BMJ Open

Effect and safety of electroacupuncture on weight loss in obese patients with pre-diabetes: study protocol of a randomised controlled trial

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To cite: Li X, Lin J, Hu C, *et al*. Effect and safety of electroacupuncture on weight loss in obese patients with pre-diabetes: study protocol of a randomised controlled trial. *BMJ Open* 2024;**14**:e075873. doi:10.1136/bmjopen-2023-075873

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-075873).

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Received 21 May 2023
Accepted 21 February 2024

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ABSTRACT

Introduction Obesity has been identified as a significant risk factor for several chronic conditions, including diabetes, tumours and cardiovascular disease, and has been associated with increased mortality rates. Despite the well-established clinical practice of electroacupuncture (EA) as a potential treatment option for obesity, its efficacy remains questionable, primarily due to the paucity of empirical evidence supporting its therapeutic benefits.

Methods and analysis The present study aims to investigate the efficacy and safety of EA for weight loss in obese individuals with pre-diabetes, using a randomised, placebo-controlled clinical trial design. A total of 256 eligible patients will be randomly assigned to one of two groups: EA (comprising EA treatment with health education) or superficial acupuncture (SA) (comprising SA treatment with health education). The intervention will be administered three times per week for the initial 12 weeks, two times per week for the subsequent 8 weeks and one time per week for the final 4 weeks, with a 24-week follow-up period. The primary outcome measure will be the percentage of patients who achieve a reduction of 10% or more in their body weight at week 24. Secondary outcome measures will include changes in body weight and body mass index, blood test results, data collected by the body composition analyser, size of adipose tissue scanned by MRI of the abdomen and the Impact of Weight on Quality of Life, the 21-item Three-Factor Eating Questionnaire-Revised and the Food Craving Questionnaire-Trait. The Treatment Emergent Symptom Scale will be employed to monitor every adverse reaction from baseline to follow-up.

Ethics and dissemination This trial has received ethical clearance from the Ethics Committee of Shanghai Municipal Hospital of Traditional Chinese Medicine under the registration number 2021SHL-KY-74. All participants will provide their written informed consent prior to their enrolment. The findings of this investigation will be disseminated through peer-reviewed publications and scholarly conferences.

Trial registration number NCT05237089.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a single-centre, randomised and controlled clinical trial with a large sample size, and a long intervention and follow-up period.
⇒ Objective outcomes including the body weight, glucolipid metabolism and body composition, as well as the adverse events will be comprehensively evaluated.
⇒ Acupuncture treatment based on 'syndrome differentiation' will be applied and will provide more pragmatic evidence.
⇒ Acupuncturists cannot be blinded to the group assignment because of the acupuncture treatment operations.
⇒ Superficial acupuncture will be used as the control method, which may cause some therapeutic effects.

INTRODUCTION

Obesity is a chronic metabolic disorder characterised by excessive accumulation of adipose tissue. It is defined by a body mass index (BMI) of 30 or more, reflecting a high level of obesity.[1 2] Epidemiological evidence has consistently shown that obesity is a significant risk factor for a variety of adverse health outcomes, including cardiovascular disease, diabetes mellitus and various types of cancer.[3] Notably, China currently has the highest proportion of patients who are obese and diabetic worldwide.[4]

In individuals with pre-diabetes and obesity, losing 10% or more of their body weight has been shown to be extremely effective in preventing the onset of type 2 diabetes.[5] Maintaining a healthy lifestyle that includes healthy eating habits, regular physical activity and effective stress management can facilitate healthy weight management.[6–8] However, sustaining lifestyle changes over the long-term can prove challenging. Therefore, some individuals may consider alternative strategies such as weight loss medications or surgery.

