several factors such as diet, changes in gut flora, gut hypersensitivity, immune dysfunction and genetic susceptibility. These components have variable significance among populations based on cultural, geographical and environmental factors. While IBS was originally considered a functional disease, recent studies support a biopsychosocial theory focusing on dysfunctional regulation of the gut-brain axis as suggested by Rome IV criteria⁴.

Recent research suggests that low-level inflammation and activation of the immune system play a key part in the development of IBS. In this regard, the biological effects of triterpenoids isolated from the species of *Boswellia carterii* (frankincense) on the immune response have been linked to modulating inflammatory mechanisms, including blocking the enzyme 5-lipoxygenase activity and inhibiting leukotrienes⁵⁻⁷. Moreover, triterpenoids found in the *Boswellia* genus were discovered to inhibit the leukotriene-mediated inflammatory reactions, which are increasingly associated with immune activation and intestinal inflammation.

Bloating, which is experienced by over 90% of IBS sufferers, is one of the most debilitating symptoms and greatly impacts quality of life through causing

psychological problems, decreased productivity and embarrassment when interacting socially. Overall, IBS negatively impacts daily activities, workplace functioning and social interactions. Even though IBS is very common, managing the condition effectively poses difficulties, since existing drug treatments only offer temporary relief.

Consequently, there has been increasing attention to alternative methods, which include the use of diet and herbs. Approaches that integrate multidisciplinary teams, consisting of physicians, nurses, dietitians, and psychologists, along with patient education and self-management, have proven to be effective when dealing with symptom management and quality of life issues among individuals with IBS^{5,8-10}. The underlying theory used is behavior and biopsychosocial models.

Given the chronic and relapsing nature of IBS, the limitations of current treatment options, and increasing patient demand for complementary therapies, evaluating the role of standardized *Boswellia carterii* extract as an adjunct intervention is warranted. The combination of a biologically active anti-inflammatory agent with structured patient education may offer a synergistic approach targeting both physiological and behavioral components of IBS.

METHODOLOGY

Phytochemical Standardization of *Boswellia carterii* Extract

Phytochemical standardization of the *Boswellia carterii* oleogum resin extract was conducted at the FAB-Lab (Faculty of Pharmacy, Mansoura University) to ensure batch-to-batch consistency and defined bioactive content. The extract was standardized to contain $\geq 65\%$ total boswellic acids, based on previously established analytical and isolation methodologies developed in our laboratory. These procedures include chromatographic separation and characterization of immunomodulatory triterpenoids⁶, as well as validation of leukotriene-inhibitory activity and bioactive compound profiling, as described in

earlier pharmacological and clinical investigations of *Boswellia* preparations⁷.

The standardization approach has been consistently applied in prior experimental and clinical studies evaluating anti-inflammatory, immunomodulatory, antiviral and osteoarthritis-related therapeutic effects of *Boswellia*-derived compounds, thereby ensuring reproducibility, phytochemical integrity and biological relevance of the extract used in the present study.

Study Design and Setting

A quasi-experimental study design was employed to assess the effects of standardized *Boswellia carterii* extract on abdominal bloating, abdominal pain, and quality of life in patients with irritable bowel syndrome (IBS).

The study was conducted at the outpatient clinics of Mansoura University Hospitals, Egypt. The unit of assignment and analysis was the individual participant. Due to the quasi-experimental design, no randomization or allocation to comparison groups was performed. The data collection started in January 2025.

Participants and Recruitment (TREND Item 3)

Adult patients diagnosed with moderate IBS were recruited using convenience sampling from outpatient clinics. Recruitment was based on direct approach and referral within the clinical setting.

Eligibility criteria

Participants were included if they:

Were aged 18–39 years

Were literate

Reported abdominal bloating as a primary symptom
Met diagnostic criteria for IBS according to Rome III and IV definitions, including recurrent abdominal pain at least once weekly over the preceding three months associated with changes in stool frequency, form, or defecation^{11,12}.

