

Shu-mu point Catgut embedding therapy for abdominal obesity: study protocol for a randomized controlled trial

Jialei Feng

Yunnan University of Chinese Medicine

Yulan Ren

Chengdu University of Traditional Chinese Medicine

Yuhao Jin

Yunnan university of Chinese medicine

Jiangqiong Meng

Yunnan university of Chinese medicine

Qiming Yang

Kunming Municipal Hospital of Traditional Chinese Medicine

Yuan Zhong

Yunnan university of Chinese medicine

Chonghui Xing

The sport trauma specialist hospital of Yunnan province

Taipin Guo (✉ gtphncs@126.com)

Yunnan University of Traditional Chinese Medicine <https://orcid.org/0000-0002-5298-8132>

Study protocol

Keywords: Acupoint catgut embedding, Abdominal obesity, Randomized controlled trial, Protocol

Posted Date: October 31st, 2019

DOI: <https://doi.org/10.21203/rs.2.12652/v2>

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

[Read Full License](#)

Abstract

Background: Obesity has become a multifactorial epidemic, affecting individuals, families, societies and countries. Abdominal obesity (AO) is the most harmful kind in obesity. Acupoint catgut embedding (ACE), one of the acupuncture therapies, has been widely used in China while its efficacy has not been tested by randomized controlled trial (RCT). The aim of this study is to evaluate the efficacy and safety of ACE for AO. **Methods:** This is a randomized, participant-blind trial. A total of ninety-two patients who met the inclusion criteria for this trial will be enrolled from two independent hospitals and randomly assigned to shu-mu point group and non-acupoint group. Treatment will be conducted once every two weeks, three times for one course. There will be a total of two courses in the whole treatment, and a follow-up will be performed after four weeks of treatment. The primary outcomes are weight and waist circumference (WC). The secondary outcomes are body mass index (BMI), hip circumference (HC), Quality of Life Scale (SF-36), Zung Self-Rating Anxiety Scale (SAS) and Zung Self-Rating Depression Scale (SDS). **Discussion:** This trial will evaluate the effectiveness and safety of ACE for AO, and will also observe the changes in the physical conditions of patients before and after the treatment. This trial will be first good quality clinical evidence of ACE for AO.

Background

Obesity is a chronic metabolic disorder characterized by fat accumulation and abnormal distribution. Researches indicate that obesity, particularly abdominal obesity (AO), can lead to many adverse health conditions, such as diabetes, cancer, cardiovascular and cerebrovascular disease, hypertension, gallstones, hyperlipidemia, mental disorders and even premature death [1-3]. The morbidity of obesity has increased rapidly due to unhealthy diet and lack of exercise. 500 million adults have obesity with a global estimation and 2 of 3 United States adults have overweight or obesity, and 1 of 3 adults has obesity [4]. The prevalence of obesity increased from 17.5% to 19.2% from 2005 to 2013 in ten European countries [5]. In China, the prevalence of AO amongst adults increased from 18.6% to 37.4% between 1993 and 2009 according to China Health and Nutrition Survey (CHNS) [7]. The amount of people struggling with obesity are still increasing globally [6]. Obesity leads to heavy healthcare costs. By 2030, the cost of obesity-related treatment and prevention in the United States is expected to reach to \$48 billion to \$66 billion a year, while in the United Kingdom it will reach to 1 billion to 2 billion pounds a year [8].

The main treatments for obesity include bariatric surgery and non-surgical treatment, such as diet therapy, physical exercise, drug therapy, adjuvant therapy etc. Surgery has a risk of failure [9]. However, there is no strong evidence shows that lifestyle changes in diet and exercise can achieve sustained weight loss, besides diet especially food restriction and high energy excise require self-persistence [10]. As for pharmacotherapy, it is affected by patients' basic diseases and has many contraindications [11]. In addition, some drugs can also cause adverse effects such as headaches, nausea, dizziness, and mental stimulation [4,12]. Therefore, clinicians have begun to use a variety of alternative therapies including acupuncture to treat obesity [13]. Many type of acupuncture method such as acupoint catgut embedding (ACE), manual acupuncture, electroacupuncture, and auricular acupuncture have effects of lowering body

mass index (BMI), reducing waistline, abdominal and hip circumference, as well as improving the quality of life [15-19]. Particularly, ACE is an special acupuncture treatments that could produce 1-2 weeks' continuous stimulation in acupoints by using the absorbable surgical suture to implant into acupoints.

