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RESEARCH

Study protocol for a prospective, investigator-initiated clinical trial on the vascular effects of acupuncture in the abdomen and lower limbs for patients with diarrhea-predominant irritable bowel syndrome

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Abstract

Background Physicians classify irritable bowel syndrome with diarrhea symptoms under the label IBS-D which represents a gastrointestinal disorder that meets specific functional diagnostic criteria. Studies show acupuncture helps manage IBS-D symptoms though researchers do not understand if specific treatment points in the abdomen provide better outcomes than standard acupuncture points in the lower body regions. The study investigates the effects acupuncture treatments using local and systemic needling techniques have on IBS-D symptom expression and gut microbial diversity features.

Methods The study employs a randomized controlled single-blinded exploratory clinical trial design which includes 36 participants diagnosed with IBS-D via Rome IV criteria. Participants are randomly allocated to one of three groups: abdominal acupuncture, lower limb acupuncture, or standard treatment. Participants who receive acupuncture treatment receive eight sessions which are distributed throughout 4 weeks as clinicians activate specific points connected to gastrointestinal function. Lifestyle education and approved medications with symptom management make up the standard treatment provided to participants. The main outcome measures assess IBS Symptom Severity Scale (IBS-SSS) score changes from baseline at Week 5. Additional evaluation measures in this study comprise stool consistency examination alongside patient global assessments and cold-heat surveys along with EQ-5D-5L quality of life assessment and gut microbiota examination as secondary outcomes.

Results Research has been designed to evaluate how abdominal and lower limb acupuncture techniques compare in symptom relief and microbiota adaptation outcomes. The preliminary data is expected to reveal distinct patterns between local and wide-reaching effects which suggests that IBS-D treatment should be tailored on a personal basis.

Conclusion The comparison of abdominal and lower limb acupuncture treatment efficacy adds to our understanding of acupuncture therapy benefit for IBS-D. The results will help guide clinical practice and support the creation of tailored acupuncture treatments.

Keywords IBS-D · Acupuncture · Abdominal acupoints · Lower limb acupoints · Gut microbiota · Clinical trial · Symptom relief · Personalized protocols

Introduction

The investigator-initiated exploratory clinical trial uses Fig. 1 to study the therapeutic treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) through abdominal and lower limb acupoint manipulation (Fig. 1). Specifically, the study seeks to:

Examine to what extent acupuncture provides relief for IBS-D symptom manifestations.

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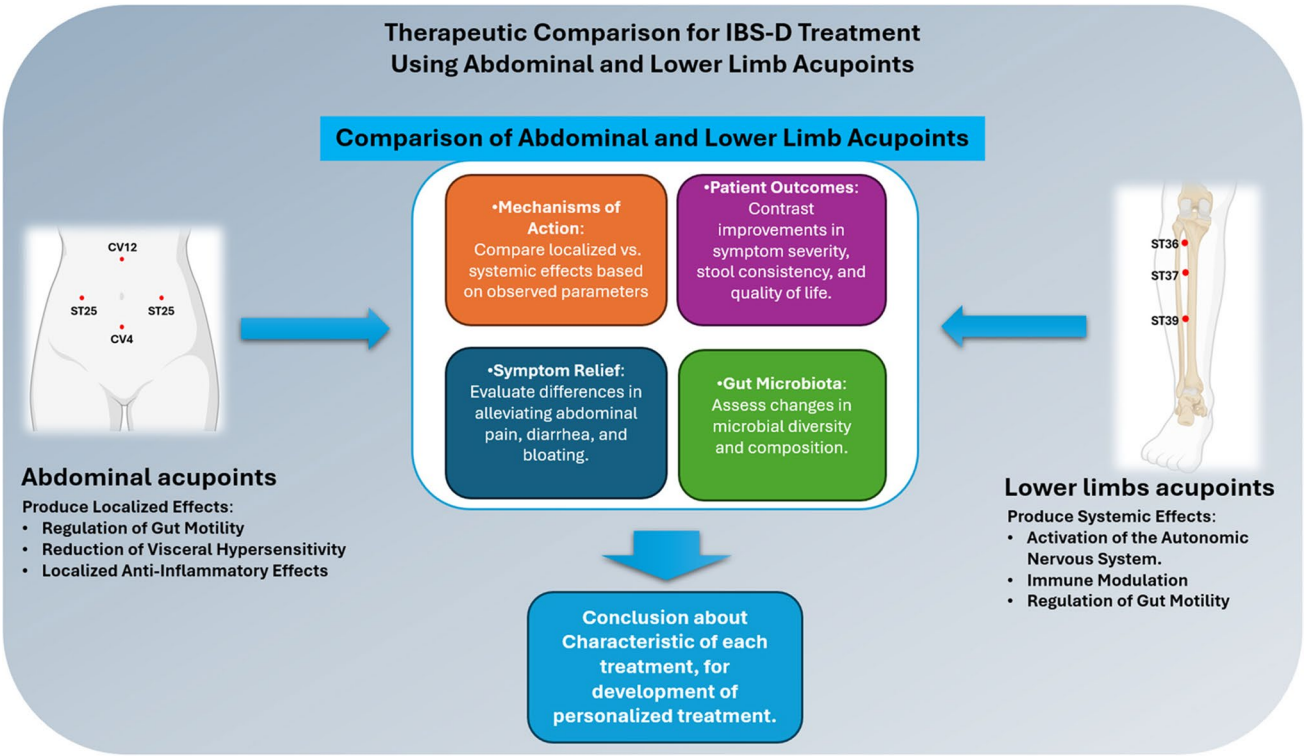


