

# Efficacy of verum and sham acupoint catgut embedding for treatment of obesity: Study protocol for a randomized controlled trial

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## Study protocol

**Keywords:** Acupoint catgut embedding, Obesity, Randomized controlled trial, Visceral fat area

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# Abstract

**Abstract Background:** Obesity has become a major public health hazard with epidemic proportions, influencing adults, adolescents and children of both genders. Previous studies suggested that acupoint catgut embedding (ACE) might be a potential therapeutic approach for obesity. The purpose of this study is to conduct a rigorous and normative trial to determine the efficacy of ACE for obesity. **Methods**—A total of 99 eligible patients who diagnosed with obesity will be recruited in this study. They will be randomly allocated to either the verum ACE group, sham ACE group, or waiting-list (WL) group with 33 patients for each group. Each patient in the two ACE-based groups will receive 8 sessions of treatment, lasting over 8 weeks. The primary outcomes will be the reduction of body mass index (BMI) after treatment. Secondary outcomes will include waist circumference (WC), hip circumference (HC), waist-hip ratio, body fat percentage, blood lipid level, subcutaneous fat area, visceral fat area, and the World Health Organization Quality of Life (WHOQOL). All the outcomes will be evaluated at baseline, ended at 8 weeks of treatments, and 3 months of follow-up. The evaluators and data analyzers will be blinded to group allocation. **Discussion:** The findings of this randomized, sham- and waiting-list-controlled trial will help to investigate the influence of ACE on clinical variables as well as visceral fat area of obesity, which will provide high-quality evidence on the efficacy of ACE for obesity. **Trial registration:** Chinese Clinical Trial Registry, ID: ChiCTR1800020248. Registered on November 21, 2018. **Keywords:** Acupoint catgut embedding, Obesity, Randomized controlled trial, Visceral fat area

## Background

Obesity is an increasingly and globally public health issue, which is characterized by the rise of body fat tissues. Genetic, dietary, lifestyle, and environment factors all could induce obesity. The prevalence of obesity has doubled over the past 10 years [1]. In 2015, in the United States, more than 20% of populations were identified to be overweight or obese, in which this phenomenon is very common in adults [2]. According to the Global Health Observatory (GHO) data released in 2016, 39% of adults suffered from overweight or obesity. To date, the prevalence of obesity has been raised in both developed and developing countries. Obesity is associated with increased risk for developing a range of comorbid conditions, such as type 2 diabetes (T2D) [3], cardiovascular disease (CVD) [4], fatty liver disease, and gastrointestinal and psychological disorders [5]. For instance, a number of scholars reported that obese adults showed a 50% increased risk of developing T2D compared with normal-weight adults [6], and were twice as likely to be hypertension and CVD as the normal ones [7]. Nowadays, obesity and its complications impose a heavy burden on socio-economic development; besides, the World Health Organization (WHO) has taken obesity as one of the most serious public health problems into consideration worldwide [8, 9].

Anti-obesity methods, e.g. lifestyle modification specifically implementation of dietary modification and regular exercise, surgery, drug, and complication therapy, are all referred by the guidelines released by the National Heart, Lung and Blood Institute (NHLBI) of National Institutes of Health (NIH), American College of Cardiology (ACC), etc. [10]. The primary and the most valid recommendations for anti-obesity are to

restrict the intake of high calorie diet and perform more physical activities. However, these two methods often associate with some challenges for patients to be adopted for long-time due to lifestyle and economic issues [11]. Additionally, according to Cochrane Database of Systematic Reviews released in 2014, there are no sufficient evidences to identify the short-term adjustment of food consumption and physical activities to attain long-term weight loss [12-13]. On the other hand, anti-obesity drugs seem to be suspicious in terms of its efficacy and safety, as the adverse events (AEs) of those drugs often pose a number of negative consequences, such as headache, dizziness, nausea and vomiting, insomnia, etc. According to a report published by the United States Food and Drug Administration (FDA) in 2010 [14-15], the consumption of anti-obesity drugs, was warned and prohibited because of their serious liver damage and high risk of CVD, respectively. Additionally, rimonabant was found to induce anxiety, depression, and other mental disorders [16]. Consequently, identification of effective and low-risk interventions is highly essential for obese individuals.