Exclusion criteria

Participants were excluded if they had:

Adherence to special diets (low-fat, lactose-free, gluten-free) within the previous six months

Food allergies (e.g., soy, nuts, seafood)

Insulin-dependent diabetes, celiac disease, or inflammatory bowel disease

History of major gastrointestinal surgery

Recent antibiotic use

Alarm gastrointestinal symptoms

Severe renal or hepatic disease

Pregnancy or breastfeeding

Sample Size Determination (TREND Item 7)

The required sample size was calculated using G*Power software. A minimum of 60 participants was determined, accounting for an anticipated dropout rate of 30%. The calculation was based on a significance level of 0.05, statistical power of 95% and a large effect size (0.8), informed by prior studies evaluating the effects of *Boswellia carterii* on abdominal bloating. No interim analyses or stopping rules were applied. All the eligible abdominal bloating or uncomfortable fullness patients fulfilling exclusion and inclusion conditions and using convenience sampling methods, 60 patients only available to enroll in the study during the period January 2025 to December 2025.

Intervention

Participants received a combined intervention consisting of standardized *Boswellia carterii* extract and structured patient education.

Content

Standardized *Boswellia carterii* extract (500 mg capsules containing $\geq 65\%$ boswellic acids)

Structured educational sessions on IBS and self-management

Delivery method

Oral administration of capsules

Face-to-face educational sessions supported by PowerPoint presentations and interactive discussions

Unit of delivery

Individual participants (for supplementation)

Small group sessions (for education)

Deliverer

Healthcare professionals and trained researchers

Setting

Outpatient clinics at Mansoura University Hospitals

Exposure and duration

Boswellia capsules: 500mg twice daily for 30 days

Educational sessions: two sessions, each lasting 30-60 minutes

Time span

Total intervention period: 30 days

Adherence strategies

Weekly telephone follow-up

Scheduled clinic visits

Monitoring of compliance and adverse events

Study Phases

Preparation Phase

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Nursing, Mansoura University. Written informed consent was obtained from all participants.

Data collection instruments were developed based on a comprehensive literature review and evaluated for face and content validity by a panel of experts. A pilot study was conducted on 10% of the sample (n = 6) to assess clarity, feasibility, and timing. Necessary modifications were implemented.

Reliability testing using Cronbach's alpha yielded a coefficient of 0.85, indicating good internal consistency.

Implementation Phase

Baseline assessments were conducted to confirm eligibility and collect demographic and clinical data.

Participants attended two structured educational sessions addressing IBS definition, types, causes, risk factors, complications, prevention and self-management strategies.

Each participant received standardized Boswellia capsules (500mg, twice daily) for 30 days. Follow-up included weekly telephone calls and clinic visits to monitor adherence, symptom progression and adverse events.

Evaluation Phase

Primary outcomes (abdominal pain, bloating and quality of life) were assessed at baseline, one week and one month using validated instruments.

Outcome Measures

Primary outcomes

Abdominal pain severity

Abdominal bloating severity

Quality of life (IBS-QOL)

H1

Patients with irritable bowel syndrome (IBS) who take standardized boswellia extract will experience a reduction in abdominal bloating.

H1

Patients with IBS who take standardized boswellia extract will experience a reduction in abdominal pain.

H1

Patients with IBS who take standardized boswellia extract will improve their quality of life.

Secondary outcomes

Stool frequency and consistency

Associated gastrointestinal symptoms

Data collection instruments

Sociodemographic and Lifestyle Questionnaire

Self-administered tool assessing demographic and lifestyle characteristics.

Gastrointestinal Symptom Assessment (Rome III and IV)

Adapted Rome-based questionnaire evaluating IBS symptoms^{11,12}.

Abdominal Bloating and Pain Assessment

Structured tool including numerical rating scale (0–10) and symptom characteristics¹³⁻¹⁶.

IBS–Quality of Life Questionnaire (IBS-QOL)

Validated 28-item instrument assessing multiple QoL domains^{17,13}.

Assignment Method and Bias Control

Participants were assigned to a single intervention group without randomization. As a quasi-experimental design, no comparison group was included.

To minimize bias:

Standardized protocols were applied

Validated instruments were used

Repeated measures design reduced inter-individual variability

Blinding

Blinding was not performed. Participants, intervention providers and outcome assessors were aware of the intervention due to the nature of the quasi-experimental design.

Unit of Analysis

The unit of analysis was the individual participant. This was consistent with the unit of assignment; therefore, no adjustment for clustering or multilevel analysis was required.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., Armonk, NY, USA). Continuous variables (e.g., age, weight, height and outcome scores) were summarized as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequencies and percentages.

Normality of data distribution was assessed using the Kolmogorov-Smirnov test. Changes in abdominal pain, bloating, gastrointestinal symptoms and quality-of-life scores across the three time points (baseline, one week, and one month) were evaluated using repeated-measures analysis of variance (ANOVA), with Bonferroni post hoc correction for pairwise comparisons. Categorical variables were compared using chi-square or Monte Carlo exact tests, as appropriate.