Fig. 1 The paper summarizes experimental research designs alongside the results examining abdominal vs. lower limb acupoint treatments for diarrhea-predominant irritable bowel syndrome (IBS-D). Abdominal acupoints CV12, CV4, and ST25 exhibit specific effects which differ from the effects of lower limb acupoints ST36, ST37, and ST39. Abdominal acupoints create localized effects that control gut motility while reducing visceral sensitivity and exhibiting anti-inflammatory properties yet lower limb acupoints produce systemic effects through activation of the autonomic nervous system alarming immune responses and modulating gut motility. The central box outlines the study's key comparison areas: The comparison explores both active methods while examining their impact on symptoms alongside patient health results and modifications in gut bacterial populations. Researchers want to establish conclusions about the unique characteristics of each acupoint group since such insights will drive the creation of individualized acupuncture strategies

Compare the effects of acupuncture administered at two different sets of acupoints:

oAbdominal acupoints (4 points): CV12, CV4, and two ST25 points.

oLower limb acupoints (6 points): ST36, ST37, and ST39 (3 on each lower limbs)

The functional gastrointestinal disorder known as diarrhea-predominant irritable bowel syndrome (IBS-D) generates substantial life disturbances in affected patients. The symptoms of IBS-D which include repeated stomach pain and distended belly and frequent bowel movements lead to severe emotional struggles along with social difficulties. The illness influences activities of daily life and professional effectiveness and adds healthcare expense burdens to the healthcare system [1, 2]. The combination of dietary modifications together with pharmacological therapies and psychological interventions does not provide sufficient treatment to many patients whose prices serve unwanted side effects [3, 4]. Scientists need to find alternative treatment approaches to tackle IBS-D's multiple-rooted pathophysiology because of its urgent requirement. Contemporary research shows acupuncture functions as a powerful non-drug treatment for patients with IBS-D because it efficiently changes gut motor patterns while lessening sensitivity to abdominal pressure and improving general digestive functions. Multiple physiological processes enable acupuncture by controlling various neural mechanisms together with vagal support and neurotransmitter regulation [5, 6]. Studies have shown acupuncture successfully promotes therapeutic outcomes by boosting gut microbiota diversity inside the human body [7]. This therapeutic approach delivers complete treatment effects which surpass IBS-D symptoms. Researchers now intensively explore the gut microbiome relationships with diarrhea-focused irritable bowel syndrome (IBS-D) to uncover multiple mechanisms that drive this widespread gastrointestinal condition's development paths. Excessive abdominal discomfort together with bowel distress that shows diarrhea patterns defines IBS-D while researchers now focus on showing how changed stomach microbiology contributes to developing and presenting symptoms [8–10].

Acupoints CV12 (Zhongwan), CV4 (Guanyuan), and ST25 (Tianshu) specifically act on the gastrointestinal

system in their localized area to treat symptoms of IBS-D effectively. The gastric electrical activity of CV12 regulates motility dynamics that also reduces bloating symptoms and improves functional dyspepsia manifestations related to IBS-D [11, 12]. The targeted triggers at these acupoints activate physiological gut function along with mood stability and acknowledge their dual impacts on body systems. Acupuncturists emphasize CV4 as a vital point in managing intestinal motility and controlling inflammatory responses in affected patients [13, 14]. CV4 addresses digestive health through a complete solution that corrects both diarrhea and constipation symptoms. ST25 serves as an essential point on the large intestine meridian to both enhance bowel function and minimize abdominal discomfort [15]. Direct stimulation of colonic motility occurs at this point where integration with other abdominal points strengthens its ability to impact localized inflammation [16]. The precise modulation of gastrointestinal function as provided by these abdominal acupoints supports the management of IBS-D core symptoms.

