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Electroacupuncture treatment for sarcopenia: study protocol for a randomized controlled trial

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Abstract

Introduction Sarcopenia is a disease primarily characterized by age-related loss of skeletal muscle mass, muscle strength, and/or decline in physical performance. Sarcopenia has an insidious onset which can cause functional impairment in the body and increase the risk of falls and disability in the elderly. It significantly increases the likelihood of fractures and mortality, severely impairing the quality of life and health of the elderly people. This disease poses a heavy burden on the healthcare system and society in our country, and currently, there are limited clinical intervention strategies for sarcopenia. This study aims to explore the clinical efficacy and safety of electroacupuncture in treating sarcopenia.

Methods and analysis In this parallel-design, randomized, sham-controlled trial, a total of 168 elderly sarcopenia patients will be randomly assigned in a 1:1 ratio to receive either electroacupuncture (EA) or sham electroacupuncture (sEA) treatment. The acupuncture points used in the study are Hegu (LI4), Shousanli (LI10), Quchi (LI11), Binao (LI14), Futu (ST32), Liangqiu (ST34), Zusanli (ST36), and Jiexi (ST41). The participants will receive EA or sEA treatment three times per week for eight weeks. The primary outcome measure is the change in grip strength (GS) of the patients after the eight-week treatment. The secondary outcome measures include the changes in grip strength at the fourth and twentieth weeks, changes in appendicular skeletal muscle mass index (ASMI), the Short Physical Performance Battery (SPPB) score, the physical activity level (PAL) assessed by the International Physical Activity Questionnaire (IPAQ), assessment of expectations regarding the efficacy of acupuncture, patient subjective evaluation of efficacy, and evaluation of blinding efficacy of acupuncture. All statistical analyses will be conducted according to the intention-to-treat principle and as per the study protocol.

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Ethics and dissemination This study protocol was reviewed and approved by the Institutional Review Board of West China Hospital of Sichuan University (permission number: 2023 – 525). The participants will provide written informed consent to participate in this study.

Trial registration Chinese Clinical Trial Registry (http://www.chictr.org.cn), Registration number: ChiCTR2300079294. Date of Registration: 2023-12-29.

Keywords Electroacupuncture, Sarcopenia, Randomized controlled trial

Introduction

Sarcopenia (SP), also known as muscle atrophy or muscle loss, is an age-related disease characterized by a decline in skeletal muscle mass, muscle strength, and/or physical performance. The prevalence of sarcopenia is estimated to be 5–13% in the 60-70-year-old population, and 11–50% in those over 80 years old [1]. The prevalence of sarcopenia in the elderly population in Asia ranges from 5.5–25.7% [2], and in China, the prevalence in community-dwelling elderly males is 12.9% and 11.2% in females [3]. Sarcopenia is insidious in the onset which can lead to functional impairment, increasing the risk of falls and disability in the elderly, significantly increasing the likelihood of fractures [4], increasing the risk of death, and severely compromising the quality of life and health of the elderly, placing a heavy burden on China's healthcare system and society. Currently, there are limited clinical intervention options for sarcopenia; therefore, exploring effective treatment strategies for sarcopenia will provide strong evidence to support the management of this disease.

Current treatment approaches for sarcopenia can be divided into pharmacological and non-pharmacological treatments. Medications mainly include vitamin D, testosterone, and selective estrogen receptor modulators. Supplementation with vitamin D has no significant effect on improving the muscle loss index in community-dwelling older adults [5]. Testosterone supplementation can increase muscle mass in patients with chronic diseases; however, current evidence does not indicate that these patients can improve muscle function through testosterone supplementation [6]. At present, there is no mature evidence for pharmacological intervention in sarcopenia [7]. Non-pharmacological treatment options mainly include resistance-based exercise training and nutritional supplementation. Exercise can effectively improve muscle strength, lower limb muscle mass, and physical fitness in elderly individuals with sarcopenia [8]. In addition, resistance training and various forms of exercise are the preferred options for improving muscle strength, but their impact on upper limb muscle mass is limited, and due to the heterogeneity of exercise modalities, duration, and intensity, training outcomes are not entirely consistent. Older adults may not be able to adequately participate in related functional exercises due to their own illnesses or age-related factors, and further research is needed [9–11]. Some evidence suggests that adequate intake of protein, antioxidants, and long-chain polyunsaturated fatty acids may be beneficial for individuals with sarcopenia [12]. However, methodological limitations in research restrict the strength of this evidence. In summary, there are currently some shortcomings in the treatment system for sarcopenia, limiting the effective management of this disease, and further enrichment and improvement are needed.