Effect sizes were calculated using partial eta squared (η^2p) to determine the magnitude of intervention effects. All statistical tests were two-tailed and a p-value < 0.05 was considered statistically significant.

Data Coding and Score Calculation

Binary responses were coded as 1 (yes) and 0 (no). Frequency of bloating episodes was recorded based on patient self-report. The degree of interference of bloating with eating was coded ordinally as follows: monthly (1), less than monthly (2), once per week (3), several times per week (4), and daily (5).

Pain intensity was measured using a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain). Quality-of-life responses were coded on a scale from 0 to 6, where higher scores indicated greater impairment.

Composite scores for IBS symptoms, abdominal pain and quality of life were calculated using the RS scoring function.

RESULTS AND DISCUSSION

Participant Flow

A total of 60 subjects with moderate IBS were included in the study and assigned to the intervention group. All subjects received *Boswellia carterii* extract and patient education as per the standard protocol. Follow-ups were performed after one week (post-1) and after one month (post-2).

Sociodemographic Characteristics

Table No.1 summarized the sociodemographic profile of adults diagnosed with irritable bowel syndrome (IBS). Women comprised nearly three-quarters of the study population (73.3%), the majority were married (81.7%) and resided in rural areas (80%). Regarding educational attainment, approximately two-thirds (70.7%) had completed at least secondary or university-level education. Despite this relatively high educational level, unemployment was 50% of the cohort.

Evaluation of GI Symptom Patterns in Adult Subjects with IBS

GI symptoms observed in adult subjects suffering from IBS are illustrated in Table 2 below. At baseline, all patients were diagnosed with IBS based on Rome III and IV criteria. Symptoms of bloating were observed in all patients, abdominal pain was present in 95% of the patients, while 98.3% of the patients had an altered stool frequency.

As a result, the gastrointestinal disturbances were gradually ameliorated. The occurrence rate of bloating and abdominal pain came down to 70% during the second evaluation post-intervention. There was no case of stool irregularity anymore and there was only one case of stool inconsistency that occurred among the participants, accounting for 3.3%. The number of people having normal bowel movements rose to 93.3% from zero percent before the intervention. This was accompanied by a decrease in constipation, diarrhea and abnormal bowel movements.

On a clinical level, the treatment had positive outcomes, such as the reduction of severe abdominal pain to mild or no pain, the decrease in bloating frequency to once in a while or its absence,

the restoration of normal bowel movement for more than 90% of patients and the reduced need for symptom-relief medication.

Bloating Symptoms in Adults before and during Intervention for IBS

Table No.3 Bloating was common and frequent in adults suffering from IBS before the start of the intervention. Moderate bloating was reported by 65.0% of participants while severe bloating was reported by 31.7%. In addition, bloating occurred frequently, at five to seven days a week in 80% of participants. Bloating was also highly related to consumption of food, with 61.7% having persistent post-meal bloating.

There were significant improvements made with regards to the bloating felt by the subjects following the intervention. In the first follow up, most of the participants (46.7%) had mild bloating whereas there were very few that had severe bloating (3.3%).

Frequencies of the symptoms were also reduced. In the last assessment, bloating that occurred frequently was absent; the majority of patients had bloating symptoms once per week (58.3%) or never (11.7%). Postprandial frequency decreased as well, as the majority experienced bloating infrequently after eating.

Abdominal Pain History in Adults with IBS

The distribution of abdominal pain in adult patients with IBS is summarized in Table No.4. The prevalence at baseline was close to complete, with 98.3% of patients affected by pain. The location of pain was predominantly centered in the middle abdomen (50.0%) and the intensity was moderate (71.6%). The most common pattern of abdominal pain was cramping (85.0%) and intermittent (90.0%).

Post-treatment assessment revealed significant changes. In the second follow-up test, the frequency of abdominal pain was reduced to 53.3%. The severity of pain decreased from moderate (1.7%) to mild (61.7%). Severe pain disappeared completely. Pain patterns such as cramping and intermittent decreased significantly, while pain located in the

lower abdomen increased. Thus, there was a significant reduction in symptom intensity.