The lower limb acupoints ST36 (Zusanli), ST37 (Shangjuxu), and ST39 (Xiajuxu) combine to create systemic effects parallel to the localized results achievable through abdominal points. Many studies demonstrate ST36 activates anti-inflammatory pathways and increases vagal tone to yield benefits across gastrointestinal symptoms and total body inflammation [17, 18]. Through mechanisms involving neural and hormonal signaling, ST37 and ST39 serve as regulators of gastrointestinal motility [13, 19]. These remote points impact the autonomic nervous system while simultaneously working to balance the vital gut-brain connection that IBS-D management requires [20, 21]. Abdominal points concentrate on single-area symptom control but lower limb acupoints focus on treating fundamental systematic health problems including stress disorders and immune system problems and visceral sensitivity dysregulation. Acupoint therapy consists of divergent approaches because abdominal points deliver fast local effects but lower body points provide lasting systemic treatment. Acupuncture-based treatments grow more complicated since different therapeutic principles define how abdominal and lower limb acupoints work. Local adjustment of tissue activity combined with neurotransmitter modulation allows abdominal acupoints to specifically affect gastrointestinal function. Rather than focusing on the gut, lower limb acupoints affect physiological alerts from their release at autonomic and endocrine levels to treat gut-based problems beyond the digestive tract [22, 23]. Separate acupoint contributions demonstrate why practitioners should understand their unique roles for optimal IBS-D acupuncture treatment protocols.

Acupuncture research has proven its benefits yet a knowledge gap exists between evaluating the relative impact between abdominal and lower limb acupoints. Previous research has mainly studied individual outcomes of separate acupuncture groups without investigating possible differences in effectiveness between these approaches. Researchers attempt to fill this knowledge gap by assessing the specific local and systemic effects on different acupoints to identify effectiveness distinctions. This study aims to discover which treatment method produces better results—abdominal acupuncture stands stronger for local GI relief or lower limb application gives more comprehensive overall relief.

The research of unique abdominal and lower limb acupoints can help develop standardized acupuncture practices which will establish better integration of this therapy into medical facilities [24, 25]. These improvements will create new possibilities for patient treatment based on individual needs while resolving research gaps surrounding acupuncture practice and delivery.

We predict that abdominal (local) acupuncture, which targets the core gastrointestinal region, may excel at alleviating diarrhea frequency and bloating symptoms relatively quickly by directly modulating local gut motility and inflammation. However, it may be slower or less robust in addressing pain sensitivity or broader stress-related factors. Conversely, lower limb (systemic) acupuncture may have a quicker impact on pain and stress-induced manifestations by engaging deeper neuroimmune pathways and potentially offering faster pain-reducing effects, though it could be slower to resolve diarrhea. These parameters are recorded in a time-dependent manner via the IBS-SSS Scale and Bristol Stool Scale tools, so we can observe this phenomenon in the study.

Methods

Study design and ethical approval

The researchers carried out a methodologically sound single-blinded randomized controlled clinical trial through Dongshin University Mokpo Oriental Hospital. This research examines how well acupuncture works as a therapy to treat diarrhea-predominant irritable bowel syndrome (IBS-D). The trial design includes three parallel groups: abdominal acupuncture, lower limb acupuncture, and standard treatment. Each participating patient will obtain treatment through eight intervention sessions during 4 weeks before measurements are collected during a subsequent 2-week observation phase. The research follows CONSORT guidelines so its methodology remains rigorous while providing transparent reporting.

Each participant undergoes a 5-week duration of research during which visits are extensively mapped out for evaluation stages along with treatment procedures. Continuous monitoring will track participants' trial compliance while

addressing any adverse health events that occur (Table 1 provides details).

This research investigation aligned with both the Helsinki Declaration standards and guidelines from Good Clinical Practice. Ethical clearance for this research emerged from the Institutional Review Board (IRB) of Dongshin University Mokpo Oriental Hospital under protocol DS-IBS-Acu-2401_Version 1.1. Each contributor granted their permission in written form before joining the study research.

Participants

Inclusion criteria

Participants eligible for the study must meet the following criteria:

- Diagnosed with diarrhea-predominant IBS according to the Rome IV criteria.
- Aged between 20 and 75 years at the time of enrollment.
- Experiencing at least two of the following: persistent abdominal pain or discomfort for over 2 days per month in the past 3 months; abdominal pain more than 1 day per week for the past 3 months; bowel movement discomfort; altered stool frequency; or changes in stool appearance. Symptoms must have started at least 6 months before enrollment.
- Reporting a weekly average abdominal pain score of 3 or higher (on a 0–10 scale) in the past 7 days.
- Experiencing at least one Type 6 or Type 7 stool on more than 2 days in the past 7 days based on the Bristol Stool Form Scale (BSFS).
- No stromal lesions in colonoscopy or barium colonography performed within the last 5 years.
- Providing written informed consent and being able to adhere to the trial requirements.

