

Efficacy of verum and sham acupoint catgut embedding in treatment of simple adult obesity: study protocol for a randomized, placebo-controlled trial

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Study protocol

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Abstract

Background Obesity has become a global health issue. The previous studies suggested that acupuncture catgut embedding (ACE) might be a potential treatment option for obesity. In this study, we will conduct a rigorous and normative trial to determine the efficacy of ACE for obesity. Methods/design A total of 99 eligible patients diagnosed with obesity will be recruited. They will be randomly allocated to either the verum ACE group, sham ACE group or waiting-list group with 33 patients in each group. Each patient in two ACE groups will receive 8 sessions of treatment over 8 weeks. The primary outcomes will be the reduction of body mass index after treatments. Secondary outcomes will include waist circumference, hip circumference, waist hip ratio, body fat percentage, blood lipid level, as well as the subcutaneous fat area, visceral fat area and the scale assessments of World Health Organization Quality of Life. All outcomes will be evaluated at baseline, end of 8 weeks treatments and 3-month follow up. The evaluators and data analysts will be blinded to group allocation. Discussion The finding 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, which will provide high-quality evidence on the efficacy of ACE for treatment of obesity.

Background

Obesity is an increasingly and globally public health issue, which is characterized by the rise of body fat stores. Genetic, dietary, lifestyle, and environment factors all could induce obesity. The prevalence of obesity has doubled over the past 10 years [1]. In the United States in 2015, more than 20% populations were identified to be overweight or obesity, from which, the adults were more common [2]. According to the Global Healthy Observatory (GHO) data in 2016, 39% of adults suffered from overweight or obesity. Yet, the prevalence of obesity has been still rising both in developed and developing countries. Obesity is related to increased risk for developing a range of comorbid conditions, such as type 2 diabetes (T2D) [3], cardiovascular disease (CVD) [4], fatty liver disease, gastrointestinal disorders, and psychological issues [5]. For instance, researches discovered 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, furtherly, the World Health Organization (WHO) has regarded obesity as one of the most serious public health problems of the 21st century [8, 9].

Antiobesity methods, such as lifestyle modification of diet and exercise, surgery, drug, and complication therapy, are all referred by various guidelines released by National Heart, Lung and Blood Institute (NHLBI) of National Institutes of Health (NIH), American College of Cardiology (ACC) and so on [10]. The primary and most valid types recommended for antiobesity are to restrict the intake of high calorie diet and get more physical activities. However, these two methods are often difficult for patients to comply with for long time owing to lifestyle and economic issues [11]. Additionally, according to cochrane system review in 2014, there are no sufficient evidences to identify the short-term adjustment of food consumption and physical activities to reach long-standing weight decrease [12], which cause the failure of weight loss and weight regain [13]. On the other hand, antiobesity drugs are considered to be suspicious

for its efficacy and safety, the adverse events (AEs) induced by which often bother obese people, such as headache, dizziness, nausea and vomiting, insomnia and so on. According to the report by the U. S. Food and Drug Administration (FDA) in 2010, the antiobesity drugs, orlistat [14] and sibutramine [15], were warned and prohibited to use because of its serious liver damage and high risk of CVD, respectively. Additionally, rimonabant [16] was found to induce anxiety, depression and other mental disorders. Consequently, identification of effective and low-risk interventions is urgently needed for obesity.

Acupoint catgut embedding (ACE) method, as one of complementary and alternative therapies, has been used for several decades for the treatment of many conditions, such as perimenopausal syndrome, chronic urticaria, depressive disorder, refractory insomnia, obesity, sciatica, etc. [17]. It is a method involving infix self-absorptivly surgical chromic catgut sutures into the the subcutaneous tissue at the region of acupoints with a specialised needle under aseptic precautions. Owing to the continuous acupoint stimulation with implanted sutures, ACE was considered to be more effective than ordinary acupuncture or electroacupuncture for obesity [18]. In past researches, scholars have found that the body weight and body mass index (BMI) of obesity could obviously decrease after ACE therapy [19]. Moreover, ACE could adjust the unbalance of obesity-related hormones, including leptin, ghrelin and adiponectin, to reduce the body weight[19, 20]. In addition, visceral fat accumulation are often considered to be accompanied with obesity, which has been recently found to play a vital role in the development of metabolic syndrome, a cluster of diabetes, dyslipidemia, and hypertension [21]. A randomized controlled study (RCT) conducted by Lei H [22] found that electroacupuncture treatment could reduce BMI and waist circumference (WC) as well as visceral fat area (VFA) of obesity. However, whether the ACE can improve the VFA of obesity and what the relationship between VFA and ordinarily obesity-related indices are still unknown, as well as there have been little RCT directly to investigate the VFA changes in the researches of ACE for obesity.