Although ACE is widely used in Chinese TCM hospitals for weight loss institutions of obesity, there is still a lack of high-quality evidence for efficacy of ACE to treat AO according to systematic review [20]. There is an urgent need for a high-quality clinical trial. Thus, we designed this RCT to evaluate the efficacy and safety of ACE in AO.

Methods And Analysis

Study design

This is a randomized, participant-blind trial. Ninety-two participants will be recruited from outpatient at Kunming Municipal Hospital of Traditional Chinese Medicine and The Sports Trauma Specialist Hospital of Yunnan Province between 2018 and 2020. Patients will be randomly assigned equally to the acupoint group and sham group by sealed envelopes with random numbers. The treatment will be conducted once every two weeks, three times for one course. Each patient will have a two treatment courses and one time of follow up after three weeks of the second course. The assessment of outcomes will be performed before treatment at the end of each treatment course and after the follow-up period. The flow chart of this trial is shown in figure 1 and the study period is shown in table 1.

Participants

Inclusion criteria

Participants who meet all the following criteria can be included: (1) aged between 18 and 60 years old with simple obesity and without gender differences; (2) $BMI \geq 28 \text{ kg/m}^2$, male $WC \geq 90 \text{ cm}$, female $WC \geq 85 \text{ cm}$ [22]; (3) agreed to participate in this study and signed written informed consent for this trial and catgut embedding therapy; (4) did not participate in other trials within past 3 months.

Exclusion criteria

Participants will be excluded from one of the following items: (1) $BMI \geq 40 \text{ kg/m}^2$; (2) secondary obesity, such as obesity caused by endocrine disease (Cushing syndrome, thyroid disease, hypothalamic disease, pituitary disease, gonadal disease, etc.) and medication (glucocorticoid or antipsychotics); (3) pregnancy, lactation and childbirth within past 6 months; (4) heart disease, hematopoietic system, liver, kidney and other important organ diseases; hypertension without effectively controlled; (5) patients with severe

mental and neurological diseases who are unable or unwilling to cooperate; (6) allergic to alcohol and animal protein or immune diseases; received other weight loss treatment within past 3 months.

Criteria for elimination

Those who meet the following criteria should be expelled: (1) misdiagnosis and misrepresentation; (2) poor treatment tendency; (3) involved with other treatment after selected; (4) participants' withdrawal before the first test recording.

Randomization

The randomized method uses central randomization and is undertaken by the Center of Clinical Research of Yunnan University of Traditional Chinese Medicine. Random number of allocation sequence will be computer-generated with the SPSS 19.0 software (IBM SPSS Statistics, New York, NY, USA). All eligible patients will be randomly assigned to the shu-mu point embedding group and non-acupoint embedding group in a 1:1 ratio. The random center will report the randomly assigned information of the selected cases to the medical center data administrators via e-mail. Each medical center data administrator collects the e-mail about the random allocation information and checks the information, prints the randomly assigned e-mail, and forwards it to the operator to paste it on the back of the case observation form.

Blinding

Due to the nature of acupuncture, blinding of acupuncturist is impossible. Patients blinding is feasible because of the selected participants has less knowledge of acupoint and they cannot distinguish accurately acupoint and sham point. Outcome assessors, statistical evaluators and outcome interpreters will also be blinded. Concealment will keep until the trial is complete.

Sample size

According to the existing literature [23], the mean BMI of simple obesity is 32.30kg/m^2 , while after 12 weeks and 6 times treatment of acupuncture combined with low energy diet, the mean BMI is 30.98kg/m^2 , and the improvement value was 1.32 kg/m^2 . In the meantime, the improvement value is 1.02 kg/m^2 in control group with the variation from 32.74 kg/m^2 to 31.73 kg/m^2 treated by sham acupuncture combined with low energy diet with, and the deviation value of the two groups is 0.31kg/m^2 . In this project, the expected improvement value of the mean BMI of shu-mu point embedding group after

treatment is 1.14kg/m², and that of non-acupoint embedding group is 0.9kg/m², with the standard deviation of each group of 0.31kg/m². The significant level is $\alpha=0.05$, the power of a test is $1-\beta=0.95$. The sample size is 84 with F test using German G*power software^{3.1.24}. According to 10% drop out, the total sample is 92 cases, and 46 cases will be assigned to each group.