Weight-loss drugs can suppress appetite and increase energy expenditure, but they can also interfere with digestive and absorption functions, leading to side effects such as

nausea, vomiting, constipation, dizziness and dry mouth. Evidence suggests that long-term use of these drugs may increase the risk of cardiovascular disease and mental illness.[9 10] Surgical procedures for weight loss, have the potential for significant benefits, but also carry significant risks. Complications such as excessive bleeding, infection, acid reflux and intestinal obstruction are possible.[11]

Electroacupuncture (EA) is an innovative form of traditional Chinese acupuncture that incorporates electrical impulses to enhance the therapeutic effects. EA has emerged as an alternative therapy for obesity. Previous studies have demonstrated its superiority over lifestyle advice or sham acupuncture in reducing BMI, body weight, body fat mass, waist-to-hip ratio, triglyceride (TG) and total cholesterol (TC) levels.[12] EA has also been shown to improve glycaemic control and insulin sensitivity in patients with type 2 diabetes mellitus, thereby possibly preventing the development of diabetes and its complications.[13 14]

To investigate the impact of EA on the treatment of obese patients with pre-diabetes and to address some of the limitations of previous studies, we designed a randomised controlled trial (RCT) with an adequate follow-up period. The study will evaluate the effectiveness of EA treatment in weight loss and diabetes prevention using subjective and objective measures while minimising the placebo effect with an appropriate superficial acupuncture (SA) method. Our findings can inform the development of optimal acupuncture treatment protocols for obesity and pre-diabetes, providing valuable insights for healthcare professionals, policymakers and the public.

METHODS/DESIGN

Hypothesis

The main objective of this study is to evaluate the efficacy of EA versus SA treatment in the treatment of obesity and pre-diabetes in a RCT. Our hypothesis is that EA will be superior to SA in promoting weight loss and preventing the onset of diabetes in obese patients with pre-diabetes. By providing conclusive evidence on the effectiveness of EA treatment, this study may help inform clinical practice and guide the development of more effective treatment strategies for this growing public health problem.

STUDY DESIGN

This study protocol describes a single-site, randomised, patient-assessor-blinded and placebo-controlled clinical study designed to evaluate the efficacy and safety of EA for weight loss in obese patients with pre-diabetes. The study will be conducted at the Acupuncture Department of the Shanghai Municipal Hospital of Traditional Chinese Medicine, recruiting 256 participants who will be randomly assigned to either the EA or SA treatment group. After a 1-week baseline assessment, the study intervention will continue for 24 weeks, with a 16-week follow-up period. Assessments of patient outcomes will be conducted during the intervention period (weeks 8, 16 and 24) and the follow-up period (weeks 32, 40 and 48). The study process is shown in figure 1 and the timeline for registration, intervention and assessment is shown in table 1. We started the study in September 2022 and planned to finish the recruitment at the end of 2024, and the whole trial might be finished in December 2026. Compliance with the Consolidated Standards for Study Reporting and the Standards for Reporting of Interventions in Clinical Trials in Acupuncture will be maintained throughout the trial.[15]

Sample size calculation

The sample size calculation for this study was based on the proportion of patients achieving weight loss of 10% or more of their body weight, with the assumption that EA treatment would be more effective than SA treatment. Previous research conducted in this area has shown that the proportion of patients achieving this level of weight loss is 26% in the EA group and 11% in the SA group, as shown in a previous RCT.[16] Sample size calculations were performed using PASS V.15.0 software (NCSS LLC, Utah, USA) which revealed that each group would require 102 cases to achieve a type I error rate of 0.025 (one-sided) and a power of 80% to reach. With a dropout rate of 20%, a total of 256 cases were required, with 128 cases allocated to each group.

Subject recruitment and randomisation

Patients are recruited via WeChat advertisements and hospital banners. Screening is conducted through telephone or in-person consultations. Eligible patients are provided with comprehensive information about the study's objectives, methods and potential benefits and risks. They are also requested to complete a set of questionnaires during their initial visit to assess their eligibility for the trial. On confirmation of eligibility, patients are invited to participate in the study and sign a written informed consent form (seen in online supplemental file 1) before the intervention begins.

Inclusion criteria

Enrolment criteria for study participants encompass the following:

1. Male or female individuals between 18 and 65 years of age.
2. Participants with a BMI of ≥24.0 kg/m^2.
3. Participants with a haemoglobin A1c (HbA1c) value between 5.7% and 6.4% or a fasting plasma glucose value between 6.1 mmol/L and <7.0 mmol/L or a 2-hour postprandial plasma glucose level (oral glucose tolerance test) between 7.8 mmol/L and<11.1 mmol/L.
4. Participants who have maintained a stable weight within 4 kg for the 3 months prior to study commencement.
5. Participants who provide their voluntary consent by signing a written consent form.