The clinical value and effects of acupuncture in the treatment of sarcopenia are gradually being recognized. Acupuncture at acupoints such as "Zusanli(ST36)" can improve walking speed and lower limb functional scores in elderly patients with sarcopenia [13]. Electroacupuncture can improve muscle mass, muscle strength, and mobility in elderly patients with sarcopenia [14]. Electroacupuncture combined with oral essential amino acids for 12 weeks can increase skeletal muscle mass in elderly sarcopenic obese patients compared to oral essential amino acids alone [15]. However, due to methodological flaws in study design, such as lack of allocation concealment, failure to implement blinding, or not assessing skeletal muscle function, it is not yet possible to draw definitive conclusions about the effectiveness of acupuncture in improving muscle mass and function in patients with sarcopenia. Other studies have also shown that acupuncture has no improvement effect on age-related sarcopenia [16]. Therefore, more high-quality evidence is needed to further confirm the clinical efficacy of acupuncture in the treatment of sarcopenia.

Therefore, we designed a rigorous, randomized controlled clinical study to explore the clinical effects of electroacupuncture treatment on elderly sarcopenia.

Methods and analysis

Study design

This study is a single-center, randomized controlled trial. Voluntary patients who meet the inclusion criteria will be openly recruited at West China Hospital of Sichuan University. All patients must understand and sign an informed consent form before enrollment. Each center will strictly follow the diagnostic criteria, inclusion criteria, and exclusion criteria to screen cases. After confirming enrollment, a random number will be obtained by

applying the random code process until the total number of observed cases is completed, ending the trial.

Recruitment

This trial will be conducted at West China Hospital of Sichuan University. The diagnostic criteria for muscular dystrophy will follow the "2019 Asian Consensus on Muscular Dystrophy Diagnosis." When patients visit the hospital, they will first be provided with informed consent, followed by an evaluation of their condition by professional researchers and completion of a preliminary screening form. Patients who pass the preliminary screening will undergo baseline evaluations and relevant examinations for further selection. Patients who meet the inclusion criteria will be further confirmed for the feasibility of being randomly assigned to either the acupuncture group or the standard treatment group. Figure 1 illustrates the study flowchart.

Diagnostic criteria

The diagnosis of sarcopenia is based on the "2019 Asian Sarcopenia Diagnosis Consensus" published by the Asian Working Group for Sarcopenia (AWGS). A diagnosis can be made if both points (1) and (2) or points (1) and (3) are met, or if all three points are met:

(1) Reduced muscle mass: bioelectrical impedance analysis (BIA) with a male ASMI < 7.0 kg/m2 and a female ASMI < 5.7 kg/m2; (2) Decreased muscle strength: male grip strength < 28 kg, female grip strength < 18 kg; (3) Decreased muscle function: Short Physical Performance Battery (SPPB) score ≤ 9.

Inclusion criteria

(1) Meets the diagnostic criteria for "sarcopenia" as outlined in the "2019 Asian Sarcopenia Diagnosis Consensus" published by the Asian Working Group for Sarcopenia; (2) Age between 60 and 80 years old, no gender