Acupoint catgut embedding (ACE), as one of complementary and alternative therapies, has been used for several decades to treat a variety of disorders, such as perimenopausal syndrome, chronic urticaria, depressive disorder, refractory insomnia, obesity, sciatica, etc. [17]. ACE involves weekly infixing surgical chromic catgut sutures into the subcutaneous tissue of the extremities and abdomen with a specialized needle under aseptic precautions. Owing to the continuous acupoint stimulation with implanting sutures, ACE was considered to be more effective than ordinary acupuncture or electroacupuncture for patients with obesity [18]. In a previous research, it was revealed that the body weight and body mass index (BMI) of obesity could be remarkably decreased after ACE therapy [19]. Moreover, ACE could adjust the imbalance of obesity-related hormones, e.g. leptin, ghrelin, and adiponectin, to reduce the body weight [19, 20]. In addition, visceral fat accumulation is often accompanied with obesity, which has been recently reported to play a vital role in the development of metabolic syndrome, a cluster of diabetes, dyslipidemia, and hypertension [21]. A randomized controlled trial (RCT) conducted by Lei et al. [22] revealed that electroacupuncture treatment could reduce BMI and waist circumference (WC), as well as visceral fat area (VFA) to assess obesity. However, whether the ACE can improve the VFA of obesity and what is the relationship between VFA and ordinarily obesity-related indices have still remained elusive. However, a limited number of RCTs have investigated the VFA changes in the study of ACE for obesity.

Hence, this study is designed as a RCT to assess the effectiveness and safety of ACE for treatment of obesity.

## **Materials And Methods**

### **Study design**

This single-center, randomized, sham-controlled will be conducted at Shenzhen Traditional Chinese Medicine Hospital (Shenzhen, China). The study protocol was approved by the Ethics Committee on Shenzhen Traditional Chinese Medicine Hospital, and conducted in accordance with the 1975 Declaration of Helsinki. The flowchart of the research procedure is shown in Fig. 1.

## **Patients' recruitment procedure**

Patients who meet the inclusion criteria will be mainly recruited through outpatient clinics, online or offline advertisements (e.g., newspaper, poster, websites), or WeChat public account of Shenzhen Traditional Chinese Medicine Hospital. If a patient is interested in joining the study, he/she can contact and consult with one of the authors. Those patients who meet the inclusion criteria will be involved in the study. All the participants will sign the written informed consent form prior to start of the study. The schedule of patients' enrolment, intervention, and assessments is illustrated in Fig. 2.

## **Inclusion criteria**

Inclusion criteria are as follows:

- (1) Diagnosed with obesity referred to Asian adult BMI criteria defined and proposed by the WHO Western Pacific region obesity working group in 2000;
- (2) WC of male  $\geq$  90 cm, or WC of female  $\geq$  80 cm;
- (3) Aged 18 to 65 years old;
- (4) Without the taboo of catgut embedding therapy;
- (5) Written informed consent.

## **Exclusion criteria**

Patients with any one of the following criteria are excluded from this trial:

- (1) With endocrine diseases (thyroid disease, pituitary disease, and diabetes mellitus) and autoimmune disease (systemic lupus erythematosus, Sjogren's syndrome, and rheumatoid arthritis);
- (2) With metabolic diseases such as hypertension and dyslipidemia;
- (3) Other methods are being used to control body mass and abdominal circumference, such as surgery, drugs, etc;
- (4) Women in pregnancy, nursing, perimenopause
- (5) With some severe diseases of the heart, liver, kidney, or tumor;;
- (6) Diagnosed with a psychiatric disorder;
- (7) Participated in other studies within 3 months.

## **Dropout criteria**

- (1) Patients who do not meet the inclusion criteria, while are mistakenly enrolled;
- (2) Occurrence of severe AEs or complications, which are resulted in stopping the trial.

### **Sample size**

The sample size is calculated on the basis of results of a previous clinical trial [19]. The primary effective parameter in the present study is BMI from baseline to the treatment after 2 months. According to a previous study [19], in the ACE group, the BMI decreased 1.65 and the standard deviation (SD) was 1.24; besides, in sham ACE group, the BMI reduced 0.38 and the SD was 1.51. Considering a two-sided significant level of 0.05 and a power of 0.90, 26 participants in each group are required which is calculated by t test in G\*Power software (Version 3, Institute for Experimental Psychology, Heinrich-Heine-University, Germany). A dropout rate of 15% was taken into account, and a total of 99 participants are recruited in this trial (n = 33 participants per each group).