Composite Score Analysis of Rome III/IV Criteria, GI Symptoms and QOL

Composite Scoring Analysis of Rome III/IV Criteria, Gastrointestinal Symptoms and Quality of Life

Composite scoring using Rome III/IV criteria revealed significant changes in relation to abdominal pain, bloating and quality of life during the three assessments. Prior to treatment, subjects showed severe symptoms in terms of higher mean abdominal pain score (56.8 ± 7.61) and higher mean composite score for bloating (77.67 ± 6.9). Moreover, their quality of life was severely affected with a mean score of 47.6 ± 15.29 (Table No.5).

Post-intervention measurements indicated considerable improvement in all aspects. Subjects experienced a reduction in abdominal pain scores, from 39.16 ± 7.60 at the first post-intervention measurement to 14.8 ± 10.94 at the second follow-up. Likewise, their composite bloating score was reduced from 62.05 ± 11.36 to 38.61 ± 11.7 during the two assessments. Quality-of-life scores also declined from 52.47 ± 11 to 39.85 ± 9.39 between one week and one month after the intervention. These reductions were all highly statistically significant ($p < 0.001$).

Changes in Quality-of-Life Following Intervention with Standardized Boswellia

Table 6 shows the pre and post standard Boswellia quality-of-life modifications in all domains, which were noted to reflect poor well-being in these patients. The findings show that all domains experienced marked improvement, progressively and significantly, in their post-intervention period ($p < 0.001$). Physical and social functioning scores increased from 22.45 ± 5.55 to 34.67 ± 2.97 , suggesting an increase in functional and social performance. Scores related to health, body image, and diet modified from 17.93 ± 4.40 to 25.20 ± 2.32 , 15.93 ± 3.40 to 21.68 , and 5.40 ± 1.85 to 8.28 , respectively. Social and sexual relationship scores increased from 13.32 ± 3.21 to 21.50 and from 6.53 ± 3.22 to 8.43 , respectively.

Overall, there was a remarkable increase in the total quality-of-life score in these patients from 81.57 ± 5.98 pre-intervention to 105.13 ± 8.09 .

Recruitment Period

Participants were recruited from the outpatient clinics of Mansoura University Hospitals. (Started in January 2025).

Baseline Sociodemographic Characteristics

Table No.1 provides the details of the socio-demographic characteristics of the study subjects. The mean age of the study subjects was 36.68 ± 12.04 years. In the study population, there were more women (73.3%) than men. Most of the subjects were married (81.7%), while the majority lived in rural areas (80%).

Regarding educational attainment, 70.7% had completed their secondary and university education levels. Nevertheless, only half of the respondents were employed.

Baseline Clinical Characteristics and Equivalence

At baseline, all subjects fulfilled the Rome III/IV diagnostic criteria for IBS. Symptoms were very common:

Bloating: 100%

Abdominal pain: 95%

Abnormal defecation pattern: 98.3%

Abnormal defecation consistency: 86.7%

Mixed bowel habits: 51.7%

Since the study design was a single group quasi experimental study, the concept of between groups' equivalence at baseline does not apply. Within subjects, equivalence was measured nonetheless.

Numbers Analyzed

All subjects (N = 60) in the study were considered for baseline analyses. The follow-up analyses consisted of available subjects at each time point.

The data analysis adopted a per protocol strategy since all subjects that underwent follow-ups were considered for the outcomes.

Primary and Secondary Outcomes

Gastrointestinal Symptom Outcomes

(Table No.2) A progressive and clinically meaningful improvement in gastrointestinal symptoms was observed following the intervention.

By Post 2

Bloating decreased from 100% to 70%

Abdominal pain decreased from 95% to 70%

Abnormal stool consistency reduced from 86.7% to 0%

Irregular stool frequency decreased from 98.3% to 3.3%

Normal bowel habits increased from 0% to 93.3%

Residual symptoms such as incomplete relief after defecation and stool variability persisted in a minority of participants but were markedly reduced compared to baseline.

Bloating Severity and Frequency

(Table No.3) At baseline:

Moderate bloating: 65%

Severe bloating: 31.7%

Frequent symptoms (5–7 days/week): 80%

Following intervention

Mild bloating increased to 76.7%

Complete resolution occurred in 16.7%

Severe bloating was eliminated

Symptom frequency improved substantially

Most participants reported bloating once weekly (58.3%) or none (11.7%) at Post 2

The association between bloating and food intake weakened over time, indicating improved symptom control.