Exclusion criteria

Participants will be excluded if they:

- Have undergone gastrointestinal surgery, except for appendectomy or hernia repair.
- Have been diagnosed with other gastrointestinal diseases such as colitis or colon cancer within the last 2 years.
- Are currently taking antithrombotic or anticoagulant medications.
- Have significant comorbidities, including cardiovascular diseases, chronic renal failure, liver cancer, or thyroid disorders.
- Are pregnant, lactating, or women of childbearing potential not using contraception.
- Have participated in acupuncture-related clinical studies within the last 6 months.
- Have skin allergies, ulcers, or infections that would interfere with acupuncture treatments.
- Are deemed unsuitable by the investigator for any reason.

Interventions

Abdominal acupuncture group

Subjects in this group receive meridian point acupuncture based on specific placements of CV12 (Zhongwan) with CV4 (Guanyuan) alongside ST25 (Tianshu) bilaterally. Traditional Chinese Medicine experts use these points because they have specific effects on gastrointestinal functions. Acupuncturists will use sterile disposable short needles measuring 0.25 mm × 40 mm to penetrate a depth of 1–1.5 cm to produce "De Qi" where participants experience heaviness or distension as the sensory response. The therapy duration for each session totals 20 min and includes a single needle manipulation during that time period/9 (Fig. 2).

Lower limb acupuncture group

ST36 (Zusanli) and ST37 (Shangjuxu) will be bilaterally punctured, along with ST39 (Xiajuxu) at these points for both legs by participants within this treatment group. Acupuncturists have carefully selected distal points because they demonstrate both regulatory functions for the gastrointestinal system and control of immune system actions. All procedures for needling and retention follow the method used in the abdominal group testing.

Standard treatment group

People in the standard treatment group will receive treatments with allowed drugs consisting of loperamide hydrochloride administered at 4 mg initial dose followed by 2 mg usage as needed to a maximum of 16 mg per day along with butylscopolamine bromide given in 10–20 mg doses not exceeding 100 mg daily. All participants will receive lifestyle management education for IBS-D as part of their care. Participants in the standard treatment segment may request a maximum of six acupuncture treatments upon completion of trial participation.

Randomization and blinding and treatment fidelity

Research participants will distribute across the three intervention groups through block randomization techniques. An independent statistician will create unopened, sealed opaque envelopes to conceal randomization. Participants receive one-blind testing which covers their group