### **Randomization and allocation concealment**

If the participants meet all the inclusion criteria and sign the written informed consent form, they ask to accept the principle of random allocation. Hence, 99 eligible participants will be randomly assigned to verum ACE group, sham ACE group, and waiting-list (WL) group at a ratio of 1:1:1. A random allocation sequence number will be generated with the Statistical Analysis System software (SAS, version 9.1.3, SAS Institute Inc., Cary, NC, USA) by an independent statistician, who will be not involved in the treatment or data collection. The sequential numbers are written on cards and sealed in an opaque envelope by an independent research assistant. After a participant randomly selects an opaque envelope and obtains an allocation sequence number, a research assistant assigns identification codes to participants and records them in the case report forms (CRFs). Then, the result of patients' allocation process will be informed to the acupuncturists.

### **Blinding**

The acupuncturists are not blinded for the entire process. For eliminating potential bias, outcomes' assessors and statisticians are blinded to group assignment. Patients' allocation will be only revealed under some special conditions, such as severe allergy, serious infection, uncontrolled pain, etc.

### **Interventions**

The ACE intervention is in agreement with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines. Patients in verum ACE group, sham ACE group, and WL group will receive real ACE therapy, sham ACE therapy, and delayed active ACE therapy 20 weeks later, respectively. The course of two ACE groups will contain 8 sessions, lasting over 8 weeks (one session per two weeks).

### **Verum ACE group**

#### ***Acupoints:***

ACE treatment is a semi-standard method in this study. According to the clinical practice, literature and the basic theory of traditional Chinese medicine, the prescription of ACE includes 6 obligatory acupoints and 2 groups of adjunct points.

The obligatory acupoints will include RN 12 (Zhongwan), ST 25 (Tianshu), SP 15 (Daheng), RN 06 (Qihai), RN 04 (Guanyuan), and GB 26 (Daimai). Adjunct acupoints will consist of 2 groups: acupoints of group 1 involving ST 36 (Zusanli), SP 09 (Yinlingquan), and ST 40 (Fenglong); acupoints of group 2 including BL13 (Feishu), BL20 (Pishu), and BL23 (Shenshu). The obligatory acupoints will be chosen in each session, and the adjunct points will be selected every other session. All acupoints will be localized according to the names and locations of acupoints drafted in 2006 by the National Standard of the People's Republic of China (GB/T 12346-2006). Locations of acupunctures are presented in Table 1 and Fig. 3.

**Table 1** Locations of acupoints in two ACE groups.

Acupoints	Locations
RN 12 (Zhongwan)	On the anterior median line, 4 cun above the umbilicus.
ST 25 (Tianshu)	Level with the umbilicus, and 2 cun lateral to the anterior median line.
SP 15 (Daheng)	Level with the umbilicus, and 4 cun lateral to the anterior median line.
RN 06 (Qihai)	On the anterior median line, 1.5 cun below the umbilicus.
RN 04 (Guanyuan)	On the anterior median line, 3 cun below the umbilicus.
GB 26 (Daimai)	On the lateral abdomen, at the intersection of the vertical line of the free end of the 11th rib and the horizontal line on the same level of umbilicus, or 1.8 inches below LR 13 (Zhangmen) at the liver meridian.
ST 36 (Zusanli)	3 cun directly below ST 35 (Dubi), and 1 digit lateral to the anterior margin of the tibia
SP 09 (Yinlingquan)	On the medial side of the calf, in the sunk spot between the medial lower margin of the tibia and the medial margin of the tibia.
ST 40 (Fenglong)	8 cun directly below ST 35 (Dubi), and 2 digit lateral to the anterior margin of the tibia
BL13 (Feishu)	On the back, on the same level of the 3 <sup>rd</sup> subspinous of thoracic spine, and 1.5 cun lateral to the posterior midline.
BL20 (Pishu)	On the back, on the same level of the 11 <sup>rd</sup> subspinous of thoracic spine, and 1.5 cun lateral to the posterior midline.
BL23 (Shenshu)	On the back, on the same level of the 2 <sup>rd</sup> subspinous of lumbar vertebra, and 1.5 cun lateral to the posterior midline.