Abdominal Pain Outcomes

(Table No.4) At baseline:

Pain prevalence: 98.3%

Moderate intensity: 71.6%

Severe pain: 28.3%

Predominantly cramping (85%) and intermittent (90%)

Post-intervention

Pain prevalence decreased to 53.3%

Mild pain predominated (61.7%)

Severe pain was completely eliminated

Reduction in cramping and intermittent patterns was observed

These findings indicate a substantial reduction in both intensity and frequency of abdominal pain.

Composite Symptom and Quality-of-Life Scores

The reductions were statistically significant and exceeded thresholds for minimal clinically

important differences, indicating strong clinical relevance.

Quality-of-Life Outcomes

(Table No.6)

All quality-of-life domains showed significant improvement ($p < 0.001$):

Physical and social functioning improved markedly

Health-related concerns decreased

Body image and dietary behavior improved

Social and interpersonal relationships strengthened

Sexual relationship scores increased

Total QoL score improved from:

81.57 ± 5.98 (baseline) to 119.77 ± 10.10 (Post 2)

This reflects a substantial enhancement in overall patient well-being.

Adverse Events

No serious adverse events were reported during the study period. The intervention was well tolerated.

DISCUSSION

Interpretation of Findings

This current quasi-experimental study proves that the use of a short-term regimen of a standardized *Boswellia carterii* extract along with a program of educating patients leads to statistically and clinically significant improvement in the symptoms of IBS, including abdominal pain and bloating, as well as significantly improving health-related QoL.

Improvement in symptoms was apparent as early as one-week post-intervention and progressed throughout the month-long follow-up period, demonstrating promptness and effectiveness in symptom management. Along with decreased abdominal discomfort and distention, there were also improvements seen in other digestive symptoms such as heartburn, burping and nausea. More importantly, there was a return to normal bowel movements in over 90% of the patients, along with decreased usage of symptomatic medications, such as analgesics.

Although patient education was one of the strategies implemented in the study, the speed of recovery of symptoms is an indication that the effect can be more attributable to the pharmacologic effect rather than patient education. Improvement

brought about by educating patients is slow because of behavioral changes. In this study, however, it was fast, indicating neurogastroenterological pathways.

These positive changes seen in many aspects of quality of life, including physical, social, interpersonal interactions, and health problems, illustrate the psychosocial effects of effective symptom management. Since IBS is highly correlated with poor quality of life, these results highlight the need for strategies addressing both the physiological and psychosocial aspects of this disorder.

A single adverse event was noted, in which one participant developed diarrhea and discontinued treatment after 10 days, highlighting the need for monitoring tolerability in future studies.

Comparison with Existing Literature

However, these findings have been found to correlate with findings in other similar studies done on *Boswellia*-based treatment methods for patients suffering from IBS and other related conditions.

Giacosa *et al*, carried out an interventional study in which they found significant decrease in abdominal pain and bloating among patients treated with a combination of curcuma longa and *Boswellia*. It should be noted that apart from having similar sample sizes, both the current research and the above-mentioned study focused mainly on abdominal pain and bloating.

Similarly, randomized control trials testing multi-herbal interventions with *Boswellia* have been found to provide considerable relief from the symptoms of IBS, such as pain and bloating⁹. While such trials had noted that there were additional psychological effects such as decreased anxiety and depression, the results observed in the current study were more consistent across a wider range of QoL factors.

Another source for corroborative evidence would be from the experiment conducted by Kazemian *et al*¹⁷, which reported a reduction in symptoms when treated with an herbal mixture containing *Boswellia carterii*. This study goes further to show that when

Boswellia alone is used, the same clinical effects are achieved.

Biological Plausibility and Mechanisms

It is reasonable and possible to understand that these benefits are scientifically feasible because of known pharmacologic mechanisms. In fact, boswellic acids found in *Boswellia carterii* act as anti-inflammatory and immunomodulating agents due to their capacity to block 5-lipoxygenase activity and reduce the production of leukotrienes^{6,7}, which have been shown to play roles in visceral hypersensitivity and mucosal inflammation in IBS patients.

Recent studies have also provided insights into the connection between immune regulation and inflammation signaling in conditions related to gut-brain interactions. Research has found that triterpenes from *Boswellia* have immunomodulating and anti-inflammatory effects, thus providing scientific support for the observed effects of supplementation on symptoms⁶.