Table 1 The detailed schedule of enrollment, interventions, and assessments

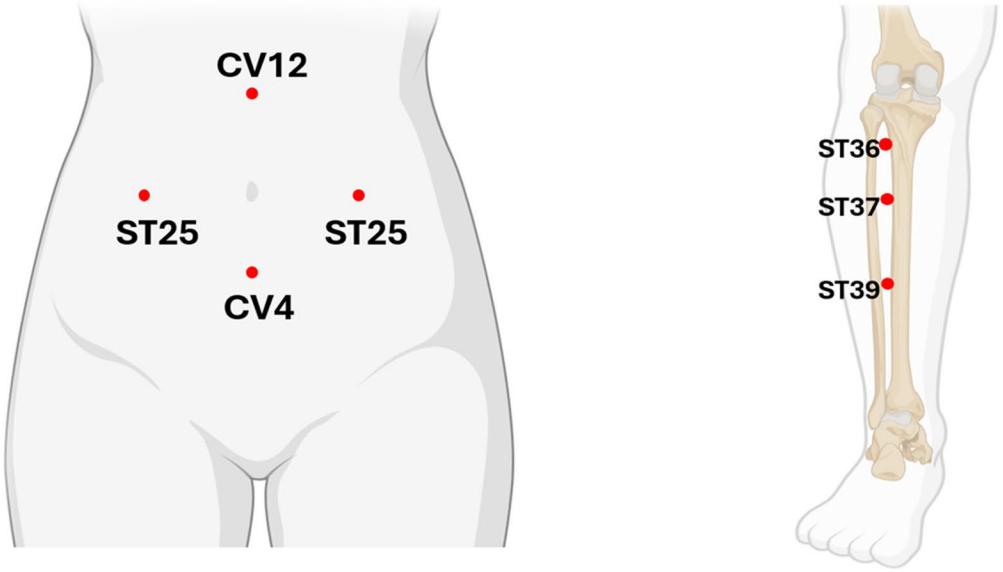
Visit[1)]		Screening	1	2	3	4	5	6	7	8	9	Phone Visit[11)]	Unexpected Visits [12)]
Window period[2)]			**+14 days**	**1–4 weeks**			**(+1 week)**				**V8 + 1 week (± 3 days)**	**V9 + 2 weeks (± 1 week)**	
Week			**1**		**2**		**3**		**4**		**5**		
Sign the agreement		●											
Demographic-Sociographic Information [3)]		●											
Vital signs		●	●	●	●	●	●	●	●	●	●		●
Medical history [4)]—Medications—Treatment history [5)]		●											
Radiography (x-ray)[(6)] (Abdomen Erect posture, AP)		●											
Physical examination		●											
Diagnostic TestsMedical Evaluation (Pregnancy Reaction Test[13)])		●											
Human Derivatives (Blood-Metabolites) Test [14)]		●									●		
Determining inclusion/exclusion criteria		●											
Randomization			●										
Validation	IBS-SSS Scale [7)]	●	●			●				●	●		
[Test/Standard of Care arm common]	Bristol Stool Scale	●	●			●				●	●		
	Quality of Life Assessment (EQ-5D-5L)	●									●		
	General Adequacy (PGA)		●								●		
	Hot/Cold Fever Questionnaire	●									●		
	Training on how to collect human derivatives and distribution of kits [8)]	●								●			
	Collecting and Submitting Human Derivatives [8)]		●								●		
Acupuncture (Group 1, Group 2 acupuncture treatment)			●	●	●	●	●	●	●	●			
Irritable bowel syndrome with diarrhea (IBS-D) Related daily living education			●										
Standard of Care Medication/Medication Log Distribution [9)]		●	●	●	●	●	●	●	●	●			
Returning Standard of Care Medications/Medication Logs [9)]			●	●	●	●	●	●	●	●	●		
Checking for adverse events			●	●	●	●	●	●	●	●	●	●	●
Treatment Schedule Training		●	●	●	●	●	●	●	●	●	●		
Medical history, medication history, Healing Power Changes [10)]			●	●	●	●	●	●	●	●	●	●	●
Case conclusion											●		

Table 1 (continued)

Visit[1)]	Screening	1	2	3	4	5	6	7	8	9	Phone Visit[11)]	Unexpected Visits [12)]
Window period[2)]		**+14 days**	**1–4 weeks● (+1 week)**							**V8 + 1 week (± 3 days)**	**V9 + 2 weeks (± 1 week)**	

1) Visit 1 must be performed within 14 days of the screening visit. If a screening test is missed, the missing test may be performed prior to Visit 1 randomization
2) Each group will complete a total of 8 treatments within 4 weeks (+1 week). The principle is two treatments per week, but the treatment schedule may be adjusted according to health status and other conditions of the subjects. The treatment period is allowed from 4 weeks to an additional 1 week and visit 9 is conducted 1 week (±3 days) after visit 8
3) Investigate and record the subject's gender, date of birth, age, height, weight, residence, marital status, occupation, smoking (cigarettes/day, year(s)), coffee (cigarettes/day, year(s)), alcohol consumption (glasses/week, year(s)), and exercise status
4) A detailed medical history within 6 months of the time of screening should be taken and recorded (2 years for diseases that may affect the evaluation of drug efficacy for digestive system pain, and 2 years for irritable bowel syndrome from the time of first occurrence to the present)
5) Check for prior medications, diagnoses (including presence of colorectal stromal lesions), and treatments within 3 months of screening
6) X-ray examination is performed to determine the presence of intestinal gas shading. However, for women of childbearing age, it is performed at visit 1 after confirming the pregnancy reaction test
7) Participants' IBS-SSS will be measured and recorded at Screening, Visits 1,4,8 (before acupuncture), and Visit 9
8) Human remains (feces, urine) should be collected at the subject's home and submitted within 2 days of collection. The human remains will be analyzed for gut microbiota for feces and metabolome for urine, and the specimens will be discarded immediately after the analysis is completed
9) The standard of care is loperamide hydrochloride (Lofmin capsules) for diarrhea and butylscopolamine bromide (Buscopan tablets) for abdominal pain. Loperamide hydrochloride (2 mg per capsule) is administered orally as an initial dose of 4 mg (2 capsules), followed by an additional 2 mg as needed for diarrhea. The usual daily dose is 6 to 8 mg, with a maximum daily dose of 16 mg. Butylscopolamine bromide (10 mg per tablet) is given as needed for abdominal pain, 10 to 20 mg once daily, with a maximum daily dose of 100 mg. At each visit (except visit 9), the standard of care (loperamide hydrochloride/butylscopolamine bromide) will be 10 capsules, 10 tablets, based on 2 capsules, 2 tablets per day, and a medication diary will be distributed. At each visit (except screening), return the standard medication diary, unused standard medication, and used PTP packaging. However, it should not be administered on the same day as the subject's visit
10) Check for changes in medical history, medication history, and treatment history at all visits after randomization
11) Telephone visits will be conducted to confirm the presence of adverse events and concomitant medication history via telephone if there are adverse events that persist until the end-of-study visit (Visit 9), or if the investigator determines that additional follow-up is warranted after the end of the study, or if requested by the patient. Evaluation of adverse events If necessary, an in-office visit will be conducted to further evaluate safety (identification of adverse events, vital signs, concomitant medications, treatment, exercise therapy, etc
12) Unscheduled visits will be made outside of the scheduled visits as needed by subject request or investigator judgment
13) A pregnancy reaction test (Urine HCG) is performed for women of childbearing age at screening, and a positive result is a criterion for exclusion
14) For human derivatives (blood), 3 ml of blood is collected in an EDTA tube, and 0.1 ml ~ 0.2 ml of plasma is separated and frozen at −20 degrees Celsius, and then transferred to a batch sample analyzer to analyze the metabolites in the serum, and the sample is immediately discarded after the analysis is completed