### ***Preparation of ACE:***

The catgut (Suzhou medical Co., Ltd., Jiangsu, China) with the length of 1.5 cm will be placed in front of an embedded needle (Zhengjianggaoguan medicine Co., Ltd., Shenzhen, China) for doing the operation. The preparation procedures of ACE will be performed under sterile conditions.

### ***Operation Procedures of ACE:***

Firstly, the acupuncturists should disinfect their hands with 75% alcohol and dress medical gloves, medical mask, and medical hat. Simultaneously, patients will lie on the bed, supine or prone position on the basis of location of acupoints, and will fully expose the skin of the acupoint area. Secondly, the acupoints' regions will be sterilized with iodophor and alcohol twice by the acupuncturists. Simultaneously, an assistant will place the catgut in front of an embedded needle. Thirdly, the acupuncturists will locate the acupoint, and then, the needle will be embedded into the skin at the acupoints' regions; consequently, the catgut will be embedded into the acupoints with the depth of about 1.5, 1 or 1 cm at the abdomen, lower limbs and back, respectively. The embedded needle will be withdrawn once the patient will have a feeling of sourness; meanwhile, catgut will leave under the tissue. Following this, sterile cotton balls will be pressed on the acupoints for hemostasis, and then, band-aids will be pasted on the acupoints to prevent wound infection. Eventually, the patients will be warned to avoid touching water on embedded acupoints for 24 h.

The frequency of the ACE treatment will be one per week, totally lasting for 8 weeks.

### **Sham ACE group**

Patients in the sham ACE group will undergo similar procedures as the verum ACE group except that nothing will be put into the catgut embedding needles before operation, thus, no catgut will leave under the patients' acupoint tissue after needle extraction. The prescription of acupuncture will also be as same as that in the verum ACE group.

In the current study, all the patients will be treated separately to avoid influencing each other. Both groups will be treated under the same conditions by acupuncturists, who will receive special training before participation in the study. In the whole ACE operation process, the acupuncturists and assistant will not talk about details.

### **WL group**

The WLC group will not have any intervention. The patients will be asked to receive delayed ACE therapy for free after a waiting period of 20 weeks.

### **Magnetic resonance imaging (MRI) data acquisition**

In this study, the MRI images of subcutaneous adipose tissue and visceral adipose tissue will be acquired by a MRI scanner (MAGNETOM; Siemens, Munich, Germany) with a matrix body coil of 18 channels at

the MRI Center of Shenzhen Traditional Chinese Medicine Hospital. Before scanning, the participants will be trained for deep-breathing exercise. During scanning process, they will be asked to hold their breath for about 15 s. The sequence parameters are as follows: flip angle, 65°; repetition time (TR)/echo time (TE), 195/3.69 ms; the number of excitation (NEX), 1; matrix, 256×131; slice thickness, 7 mm; and echo train length, 4. In order to guarantee the passage of image plane through the center of the vertebral disc between L4 and L5, the MRI data will be acquired from a sagittal scout. Qualitative image analysis will be performed by two independent reviewers as well.

## **Outcome measurement**

The clinical outcomes will be used to assess patients' obesity levels and their quality of life. All measurements will be undertaken at baseline (after 8 weeks of treatments, and at 12 weeks of follow-up).

The primary outcome is the change of BMI from baseline. The BMI is calculated as follows:  $BMI = \text{mass (kg)} / (\text{height(m)})^2$ . According to the BMI-based criteria presented by the WHO and Asia-Pacific classifications in 2000, BMI scores are ranked as "23.0 - 24.9 (pre-obesity)", "25 - 29.9 (level I of obesity)", and "more than 30 (level II of obesity)".

The secondary outcomes will include WC, hip circumference (HC), waist-hip ratio (WHR), body fat percentage (BFP), and the WHO Quality of Life (WHOQOL). WC will be measured by a stretch-resistant tape at the midpoint between the top of the iliac crest and the lower margin of the least palpable rib. In addition, HC will be measured around the widest portion of the buttocks using a tape parallel to the floor [23]. Besides, BFP will be measured with bioelectrical impedance.