Interventions

Shu-mu point group

The trial will adopt the combination of back-shu and front-mu, and 11 points will be used. They are BL20(Pishu), BL21(Weishu), BL25(Dachangshu), RN12(Zhongwan), ST25(Tianshu), LR13(Zhangmen) on both sides, and Zhongwan on only on side. The location of these points is shown in **Table 2 and Figure 2** Marked as black points.

Non-acupoint group

The study chooses 11 points besides the shu-mu point as non-acupoints, and they are labelled NA1, NA2, NA3, NA6, NA5 on both sides and NA4 on one side. The location of these points is shown in table 3 and figure 2 and they are marked as red points.

Operation instruments

The thread-embedding needle used in this study is 8# disposable needle (Jiangxi glance medical equipment co. Ltd. Production), and the medical protein string is an absorbable collagen line specially made of 2-0, 2cm*20 length (Jiangxi longteng biotechnology co. LTD).

Manipulation

All acupoint embedding manipulations are performed by well-trained doctors. The specific manipulation is as follows: the patient will be placed in an appropriate position, and the acupoint skin will be routinely disinfected. Take a sterile protein string with a length of 1-2cm (the length depends on the location of the acupoint), place it on the front end of the trocar, then connect the needle core, lift the partial skin with the thumb and forefinger of one hand, pierce the needle with the other hand. When the piercing reaches the desired depth, apply appropriate push-and-twist techniques, then the needle core will be pushed out and the needle tube will be removed, and the sterile protein string will be implanted in the subcutaneous tissue or muscle layer of the acupoint. After removing the needle, press the needle hole with a dry cotton ball for

half a minute to prevent bleeding. Meanwhile, check that there is no thread residue exposure, no bleeding, and then paste a bandage to protect the needle hole. It is recommended that patients do not take bath in 24 hours and the embedding place should be kept dry.

Postoperative reaction and treatment of acupoint embedding

Some patients will have some reactions after ACE. Due to the stimulation of injury and catgut, local aseptic inflammation reaction may occur within 1-5 days, such as redness, swelling, fever and pain. A small number of patients will have a relatively serious reaction, the wound will be a small amount of leakage. This is normal and generally does not need to be dealt with. If patients have more exudate and the skin surface is convex, they can squeeze out all the milky white exudate, dry it with 75% alcohol cotton ball and cover with sterile gauze. Postoperative patients may experience local temperature rise for 3-7 days. A few patients may have elevated body temperature, usually around 38°C without local infection. The body temperature will fall back to normal after 2-4 days. All of these are normal postoperative reactions. However, individual patients may have some adverse reactions that need to be addressed accordingly. Some patients may be allergic to catgut. Symptoms including local redness, pruritus, fever, even catgut overflow, fat liquefaction of the wound, etc. They should be given appropriate anti-anaphylactic treatment. Very few people may suffer from nerve damages. Sensory nerve injury can cause skin sensory disturbance in the nerve distribution area, and motor nerve injury will result in paralysis of dominant nerve group. In this case, the catgut should be taken out in time, and patient will have appropriate treatment.

Outcomes

The outcomes will be evaluated before treatment, after each course of treatment and after follow up. At the same time, the treatment times and shedding cases will be recorded to assess patient compliance. The primary outcomes are weight and waist circumference (WC). The secondary outcomes are BMI, hip circumference (HC), Quality of Life Scale (SF-36), Zung Self-Rating Anxiety Scale (SAS) and the Zung Self-Rating Depression Scale (SDS).

Statistical analysis

All data will be analyzed by SPSS 19.0 statistical software (IBM SPSS Statistics, New York, NY, USA). Measurement data will be shown as the means \pm standard deviation ($M \pm SD$). A paired t-test will be used to compare before and after the intervention of catgut embedding. Covariance analysis will be used to compare the data of multiple groups of sample data. The baseline indicators will be used as covariant and the center will be used as a correction factor. Least Significant Difference (LSD) test will be used to a

pairwise comparison between groups, and $p < 0.05$ will be considered the statistically significant difference.

Discussion

Obesity is one of the risk factors for cardiovascular disease, diabetes and cancer and other diseases [25]. In particular, AO increases the incidence of these diseases and increases all-cause mortality to some extent [26].

According to TCM theory, shu-mu point is mainly used to regulate visceral diseases. Fat accumulation in AO is mainly located in the lower back and abdomen, and its position is consistent with the description of the main organs of TCM. Therefore, shu-mu point has a better effect on AO.