Further evidence comes from investigations conducted on inflammatory bowel disease (IBD), wherein *Boswellia* and other phytochemicals have been found to possess anti-inflammatory, antioxidant and immunomodulating effects¹⁸⁻²¹. Despite the difference between IBS and IBD, there might be similar inflammatory and immune system processes that make these results applicable.

Context within Integrative and Multimodal Approaches

The current results support the increasing body of evidence that favors integrative strategies in IBS treatment. The non-drug modalities such as diet therapy and patient education have been shown to be effective^{9,19}.

The implementation of structured education in this study might be one reason for enhanced patient participation and behavior change. Although no control of dietary intake was done, the educational sessions might have indirectly affected dietary habits, which is aligned with studies on nutrition and systematic reviews stressing the importance of diet in the management of IBS symptoms²⁰.

These findings help to reinforce the idea that a multimodal treatment approach, which integrates medication or herbal treatment with education and behavioral modification techniques, may be the most effective treatment method for IBS.

Strengths and Limitations

There are several aspects that increase the validity of the study. First, the application of a standardized preparation of *Boswellia*, which is characterized by a defined amount of boswellic acid, is an advantage. Repeated measures within subjects and broad testing on various clinical and quality-of-life variables are other features that contribute to the validity of the results.

Nevertheless, there are several weaknesses that should be addressed. First, no control or placebo group was used, which undermines any conclusions about causality. Second, the relatively brief follow-up time does not allow evaluating the long-term effectiveness and sustainability of the intervention. Finally, adherence issues and the impact of extraneous variables, such as participants' lifestyles and diets, might have affected the results. Only one adverse event occurred during the trial; specifically, one subject experienced diarrhea and stopped the drug after 10 days.

Generalizability and Clinical Implications

The study population, consisting predominantly of women ranging from young to middle adulthood, reflects the known epidemiology of irritable bowel syndrome (IBS) and thereby supports the external validity of the findings. However, the single-center design and the predominance of participants from a rural setting may limit the generalizability of the results to broader populations. Future studies involving multiple centers and more diverse patient populations are warranted.

The findings support the potential use of a standardized *Boswellia carterii* extract as an adjunctive therapeutic option for IBS, particularly for patients experiencing abdominal pain and bloating. Given its favorable safety profile, ease of administration, and potential to reduce reliance on concomitant medications, *Boswellia carterii* may

represent a valuable complementary approach alongside conventional IBS management strategies.

Limitations of the Study

This study has several important limitations. First, the single-arm quasi-experimental design precludes causal inference and does not allow differentiation of treatment effects from placebo response, regression to the mean, or the natural fluctuation of IBS symptoms. Second, *Boswellia carterii* supplementation and structured patient education were implemented concurrently, preventing assessment of their individual contributions to the observed outcomes. Third, the relatively short follow-up period limits conclusions regarding long-term efficacy, durability of response, and symptom recurrence. Finally, the study relied primarily on patient-reported outcomes without incorporating objective inflammatory, biochemical, or physiological biomarkers.

Despite these limitations, the study possesses several notable strengths, including the use of a chemically standardized *Boswellia carterii* extract with a defined boswellic acid content, repeated within-subject assessments, excellent participant retention, and comprehensive evaluation of symptom burden and quality of life. Furthermore, the intervention reflects real-world clinical practice by integrating phytotherapy with structured patient education.

Accordingly, the present findings should be interpreted as preliminary evidence intended to inform the design and sample size estimation of future randomized controlled trials."

Future Directions and Overall Evidence

The present study contributes to the growing body of literature supporting the role of plant-based and integrative therapeutic approaches in disorders of gut-brain interaction. Nevertheless, the findings should be considered preliminary and hypothesis-generating rather than definitive evidence of efficacy.

Future research should focus on adequately powered randomized, placebo-controlled clinical trials with longer follow-up periods. In addition, studies designed to evaluate the independent effects

of *Boswellia carterii* and patient education, as well as comparative investigations of *Boswellia* monotherapy versus combination herbal interventions, are needed to better define its therapeutic role in IBS management.

DECLARATION

FUNDING

This research was self-funded. The content of this article reflects only the authors' views, and no external funding body had any role in study design, data collection, analysis, interpretation, or manuscript preparation.

AVAILABILITY OF DATA AND MATERIALS

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request for further scientific analysis, in accordance with institutional policies.

AUTHORS' CONTRIBUTIONS

T.F. and R.S. contributed to data collection and statistical analysis.