WHOQOL is a widely used questionnaire for measuring the physical and mental health status. WHOQOL scale includes 26-item, involving four domains of patient's quality of life: physical, psychological, social, and environmental [24, 25]. The total score ranges from 0 to 100. The lower the score, the poorer the patient's quality of life.

Here, other outcome parameters, including basal metabolic rate, blood pressure (BP), heart rate (HR), total cholesterol (TC), triglyceride (TG), and high-density lipoprotein (HDL) levels will be tested at each time-point.

## **Statistical analysis**

The statistical analysis will be conducted by independent statisticians who will be blinded to group allocation and intervention methods. Before data analysis, the research group will draw up a statistical plan, including the required data and method of data processing.

Data will be analyzed by using SPSS 22.0 software (IBM, Armonk, NY, USA). For MRI data, the images will be analyzed on a workstation (Syngo Multimodality Workplace) for the quantification of VAT and SAT.

Demographic information and levels of measured variables are analyzed by descriptive statistics. Categorical data are described as percentage (n%) or analyzed using the Chi-square ( $\chi^2$ ) test. Additionally, for continuous variables, if data are normally distributed, one-way analysis of variance (ANOVA) is used to detect differences among the 3 groups. Otherwise, the Kruskal–Wallis (K-W) test can be considered. The longitudinal and repeated measured data are analyzed by the repeated measure analysis.

In this study, SFA is quantified as an area between outline of abdominal skin and the outer abdominal muscle, while VFA is defined as enterocoelia and retroperitoneal region between the inside edge of abdominal muscles and the spinal front. Detailed methods have been described previously [26-28]. The correlation coefficients between two reviewers who analyzed the same image for SFA and VFA (n=30) were  $r=0.99$ ,  $P<0.001$  and  $r=0.98$ ,  $P<0.001$ , respectively.

Eventually, the Pearson's correlation between the changes of SFA and VFA and improvement of clinical variables will be calculated in each group.

For the above-mentioned statistical analyses, a P-value < 0.05 is considered statistically significant.

## **Safety**

To guarantee that the ACE operation is standard and safe, the acupuncturists in this study should pay attention to those announcements as follows: (1) perform aseptic operation strictly to prevent infection; (2) catgut should not be embedded in adipose tissue that could prevent fat liquefaction; (3) catgut should not be exposed to body surface to prevent infection; (4) master the angle and depth of the embedding in order to avoid injury to the internal organs, great vessels, nerve, etc.; (5) acupoints can't touch water for 24 h after embedding; (6) informing patients' acupoints embedded catgut may keep sensation of soreness, distension and numbness for one or two days, and even more than three to five days.

## **Management of adverse events**

ACE therapy may lead to different AEs, such as fainting during operation, subcutaneous hematoma, allergy, infection, severe pain, etc. Any experienced AEs by participants should be reported to the researchers. After confirming the validity of the AEs by an evaluator, the acupuncturists will immediately stop the treatment procedure and deal with the AEs. All the AEs, as well as managing the AEs, will be carefully recorded during treatment and follow-up phases.

## **Quality control**

Acupuncturists, assistants, data collectors, and statisticians who participated in the study should abide the rules and regulations. Before the study, each researcher took a basic study training to understand design, purpose, and basic information of this research. The acupuncturists should be at least 3 years of practical acupuncture experience, and they also should be familiar with the operation process and be able to cope with any possible AEs. Data collectors are responsible for saving and managing various data, and strictly proofread data. Patients' withdrawal and AEs during the study will be recorded in detail.

Statisticians will be fully responsible for data management and statistical analysis. Regular team meetings will be held and fully documented.

### **Ethical approval**

This study was approved by the Chinese Clinical Trial Registry. The registration number of this trial is ChiCTR1800020248. In addition, the study protocol was approved by the Ethics Committee on Shenzhen Traditional Chinese Medicine Hospital. Prior to start of the study, patients will be informed about the potential risks of the study. Patients voluntarily participated in the study with informed consent. If the protocol requires to be amended, all the materials on trial will be reported to the Ethics Committee, and the amended protocol can be only implemented after consent acquirement.

### **Data management and monitoring**

The research associates will record the information on the CRFs, and verify that the data will be fully, swiftly, and accurately collected. The private information and medical records of patients, including their name, phone number, and ID number, will be anonymous to ensure confidentiality. All the research documents will be kept in specialized cabinets and preserved for at least 5 years after publication.