Hence, this study is designed as a RCT trial to investigate the effectiveness of ACE on obesity, and the safety of ACE will be also examined.

Methods

Study design

This single-center, randomized, sham-controlled trial will be conducted at Shenzhen Traditional Chinese Medicine Hospital. The study protocol has been approved by the ethics committee on Shenzhen Traditional Chinese Medicine Hospital. The protocol follows the Declaration of Helsinki and will be reported based on SPIRIT guidelines (Additional file 1). The flow diagram of the trial has been shown in the Fig. 1.

Population and recruitment

Patients meeting the inclusion criteria of obesity will be recruited mainly through outpatient clinics, advertisements, online or offline (such as newspaper, poster, websites), Wechat public account of Shenzhen Traditional Chinese Medicine Hospital. Informed consent will be required to write before randomisation for all patients. The schedule of enrolment, intervention and assessments is shown in Fig. 2.

Inclusion criteria

The participants in this study have to:

- (1) be diagnosed with obesity referred to Asian adult BMI criteria defined and proposed by the WHO Western Pacific region obesity working group in 2000;
- (2) be WC of male ≥ 90 cm, or WC of female ≥ 80 cm;
- (3) be aged 18 to 65 years old;
- (4) be without the taboo of catgut embedding therapy;
- (5) be written informed consent.

Exclusion criteria

Patients with any one of the following conditions will be excluded from this trial:

- (1) obesity caused by certain endocrine, genetic and neurological diseases or drug-induced;
- (2) merge other metabolic diseases such as diabetes, hypertension, dyslipidemia and so on;
- (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) severe audio-visual handicap;

(7) diagnosed with a psychiatric disorder.

(8) participated in other tests within 3 months;

Dropout criteria

Patients meeting any of the following criteria will be dropout:

(1) do not meet the inclusion criteria but mistakenly enrolled;

(2) patients with poor compliance, withdrawal during the course of treatment, or receive others treatment;

(3) severe adverse events or complications occur, which is not appropriate to continue treatment and have to discontinue the trial.

Sample size calculation

The sample size was confirmed on a basis of the results of a previous clinical trial [19]. The primary efficacy parameter in the present study is also BMI from baseline to the treatment after 2 month. According to previous study [19], in the ACE group, the BMI decreased 1.65 and the standard deviation (SD) was 1.24, additionally, in sham ACE group, the BMI decreased 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 considered, a total of 99 participants will be recruited in this trial and 33 participants per group.

Randomization and allocation concealment

A total of 99 eligible participants will be randomly assigned to verum ACE group, sham ACE group and waiting-list (WT) group at a ration of 1:1:1. The random allocation sequence number will be generated with the Strategic Applications Software (SAS, version 9.1.3, SAS Institute Inc, Cary, NC, USA) by an independent statistician, who is not involved in the treatment or data collection. The randomization allocation numbers will be sequential, and written on cards and sealed in an opaque envelope by an independent assistant. The three groups will be concealed from the researchers until completion of the statistical analysis.

Blinding

The acupuncturists could not be blinded for the entire process. For eliminating potential bias, outcome assessors and statisticians will be blinded to group assignment. Patients' allocation is only revealed under some special cases, such as severe allergy, serious infection, uncontrolled pain and so on.

Interventions

The ACE intervention conforms with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines. Patients in verum ACE group, sham ACE group and WT 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 over 8 weeks (one session per two weeks).

Verum ACE group

Acupoints:

ACE treatment is semi-standardised in this study. According to the clinical practice, literature and the basic theory of traditional Chinese medicine, the ACE prescription includes 6 obligatory acupoints and two group adjunct points.