Exclusion criteria

The exclusion criteria for study participants are as follows:

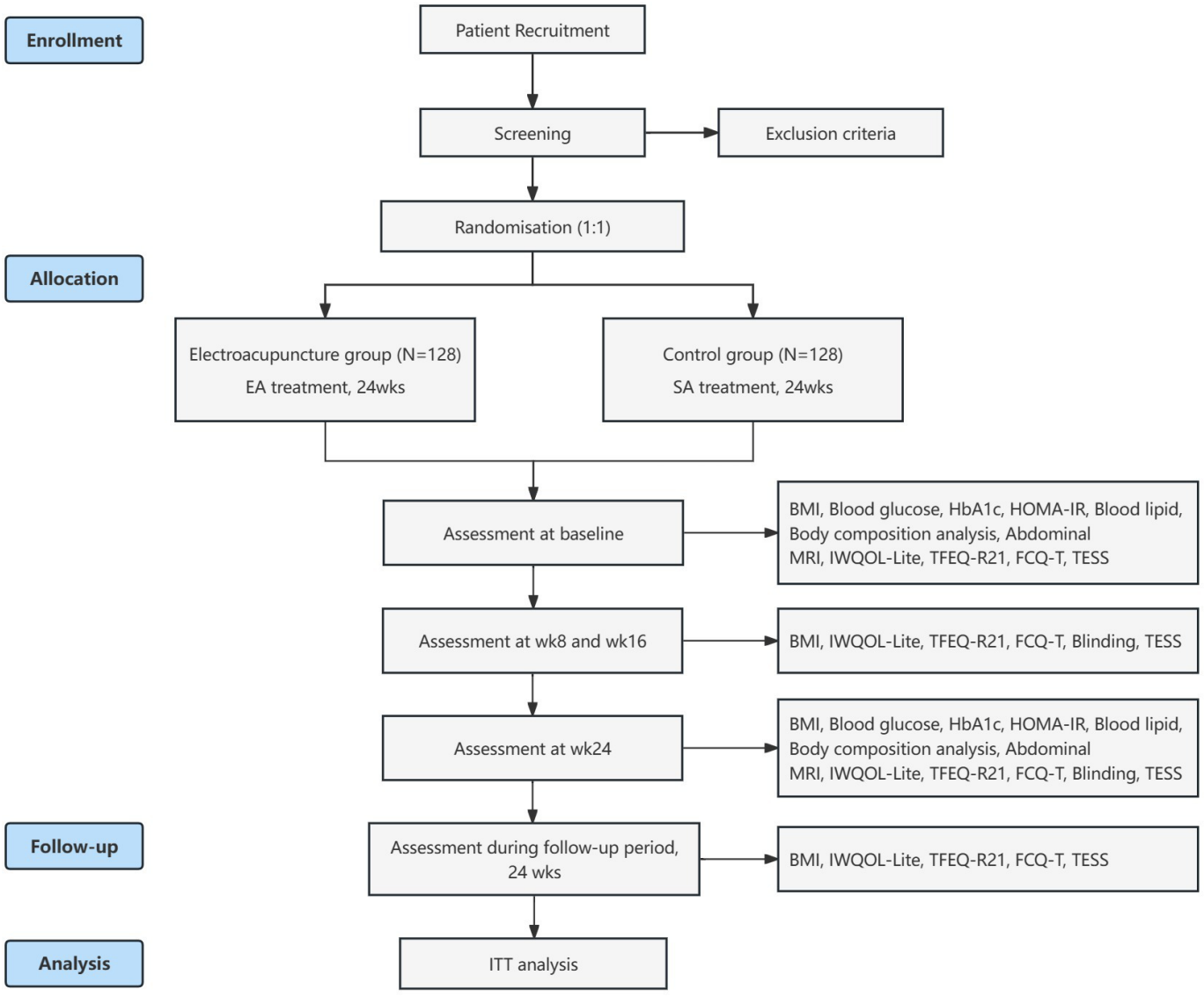

Figure 1 Flowchart of the trial. BMI, body mass index; EA, electroacupuncture; FCQ-T, Food Craving Questionnaire-Trait; HbA1c, haemoglobin A1c; HOMA-IR, Homoeostasis Model Assessment of Insulin Resistance; ITT, intention-to-treat; IWQOL, Impact of Weight on Quality of Life; MRI: Magnetic Resonance Imaging; SA, superficial acupuncture; TESS, Treatment Emergent Symptom Scale; TFEQ-R21, 21-item Three-Factor Eating Questionnaire-Revised.

