

Electro-acupuncture for Irritable Bowel Syndrome Patients: Study Protocol for A Single-blinded Randomized Sham-controlled Clinical Trial

Linda LD Zhong (✉ ldzhong@hkbu.edu.hk)

Hong Kong Baptist University <https://orcid.org/0000-0002-3877-1914>

Tsz Fung Lam

Hong Kong Baptist University

Wei Yang

Hong Kong Baptist University

Ya Zheng

Hong Kong Baptist University

Zipan Lyu

Hong Kong Baptist University

Zhaoxiang Bian

Hong Kong Baptist University

Study protocol

Keywords: Irritable Bowel Syndrome, IBS, Electro-acupuncture

Posted Date: March 24th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-270751/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background: Irritable bowel syndrome (IBS) is one of the most commonly functional gastrointestinal disorders in clinical practice. The diagnosis of IBS is based on symptoms defined by abdominal pain or discomfort associated with defecation or changes in bowel habit, and no absence of organic diseases. Acupuncture has been used for the treatment of internal medicine including digestive disorders and depressive disorder in Chinese medicine. This study aims to determine whether electro-acupuncture could have significant benefits than sham acupuncture for IBS.

Methods/Design: This is a single blinded randomized sham controlled clinical trial with two arms. 120 IBS patients will be recruited. After a 2-week run-in period, eligible subjects will be randomly assigned to one of two arms, acupuncture (AC) arm and sham acupuncture (SAC) arm. Each eligible subject will go through a 2-wk run-in-period, 6-wk treatment period and follow by a 6-wk of follow-up period. Five visits in total were scheduled for each subject in week 0, week 2, week 5, week 8 and week 14. The outcomes would be measured with 1) IBS-SSS; 2) Hamilton Depression Rating Scale (HAMD-17); 3) Clinical Global Impression-severity (CGI-S); 4) Self-Rating Depression Scale (SDS); 5) IBS Quality of Life (IBS-QoL).

Discussion The study will compare electro-acupuncture with sham acupuncture to explore the feasibility for electro-acupuncture in improving IBS symptoms.

Trial registration: ClinicalTrials.gov Identifier: NCT04387383

Background

Irritable bowel syndrome (IBS) is one of the most commonly functional gastrointestinal disorders in clinical practice. The diagnosis of IBS is based on symptoms defined by abdominal pain or discomfort associated with defecation or changes in bowel habit, and no absence of organic diseases [1]. Recent pooled population-based meta-analysis indicated that the global prevalence of IBS was approximate 11.2% [2], and early epidemiological study in Hong Kong showed 13% of males and 21% of females in Hong Kong suffered from IBS [3]. To date, the treatment for IBS is unsatisfactory. Moreover, people with IBS frequently suffer from anxiety and depression, which can worsen symptoms. Of those who do seek treatment, research has found that 54 to 94 percent have a psychiatric disorder such as an anxiety disorder or depression [4–6]. A review of published drug trials for IBS from 1966 to 1999 concluded that there was no proof that any western medicine is effective for all IBS patients [7]. One recently released systematic review about the safety and tolerability of pharmacological agents for treatment of IBS came to same conclusion [8]. Failing to receive satisfactory treatment from western medicine, many IBS sufferers turned to alternative treatment modalities [9], including acupuncture treatment.

Acupuncture has been practiced empirically in China for several millennia, and it is being increasingly accepted by practitioners and patients worldwide, especially during last three decades [10, 11]. Currently,

acupuncture treatment for IBS is a research hotspot in alternative medicine. Some reviews indicated the effective therapy of acupuncture for the IBS global symptoms [12, 13]. Research showed that electroacupuncture had the same effectiveness as medication in decreasing diarrhea on IBS patients with additional improvement on the consistency of stool and visceral pain symptoms [30]. Besides, it is well demonstrated that acupuncture has broad therapeutic benefits in treating various psychiatric disorders. Recent meta-analysis indicated that acupuncture treatment was effective in alleviating various depressive symptoms [14].

A cohort study concluded that IBS patients had increased risk of developing depressive disorder [31]. At the same time, the disorder is also a risk factor of IBS, therefore, the intervention on depression is critically important. Among the previous researches, abdominal points are most frequently selected and used as core points for IBS treatment but these points are mainly for relieving IBS local symptoms such as bloating, visceral pain [15–17, 22]. For the treatment of global symptoms like headache, fatigue or mood change, scalp points can be used in combination with the abdominal ones. we may infer that the scalp-abdominal points acupuncture is an effective treatment option for overall symptoms of IBS. However, there is no available clinical research to demonstrate this conclusion [17]. Thus, we hypothesized that acupuncture could produce greater clinical improvement compared to sham acupuncture for IBS symptoms.

Objectives

To test the hypothesis, a single blinded, randomized, sham controlled trial is designed to determine whether acupuncture could have significant benefits than sham acupuncture for IBS.

Materials And Methods

Study design

This is a single blinded randomized sham controlled clinical trial with two arms. 120 IBS patients will be recruited. The study will cooperate with Hong Kong Baptist University, and University of Toronto. After a 2-week run-in period, eligible subjects will be randomly assigned to one of two arms, acupuncture (AC) arm and sham acupuncture (SAC) arm. Each eligible subject will go through a 2-wk run-in-period, 6-wk treatment period and follow by a 6-wk of follow-up period. Five visits in total were scheduled for each subject in week 0, week 2, week 5, week 8 and week 14. The participant flowchart is listed in Fig.1 and participant timeline is listed in Fig.2.

Participants

Diagnostic criteria for IBS (Rome IV) [19]: Recurrent abdominal pain, on average, at least 1 day per week in the last 3 months with symptom onset at least six months, associated with two or more of the following

criteria: 1). Related to defecation; 2) Associated with a change in frequency of stool; 3) Associated with a change in form (appearance) of stool

Inclusion criteria:

Patients will be included if they have all the follows at baseline and during the 2-week run-in period:

- 1).Fulfillment of the Rome IV criteria for IBS;
- 2).Age of 18 to 65 years (inclusive);
- 3). IBS Symptom Severity Scale (IBS-SSS) (Appendix. 1) > 75 points (a range of 0-500 points of VAS on five questions);
- 4). Written informed consent.

Exclusion criteria:

Patients will be excluded if they have one or more of follows:

- 1).Pregnancy or breast-feeding;
- 2).Medical history of inflammatory bowel diseases, carbohydrate malabsorption, hormonal disorder, known allergies to food additives, and/or any other serious diseases; 3).Unstable medical conditions;
- 4).Unstable mental condition or with history of mental illness;
- 5).Patients who have received acupuncture treatment in last three months, or took concomitant medication with affect gastrointestinal motility or visceral sensation, such as antidiarrheal agent, antidepressant, narcotic analgesic, and anticholinergic;
- 6). Alcoholism or drug abuse in past 1 year;
- 7). Having needle phobia

Withdraw from the trial

Participants will be allowed or asked to dropout from the trial if they:

- 1)are lost to follow-ups;
- 2)become pregnant;
- 3)develop serious adverse event (SAE)

Participants can withdraw from this clinical trial at any time. The date and reason for withdrawal should be stated. If possible, all subjects withdrawing from the study should continue to be followed up regularly on a measurement schedule with a final assessment. Participants who discontinue early will not be replaced.

Recruitment

We will recruit participants through advertisements on newspapers and TV programs. Screening will be done by researchers. Informed consent will be obtained from eligible patients before randomization.