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

Catgut embedding preparation:

The catgut (Suzhou medical Co., Ltd., Jiangsu, China) size 3-0 with the length of 1.5 cm will be placed in front of an embedding needle (Zhengjianggaoguan medicine Co., Ltd., Shenzhen, China) for the operation of each acupoint. All the catgut embedding preparation processes were performed under sterile conditions.

Operation Procedures of ACE:

Firstly, the acupuncturists have to disinfect hands with 75% alcohol and dress medical gloves, medical mask and medical hat. Simultaneously, let patients lie on the bed, supine or prone position depended on the location of acupoints, and fully expose the skin of the acupoint area. Secondly, the acupoints regions will be sterilized with iodophor and alcohol twice by the acupuncturists. Thirdly, the acupuncturists will locate the acupoint, then, stab the embedding needle into the skin at the acupoint regions, in result, the catgut will be embedded into the acupoints with the depth of about 1.5 cm, 1cm or 1cm at the abdomen, both feet or back, respectively. The embedding needle will be withdrawn until the patient has a feeling of sourness, meanwhile catgut will be left 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. Finally, warn the patients don't touch water on embedded acupoints within 24 hours.

The frequency of the catgut embedding treatment is once per week for a duration of 8 weeks.

Sham ACE group

Patients in the sham ACE group will undergo similar procedures as the verum ACE group except that nothing is put into the catgut embedding needles before operation, so no catgut leave under the acupoints tissue of patients after needle extraction. The acupuncture prescriptions are also as same as that in the verum ACE group.

Waiting-list control group

The WT group will donnot have any intervention. The patients will be required to receive delayed ACE therapy for free after a waiting period of 20 weeks.

MRI data acquisition

In this study, the MRI images of subcutaneous adipose tissue and visceral adipose tissue will be acquired by MRI scanner (MAGNETOM, SIEMENS) with a matrix body coil 18 channel at the MRI Center at Shenzhen Traditional Chinese Medicine Hospital of China. Before scanning, the participants will be trained for deep-breathing exercise. Through the duration of the scan, they need to hold their breath for about 15s. The parameters for the sequence are flip angle, 65°; TR/TE, 195/3.69 ms; number of excitation (NEX), 1; matrix, 256×131; slice thickness, 7 mm and echo train length, 4. In order to guarantee the image plane pass through the centre of the vertebral disc between L4 and L5, the MRI datas will be obtained from a sagittal scout. Qualitative image analysis was performed by two independent reviewers.

Outcome measurement

The clinical outcomes will measure patients' obesity levels and quality of life. All measurements will be performed at baseline; after 8-week treatments; at 12-week follow-up.

The primary outcome is the BMI change from baseline. The formula for BMI is as follows: $BMI = \text{mass (kg)} / (\text{height(m)})^2$. BMI scores evaluate as "18.5 - 23.9 (normal)," "24 - 27 (overweight)," "28 - 32 (obesity)," and "more than 32 (very fat)".

The secondary outcomes include waist circumference (WC), hip circumference (HC), waist hip rate (WHR), body fat percentage (BFP), and World Health Organization 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. Hip circumference will be measured around the widest portion of the buttocks using a tape parallel to the floor [23]. The BFP will be measured with bioelectrical impedance.

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

Other outcome parameters, including basal metabolic rate, blood pressure (BP) and heart rate (HR), and blood total cholesterol (TC), triglyceride (TG), and high density lipoprotein (HDL) levels also will be tested at each timepoint.

Statistical analysis

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

For the clinical data, SPSS 22.0 software (IBM SPSS Statistics, New York, NY, USA) will be used. For the MRI data, the images generated will be analyzed on a workstation (Syngo Multimodality Workspace) for the quantification of VAT and SAT.

Demographic information and levels of measured variables will be analyzed by descriptive statistics. The categorical data will be described as percentage (n%) or analyzed using the Chi-square (χ^2) test. Additionally, for the continuous variables, t-test will be performed, and presented with mean \pm standards deviations. The paired *t*-tests will be used to analyze the difference of evaluation scores before and after

each examination. The longitudinal and repeated measured data for variables across the 3 data collection points will be analyzed by the repeated measure analysis.