Recent subjects have proved that diet pills have a variety of side effects [17]. With the increasing acceptance of TCM, acupuncture as a safe and effective alternative therapy is being accepted by more and more people [27]. As one of the treatments for acupuncture, ACE has been widely used in clinical practice. At the same time, due to its short treatment period, small impact on daily life, low cost, and small side effects, there is growing acceptance of acupuncture. In this trial, we chose a slower absorption catgut to achieve better efficacy through persistent stimulate acupoints, while reducing the impact on participants' daily lives.

Both weight lost and WC reduction are import to AO patient, and we have selected the two as the primary outcomes. Either one of them acquires positive result is deemed to be meaningful, and they do not belong to simultaneously satisfy to be able to infer the conclusion. So it unnecessary to consider the multiple correction test.

There are some limitations of this trials. First, in order to control the research cost, there is no multi-center large sample size observation. Second, the participants are mainly from Yunnan province, so there may have some regional differences. Third, during the experiment, participants are only advised to maintain a normal diet. We do not conduct strict diet and there is no way to quantify it. Finally, participants were not required to do exercise.

Upon completion, in this study, researchers will assess the efficacy and safety of ACE for obesity by observing changes in the patient's physical condition. This trial will be the first good quality clinical evidence of ACE for AO.

Trial Status

The trial is currently recruiting patients.

Abbreviations

AO: Abdominal obesity; TCM: Traditional Chinese medicine; ACE: Acupoint catgut embedding; RCT: Randomized controlled trial; WC: Waist circumference; BMI: Body mass index; HC: Hip circumference; SF-36: Quality of Life Scale; SAS: Zung Self-Rating Anxiety Scale; SDS: Zung Self-Rating Depression Scale; CHNS: China Health and Nutrition Survey; GDP: Gross Domestic Product; NA: Non-acupoint; M ± SD: Means ± standard deviation; LSD: Least Significant Difference

Declarations

Acknowledgements

The authors would like to thank all team members, therapists, assessors, and other participants who participated in the study. The authors also thank all patients, patient advisors and caregivers who participated in the study.

Funding

This paper is funded by Yunnan provincial government program of Yunnan Provincial Science and Technology Department-Applied Basic Research Joint Special Funds of the Yunnan University of Chinese Medicine (NO.: 2017FF117-011), as well as Yunnan education department scientific research fund project (NO.: 2018Y085).

Authors' contributions

FJL and RYL were responsible for the design and drafting of the manuscript. JYH, MJQ, YQM and ZY participated in the implementation of the trial. XCH and GTP provided the funding, ethical approval and total design. All authors contributed to the revision and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Hospital Ethics Committee of The Sports Trauma Specialist Hospital of Yunnan Province (No. 2018CK-001). Written informed consent will be obtained from each participant.

Competing Interests

The authors declare that they have no conflicts of interest.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Author details

¹School of Acupuncture-Moxibustion and Tuina and Rehabilitation, Yunnan University of Chinese Medicine, Kunming 650500, China.

²School of Acupuncture-Moxibustion and Tuina, Chengdu University of Traditional Chinese Medicine, Chengdu 610075, China.

³Kunming Municipal Hospital of Traditional Chinese Medicine, Kunming 650051, China.

⁴The Sports Trauma Specialist Hospital of Yunnan Province, Kunming 650041, China.