Intervention

Each patient will be scheduled for a total of 12 treatment sessions, 30 minutes for each session, two times a week over 6-week period. Selection of acupuncture points is based on Traditional Chinese Medicine (TCM) theory [19-21] and evidence-based clinical research [22]. According to the traditional Chinese medicine (TCM) theory, the Spleen transforms the food digested by the Stomach into essences and helps to transport throughout the body, while the Liver ensures the smooth flow of Qi, modifies the activity of internal organs (Zang Fu), and is highly related to emoto-psychological stage. Therefore, most of TCM experts agree the weakness of Spleen and Stomach is the basic pathogenesis of IBS, while the stagnant among Liver and Spleen can also cause a serious of symptom of IBS [23]. Therefore, the principles of treatment of IBS are regulating the Qi movement among Liver and Spleen. Thus, the following acupuncture points are selected for treatment (Table 2).

Acupuncture (AC) group

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at a depth of 10-30 mm obliquely into scalp acupuncture points (Baihui, Toulinqi) or straightly into body acupuncture points (Guanyuan, Zhongwan, Tianshu, Zusanli, Sanyinjiao, Taichong, Zhangmen). Electroacupuncture will be applied to the abdominal points at fast and dispersed waves through electric needle stimulator (ES-160 6-Channel Programmable Electro-acupuncture) for 30 min. The intensity is adjusted to a level at which patients feel comfortable. The alternating stimulation is believed to produce maximal biochemical responses in the brain [24].

Sham-Acupuncture (SAC) group

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulinqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

Table 2 Acupuncture Points

Acupuncture point	Anatomical location	Function according to TCM
Baihui (GV20)	7 cun directly above the midpoint of the posterior hairline	Easing mental stress
Toulinqi (GB15)	Directly above the pupils when the eyes are looking straight ahead, 0.5 cun within the anterior hair line, at the midpoint of the line connecting Shenting (GV24) and Touwei (ST8)	Tranquilizing mind
Guanyuan (CV4)	On the anterior midline, 3 cun below the umbilicus	Regulating qi
Zhongwan (CV12)	On the anterior midline, 4 cun above the umbilicus	Regulating stomach to smooth qi
Tianshu (ST25)	2 cun lateral to the umbilicus	Regulating qi-flow for activating stagnancy
Zusanli (ST36)	3 cun below Dubi (ST35), one finger width lateral to the anterior crest of the tibia	Strengthening spleen and stomach
Sanyinjiao (SP6)	3 cun above the medial malleolus, on the posterior border of the medial aspect of the tibia	Strengthening spleen and stomach
Taichong (LR3)	In the depression distal to the junction of the 1 st and 2 nd metatarsal bones	Calming down the liver and stop pain
Zhangmen (LR13)	On the lower border of the free end of the 11 th rib	Spreading the liver Qi and stop pain

Table 3 Sham acupuncture points

Sham points	location
Sham-Baihui (GV20)	0.5 cun lateral from GV20
Sham-Toulinqi (GB15)	At the midpoint of the line connecting GB15 and ST8 (0.5 cun above the hairline, at the corner of the forehead, 4.5 cun lateral from the midline), 0.5 cun within the anterior hairline
Sham-Guanyuan (CV4)	In the mid-way of CV4 and ST28, 1 cun lateral to the anterior midline, 3 cun below the umbilicus
Sham-Zhongwan (CV12)	In the mid-way of CV12 and ST21, 1 cun lateral to the anterior midline, 4 cun above the umbilicus
Sham-Tianshu (ST25)	In the mid-way of ST25 and SP15 3 cun lateral to the umbilicus
Sham-Zusanli (ST36)	Horizontal to ST36, on the edge of fibula
Sham-Sanyinjiao (SP6)	Horizontal to SP6, 3 cun above the depression between the tip of the medial malleolus and tendo calcaneus (KI3)
Sham-Taichong (LR3)	In the depression distal to the junction of the 3rd and 4th metatarsal bones, between the stomach and gall bladder channel
Sham-Zhangmen (LR13)	In the mid-way of LR13 and ST23 horizontally, 2 cun above the umbilicus, on the outer edge of rectus abdomius

Outcomes

Outcomes included 1) the difference between baseline and 8 weeks,14 weeks after randomization on IBS symptom severity scale (IBS-SSS); 2) the difference between baseline and 8 weeks,14 weeks after randomization on Hamilton Depression Rating Scale (HAMD-17); 3) the difference between baseline and 8 weeks,14 weeks after randomization on Clinical Global Impression-severity (CGI-S) and Self-Rating Depression Scale (SDS); 4). the difference between baseline and 8 weeks,14 weeks after randomization on IBS Quality of Life (IBS-QoL). The specific assessment schedule can refer to Fig.2. Safety profiles will be assessed by determining important adverse events reported on in every treatment and in follow-up interviews.

Assignment and blinding

Simple, complete, non-sequential randomization numbers will be generated by Random Allocation Software (Version 1.0.0), Isfahan, Iran and kept by Principal Investigator (PI). After patient's eligibility is confirmed, patients will be randomized to AC arm or SAC arm for 6 weeks. Only acupuncturists are allowed to know patients' treatment. All other research members will be blind to the assignment. In addition, patients cannot visually detect sham or active acupuncture procedures.

Sample Size Calculation

According to a previous study, placebo is associated with high rates of resolution in a functional bowel disorder. Assuming that a difference of at least 30 % between acupuncture and placebo is needed for a clinically important outcome, 51 patients per treatment group were deemed sufficient to achieve 80 % power in detecting a treatment difference, based on two-sided χ^2 test without continuity correction at a significance level of 0.025 (used to maintain the overall significance level at 5%). Further assuming a 15 % dropout rate, we concluded that we needed to recruit a total of 120 patients (60 per arm) for this trial to ensure statistically significant results. The calculation was performed using StudySize 3.0 software (V. Frolunda, Sweden).

Statistical Analysis

All efficacy and safety analyses will be conducted according to the intention-to-treat (ITT) principle. Missing values will be imputed by the last-observation-carried forward method. The statistical analysis will be performed using the Statistical Packages of Social Sciences (SPSS) for Windows version 25.0. The statistical significance is defined as two-sided P-value of <0.05. Baseline differences between the groups will be assessed with the use of Student's t-test for normally distributed continuous variables and nonparametric Mann-Whitney U test for non-normally distributed. For categorical variables, chi-squared test or Fisher's exact test will be used. Changes in IBS-SSS, HAMD-17, SDS, and IBS-QoL at each evaluation time point from baseline will be analyzed using ANCOVA model, followed by Bonferroni t-test to detect differences between two groups at each time point. Incidence of adverse events will be examined using Chi-square test.

Discussion And Conclusion

The study is a single-blinded, randomized controlled clinical trial to evaluate the efficacy and safety of acupuncture for IBS. In addition to the change of bowel habit, people with IBS are frequently suffered with anxiety and depression or the change of mood further worsens the IBS. Currently, there is not any study on acupuncture in treating IBS digestive-psychological symptoms, therefore, scalp points and abdominal points are included in this clinical trial which would be the first of such research.

If the outcome from this study shows improvement in IBS, we may expect a larger scale of study. Research on integration of non-medication treatments can be developed with the data from this clinical trial such as electro-acupuncture with diet or lifestyle change, or integration of acupuncture and psychological cognitive-behavioral therapy.

The limitation of this study is that the selection of acupuncture points is standardized and utilized for every subject without syndrome differentiation. IBS can be differentiated into 4 subtypes: IBS-C, IBS-D, IBS-M, IBS-U, and each of them can be further sub-divided with Chinese medicine syndrome differentiation such as Spleen dysfunction, Liver depression, Kidney Yang deficiency, Intestinal Heat Dampness. Although dysfunction of the Spleen system is the leading cause of the problem, point selection according to each subtype may optimize the effectiveness of acupuncture. In addition, the environmental factors and dietary factors of the participants exposed to may affect the study result.