In addition, the data monitoring committee is established consisting of experienced experts in Good Clinical Practice Department of the Shenzhen Traditional Chinese Medicine Hospital, to periodically review the progress of the trial, and monitor collection of the data, allocation concealment, etc. The modification or termination of the trial can be performed by the committee. The data monitoring committee is independent from the sponsor and has no conflict of interest.

## **Discussion**

It is noteworthy that ACE is extensively applied for weight loss. Although previous studies have shown that ACE might be effective in improving the overweight, high-quality trials with rigorous design are still urgently required to assess the effects of ACE on obesity [29]. The results of the present study may contribute to a better understanding that ACE can exert its potential therapeutic effects on obesity.

Recently, an increasing attention has been paid to visceral fat of obesity, which is related to energy storage, and is considered as an endocrine and paracrine organ, influencing a number of metabolic processes by releasing the cytokines and bioactive mediators [30-33]. The body weight can be adjusted by cytokines and mediators. Thus, VFA is a significant indicator to estimate the metabolic risk in obese populations [34, 35]. However, in previous studies, the influences of ACE on obesity were mainly assessed by BMI or WC, and a limited number of studies have assessed those influences by VFA. Hence, this study is evaluated by both ordinarily obesity-related indices (BMI, WC, etc.) and VFA, in order to clearly illuminate the effects of ACE on obesity.

The purpose of this study is to compare the changes of measurements after 2 months of treatment with three different intervention methods: verum ACE, sham ACE, and no intervention (WLC group). Several

studies [36, 37] have indicated that a sham-controlled design could separate the specific and non-specific effects, which may play a pivotal role on evaluating the effectiveness of treatment. Thus, the ACE and sham ACE treatments are both applied to investigate the anti-obesity effects in this study. The sham ACE is only operated with needling pierced into the acupoints, while catgut isn't fixed, and other operations are all the same as those in the ACE group. Thus, it can successfully blind the patients and estimators; as a result, it can minimize the placebo effect. In addition, as far as non-specific effects (sham ACE versus no intervention) and bias caused by psychological influences, the third group without any intervention is considered to avoid the placebo effects of group allocation or the patients' beliefs on weight loss. A possible limitation of this trial is that the follow-up might be difficult to completely comply with participants due to a long interval science at the end of 2 months of treatment. A number of proper actions, such as phone interview, should be taken to improve compliance.

The design and methodological rigor of this trial may hopefully provide consolidated evidence regarding the efficacy and safety of ACE for treating obesity, through collecting valuable and high-quality data, and also contribute to the future research in ACE therapy.

## **Trial Status**

This trial is currently recruiting patients. The trial began recruitment on January 1, 2019 and anticipated to be completed on December 31, 2021. The version number and date of the protocol are v1.0, and October 25, 2018, respectively.

## **Abbreviations**

ACE: acupoint catgut embedding; GHO: Global Health Observatory; T2D: type 2 diabetes; CVD: cardiovascular disease; WHO: World Health Organization; NHLBI: National Heart, Lung and Blood Institute; NIH: National Institutes of Health; ACC: American College of Cardiology; AEs: adverse events; FDA: Food and Drug Administration; BMI: body mass index; RCT: randomized controlled trial; WC: waist circumference; VFA: visceral fat area; SFA: subcutaneous fat area; SD: standard deviation; WT: waiting-list; STRICTA: Standards for Reporting Interventions in Clinical Trials of Acupuncture; MRI: magnetic resonance imaging; WHR: waist-hip ratio; BFP: body fat percentage; HC: hip circumference; WHOQOL: World Health Organization Quality of Life; BP: blood pressure; HR: heart rate; TC: total cholesterol; TG: triglyceride; HDL: high-density lipoprotein.

## **Declarations**

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## Availability of data and materials

The full data of the study will be published in papers in a peer-reviewed academic journal. The data of the will be available upon reasonable request after completion of the study.

## Authors' contributions

YM Z, B Y, and WQ Y contributed equally to this paper. ZX Y is the corresponding author. YM Z participated in the conception and design of the trial. YM Z and WQ Y drafted the manuscript. HB Y is in charge of the recruitment and treatment of patients. B Y participated in data collection. WQ Y analyzed the data. ZX Y proofread the final manuscript. All the authors approved the submitted version of the manuscript.