1. Participants with secondary obesity induced by drugs or neuroendocrine-metabolic disorders (such as hypothalamic disease and hypopituitarism).
2. Participants diagnosed with type 1 or type 2 diabetes.
3. Participants who are taking medications that may interfere with the study outcomes (which cause weight loss, such as liraglutide or semaglutide; or that may cause weight gain, such as dexamethasone).
4. Participants with a score of >18 on the 17-item Hamilton Depression Scale.
5. Participants with severe ulcers, abscesses or skin infections in the local acupuncture area.
6. Participants with severe cardiac, cerebral, pulmonary, hepatic, renal, haematological or other serious medical conditions.
7. Participants who have participated in other clinical trials within the last month.
8. Pregnant or lactating women.

Randomisation and allocation concealment

Participant allocation will be accomplished through a process of randomisation employing random block sizes of 4, 6 and 8. Stratification will be based on three criteria: (1) BMI; (2) gender; and (3) age. Eligible participants will be randomly assigned to either the EA or SA group at a 1:1 ratio, using computer-generated random sequences. Distribution cards will be generated and enclosed in opaque, sealed envelopes. Participants will receive envelopes sequentially according to the order of enrolment from an independent researcher, and envelopes will be opened by an acupuncturist prior to treatment. All randomisation procedures will be executed at a central office by researchers not associated with intervention, evaluation or data collection. Throughout the trial,

Table 1 Schedule of enrolment, intervention and assessments

	Baseline	Treatment phase			Follow-up phase		
	Week 0	Week 8	Week 16	Week 24	Week 32	Week 40	Week 48
Patients							
Enrolment	×						
Signed informed consent	×						
Medical history	×						
Randomisation	×						
Intervention		×	×	×			
Outcome measures							
BMI	×	×	×	×	×	×	×
Blood glucose	×			×			
HbA1c	×			×			
HOMA-IR	×			×			
Blood lipid	×			×			
Body composition analysis	×			×			
Abdominal MRI	×			×			
IWQOL-Lite	×	×	×	×	×	×	×
TFEQ-R21	×	×	×	×	×	×	×
FCQ-T	×	×	×	×	×	×	×
Blinding		×	×	×			
TESS	×	×	×	×	×	×	×
Patients' compliance		×	×	×	×	×	×

BMI, body mass index; FCQ-T, Food Craving Questionnaire-Trait; HbA1c, haemoglobin A1c; HOMA-IR, homoeostasis model assessment of insulin resistance; IWQOL-Lite, Impact of Weight on Quality of Life; MRI, Magnetic Resonance Imaging; TESS, Treatment Emergent Symptom Scale; TFEQ-R21, 21-item Three-Factor Eating Questionnaire-Revised.

the study sponsor will maintain records of the randomisation results.

Blinding and researcher shielding

This study will employ a patient-assessor-blinded approach. Participants will be informed, during the screening process, of their equal chance of receiving either conventional EA or SA treatment. Patients will be treated in the supine position, with a specialised shield positioned over the chest to prevent movement during treatment. All treatment sessions will be conducted in a secluded environment without private communication between patients to ensure the implementation of blinding procedures. Acupuncturists will be the only individuals informed of the participants' allocation. All researchers will undergo pre-study training and follow strict segregation of duties policies throughout the study.

Intervention

During the intervention period, patients in both EA and SA groups will undergo 56 treatment sessions. The interventions will be administered three times per week, every other day, for the initial 12 weeks. Subsequently, the interventions will be given two times per week, on Mondays and Fridays, for an additional 8 weeks and one time per week during the final 4 weeks. The duration of each session will be 30 min. To ensure patient comfort and safety, the treatment room temperature must remain above 25°C. Additionally, all patients will receive identical health education brochures detailing the benefits of personalised lifestyle practices during the 24-week intervention period.