(A)



(B)

Acupoints	Chinese Name (Pinyin)	Anatomical Location	Group
CV12	Zhongwan	Midline of the abdomen, 4 cun above the umbilicus	Abdominal Group
CV4	Guanyuan	Midline of the abdomen, 3 cun below the umbilicus	Abdominal Group
ST25	Tianshu	2 cun lateral to the center of the umbilicus	Abdominal Group
ST36	Zusanli	3 cun below the inferior border of the patella, lateral to the tibial tuberosity	Lower Limb Group
ST37	Shangjuxu	3 cun below ST36, along the anterior crest of the tibia	Lower Limb Group
ST39	Xiajuxu	3 cun below ST37, along the anterior crest of the tibia	Lower Limb Group

Fig. 2 Study design and acupuncture treatment groups. **A** Acupoint locations: The abdominal group received needle placement at CV12 CV4 and two ST25 points for local effects but ST36, ST37 and ST39 points on both lower limbs for systemic effects. **B** You will find an organized summary of the acupoints which includes their precise locations grouped by trial purpose for treating IBS-D

assignment knowledge but they understand their exposure to varying interventions is possible. The trial will keep both outcome assessors and statisticians in total blinding status from beginning to end to minimize assessment bias. Acupuncturists will receive uniform training to guarantee regular therapy delivery across practices. The usage of needles along with positioning depth and stimulation will be evaluated through direct observation and periodic video assessments. The research team manages immediate corrective actions toward protocol maintenance for all protocol violations. To minimize bias, the following steps will be put into place, even though participants know which treatment group they are in: (1) outcome assessors and data critics will be blinded to the group allocation, (2) both groups will receive standardized communication related to the study to minimize expectation effects, (3) subjective endpoints, such as those involving microbiota compositional analysis and short-chain fatty acid (SCFA) analysis, will not be prioritized, and (4) equal participation engagement will be ensured through structured telephone follow-up with all participants regardless of their group assignment.

Outcome assessments

Primary outcome

Participants will measure their response using the IBS Symptom Severity Scale (IBS-SSS) score between baseline measurements and Week 5 assessments. The IBS-SSS evaluates six IBS key features which include abdominal pain intensity measures alongside pain frequency indicators and evaluations of bowel habits and their impact on social life. Altogether the components utilize 0–100 rating scales and combine into a total 0–500 scoring system. A person's symptoms become worse as their score increases.

Secondary outcomes (tables in the Supplemental Material)

1. Bristol Stool Form Scale (BSFS): Stool changes from Week 1 to Week 5 will be determined using the Classification System of the BSFS that organizes stool types into seven categories. Patients experience improvements when they move from Type 6–7 diarrhea to Type 4 normal stool classification.
2. Quality of life (EQ-5D-5L): The validated instrument collects data about health-related quality of life through measures that span five dimensions including mobility and self-care alongside usual activities and pain and distress and anxiety and depression. The investigators will compare patient ratings from baseline to Weeks 1 through 5.
3. Patient global assessment (PGA): Each evaluation period requires participants to use a 7-step rating scale which begins at "very much worse" then progresses to "very much improved."
4. Deficiency-excess/cold-heat syndrome: Participants use this questionnaire based on Traditional Medicine principles to describe their bodily conditions as they perceive their health status. Research teams will examine the data points collected during Weeks 1 to 5 against baseline measurements.
5. Gut microbiota composition and metabolites: Research teams will test microbial diversity through alpha and beta diversity metrics alongside measuring short-chain fatty acid levels in stool samples obtained at baseline then at Week 5.