In conclusion, this study will provide the basis for the effectiveness and safety of electro-acupuncture on IBS global treatment and would explore the possibility for acupuncture in the integrative treatment of psychological conditions.

Trail Status

A pilot study with sample size of 20 (10 in each arm) has been done to estimate the efficacy of this protocol, to observe the outcomes and any development of adverse events on participants. Another 120 participants will be recruited from March 2021. The study will be completed in February 2022.

Declarations

Supplementary information

Additional files 1: IBS-SSS

Additional files 2: HAMD-17

Additional files 3: CGI-S

Additional files 4: SDS

Additional files 5: IBS-QoL

Additional files 6: Consent form

Acknowledgements

We thank K.Y. and Betty Ho for sponsoring us. We also thank all the participants in this study.

Authors' contributions

LDZ and ZXB designed and supervised the study. LDZ and TFL drafted the manuscript. LDZ, TFL, YZ enrolled the participants and conducted the treatments. LDZ, WY, ZL analyzed the data. All authors read and approved the final manuscript.

Funding

This research was financially supported by the donation from K.Y. and Betty Ho. The sponsor has no role in designing and analyzing the study.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Ethnics approval and consent to participate

This study protocol has been approved by Hong Kong Baptist University Ethics Committee on the Use of Human Subjects for Teaching and Research (approval number: REC/18-19/0227).

Consent is obtained from every participant.

Consent for publication

Written informed consent was obtained from the patient(s) for publication of this manuscript and accompanying images.

Competing interests

The authors declare that they have no competing interests.

Author details

1. Hong Kong Chinese Medicine Clinical Study Centre, Hong Kong Baptist University, Jockey Club School of Chinese Building, 7 Baptist Road, Kowloon Tong, Hong Kong SAR
2. School of Chinese Medicine, Hong Kong Baptist University, Jockey Club School of Chinese Building, 7 Baptist Road, Kowloon Tong, Hong Kong SAR

References

- [1] Drossman DA, Corazziari E, Delvaux M, et al (Ed). *Rome III: The Functional Gastrointestinal Disorders*. McLean, VA: Degnon Associates; 2006.
- [2] Lovell RM, Ford AC. Global prevalence of and risk factors for irritable bowel syndrome: a meta-analysis. *Clinical Gastroenterology and Hepatology*, 2012, 10(7): 712-721. e4.
- [3] Lau EM, Chan FK, Ziea ET, et al. Epidemiology of irritable bowel syndrome in Chinese. *Dig Dis Sci*. 2002; **47**: 2621-4.
- [4] Whitehead WE, Palsson O, Jones KR. Systematic review of the comorbidity of irritable bowel syndrome with other disorders: what are the causes and implications? *Gastroenterology*, 2002, 122:1140–1156.
- [5] American Gastroenterological Association. AGA technical review on irritable bowel syndrome. *Gastroenterology*, 2002, 123:2108–2131.
- [6] Drossman DA, Toner BB, Whitehead WE, et al. Cognitive-behavioral therapy versus education and desipramine versus placebo for moderate to severe functional bowel disorders. *Gastroenterology*, 2003, 125:19–31.

- [7]Jailwala J, Imperiale TF, Kroenke K. Pharmacologic treatment of the irritable bowel syndrome: a systematic review of randomized, controlled trials. *Ann Intern Med.* 2000; 133: 136-47.
- [8] Heading R, Bardhan K, Hollerbach S, et al. Systematic review: the safety and tolerability of pharmacological agents for treatment of irritable bowel syndrome—a European perspective. *Aliment Pharmacol Ther.* 2006; 24(2):207-36.
- [9] Spanier JA, Howden CW, Jones MP. A systematic review of alternative therapies in the irritable bowel syndrome. *Arch Intern Med* 2003; 163: 265-74.
- [10] NIH Consensus Conference. Acupuncture. *JAMA* 1998; 280: 1518-24.
- [11] Kaptchuk TJ. Acupuncture: theory, efficacy, and practice. *Ann.Intern.Med* 2002; 136: 374-83.
- [12]Ouyang H, Chen JDZ, Review article: therapeutic roles of acupuncture in functional gastrointestinal disorders, *Aliment Pharmacol ther*, 2004; 20:831-841.
- [13] Hakahashi T, Acupuncture for functional gastrointestinal disorders, *J Gastroenterol* 2006; 41:408-417.
- [14] Zhang ZJ, Chen HY, Yip KC, et al. The effectiveness and safety of acupuncture therapy in depressive disorders: systematic review and meta-analysis. *J Affect Disord.* 2010; 124:9-21.
- [15] Lembo AJ, Conboy L, Kelley JM, Schnyer RS, McManus CA, Quilty MT, Kerr CE, Drossman D, Jacobson EE, Davis RB. A treatment trial of acupuncture in IBS patients. *Am J Gastroenterol* 2009; 104: 1489-1497.
- [16] MacPherson H, Tilbrook H, Bland JM, Bloor K, Brabyn S, Cox H, Kang'ombe AR, Man MS, Stuardi T, Torgerson D, Watt I, Whorwell P. Acupuncture for irritable bowel syndrome: primary care based pragmatic randomised controlled trial. *BMC Gastroenterol* 2012; 12: 150
- [17] Manheimer E, Wieland LS, Cheng K, Li SM, Shen X, Berman BM, Lao L. Acupuncture for irritable bowel syndrome: systematic review and meta-analysis. *Am J Gastroenterol.* 2012; 107(6):835-47.
- [18] American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition DSM-5™*. American Psychiatric Pub, 2013.
- [19] Drossman D, Chang L, Chey W, Kellow J, Task J, Whitehead W. *Rome IV Functional Gastrointestinal Disorder-Disorder of Gut Brain Interaction (Fourth Edition)*. Rome Foundation. 2016.
- [20] China Academy of Chinese Medical Sciences. *Evidence-based Guidelines of Clinical Practice in Chinese Medicine Internal Medicine*. China Press of Traditional Chinese Medicine. 2011. [Chinese]

- [21] Shen XY, Wang H (Ed). Acupuncture and Moxibustion. People's Medical Publishing House. 2007.
- [22] Schneider A, Enck P, Streitberger K, et al. Acupuncture treatment in irritable bowel syndrome. *Gut*. 2006;55(5):649-54.
- [23] Xiao HT, Zhong L, Tsang SW, Lin ZS, Bian ZX. Traditional Chinese medicine formulas for irritable bowel syndrome: from ancient wisdoms to scientific understandings. *Am J Chin Med*. 2015 ;43(1):1-23.
- [24] Han JS. Acupuncture: neuropeptide release produced by electrical stimulation of different frequencies. *Trends in Neurosciences* 2003;26:17-22.
- [25] Liu Z, Yan S, Wu J, He L, Li N, Dong G, et al. Acupuncture for chronic severe functional constipation: a randomized, controlled trial. *Ann Intern Med*. 2016
- [26] Shin KM, Kim JH, Lee S, Shin MS, Kim TH, Park HJ, et al. Acupuncture for lateral epicondylitis (tennis elbow): study protocol for a randomized, practitioner-assessor blinded, controlled pilot clinical trial. *Trials*. 2013;14(1):174.
- [27] Fleckenstein J, Baeumler PI, Gurschler C, Weissenbacher T, Simang M, Annecke T, et al. Acupuncture for post anaesthetic recovery and postoperative pain: study protocol for a randomised controlled trial. *Trials*. 2014;15(1):292.
- [28] Man S-C, Hung BH, Ng RM, Yu X-C, Cheung H, Fung MP, et al. A pilot controlled trial of a combination of dense cranial electroacupuncture stimulation and body acupuncture for poststroke depression. *BMC complementary and alternative medicine*. 2014; 14(1):255.
- [29] Chao GQ, Zhang S. Effectiveness of acupuncture to treat irritable bowel syndrome: a meta-analysis. *World J Gastroenterol*. 2014;20(7):1871-7.
- [30] Hui Zheng, Ying Li, et al. Electroacupuncture for patients with diarrhea predominant irritable bowel syndrome or functional diarrhea: A randomized controlled trial. *Medicine* 2016; 95:24
- [31] Yao-Tung Lee, Li-Yu Hu, et al. Risk of Psychiatric Disorders following Irritable Bowel Syndrome: A Nationwide Population-Based Cohort Study. *PLoS ONE*. 2015;10(7):e0133283.