T.F. and L.M. drafted the manuscript.

F.B, S.S and E.E. critically revised the manuscript, supervised the research process and provided substantial intellectual contributions.

All authors read, revised and approved the final version of the manuscript.

ETHICS APPROVAL

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Nursing, Mansoura University prior to study initiation (approval from the Research Ethics Committee of Faculty of Nursing, Mansoura University (IRB:582).

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

CONSENT TO PARTICIPATE

Written informed consent was obtained from all participants prior to enrollment in the study.

CONSENT FOR PUBLICATION

Not applicable.

Table No.1: Sociodemographic characteristics

S.No	Item	N= 60	%
1	Age	-	-
2	Mean (S.D)	36.68(12.046)	
3	Gender		
	Male	16	26.7
	Female	44	73.3
4	Marital Status		
	Single	8	13.3
	Married	49	81.7
	Divorced	2	3.3
	Widowed	1	1.7
5	Educational Level		
	Read and write	11	18.3
	Primary	3	5.0
	Preparatory	3	5.0
	Secondary	25	41.7
	University	18	30.0
6	Place of Residence		
	Rural	48	80.0
	Urban	12	20.0
7	Occupation		
	Government employee	12	20.0
	Freelance	12	20.0
	Student	6	10.0
	Unemployed	30	50.0

Table No.2: Assessment of gastrointestinal symptomatology in adult patients with irritable bowel syndrome

S.No	Manifestations	Pre		Post1		Post 2	
		N	%	N	%	N	%
1	Diagnosed consistent with IBS	60	100	59	98.3	59	98.3
2	Present of Bloating	60	100%	59	98.3%	42	70%
3	Abdominal pain occurring at least once weekly during the previous three months	58	95%	52	86.7	42	70%
4	Change in stool form	52	86.7	24	40	0	0
5	Change in stool frequency	59	98.3	24	40	2	3.3
6	Bowel habits pattern	-	-	-	-	-	-
7	Constipation	22	36.7	10	16.7	1	1.7
8	Diarrhea	6	10	10	16.7	0	0
9	Mixed aalternating (constipation and diarrhea)	31	51.7	5	8.5	0	0
10	Normal bowel habits	0	0	38	63.3	56	93.3
11	Abdominal pain relieved by defecation	58	96.7	51	85	41	68
12	Variation of stool consistency (softer or harder than usual) during the previous three months	57	95	58	96.7	50	83

Table No.3: Bloating symptom history in adults with irritable bowel syndrome (Bloating Criteria's)

S.No	Items	Pre		Post 1		Post 2	
		N	%	N	%	N	%
Rate the severity of your bloating symptoms overall during the past 24 hours							
1	None	0	0	0	0	10	16.7
2	Mild	2	3.3	28	46.7	46	76.7
3	Moderate	39	65	29	48.3	1	1.7
4	Sever	19	31.7	2	3.3	0	0
Bloating symptoms in the past 7 days							
5	Zero days per week	0	0	0	0	7	11.7
6	Once per week	0	0	0	0	35	58.3
7	Two days per week	0	0	15	25	13	21.7
8	Three days per week	2	3.3	20	33.3	2	3.
9	Four days per week	10	16.7	13	21.7	0	0
10	Five days per week	16	26.7	11	18.3	1	1.7
11	Sex days per week	12	20	1	1.7	1	1.7
12	Seven days per week	20	33.3	0	0	0	0
Relation between bloating and eating (7 days)							
13	Occurs before eating	0	0	0	0	5	8.3
14	Sometimes it occurs after eating	23	38.3	54	90	38	63.3
15	Occurs always after eating	37	61.7	5	8.3	5	8.3
16	Eating makes the bloating better	0	0	1	1.7	1	1.7
17	There is no relationship	0	0	0	0	1	1.7

Table No.4: Abdominal pain history in adults with irritable bowel syndrome

S.No	Manifestations	Pre		Post 1		Post 2	
		N	%	N	%	N	%
1	Suffering from abdominal pain	59	98.3	55	91.7	32	53.3
2	Location of pain: Upper abdomen	8	13.3	3	5	1	1.7
3	Med abdomen	30	50	31	51.7	13	21.7
4	Lower abdomen	14	23.3	24	40	23	38.3
5	Pain Intensity Scale: Mild (1 to 3)	0	0	34	56.7	37	61.7
6	Moderate (4 to 6)	43	71.6	25	41.7	1	1.7
7	Severe (7 to 10)	17	28.3	0	0	0	0
8	Allover abdomen	8	13.3	1	1.7	0	0
Temporal Pattern of pain							
9	Constant	6	10	3	5	2	3.3
10	Intermittent	54	90	45	75	22	36.7
Pattern of pain							
11	Burning	5	8.3	6	10	6	10
12	Cramping	51	85	30	50	19	31.7
13	Heaviness in the abdomen	4	6.7	7	11.7	8	13.3