## Conflict of interest

All the authors declare that they have no conflict of interest.

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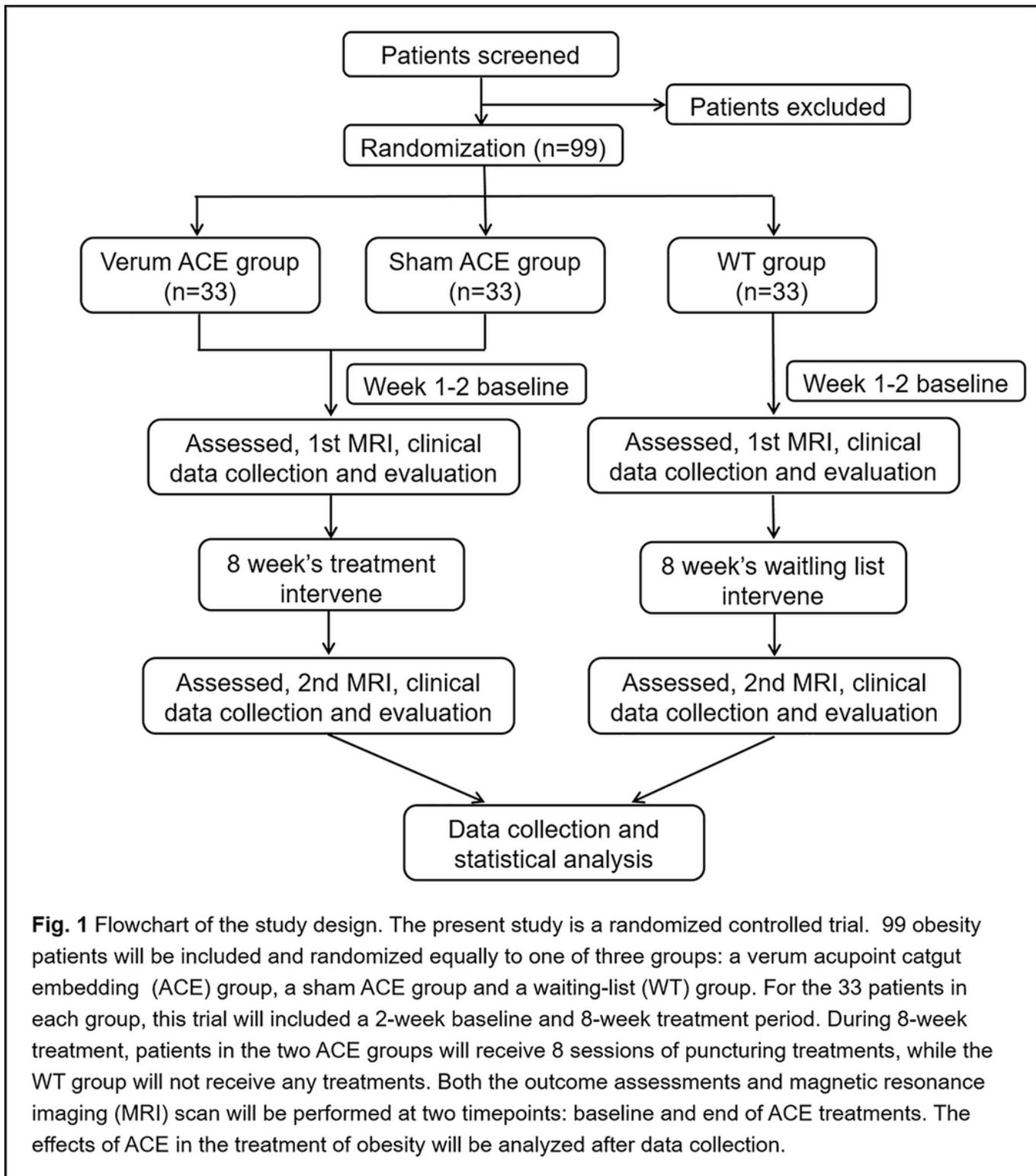
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## Additional File

Additional file 1: SPIRIT 2013 Checklist (DOCX 130 kb)