Table 1

Table 1 Checklist for items in STRICTA 2010

<u>Item</u>	<u>Detail</u>
1. Acupuncture rationale	1a) Style of acupuncture Manual and electro acupuncture base on traditional Chinese medicine theory
	1b) Reasoning for treatment provided, based on historical context, literature sources, and/or consensus methods, with references where appropriate According to systematic reviews and clinical experiences of our principle investigator and co-investigators.
	1c) Extent to which treatment was varied Standard treatment is used. No variation of treatment among patients.
2. Details of needling	2a) Number of needle insertions per subject per session (mean and range where relevant) 15 needles
	2b) Names (or location if no standard name) of points used (uni/bilateral) Bilateral - Tianshu (ST25), Zusanli(ST-36), Sanyinjiao(SP-6), Toulinqi (GB15), Taichong (LR3), Zhangmen (LR13) Unilateral - Baihui (GV20), Guanyuan (CV4), Zhongwan(CV-12),
	2c) Depth of insertion, based on a specified unit of measurement, or on a particular tissue level 10-30 mm
	2d) Response sought (e.g. <i>de qi</i> or muscle twitch response) De qi
	2e) Needle stimulation (e.g. manual, electrical) Manual and Electrical - dense-disperse waves with 50Hz at 10 volts
	2f) Needle retention time 30 minutes
	2g) Needle type (diameter, length, and manufacturer or material) Disposable stainless steel acupuncture needles (Dong Bang acupuncture needles, 0.25 mm in diameter and 40 mm in length with guide tube, manufactured by Dong Bang Acupuncture Inc Korea)
3. Treatment regimen	3a) Number of treatment sessions 12 sessions
	3b) Frequency and duration of treatment sessions 2/week for 6 consecutive weeks
4. Other components of treatment	4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice) None
	4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients University Clinics; Participants will be informed about acupuncture treatment in the study as follows: "In this study, acu-points for IBS will be used based on related reports and clinical experience of our investigators."
5. Practitioner background	5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience) Hong Kong registered Chinese medicine practitioners having at least 3 years of clinical experience, who have undergone training, are able to provide identical acupuncture treatment in accordance with a pre-defined protocol.
6. Control or comparator interventions	6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice To assess the efficacy and safety of electro-acupuncture compared to sham acupuncture.
	6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.- 1. Style of acupuncture: Sham acupuncture (needling at sham acu-points)

- | |
|--|
| 1. Number of needle insertions per subject per session:
15 needles |
| 1. Depth of insertion:
10-30 mm |
| 1. Needle retention time:
30 minutes |
| 1. Needle type
Same as treatment group |
| 1. Number of treatment sessions:
12 sessions |
| 1. Frequency and duration of treatment sessions:
2/week for 6 consecutive weeks |

Note: This checklist, which should be read in conjunction with the explanations of the STRICTA items, is designed to replace [CONSORT 2010's item 5](#) when reporting an acupuncture trial.

Figures

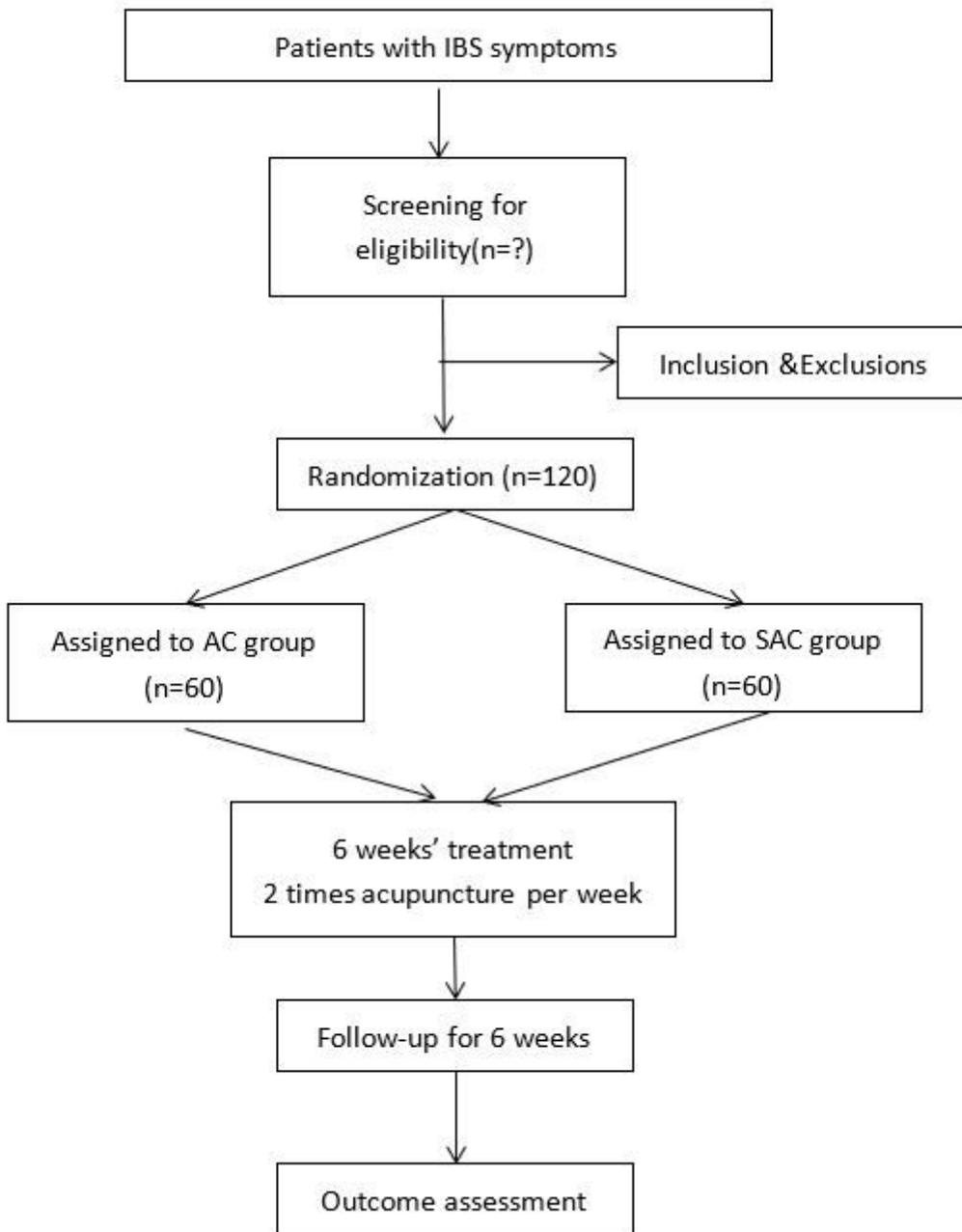


Figure 1

Participants flow chart

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT*	0	2	5	8	14
ENROLMENT:					
Eligibility screen	×				
Informed consent	×				
Allocation		×			
INTERVENTIONS:					
<i>AC arm</i>	×	×	×	×	
<i>SAC arm</i>	×	×	×	×	
ASSESSMENTS:					
<i>HAMD-17</i>		×	×	×	×
<i>SDS</i>		×	×	×	×
<i>IBS-SSS</i>	×	×	×	×	×
<i>IBS-QoL</i>		×	×	×	×

