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

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Study protocol

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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 an acupuncture therapy, has been widely used in China although it's efficiency has not been tested by randomized controlled trial (RCT). The aim of this study is to evaluate the efficacy and safety of the ACE on AO. Methods This is a blinding, RCT. 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. ACE 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 in the fourth week after the end 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 The results of this study will be obtained by RCT, and the outcomes will be analyzed to prove that ACE is effective and safe for AO. The results of this study will be derived from RCT. We expect that this experiment 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 from the two groups.

Background

Obesity is a chronic metabolic disorder characterized by fat accumulation and abnormal distribution. Evidences indicate that obesity, particularly AO, can lead to many adverse health conditions, such as diabetes, cancer, cardiovascular and cerebrovascular diseases, hypertension, gallstones, hyperlipidemia, mental disorders and even premature death [1–3]. The morbidity of obesity has increased rapidly as the result of changes in dietary structure and exercise patterns. According to the World Health Organization (WHO) reported in 2012, the number of obese men grow from 5% to 10%, and women from 8% to 14% [4]. In a study of obesity incidence in 10 European countries between 2005 and 2013, the prevalence of obesity increased from 17.5% to 19.2%, especially in Germany, with a growth rate of 5.8 percentage [5]. According to the China Health and Nutrition Survey (CHNS), the prevalence of adult overweight/obesity increased from 13.4% to 26.4% in 1993–2009, and the prevalence of adult AO increased from 18.6% to 37.4% in some regions [7]. Projections estimate that overweight individuals are still increasing globally according to a 2019 study [6].

Huge obesity population and severe and multi-system conditions caused heavy healthcare costs. By 2030, the cost of obesity-related treatment and prevention in the United States is expected to reach $48 billion to $66 billion a year, while in the United Kingdom it will reach 1 billion to 2 billion pounds a year [8]. Data shows that China has spent 858.054 billion Yuan on chronic non-communicable diseases including obesity in 2003, accounting for 7.31% of the Gross Domestic Product (GDP) [8]. Meanwhile the economic burden caused by a premature death in China reached 425.1 billion Yuan, of which chronic non-communicable diseases accounted for 67.1% in 2012 [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 injury and side-effects [9]. However, there is no strong evidence that lifestyle changes in diet and exercise can achieve sustained weight loss, besides diet especially food restriction and high energy excise require personal persistence [10]. As for pharmacotherapy, it is affected by patients' basic diseases and is contraindicated in special circumstance such as pregnancy and children [11]. In addition, some drugs can also cause adverse effects like headaches, nausea, dizziness, and mental stimulation, so safety and efficacy are still unclear [4,12]. Therefore, clinicians have begun to use a variety of alternative therapies including acupuncture to treat obesity [13].

Acupuncture is a very characteristic of traditional Chinese medicine (TCM) therapy with a long history of more than 2500 years. Historical data proves that acupuncture has a positive effect on many diseases [14]. Different acupuncture method, i.e. acupoint catgut embedding (ACE), manual acupuncture (MA), electroacupuncture (EA), and auricular acupuncture (AA) have lowered body mass index (BMI), reduced waistline, abdominal and hip circumference, as well as improved the quality of life [15–19].

Particularly, ACE is one of the special acupuncture treatments that using the absorbable surgical suture to implant into acupoint which could produce 1–2 weeks continuous stimulation. According to one of our previous study on systematic review [20], the therapy of ACE for obesity indicates a better effect than a sham, MA, EA, AA and other acupuncture methods. Meanwhile, our another study also found ACE has advantages over MA and EA in term of treatment time and costs [21]. Despite the lack of rigorous randomized controlled trial (RCT) evidence, ACE is applying widely in most Chinese TCM hospitals and weight loss institutions for obesity. So, we have designed this RCT protocol and further to observe the efficacy and safety of ACE in the treatment of AO.

Methods And Analysis

Study design

This study is designed to run an RCT on ACE for AO. Ninety-two participants will be recruited from outpatient at the 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. The trial 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. The assessment of outcomes will be carried out at the end of each course. The flow chart of the trial is shown in figure 1and 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 between 28–39.9kg/m^2, male WC≥90cm, female WC≥80cm [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≥40 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 for Clinical Research, Yunnan University of Traditional Chinese Medicine, for central randomization and data management. The data center administrators of each medical center can apply for random treatment allocation to the Central Randomization System of Yunnan University of Traditional Chinese Medicine by mail. The random center will report the randomly assigned information of the selected cases to the medical center data administrators via email. 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