References

1. Stein CJ, Golditz GA. The epidemic of obesity. *J Clin Endocrinol Metab.* 2004;89(6):2522-5.
2. Yuan H, Qiang Z, Xiao-lan Z. Association of body mass index and waist circumference with a risk of hypertension and diabetes in Chinese adults. *Med J Chin PLA.* 2017;40(10):803-8.
3. Hypertension group, Chinese Society of Cardiology. The consensus of Chinese expert on obesity-related hypertension. *Chinese Journal of Cardiology.* 2016;44(3):212-9.
4. Garvey WT, Mechanick JI, Brett EM, et al. American Association Of Clinical Endocrinologists And American College Of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care Of Patients With Obesity. *Endocrine Practice.* 2016;22(7): 842-884.
5. Peralta M, Ramos M, Lipert A, Martins J, Marques A. Prevalence and trends of overweight and obesity in older adults from 10 European countries from 2005 to 2013. *Scandinavian journal of public health.* 2018;46(5):522-9.
6. Wang LH, Huang W, Wei Dan, et al. Mechanisms of Acupuncture Therapy for Simple Obesity: An Evidence-Based Review of Clinical and Animal Studies on Simple Obesity. *Evidence-based complementary and alternative medicine.* 2019;2019:1-12.
7. Chen W, Jiang H. Interpretation of the consensus of Chinese experts on nutritional medical treatment for overweight/obesity in 2016. *Chinese Journal of Practical Internal Medicine.* 2017;37(5):430-3.
8. Li Q, Cai L. Study on the Burden of Obesity-related Chronic Diseases and Its Impact on Social Economy. *Journal of Kunming Medical University.* 2016;37(2):1-4.
9. Luca MD, Angrisani L, Himpens J, et al. Indications for Surgery for Obesity and Weight-Related Diseases: Position Statements from the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO). *Obesity Surgery.* 2016;26(8):1659-1696.
10. Mastellos N, Gunn LH, Felix LM, et al. Transtheoretical model stages of change for dietary and physical exercise modification in weight loss management for overweight and obese adults. *Cochrane Database of Systematic Reviews.* 2014;(2):1-87.
11. Garvey WT, Mechanick JI, Brett EM, et al. American Association of clinical endocrinologists and American college of endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocrine Practice.* 2016;22(3):1-203.

12. Zhong LD, Kun W, Lam TF, et al. The combined effects of body acupuncture and auricular acupressure compared to sham acupuncture for body weight control: study protocol for a randomized controlled trial. *Trails*. 2016;17(1):346-52.
13. Steyer TE, Ables A. Complementary and alternative therapies for weight loss. *Primary Care: Clinics in Office Practice*. 2009;36(2):395-406.
14. Peplow PV. Topical Issue: Acu-obesity and Diabetes. *Journal of Acupuncture and Meridian Studies*. 2016;9(3):107-8.
15. Belivani M, Dimitroula C, Katsiki N, et al. Acupuncture in the treatment of obesity: a narrative review of the literature. *Acupuncture in Medicine*. 2013;31(1):88-97.
16. Ren BB, Liu ZC, Xu B. Observation on the efficacy of female obesity complicated with climacteric syndrome treated by acupuncture and moxibustion. *Chinese Acupuncture and Moxibustion*. 2012;31(10):871-6.
17. Sui Y, Zhao HL, Wang VCW, et al. A systematic review of the use of Chinese medicine and acupuncture for treatment of obesity. *Obesity Reviews*. 2012;13(15):409-30.
18. Tong J, Chen JX, Zhang ZQ, et al. Clinical observation of simple obesity treated by acupuncture. *Chinese Acupuncture and Moxibustion*. 2011;31(8):697-701.
19. Zheng YH, Wang XH, Lai MH, et al. The effectiveness of abdominal acupuncture for patients with obesity-type polycystic ovary syndrome: a randomized controlled trial. *The Journal of Alternative and Complementary Medicine*. 2013;19(9):740-5.
20. Guo TP, Ren YL, Kou J, et al. Acupoint Catgut Embedding for Obesity: Systematic Review and Meta-Analysis. *Evidence Based Complementary and Alternative Medicine*. 2015;2015(401914):1-20.
21. Zhu B, Guo TP. Superiority of acupoint catgut embedding therapy for obesity. *Negative*. 2018;9(3):42-4.
22. The obesity group of Chinese Society of Endocrinology. The Expert Consensus on the Prevention and Control of Adult Obesity in China. *Chinese Journal of Endocrinology and Metabolism*. 2011;27(9):711-7.
23. Abdi H, Zhao B, Darbandi M, et al. The effects of body acupuncture on obesity: anthropometric parameters, lipid profile, and inflammatory and immunologic markers. *The Scientific World Journal*. 2012;(603539):11.
24. Faul F, Erdfelder E, Buchner A, et al. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behaviour Research Methods*. 2009;41(4):1149-1160.
25. Wlodarczyk M, Nowicka G. Obesity, DNA Damage, and Development of Obesity-Related Diseases. *International Journal of Molecular Sciences*. 2019;20(5): E1146.
26. Hu LH, Huang X, You CJ, et al. Prevalence of overweight, obesity, abdominal obesity and obesity-related risk factors in southern China. *PLoS ONE*. 2017;12(9): e0183934.
27. Zhang RQ, Tan J, Li FY, et al. Acupuncture for the treatment of obesity in adults: a systematic review and meta-analysis. *Postgraduate medical journal*. 2017;93(1106):743-51.