Figure 2

Participant timeline

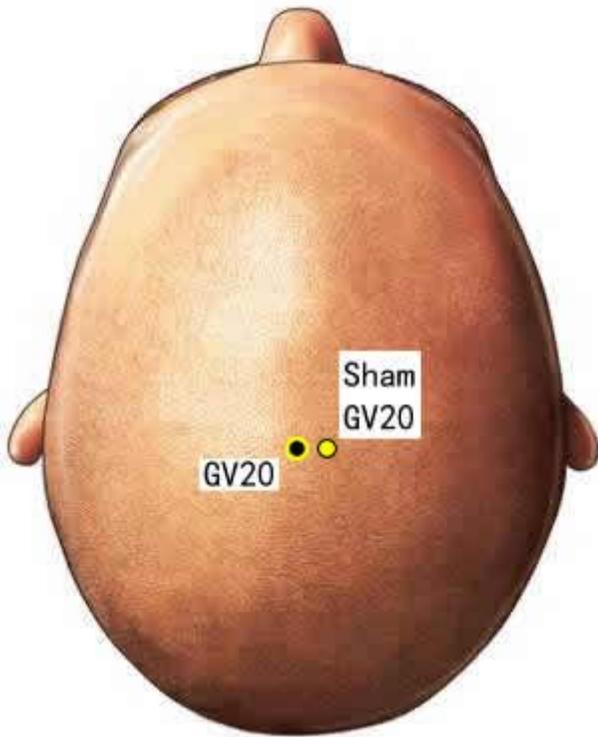


Figure 3

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

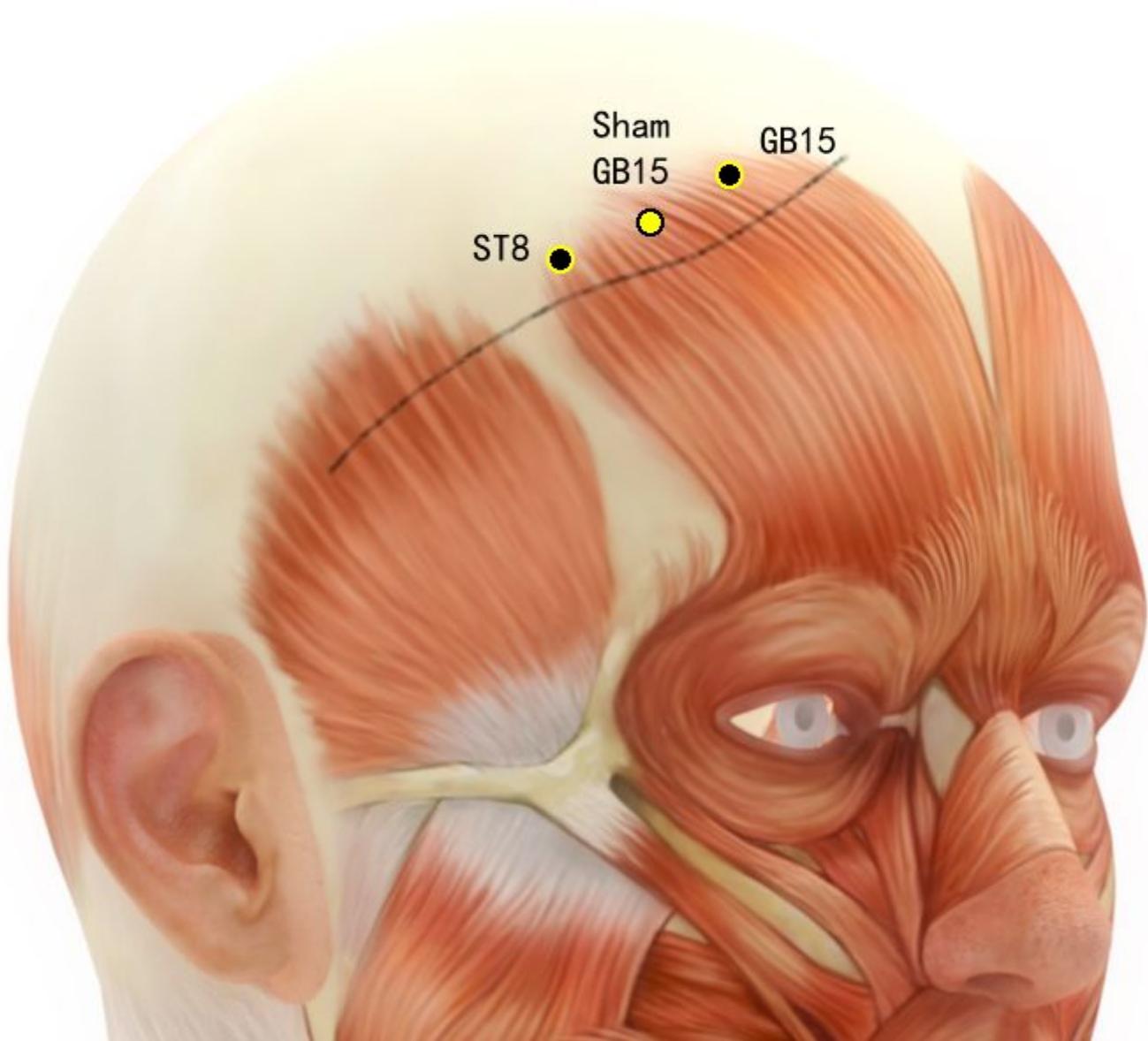


Figure 4

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

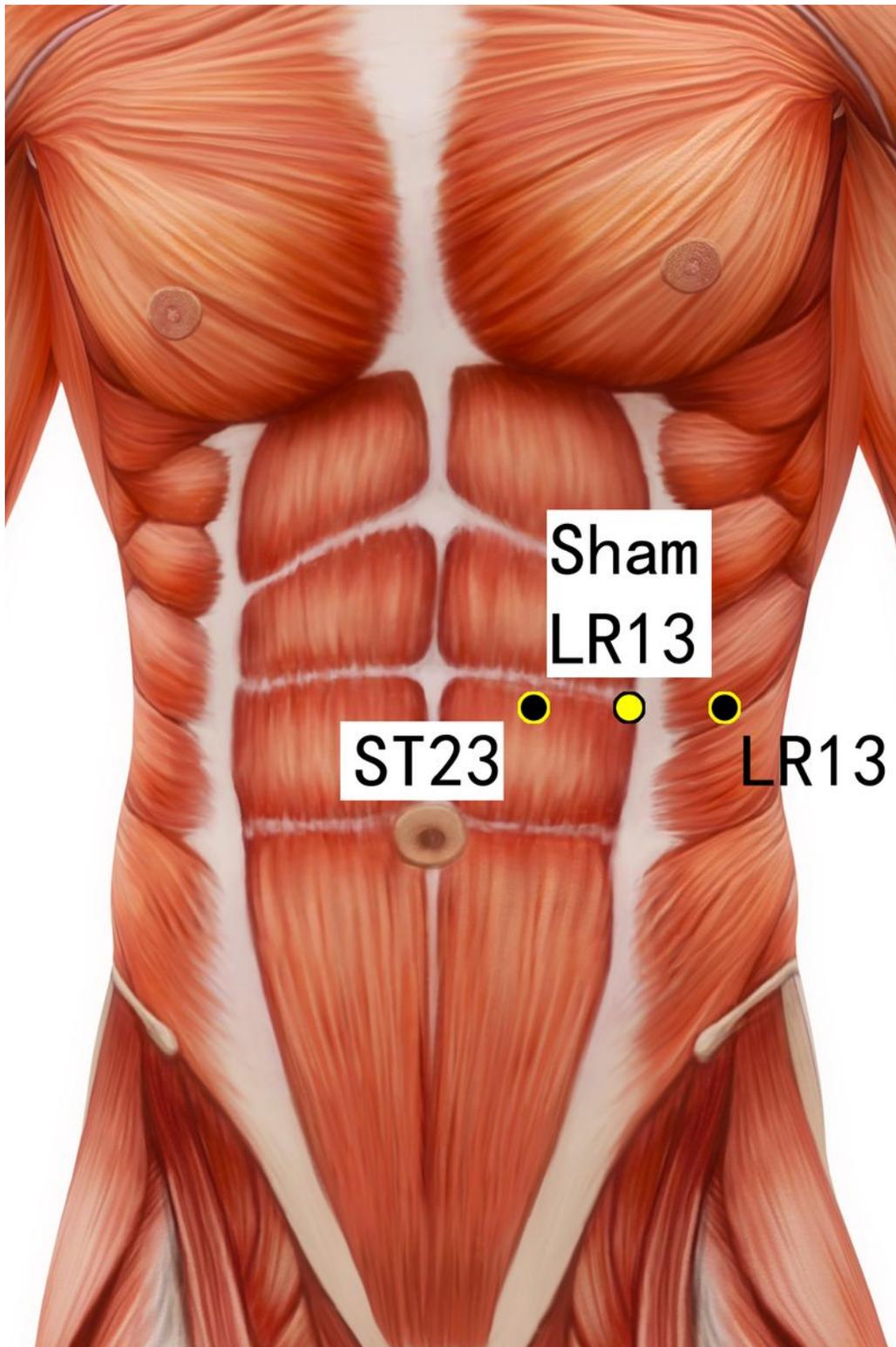


Figure 5

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

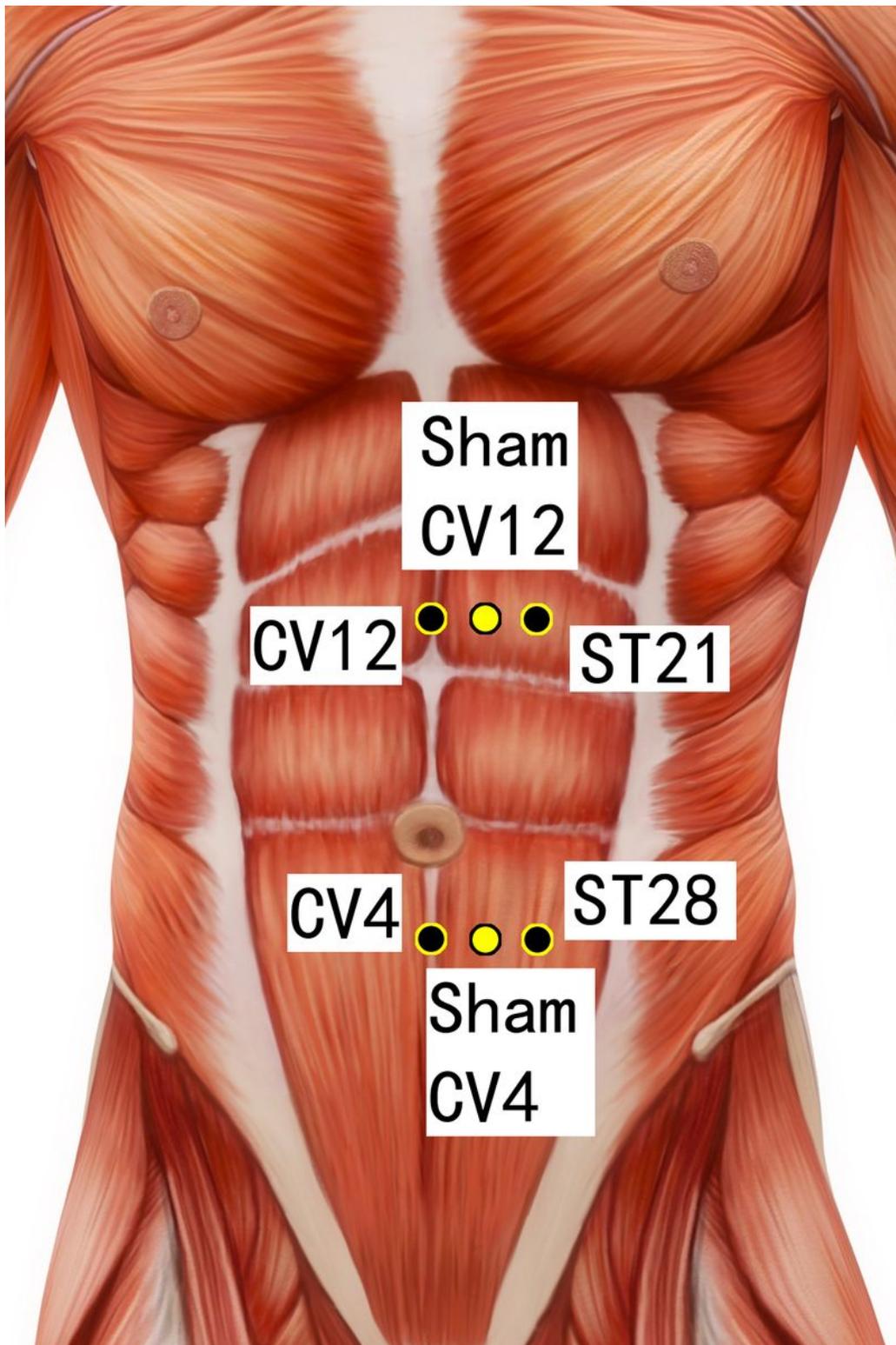