Gut microbiota and metabolite analysis

Stool samples will be taken at baseline and Week 5 using a sterile collection kit. They will be stored right away at − 20 °C and forwarded under cold-chain conditions for laboratory analysis. DNA from the stool samples will be extracted using the QIAamp DNA Stool Mini Kit and the 16S rRNA gene sequenced for the V3–V4 region on the Illumina MiSeq platform. Changes in composition of the Microbiome populations will be the focus of bioinformatics analysis. To determine metabolic changes, short-chain fatty acids (SCFA) will be analyzed using gas chromatography-mass spectrometry (GC–MS). Responders who had greater than or equal to 50 point reduction of IBS-SSS and non-responders will be compared for changes in gut microbiota profile besides overall composition and diversity.

Building upon our past work using alpha diversity metrics (Shannon, Chao1, Observed Species, PD Whole Tree) and beta diversity metrics (Unweighted UniFrac), where we characterized shifts in microbial population, we aim to use these methods to find microbial correlates of acupuncture response in IBS-D and hypothesize their therapeutic mechanism action [26].

Sample size calculation

A systematic review of clinical trials and meta-analyses of IBS employing the IBS Symptom Severity Scale (IBS-SSS) confirms that the 50-point reduction is well accepted as clinically significant [27, 28]. Studies report standard deviations of around 40 points, which further justifies its application in sample size calculations [29, 30]. Most trials utilize 80% statistical power with alpha level of 0.05, which guarantees sufficient specificity to identify treatment effects [31]. Approximately 20% participant attrition is common in long-term IBS interventions[32, 33].

Adverse event and compliance monitoring

Every visit includes recording adverse event occurrence alongside assessing their severity. AEs will be classified through a severity system that examines participant response levels. Participants must report SAEs directly to the IRB in less than 24 h and provide regular updates until resolution occurs.

The researcher will track participant adherence through comprehensive visit attendance records during all nine visits. Standard treatment participants must maintain their medicines by either providing diary evidence or undergoing pill count verification. Any lost visits will need to be rescheduled and documented findings will assist with study analysis.

Statistical analysis

This research follows both Intent to Treat (ITT) and Per Protocol (PP) analysis models to determine the impact of acupuncture on IBS-D. The ITT population consists of all participants who were randomized and attended at least one session of acupuncture and one post-baseline efficacy evaluation. The Participant population consists of those with ≥ 75% compliance (six out of eight treatments) without any significant breach of protocol.

Data is set as Missing Not At Random (MNAR) with Last Observation Carried Forward (LOCF) as previously outlined for the protocol. This will be done to maintain coherence on the analysis. In order to test the robustness, sensitivity analysis using multiple imputation (MI) will be executed [34].

With consideration of the longitudinal design, changes of the IBS Symptom Severity Scale (IBS-SSS), stool type (Bristol Stool Scale), and quality of life indicators (EQ-5D-5L) over a given period will be analyzed using repeated measures ANOVA analysis. If the sphericity conditions are not met, Greenhouse–Geisser corrections will be made. Independent comparisons will be done via Student's *t* test

or the Mann–Whitney *U* test, and dependent comparisons will be done via related samples *t* test or Wilcoxon signed-rank test.

Ethical considerations.

The study received approval from the Institutional Review Board of Dongshin University Mokpo Oriental Hospital. Every trial participant must sign consent documents prior to joining and the study protects participant privacy from the start through the entire research period. A structured draft for this manuscript's "Discussion" section exists below. This section establishes the importance of your investigation through detailed comparisons with existing research alongside interpretation of outcomes and identification of project strengths and weaknesses.

Discussion

Main findings

This study investigates the efficacy of abdominal and lower limb acupuncture in the management of diarrhea-predominant irritable bowel syndrome (IBS-D). This research examines localized and systemic acupuncture approaches to establish the most effective method for symptom relief while enhancing patient life quality. Research results will produce individualized acupuncture treatments by filling extant knowledge gaps about how different acupoints work and what specific effects they produce.