EA group

In the EA group, patients will receive authentic acupuncture treatment combined with low-frequency pulse electrical stimulation. The acupuncture treatment will involve the use of disposable sterile stainless-steel needles (Wuxi Jiajian Medical Device, China), with a diameter of either 0.25 mm×40 mm or 0.30 mm×75 mm at acupoints in different parts of the body. The acupuncturists will manipulate the needles by lifting-thrusting or twirling to achieve the De-qi sensation. The acupuncturists will use the main acupoints and choose the combined acupoints based on the syndrome differentiation during each session of the treatment. The main acupoints will include Shangwan (CV13), Zhongwan (CV12), Jianli (CV11), Xiawan (CV10), bilateral Quchi (LI11), Hegu (LI4), Liangmen (ST21), Tianshu (ST25), Daheng

Table 2 Treatment methods of electroacupuncture and acupoints

	EA group	SA group
Main acupoints	CV13, CV12, CV11, CV10, LI11, LI4, ST21, ST25, SP15, SP14, ST28, ST36, ST40, ST26 and ST29.	CV13, CV12, CV11, CV10, LI11, LI4, ST21, ST25, SP15, SP14, ST28, ST36, ST40, ST26 and ST29.
Combined acupoints	ST37, ST44, SP9, CV9, CV6 and CV4.	None.
Needle type	Steel needles, 0.25×40 mm at acupoints in the limbs and 0.30×75 mm at acupoints in the abdomen.	Steel needles, 0.22×25 mm at all acupoints.
Needle sensation	With *De-qi* sensation.	Without *De-qi* sensation.
Electrical stimulation	Bilateral ST21, ST25 and SP15, with continuous wave, 3 Hz frequency and 4–5 mA current.	Bilateral ST21, ST25 and SP15, with no current.

CV, Conception Vessel; CV4, Guanyuan; CV6, Qihai; CV9, Shuifen; CV10, Xiawan; CV11, Jianli; CV12, Zhongwan; CV13, Shangwan; EA, electroacupuncture; LI, large intestine meridian; LI4, Hegu; LI11, Quchi; SA, superficial acupuncture; SP, spleen meridian; SP9, Yinlingquan; SP14, Fujie; SP15, Daheng; ST, stomach meridian; ST21, Liangmen; ST25, Tianshu; ST26, Wailing; ST28, Shuidao; ST29, Guilai; ST36, Zusanli; ST37, Shangjuxu; ST40, Fenglong; ST44, Neiting.

(SP15), Fujie (SP14), Shuidao (ST28), Zusanli (ST36), Fenglong (ST40), Wailing (ST26) and Guilai (ST29). The combined acupoints will include bilateral Shangjuxu (ST37), Neiting (ST44), Yinlingquan (SP9), Shuifen (CV9), Qihai (CV6) and Guanyuan (CV4). The electrodes of the EA apparatus (Type G6805-2B, Shanghai Huayi Medical Instrument, China) will be connected to the needles at the bilateral ST21, ST25 and SP15 acupoints. The EA stimulation will be continuous wave type, with a frequency of 3 Hz and an intensity of 4–5 mA, adjusted based on the endurance of each patient. The details of the acupoints and EA parameters are presented in table 2.

SA group

In the SA group, participants will receive SA treatment applied to the same main acupoints as those used in the EA group, while no combined acupoints will be used for intervention. Sterile disposable stainless-steel needles with a diameter of 0.22×0.25 mm will be inserted into the skin for about 2–3 mm in depth, and no De-qi sensation will be intentionally achieved. The electrodes of the EA apparatus will be connected to the needles at the bilateral ST21, ST25 and SP15 acupoints as well. However, the electric wires will be intentionally broken inside the apparatus, without current output during the treatment.

Health education

The health management brochure will be disseminated to all participants on enrolment, and health education sessions will be conducted either online or offline at weeks 8, 16 and 24, with a duration of approximately 60 min each. The researchers will offer personalised advice on healthy lifestyle practices tailored to each individual patient's characteristics, with no imposed restrictions on their dietary habits or physical activity levels.

Outcome measures

The primary outcome of this study is the proportion of patients who have lost 10% or more of their initial body weight at week 24 in both groups. Secondary outcomes include changes in body weight, BMI, blood test results, abdominal MRI measurements of fat tissue size, data collected from the body composition analyser and scores on the Impact of Weight on Quality of Life (IWQOL-Lite), the 21-item Three-Factor Eating Questionnaire-Revised (TFEQ-R21) and the Food Craving Questionnaire-Trait (FCQ-T). All adverse effects will be assessed using the Treatment Emergent Symptom Scale (TESS) from baseline to the follow-up period.