Because of the selected participants has less knowledge of acupoint and they cannot distinguish accurately acupoint and sham, so they did not know which group they have been. As the generation and distribution of the random number are operated by the center, the acupuncture doctors, outcome assessors and statistical evaluators will 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/m^2, and that of non-acupoint embedding group is 0.9kg/m^2, with the standard deviation of each group is 0.31kg/m^2. The significant level is = 0.05, the power of a test is 1-β = 0.95. The sample size is 84 with F test using German G*power software3.1.[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 adopted the combination of back-shu and front-mu, the points are BL20(Pishu), BL21(Weishu), BL25(Dachangshu), RN12(Zhongwan), ST25(Tianshu), LR13(Zhangmen), only one side of Zhongwan, a total of 11 points. The location of these points is shown in *Table 2 and Figure 2* Marked as black points.

Non-acupoint group

The study chooses six points besides the shu-mu point as non-acupoints, and they are labelled NA1, NA2, NA3, NA4, NA5 and NA6. These acupoints are taken from both sides (except NA4), with a total of 11. The location of these points is shown in table 3 and figure 2 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 with the specification of 2–0, 2cm*20 length (Jiangxi longteng biotechnology co. LTD).

Manipulation

All acupoint embedding manipulations are performed by doctors with national medical qualifications. The specific manipulation is as follows: the patient was placed in an appropriate position, and the acupoint skin was routinely disinfected. Take a sterile protein string with a length of 1–2cm (the length

depends on the location of the acupoint), placed it on the front end of the trocar, then connect the needle core, lifted the partial skin with the thumb and forefinger of one hand, pierced the needle with the other hand. When the piercing reaches the desired depth, apply appropriate push-and-twist techniques, then the needle core was pushed and the needle tube removed, implant the sterile protein string in the subcutaneous tissue or muscle layer of the acupoint. After removing the needle, pressed the needle hole with a dry cotton ball for half a minute to stop 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 did not take a bath for 24 hours and keep the embedding place 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 serious reaction, the wound will ooze out in a small amount. 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 return 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. A small number of patients are infected with the nonstandard operation and improper wound protection by doctors, resulting in local redness, swelling and increased pain. They need local hot compress and anti-inflammation treatment. Some patients may be allergic to catgut, with allergic reactions such as 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 damage. Sensory nerve injury can cause skin sensory disturbance in the nerve distribution area, and the dominant nerve group paralyzed will appear in the motor nerve injury. In the case of this, the catgut should be taken out with operation in time, and given appropriate treatment.

Outcomes

The outcomes of this study will be evaluated before treatment, after 1 course, 2 courses 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 ± standard deviation (M ± 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

Studies have shown that obesity is one of the risk factors of diseases such as cardiovascular disease, diabetes and cancer [25]. In particularly, AO increases the incidence of these diseases and increases all-cause mortality to some extent [26].

According to the TCM theory, shu-mu point is mainly used to regulate visceral diseases. Similarly, 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 been 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 that is being chosen by 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, people's acceptance is getting higher and higher. In this trial, we chose a slower absorption catgut to achieve better efficacy while reducing the impact on participants' daily lives.

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, and there may be regional differences. Third, during the experiment, only participants are advised to maintain a normal diet. Strict diet control was without conducted and there was no way to quantitatively monitor the diet; finally, participants were not required to exercise.

In general, in this study, researchers will assess the efficacy and safety of ACE for obesity by observing changes in the patient's physical condition.

Trial Status

The trial is currently recruiting patients. This is version 2.0 of this protocol, and the date is June 5, 2019. The date recruitment began on July 1, 2019, and the approximate date when recruitment will be completed on July 1, 2021.

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; WHO: World Health Organization; MA: Manual acupuncture; EA: Electroacupuncture; AA: Auricular acupuncture; NA: Non-acupoint; M ± SD: Means ± standard deviation; LSD: Least Significant Difference

Declarations

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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. XCHand GTP provided the funding, ethical approval and total design. All authors contributed to the revision and approved the final manuscript.

Availability of data and materials

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

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.

Consent for publication

Not applicable

Competing Interests

The authors declare that they have no conflicts of interest.