SFA was quantified as the area between outline of abdominal skin and the outer abdominal muscle, while VFA was 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 analysing the same image for SFA and VFA (n=30) were $r=0.99$, $p<0.001$ and $r=0.98$, $p<0.001$, respectively.

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

For the above statistical analyses, a value of $P < 0.05$ will be regarded as statistically significant.

Safety

To guarantee the ACE operation is standardized 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 within 24 hours after embedding; (6) inform patients acupoints embedded catgut may keep sensation of soreness, distension and numbness for one or two days, even more than three to five days.

Management of adverse events

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

Quality control

Acupuncturists, assistants, data collectors and statisticians have made up the study group, all of whom should abide by the rules and regulations enacted by the study group. Before the study, each researcher will take a basic study training to understand the design, purpose, and basic information of this research,

as well as master their own independent division of work. The acupuncturists will be required to be at least 3 years of practical acupuncture experience, moreover, they should be familiar with the operation process and be able to cope with any possible adverse events. Data collectors will be responsible for saving and managing the various data, and strictly proofread data. Patient withdrawal and adverse events during the study will be recorded in detail. Statisticians are fully responsible for data management and statistical analysis. Regular team meetings will be held and fully documented.

Regulatory and ethics approval

This study has been approved by the Chinese Clinical Trial Registry. The registration number of this trial is ChiCTR1800020248. In addition, Our study protocol has been approved by the Ethics Review Committee on Shenzhen Traditional Chinese Medicine Hospital. All crucial protocol adjustment will be submitted to the Ethics Review Committee on Shenzhen Traditional Chinese Medicine Hospital. Before the study, patients will be informed about the potential risks of the study. Patients voluntarily participate in our study with informed consent. All personal information and medical records about patients will be properly protected and keep in specialized cabinets during the whole study.

Discussion

ACE was applied widely for weight loss. Although previous studies have shown that ACE might be effective in improving the overweight, the high quality trials with rigorous design are still urgently needed to assess the effect of ACE for obesity [29]. The results of the present RCT study will contribute to a better understanding that ACE could exert the potential therapeutic effect for obesity.

Recently, increasing attention has been paid to visceral fat of obesity, which is related to energy storage, and considered to be an endocrine and paracrine organ that influences some 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 efficacy of ACE on obesity were estimated mainly by BMI or WC, and few studies have been assessed by VFA. Hence, this study will be evaluated by both ordinarily obesity-related indices (BMI, WC, ect.) and VFA, in order to illuminate the efficacy of ACE on obesity clearly.

The study, designed with three-arm trials, aims to compare the changes of measurements after 2 month treatments with three different interventions methods: verum ACE, sham ACE and no intervention (waiting-list group). Various numbers of studies [36, 37] have indicated that the sham control design could separate the specific and non-specific effects, which may play an important role on evaluating the effectiveness of a treatment. Thus, the ACE and sham ACE treatments are both applied to investigate the antiobesity effects in this study. The sham ACE is operated with needling pierced into the acupoints only but without catgut infixed, and other operations are all the same as those in the ACE group. So, it could

successfully blind the patients and estimators, as a result it could minimize the placebo effect. In addition, as far as non-specific effects (sham ACE vs. no intervention) and bias caused by psychological influences concerned, the third group without any intervention is set to avoid the placebo effects of group allocation or the patients' beliefs in ACE for weight loss. A possible limitation of this trial is that the follow-up might be difficult to completely comply with for participants due to a long interval since the end of 2 month treatment. Some proper actions, such as telephone interview, will be taken to improve compliance.

The design and methodological rigor of this trial will hopefully provide consolidated evidence on the efficacy and safety of the ACE for treating obesity, through collecting the 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, 2019. The version number and date of the protocol is v1.0, April 7, 2019.

Abbreviations

ACE: acupoint catgut embedding; GHO: Global Healthy 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 study; 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

Funding

This work will be supported by the Shenzhen "Sanming project" (SZSM201612001). The funding plays no role in the design of the trial, collection, management, analysis and interpretation of data, writing of the report, or the decision to submit the report for publication.