Previous studies on acupuncture for IBS-D primarily focused on single sets of acupoints, often without directly comparing abdominal and distal acupoints. The examination of ST25 and CV12 abdominal acupoints has shown both localized impact on digestive tract motility and sensitivity of visceral sensations within that area [35, 36]. Research indicates lower limb acupoints ST36 and ST37 produce systemic results by controlling gut-brain communication and immune system function [23, 37]. This research examines the distinct features between these acupoints and demonstrates the combined treatment potential by conducting a direct comparison. It is hypothesized that abdominal acupuncture will primarily address localized symptoms, such as abdominal pain and bloating, through direct modulation of visceral hypersensitivity and gastrointestinal motility. In contrast, lower limb acupuncture is expected to provide broader systemic benefits, including stress reduction and improved gut-brain communication, by activating distal meridians.

If the results confirm these hypotheses, it will underscore the importance of tailoring acupuncture treatments to individual symptom profiles. For instance, patients with severe abdominal pain may benefit more from abdominal acupoints, while those with stress-related IBS-D may respond better to lower limb acupoints.

The inclusion of gut microbiota analysis adds another layer of understanding to acupuncture's mechanisms. Previous studies suggest that acupuncture can restore microbiota diversity and abundance, which are often disrupted in IBS-D patients [7, 38]. This study's microbiota analysis will provide valuable insights into whether the effects of abdominal and lower limb acupuncture differ in modulating gut microbiota composition and function.

Strengths of the study

This study has several strengths:

- Comparative approach: A direct evaluation between abdominal and lower limb acupoint locations unveils their individual performance capabilities to fill a missing space in present-day medical research.
- Rigorous design: Methodological robustness and elimination of research bias enter through the use of this randomized controlled single-blinded design protocol.
- Comprehensive outcomes: The inclusion of primary and secondary outcomes, such as IBS-SSS, BSFS, quality of life, and microbiota analysis, offers a holistic evaluation of acupuncture's effects.
- Personalized protocol development: The research outcome could lead to individualized acupuncture treatment plans which match specific patient requirements and symptom distribution patterns.

Despite its strengths, this study has some limitations:

- Sample size: With only 36 participants in the study, the findings risk losing their ability to apply to broader groups of individuals.
- Short follow-up period: Research based on telephone follow-ups lasting 1 to 3 weeks does not properly measure long-term results regarding acupuncture treatment of IBS-D symptoms as well as gut microbiota changes.
- Blinding challenges: Staff members find it challenging to blind practitioners from acupuncture treatments leading to performance bias possible in the study.
- Single-center design: Limitations in the study's results apply when conducting research at only one research center.

Limitations and future directions

The findings from this study will lay the groundwork for future research in several areas:

- Long-term studies: Future research trials need to explore how acupuncture influences both symptom

improvement and gastrointestinal microbiome composition development while assessing total quality in patients suffering from IBS-D.
- Larger sample sizes: Additional large-scale studies across multiple centers need to be conducted in order to verify the wide applicability of these research findings.
- Combination approaches: Further exploration into combining abdominal and lower limb acupuncture might expose additional therapeutic benefits which can enhance our current treatment methods.
- Mechanistic studies: Our understanding of acupuncture's therapeutic potential in IBS-D can be improved through expanded investigations of the neural and endocrine pathways and immune system responses.

Conclusion

The study completes an extensive review of abdominal and lower limb acupuncture treatments for IBS-D while demonstrating their specific therapeutic effects. This research both fills knowledge gaps and delivers guidance for tailored therapeutic planning thus expanding the evidence foundation for acupuncture as IBS-D treatment. The acquired results present opportunities to improve medical treatment methods while simultaneously enhancing therapeutic effects for patients which leads to individualized treatment approaches.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00384-025-04868-z.

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Author Contribution The study design along with supervision came from Jeon Suk-hee while she worked on writing the manuscript. Kim and Choi sowie Choi along with Kim participated in all aspects of collecting data while handling patients and carrying out the intervention. Soeun Son together with Jeongsun Choi participated in data analysis and performed manuscript writing. Dr. Jae Wook Sul and Dr. Jaehyung Park delivered clinical expertise then helped assess the paper's publication material. Statistical analysis along with manuscript revision received input from Yoo Yanghee and Myungjeong Chae. Establishing a which included manuscript editing and enhancement followed by submission management at the journal stage was the responsibility of Cong Duc Nguyen. Changsu Na both brought Traditional Korean Medicine principles into the research process and supplied guidance regarding protocol construction. The authors gave their approval to the ultimate manuscript version.

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Data Availability No datasets were generated or analysed during the current study.

Declarations

Ethics This research investigation aligned with both the Helsinki Declaration standards and guidelines from Good Clinical Practice. Ethical clearance for this research emerged from the Institutional Review Board (IRB) of Dongshin University Mokpo Oriental Hospital under protocol DS-IBS-Acu-2401_Version 1.1. Each contributor granted their permission in written form before joining the study research.

Competing Interests The authors declare no competing interests.

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