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Tables

Table 1: Schedule of this trial

Items	Weeks														
	-4-0	0	1	2	3	4	5	6	7	8	9	10	11	12	16
Inclusion criteria	×														
Exclusion criteria	×														
Informed consent		×													
Allocation		×													
Intervention			×		×		×		×		×		×		
Follow-up															×
Assessment															
Weight	×							×						×	×
WC	×							×						×	×
BMI	×							×						×	×
HC	×							×						×	×
SF-36	×							×						×	×
SAS	×							×						×	×
SDS	×							×						×	×

Table 2: The location of the shu-mu points

Shu-mu point	Location
Pishu (BL20)	In the upper back region, at the same level as the inferior border of the spinous process of the 11th thoracic vertebra (T11), 1.5 B-cun lateral to the posterior median line.
Weishu (BL21)	In the upper back region, at the same level as the inferior border of the spinous process of the 12th thoracic vertebra (T12), 1.5 B-cun lateral to the posterior median line.
Dachangshu (BL25)	In the lumbar region, at the same level as the inferior border of the spinous process of the fourth lumbar vertebra (L4), 1.5 B-cun lateral to the posterior median line.
Zhongwan (RN12)	On the upper abdomen, 4 B-cun superior to the centre of the umbilicus, on the anterior median line.
Tianshu (ST25)	On the upper abdomen, 2 B-cun lateral to the centre of the umbilicus.
Zhangmen (LR13)	On the lateral abdomen, inferior to the free extremity of the 11th rib.