Figure 6

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

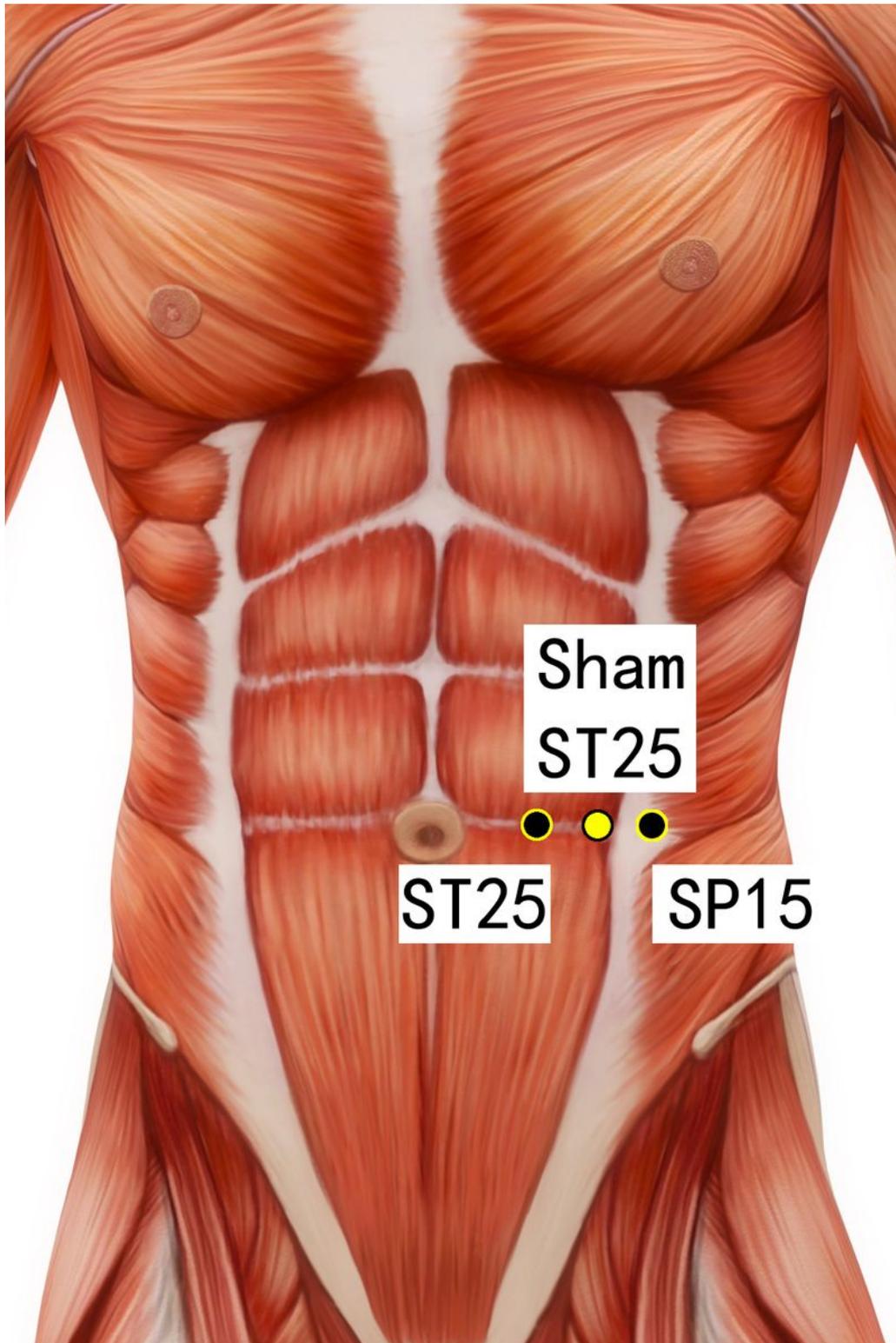


Figure 7

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

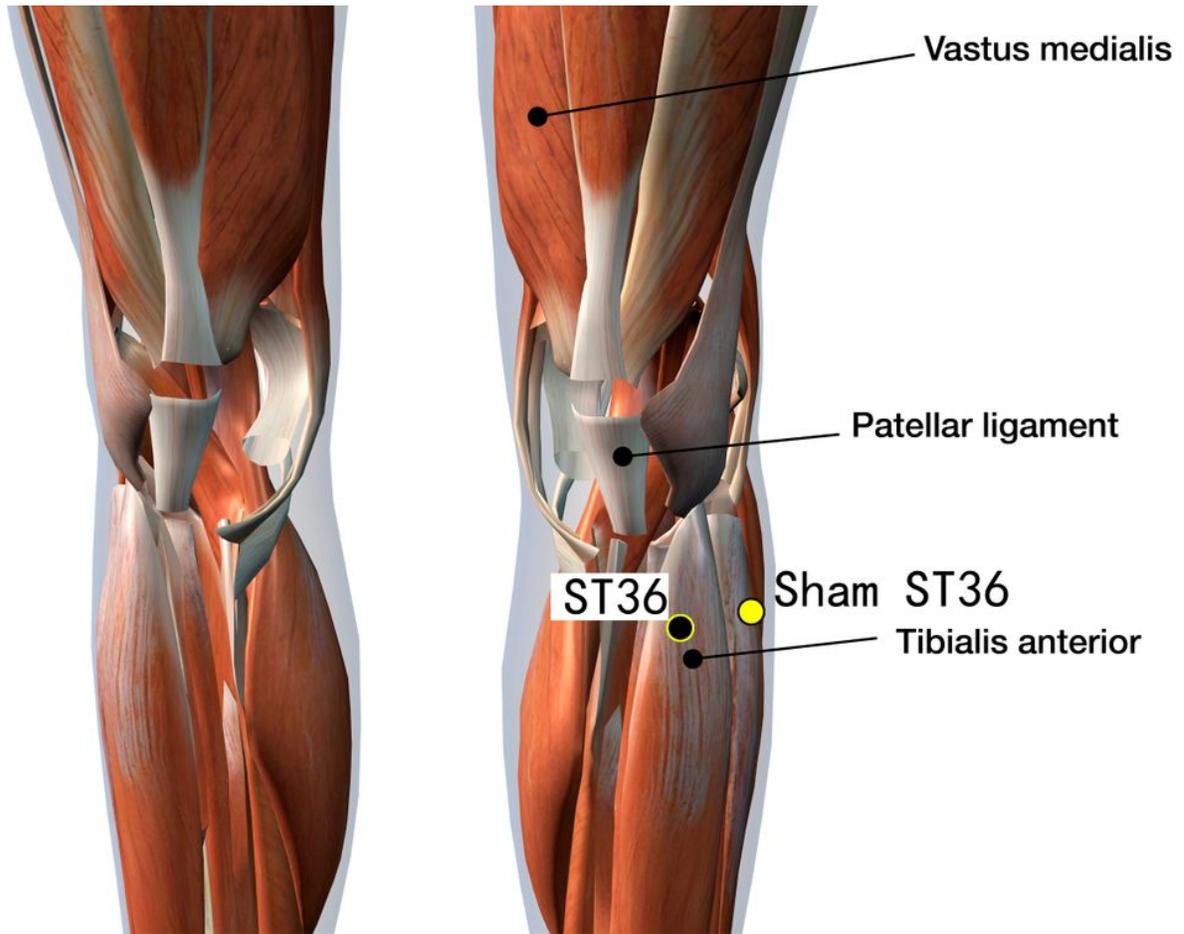


Figure 8

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

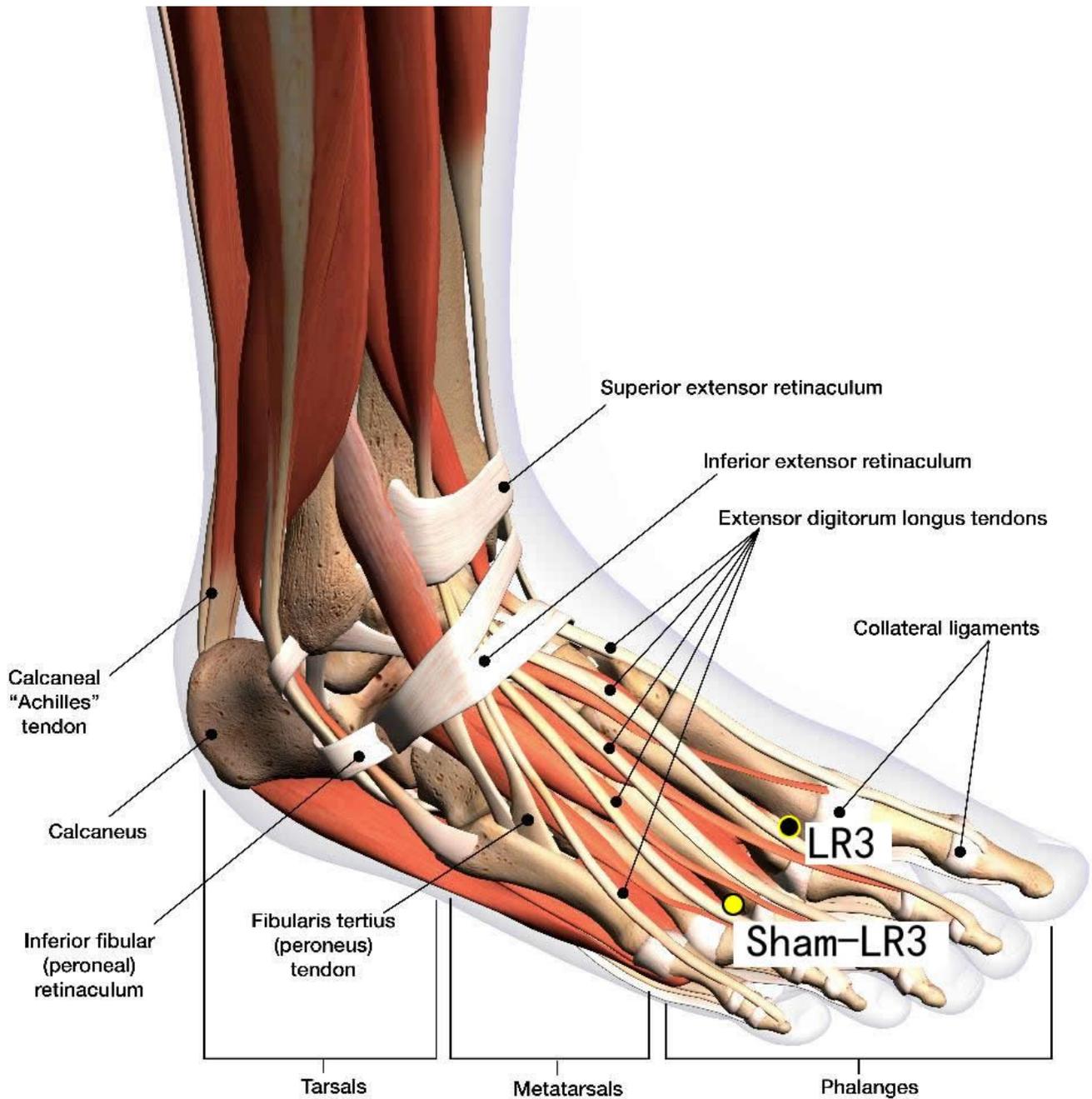


Figure 9