Non-acupoint	Location
NA1	The sitting position of the patient, alignment with Pishu, and the midpoint of the first and second lateral line of the bladder channel.
NA2	The sitting position of the patient, alignment with Weishu, and the midpoint of the first and second lateral line of the bladder channel.
NA3	The sitting position of the patient, alignment with Dachangshu, and the midpoint of the first and second lateral line of the bladder channel.
NA4	The supine position of the patient, alignment with Zhongwan, and the midpoint of the left kidney and stomach channel.
NA5	The supine position of the patient, alignment with Tianshu, and the midpoint of the stomach and spleen channel.
NA6	The sitting position of the patient, alignment with Zhangmen, a vertical line is made from Zhangmen to the spleen channel and the midpoint of the vertical line.

Figures

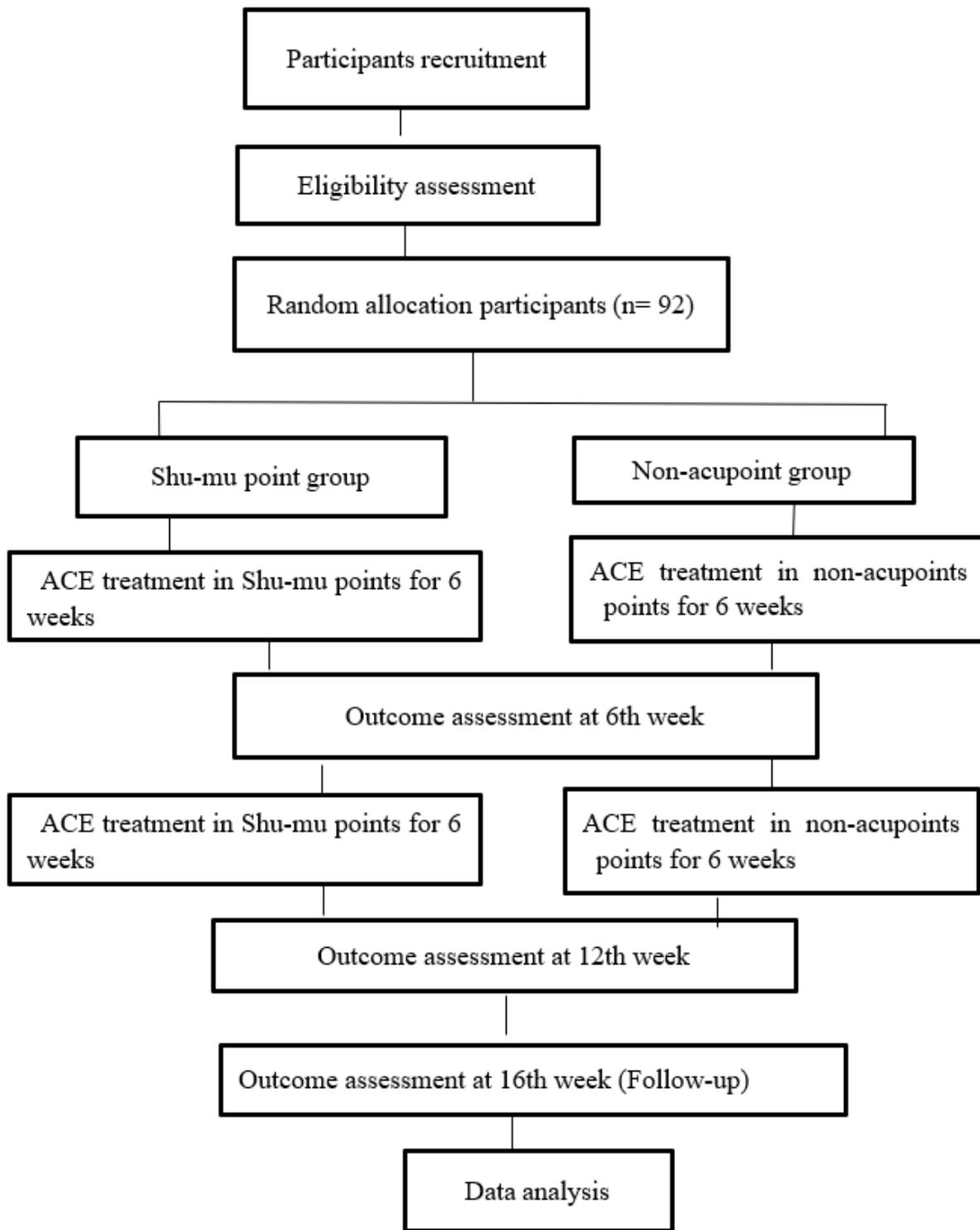


Figure 1

The flow chart of the trial

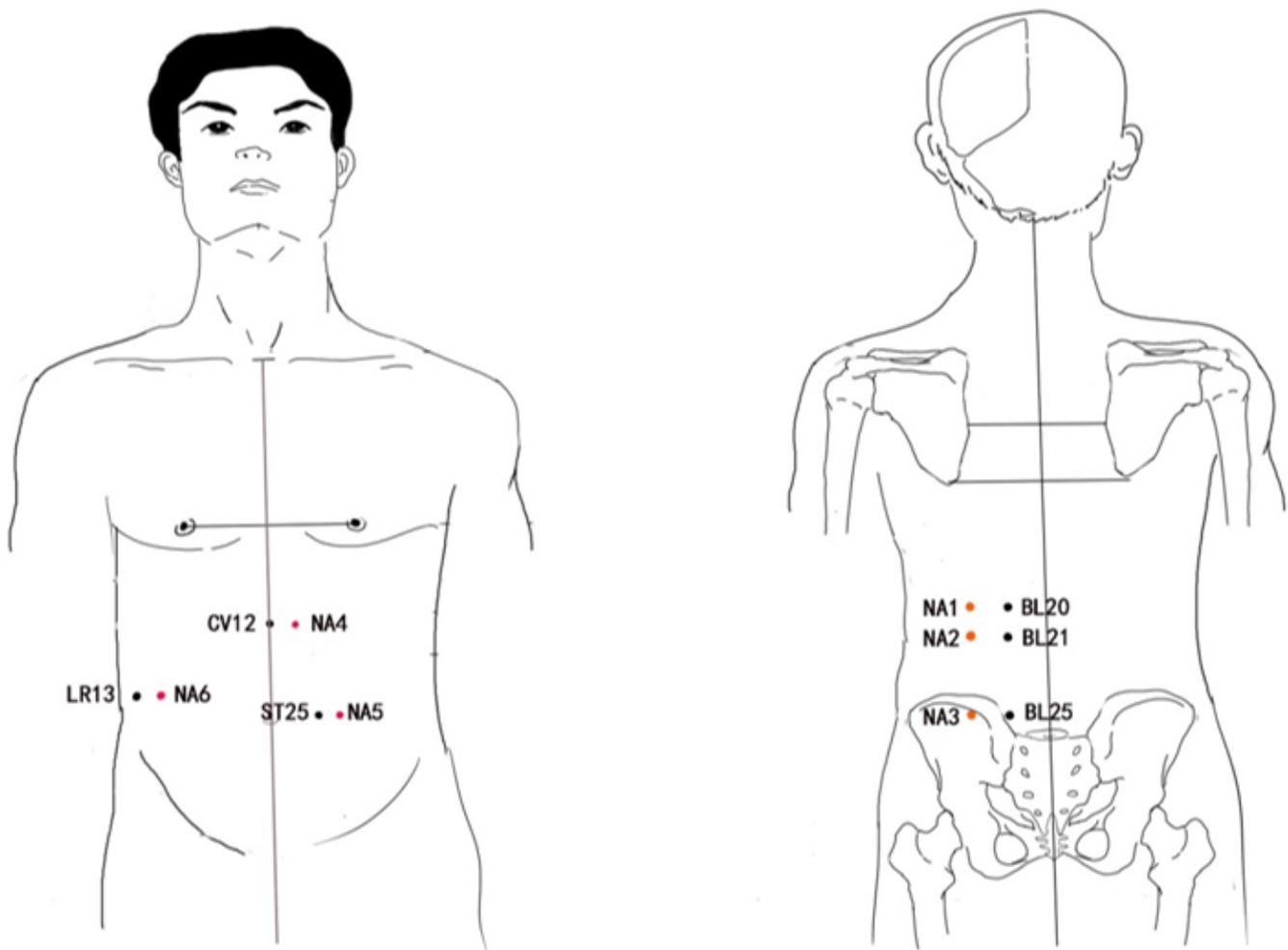


Figure 2

Location of the non-acupoint group and shu-mu point group

Supplementary Files

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

- [SPIRITChecklistdownload8Jan13.doc](#)