Table 3: The location of non-acupoints

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

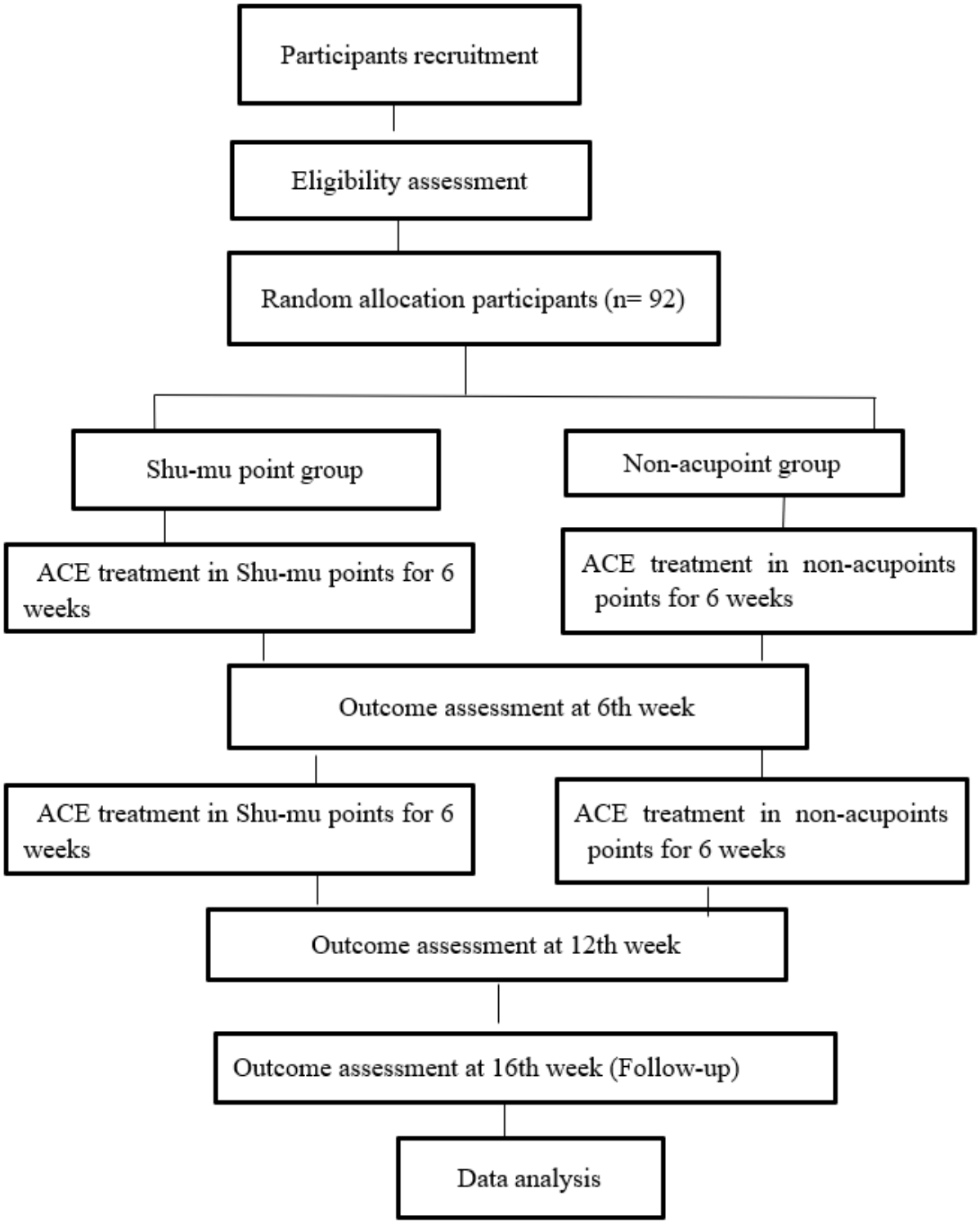

Figure 1

The flow chart of the trial

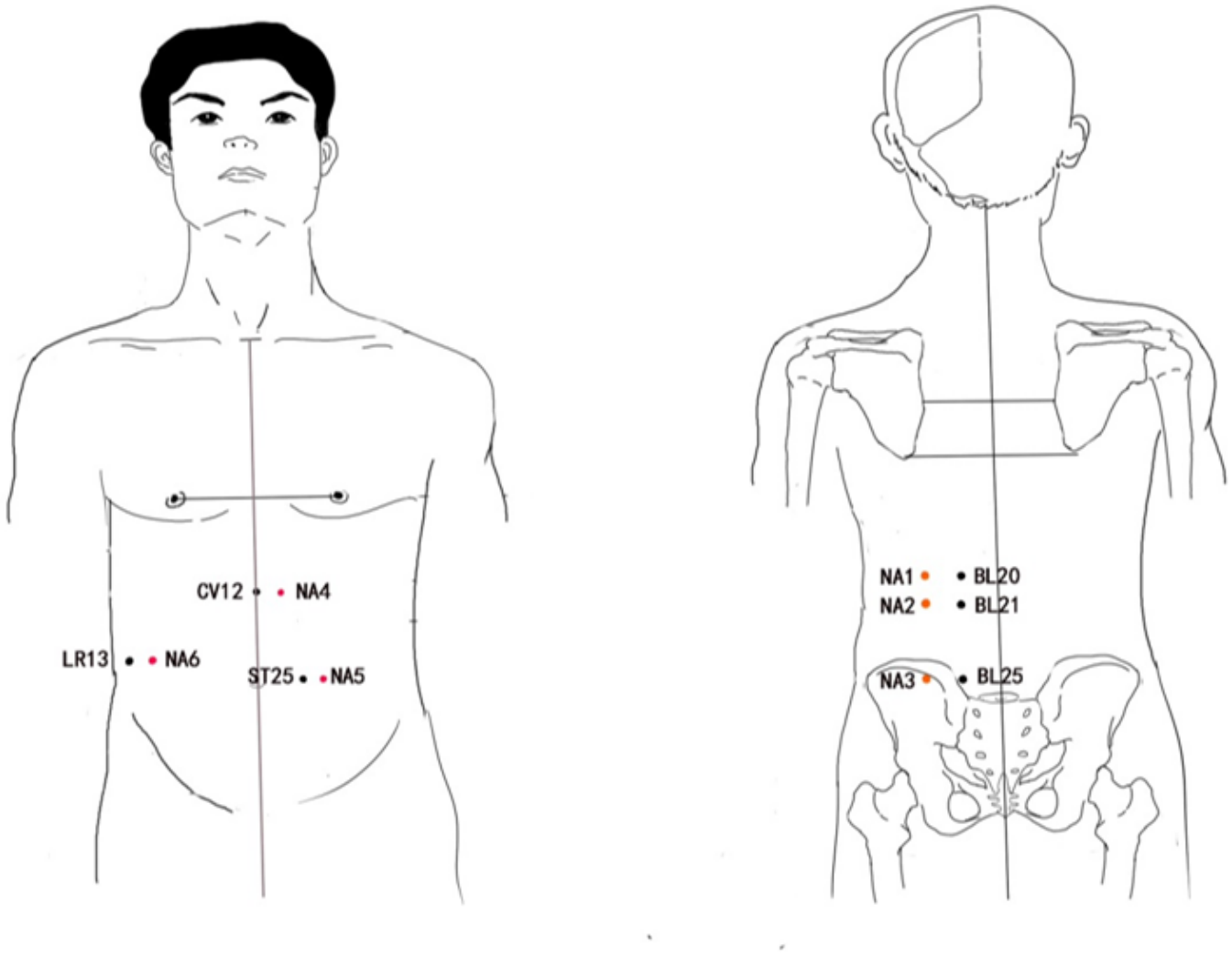

Figure 2

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

Supplementary Files

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- supplement1.doc