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulinqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

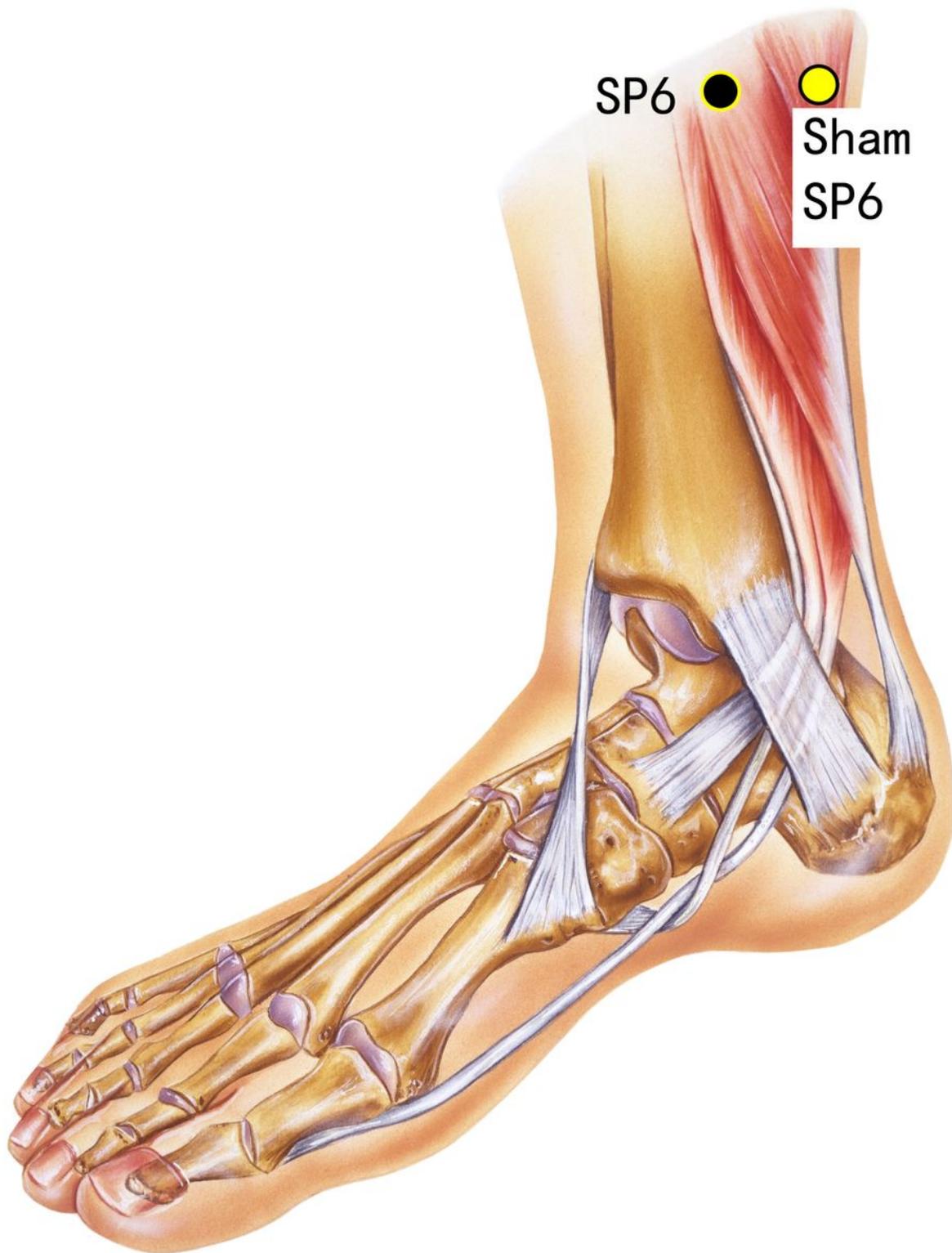


Figure 10

Disposable acupuncture needles (0.30 mm in diameter and 25-40 mm in length) are inserted at the same way as in the acupuncture group but on sham-acupuncture points (Sham-Baihui, Sham-Toulingqi, Sham-Guanyuan, Sham-Zhongwan, Sham-Tianshu, Sham-Zusanli, Sham-Sanyinjiao, Sham-Taichong, Sham-Zhangmen. Table 3, Fig 3-10). The sham points are non-acupuncture points nor located on meridians [25].

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1.docx](#)
- [Additionalfile2.docx](#)
- [Additionalfile3.docx](#)
- [Additionalfile4.docx](#)
- [Additionalfile5.docx](#)
- [Additionalfile6.docx](#)
- [Additionalfile7SPIRITChecklistElectroacupforIBS.doc](#)