Availability of data and materials

The datasets generated in the study are available from the corresponding author on reasonable request.

Authors' contributions

YM Z, B Y and WQ Y contributed equally to this paper. ZX Y is the corresponding author. YM Z participate in the conception and design of the trial. YM Z and WQ Y complete to draft the manuscript. HB Y is in charge of the recruitment and treatment of patients. B Y participate in data collection. WQ Y will analyze the data. ZX Y proofread the final manuscript. All authors discussed, read the manuscript, and all approved the publication of this protocol.

Ethics approval and consent to participate

The protocol has been approved by the Ethics Review Committee on Shenzhen Traditional Chinese Medicine Hospital (ethical approval: Shenzhen Chinese Medicine Ethics approve (research) 2018077). The study is registered at Chinese Clinical Trial Registry (registration ChiCTR1800020248). It was registered on 21 November 2018; <http://www.chictr.org.cn>. Before all surveys, the acupuncturists will give the participants specific details about the research. After the approval of participants, informed consent will be signed and documented.

Competing interests

The authors declare that they have no competing interests.

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Tables

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 rd 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 th 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 nd subspinous of lumbar vertebra, and 1.5 cun lateral to the posterior midline.

Figures

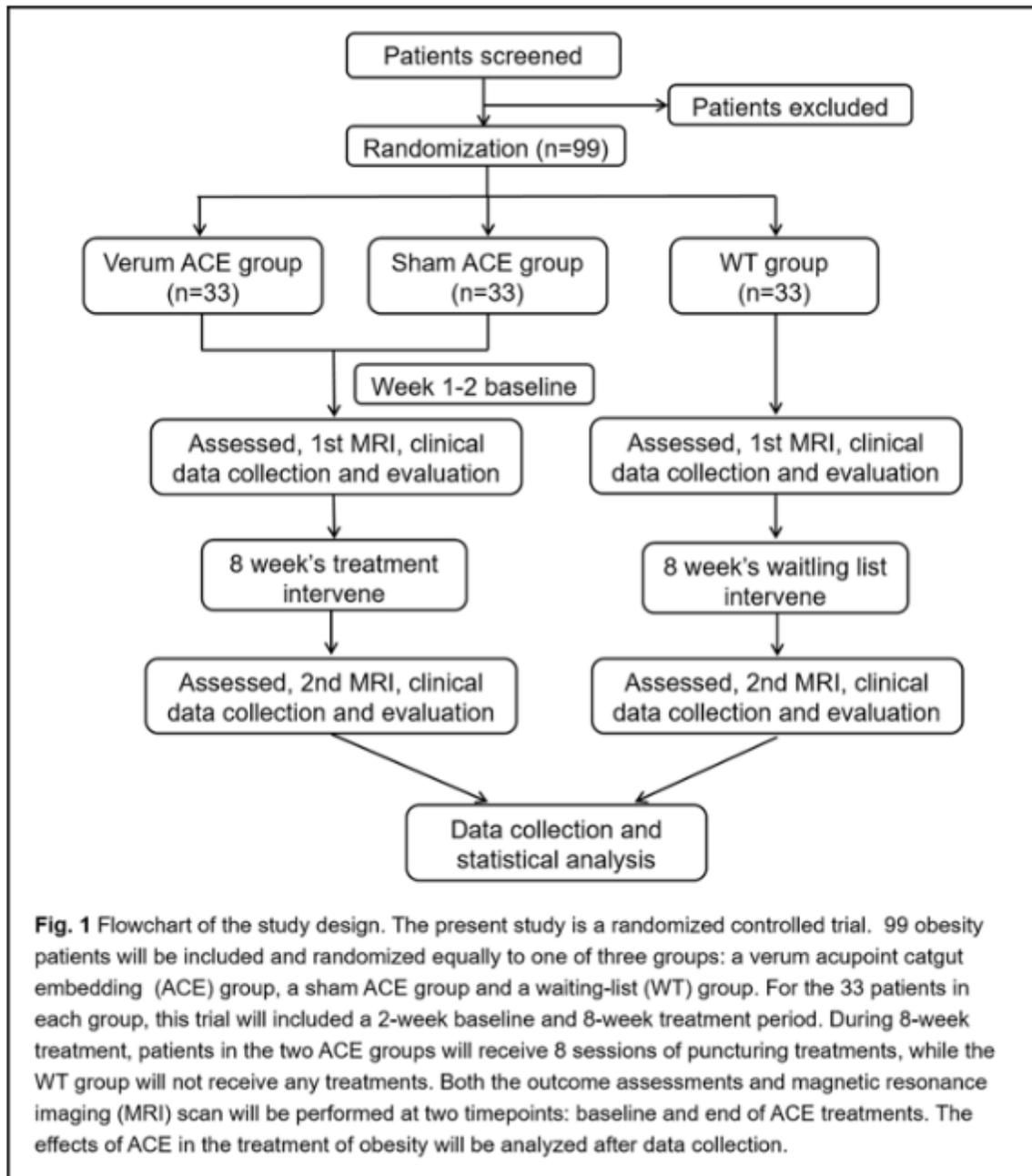


Figure 1

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)
ENROLMENT:					
Eligibility screen	×				
Informed consent	×				
Randomization		×			
INTERVENTIONS:					
Verum ACE group (n=33)			×	×	×
Sham ACE group (n=33)			×	×	×
Waiting-list (n=33)			●—————●		×
MRI SCAN:					
Verum ACE group (n=33)		×		×	×
Sham ACE group (n=33)		×		×	×
Waiting-list (n=33)		×		×	×
ASSESSMENTS:					
BMI		×		×	×
WC, HC, WHR, BFP		×		×	×
basal metabolic rate, BP, HR		×		×	×
TC, TG, HDL		×		×	×
WHOQOL		×		×	×
PARTICIPANTS SAFETY:					
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

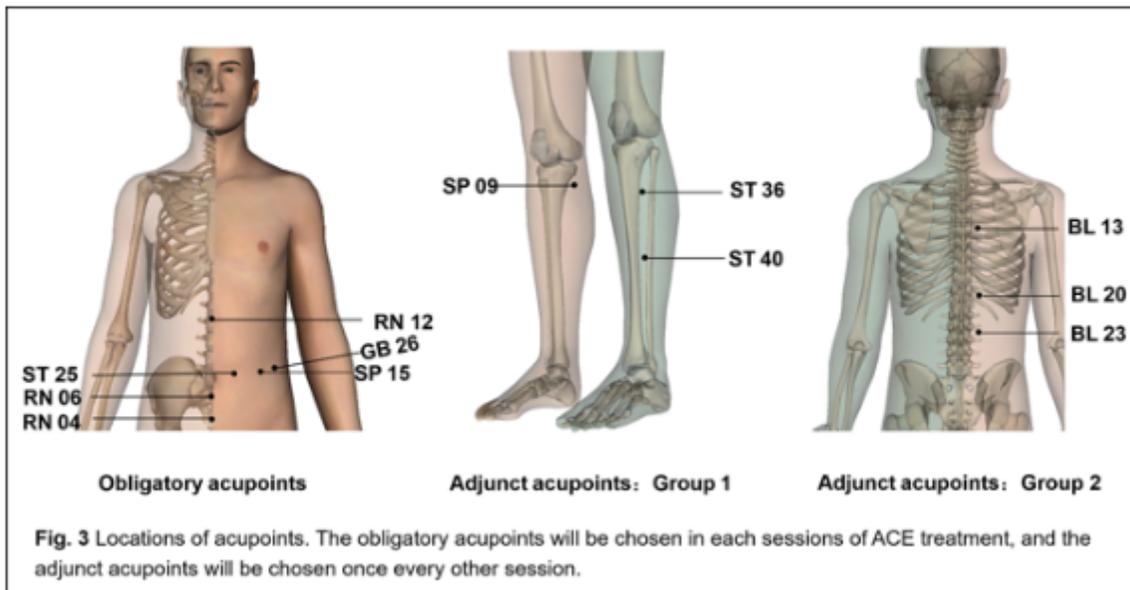


Figure 3

Supplementary Files

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- [supplement1.doc](#)