Body weight and BMI will be calculated at baseline, week 8, week 16, week 24, week 32, week 40 and week 48, and IWQOL-Lite, TFEQ-R21 and FCQ-T scores will also be collected at these time points. Blood tests will be performed at baseline and week 24, while the body composition analyser and abdominal MRI scan will be conducted at baseline and week 24. A detailed schedule of assessments can be found in table 1.

Primary outcome measure

The primary objective of this study is to assess the proportion of participants who achieved a weight loss of 10% or more of their baseline body weight at the end of the intervention period (week 24) and compare the between-group difference. Previous research suggests that a weight loss of 5–15% in obese individuals can lead to significant improvements in glucose control and reduce the risk of type 2 diabetes and its associated complications.[17] As such, the 10% weight loss threshold is an important clinical marker of success in weight management interventions.

Secondary outcome measures

Obesity level

We will calculate the mean difference in body weight of the subjects during the intervention and follow-up

periods compared with baseline measurements. The BMI can estimate body fat in relation to a person's height and weight. It is determined by dividing the weight of an individual in kilograms by the square of their height in metres. We will supplement our analysis with data from the InBody 770 non-invasive body composition analyser (Biospace Dba InBody, California, USA), which uses bioelectrical impedance analysis to determine high-density body composition, including body fat mass, skeletal muscle mass, body fat percentage and basal metabolic rate at baseline and week 24. Body fat mass provides an insight into the quantity of body fat contributing to weight, including subcutaneous and visceral deposits. Skeletal muscle mass is a proxy for the amount of muscle tissue that can be stimulated and developed through exercise. Furthermore, the muscle-fat analysis furnishes information on whether the patient has a harmonious distribution of skeletal muscle mass and body fat mass concerning their weight. Body fat percentage might be a superior indicator of the risk of obesity compared with BMI,[18] and basal metabolic rate represents the number of calories a person requires to sustain basic bodily functions. Quantitative assessments of the size of abdominal adipose tissues and the intra-abdominal to subcutaneous adipose tissue ratio can be accomplished using an abdominal MRI scan.

Glucolipid metabolism

We will access the blood test of glucose and lipid metabolism to find out the differences between patients in the two groups. Patients must abstain from food and water twice in the evening before the blood test, after 22:00, and at baseline and week 24. It is the blood glucose concentration, including fasting plasma glucose (FPG), which reflects the secretory function of the islet cell, and 2-hour postprandial blood glucose, reflecting the reserve function of the islet cell.[19] HbA1c levels of 5.5% indicate the presence of insulin resistance, while levels of 6.5% indicate the occurrence of diabetes.[20] Insulin resistance is commonly assessed using the homoeostasis model assessment of insulin resistance (HOMA-IR). This index increases in severity as insulin resistance becomes more pronounced.[21] HOMA-IR is calculated by multiplying fasting plasma insulin by FPG, and dividing the product by the constant 22.5.[22] Blood lipids, including low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol, TC and TG, can reflect the body's lipid metabolism. Elevated LDL-C levels in obese patients increase the risk of cardiovascular disease, and may also serve as a predictor of diabetes.[23]

Questionnaires

The present study used three standardised self-report questionnaires to assess the quality of life and eating behaviours of individuals with obesity. IWQOL-Lite consists of 31 items and evaluates five dimensions of quality of life, namely physical functioning, self-esteem, sex life, public stress and work.[24] TFEQ-R21 assesses three aspects of eating behaviour, including emotional eating (eating in response to negative emotions), uncontrolled eating (eating in response to food exposure or hunger) and cognitive restraint (deliberate attempt to limit eating). Scores range from 0 to 100, with higher scores indicating greater levels of eating behaviour.[25] FCQ-T comprises 39 items grouped into nine subscales that assess food cravings, including intentions and plans about eating, expectation of positive reinforcement that eating may produce, expectation of alleviation of negative states and feelings as a result of eating, lack of control over eating, thoughts or preoccupation with food, cravings as a physiological state, emotions that may be experienced before or during cravings or while eating, cues that can trigger cravings and guilt about cravings and/or giving in.[26] These questionnaires are widely used and have been validated for measuring quality of life and eating behaviours in individuals with obesity, providing valuable insights into the impact of obesity on daily living.