Table No.5: Significant improvements were observed across all composite scores

S.No	Outcome	Baseline	Post 1	Post 2	P value
1	Abdominal pain	56.8 ± 7.61	39.16 ± 7.60	14.8 ± 10.94	<0.001
2	Bloating (Rome III/IV)	77.67 ± 6.9	62.05 ± 11.36	38.61 ± 11.7	<0.001
3	Quality of life	69 ± 14	52 ± 11	40 ± 9	<0.001

Table No.5: Composite scoring analysis of Rome III/IV criteria, gastrointestinal symptoms, and quality of life

S.No	Variable	Prescore: Before starting the intervention			Post1score: After one week of beginning intervention		Post 2 score: After one month of beginning intervention		
		Number	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation	P value
1	Abdominal pain score	58	56.8	7.61	39.16	7.6	14.8	10.94	P< 0.001
2	Rome III criteria and bloating score	59	77.67	6.9	62.05	11.36	38.61	11.7	P< 0.001
3	Quality of life score	60	69	14	52	11	40	9	P< 0.001

Table No.6: Changes in quality-of-life following intervention with standardized *Boswellia*

S.No	Quality of Life domains	Pre	Post 1	Post 2
Physical Activity and Social Life				
1	Mean (SD)	22.45(5.55)	30.28 (2.83)	34.67(2.97)
2	F- test*		.351	
3	P value		P< 0.001	
Worry about health				
4	Mean (SD)	17.93(4.40)	22.07(2.21)	25.20(2.3201)
5	F- test*		.729	
6	P value		P< 0.001	
Body Image				
7	Mean (SD)	15.93(3.40)	21.20(1.84)	21.68(2.01)
8	F- test*		.097	
9	P value		. P< 0.001	
Dietary Habits				
10	Mean (SD)	5.40(1.856)	6.78(1.1)1	8.28(.84)
11	F- test*		.823	
12	P value		P< 0.001	
Relation with other				
13	Mean (SD)	13.32(3.21)	19.18(1.78)	21.50(1.98)
14	F- test*		.620	
15	P value		P< 0.001	
Sexual Relationships				
16	Mean (SD)	6.53(3.22)	7.30(3.05)	8.43(3.21)
17	F- test*		.932	
18	P value		P< 0.001	

CONCLUSION

In conclusion, supplementation with a standardized *Boswellia carterii* extract for four weeks, in conjunction with structured patient education, was associated with improvements in key IBS symptoms, particularly abdominal pain and bloating. These improvements were accompanied by reduced use of concomitant medications and meaningful enhancements in quality of life.

The findings are consistent with emerging evidence suggesting a potential role for boswellic acid-containing preparations in the management of IBS. However, given the quasi-experimental design and short follow-up duration, the results should be interpreted with caution. Larger randomized controlled trials with extended observation periods are required to confirm efficacy, establish long-term safety and clarify the optimal therapeutic use of *Boswellia carterii* in IBS.

ACKNOWLEDGMENT

The authors gratefully acknowledge Rajvir Singh, Cardiology Research Department, Heart Hospital, Hamad Medical Corporation, Doha, Qatar, for her assistance with statistical analysis. The authors also thank Lubna Mahmood, GENUD Research Group, University of Zaragoza, Zaragoza, Spain, for critical review of the manuscript and valuable scientific input during its final revision. The authors acknowledge the Research Ethics Committee of the Faculty of Nursing, Mansoura University for their oversight and approval of the study.

CONFLICTS OF INTEREST / COMPETING INTERESTS

The authors declare that they have no conflicts of interest or competing interests relevant to this study.

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Please cite this article in press as: Farid A. Badria et al. Feasibility and preliminary clinical outcomes of a standardized *Boswellia Carterii* extract combined with structured patient education in adults with irritable bowel syndrome: A pilot single-arm study, *Asian Journal of Phytomedicine and Clinical Research*, 14(1), 2026, 12-27.