## Figures



**Figure 1**

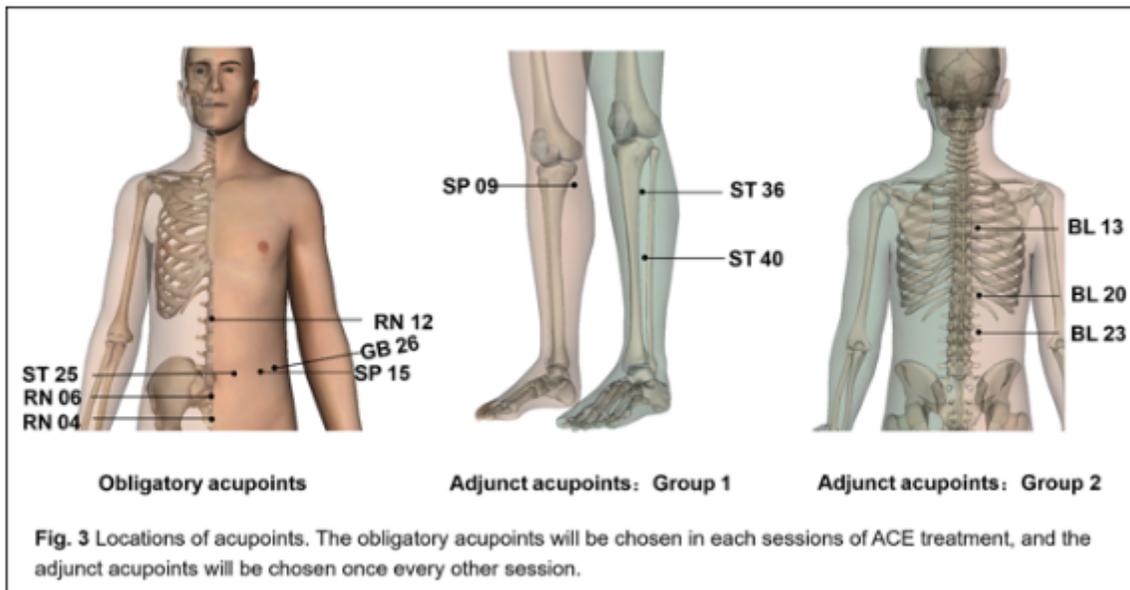
Flow Chart of the study design

TIMEPOINT	STUDY PERIOD				
	Baseline		Treatment phase		Follow-up
	0 week	1-2th week	2-10th week of treatment	Post of treatment (10th week)	Follow-up (22th week)
<b>ENROLMENT:</b>					
Eligibility screen	×				
Informed consent	×				
Randomization		×			
<b>INTERVENTIONS:</b>					
Verum ACE group (n=33)			×	×	×
Sham ACE group (n=33)			×	×	×
Waiting-list (n=33)			●—————●		×
<b>MRI SCAN:</b>					
Verum ACE group (n=33)		×		×	×
Sham ACE group (n=33)		×		×	×
Waiting-list (n=33)		×		×	×
<b>ASSESSMENTS:</b>					
BMI		×		×	×
WC, HC, WHR, BFP		×		×	×
basal metabolic rate, BP, HR		×		×	×
TC, TG, HDL		×		×	×
WHOQOL		×		×	×
<b>PARTICIPANTS SAFETY:</b>					
Adverse events			×	×	×

**Fig. 2** Study schedule for data collection. The informed consent will be conducted after recruitment. Then, matched obesity patients will be randomized into three groups, only two ACE groups will receive treatment. Both clinical outcomes and magnetic resonance imaging (MRI) scans will be performed at two time points including: the baseline and the end of ACE treatments. Adverse events will be recorded in the case report form at any time during the study. ACE: acupoint catgut embedding; BMI: Body Mass Index; WC: waist circumference; HC: hip circumference; WHR: waist hip rate; BFP: body fat percentage; WHOQOL: World Health Organization Quality of Life; BP: blood pressure; HR: heart rate; TC: blood total cholesterol; TG: triglyceride; HDL: high density lipoprotein.

**Figure 2**

Study schedule for data collection



**Figure 3**

Locations of acupoints

## Supplementary Files

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- [supplement1.pdf](#)