Adverse events

Common adverse events (AEs) associated with acupuncture include bleeding, fainting, subcutaneous haematoma and severe pain. The acupuncturists responsible for the treatment will evaluate these AEs based on their severity and document their incidence. The grading system for severity of AEs consists of three levels: grade 1 for mild, grade 2 for moderate and grade 3 for severe or medically significant. The incidence of AEs will be expressed as the number of AEs per number of acupuncture sessions, calculated as a percentage.

In addition, any diseases or events that may be affected by acupuncture treatment or that may affect the efficacy of the treatment, such as cold, fever, abdominal pain, diarrhoea and constipation, will be recorded by the TESS in the case report form. The TESS will also document the resolution of these events. By doing so, the study can obtain a comprehensive understanding of the potential AEs and their severity associated with acupuncture treatment, as well as any confounding factors that may influence the outcome.

Statistical analysis

Analyses were conducted on the intention-to-treat population, which included all participants who received at least one treatment. To address missing data, multiple imputation was used, assuming a specific distribution of values at each time point calculated by the R software. Linear mixed-effects models were employed for analysis, using IBM SPSS Statistics for Windows (V.24.0; IBM Corp, Armonk, New York, USA).

For comparison of measurement data between the groups at baseline and follow-up, the t-test was employed, while the rank sum test was used for ranked data and the χ^2 test for categorical data. All statistical analyses employed two-tailed tests at a level of significance of 5%. Results were primarily presented as mean±SD.

Ethics and clinical trial registration

All practitioners of acupuncture in this study are licensed acupuncturists with 3–5 years of clinical experience in the department of acupuncture and moxibustion at Shanghai Municipal Hospital of Traditional Chinese Medicine. To ensure the quality of the study, all practitioners undergo clinical training before the intervention.

This RCT has been approved by the Ethics Committee of Shanghai Municipal Hospital of Traditional Chinese Medicine (2021SHL-KY-74) on 19 November 2021, and is registered with ClinicalTrials.gov. Before participating in the trial, all patients are required to sign a written informed consent.

An independent Data and Safety Monitoring Board (DSMB) has been established, including three experts in the field, namely Professor Lixing Lao, a specialist in clinical trials of acupuncture therapy; Chief Xianyu Tang, a specialist in diabetes; and Director Ruiping Wang, a specialist in statistics. The DSMB monitors the progress of the trial, examines collected data and controls for bias. The members are authorised to supervise the process at any time and may raise objections directly or even halt the trial in the event of serious adverse events until the problem has been resolved.

Patient and public involvement

Prior to the design phase of the trial, the researchers consulted obese patients, with or without abnormal glucose metabolism, in the outpatients of the acupuncture department. The suggested treatment frequency, duration and follow-up period of the study were informed by endocrinologists and epidemiologists. Eligible participants will be recruited from Shanghai Municipal Hospital of Traditional Chinese Medicine. Patients who participated in the consultation process for the trial design will be excluded. On completion of the trial, a manuscript with a comprehensive account of the results will be written for publication in a scholarly journal. Additionally, a summary of the findings, written in plain language, will be distributed to all participants.

DISCUSSION

Recent decades have witnessed a dramatic surge in the prevalence of obesity, with nearly half (48.5%) of obese adults exhibiting pre-diabetes or diabetes. The WHO reports that obesity significantly elevates the risk of developing type 2 diabetes, underscoring the gravity of the global obesity pandemic.[27] Mitigating the comorbidities associated with obesity mandates weight loss, yet current treatment modalities are limited in their efficacy. Bariatric surgery, while efficacious, is available to only a minority of patients and poses serious complications.[28] Alternative therapies remain suboptimal, and further research is necessary to develop more effective interventions.

Acupuncture therapy is a popular non-pharmacological alternative treatment for obesity due to its demonstrated efficacy and safety. Previous RCTs have focused primarily on acupuncture for simple obesity, neglecting comorbid symptoms of obesity, such as abnormal glucose metabolism. Research has shown that acupuncture could regulate insulin secretion by regulating the neuroendocrine pathway[29 30] and regulate glucose and lipid metabolism of insulin target organs (eg, liver, adipose tissue and skeletal muscle). Acupuncture can improve insulin resistance through the modulation of adipocytokines to promote glucose and lipids metabolism and increase energy consumption.[31] However, there is a significant lack of comparable RCTs investigating acupuncture for the treatment of abnormal glucose metabolism in obese patients with a large sample size and a long follow-up period.

Therefore, this study proposes a protocol for an RCT to examine the effectiveness and safety of EA in treating obesity and abnormal glucose metabolism. The study aims to address the existing limitations of previous clinical studies on acupuncture, including illogical design, imperfect blinding methods and other difficulties in practical application. The trial will incorporate a more prolonged follow-up period to explore the sustained effects of acupuncture on obesity and ascertain the duration of such effects.

To eliminate possible placebo effects of EA treatment as well as to ensure the success of the blinding method, the SA method will be employed as a control, which uses thinner and shorter needles inserted at the same main acupoints as the EA group. The fundamental principle of Traditional Chinese Medicine, 'treatment based on syndrome differentiation,' will guide the selection of acupoints for the treatment of obesity based on dialectical classification. The acupoints chosen for treatment are mainly located in the abdomen, where the acupoints from the stomach, kidney and spleen meridians and the conception vessel are closely located to each other. Thus, it is hard to use the needling at the non-acupoints as the sham acupuncture method to treat obese patients. In the previous studies, the results showed that SA is not more effective than the acupuncture at non-acupoints or placebo acupuncture with sham acupuncture devices for the treatment of knee osteoarthritis.[32] Besides, an RCT in neck pain patients showed that neither non-acupoint shallow puncture nor non-penetration had a significant therapeutic effect. Interestingly, the non-acupoint shallow puncture produced even less placebo response than non-penetration acupuncture.[33]

This trial aims to address two key technical issues, namely the application of the SA treatment and patients' compliance. To ensure the appropriate administration of SA, all acupuncturists will receive extensive training before the commencement of the trial. Additionally,

researchers will educate patients on medical knowledge to promote overall health and wellness, as good compliance is crucial for the successful completion of the trial.

There are some limitations of this study. First, the acupuncturists cannot be blinded to the group assignment because of the EA treatment operations. To minimise deviations, the acupuncturists will strictly adhere to the task separation principle and will be asked to avoid communication about the therapeutic effect with the participants. Second, SA applied in the control group is a kind of conventional acupuncture treatment and it will produce little effect for acupoints in the abdomen in this trial. To ensure patients' blindness to the group assignment and to reduce the dropout rate during such a long intervention period, we decide to insert the needles into the skin as a control, with only about 2–3 mm in depth. Besides, patients with pre-diabetes may progress to diabetes during the trial. We will focus on the patients' symptomatic changes when assessing the primary outcome and will provide free EA treatment sessions to patients in the control group after the end of the follow-up period.

The primary objective of this clinical trial is to assess the efficacy of EA treatment in reducing weight among obese patients, regulating their blood glucose and metabolism and improving their quality of life. By conducting this trial, we aim to provide reliable scientific evidence for the clinical application of acupuncture in weight management and blood glucose control.

Trial status

This trial is now recruiting participants.

Acknowledgements The authors would be grateful to Dr Victor W Zhong, a professor from the School of Public Health, Shanghai Jiao Tong University School of Medicine, for his valuable advice during the design process. We would like to thank Rayan Abuhait, a student from the International Education College, Shanghai University of Traditional Chinese Medicine, for her language polish on the manuscript.

Contributors SX is the main researcher who provided the conception and designed the study. XY is the co-researcher who contributed to the design of the study and critical revision of the manuscript. XL contributed to the design of the protocol, and writing of the manuscript. JJL and CH contributed to the manuscript draft. BL and FL contributed to the design of the interventions. JYL, XZ and SL contributed to the statistical design and the design of the randomisation method. YM is the project manager and contributed to the revision of the manuscript. All authors read and approved the final manuscript.

Funding This work was supported by Open Projects from the National Major Science and Technology Infrastructure for Translational Medicine (Shanghai) (TMSK-2021-408) and Future Plans from Shanghai Municipal Hospital of Traditional Chinese Medicine (WL-JXXK-2021002K).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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