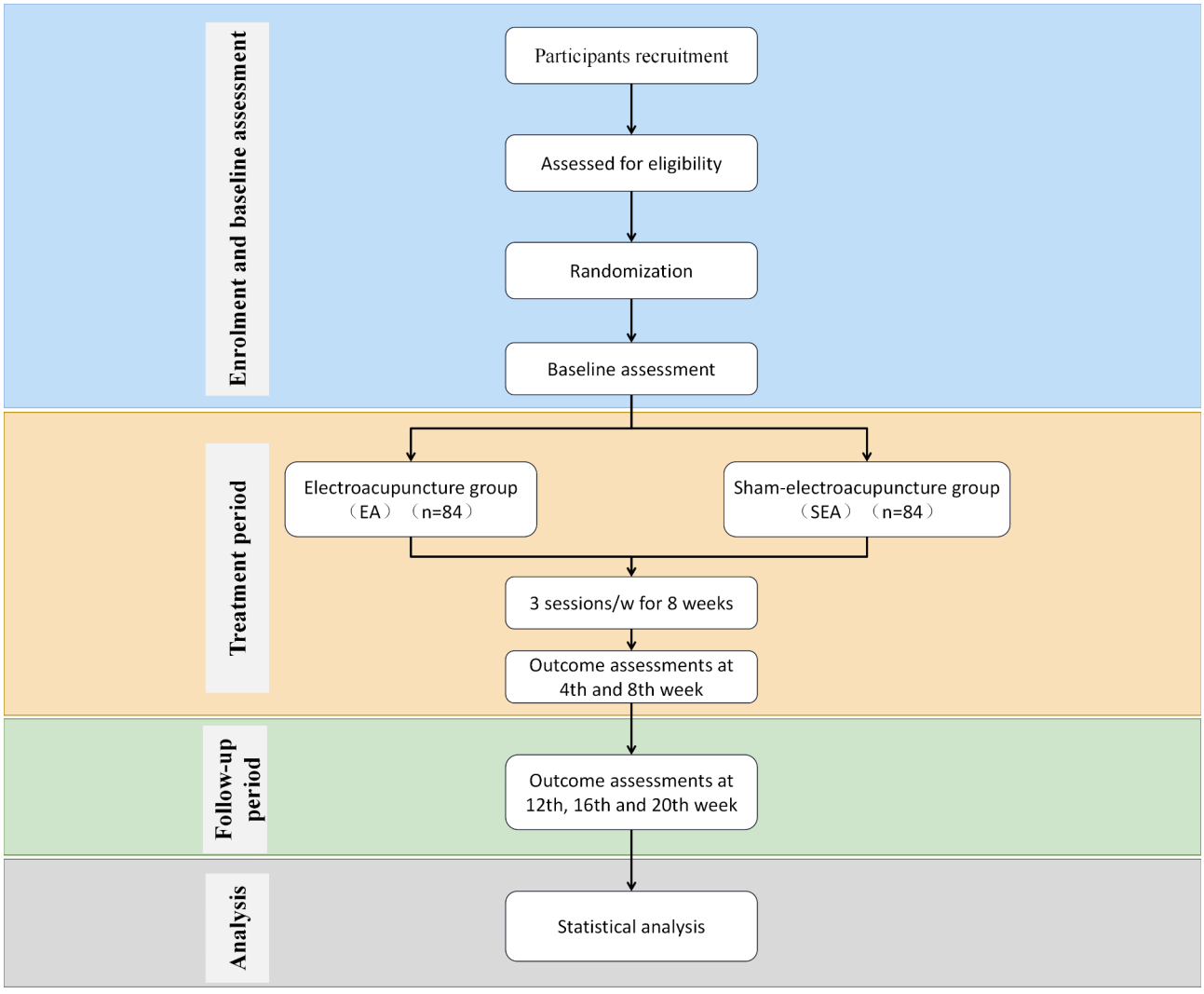

Fig. 1 Flow chart of the study procedure

restrictions; (3) Signs the informed consent form and voluntarily participates in this trial.

Exclusion criteria

(1) Suffering from severe kidney disease (glomerular filtration rate < 30 mL/min); (2) Suffering from moderate to severe liver function failure (Child-Pugh Class B or C); (3) Suffering from endocrine diseases related to calcium metabolism disorders (excluding osteoporosis); (4) Suffering from neuromuscular diseases; (5) Taking medications that have a significant impact on musculoskeletal function; (6) Suffering from mental illness, cancer (within the past 5 years); (7) Individuals with drug or alcohol dependence or abuse; (8) Patients participating in other clinical trials.

Withdrawal criteria

(1) Specialist physicians are responsible for assessing serious adverse reactions that occur during the study, determining whether to continue or terminate the study; (2) During the study, if symptoms worsen or severe complications or other serious diseases occur that require emergency measures; (3) Researchers discover serious safety issues; (4) Patients who cannot continue treatment for various reasons; (5) The trial participant withdraws informed consent.

Randomization and masking

This study has a single-blind design. Participants will be unaware of their group allocation, which will only be known to the lead investigator and acupuncture physician. The participants are randomly assigned to EA group and sEA group at a 1:1 ratio. The random sequence will be generated and masked by an online response system maintained by the statisticians. Randomization is stratified by site and defined with a block size of 6. All relevant parameters set during the randomization process are saved in the blinding information. When a qualified participant is enrolled, the person responsible for randomization or clinical researchers will apply for a random number using the central randomization system.

Intervention

Electroacupuncture (EA) group

1) Main Acupoints: Binao (LI14), Quchi (LI11), Shousanli (LI10), Hegu (LI4), Futu (ST32), Liangqiu (ST34), Zusanli (ST36), and Jiexi (ST41).

2) Procedure: Routine disinfection of acupoints. The Hegu (LI4) Point is located on the back of the hand, at the midpoint of the second metacarpal bone on the radial side. Insert a 0.30 mm×25 mm filiform needle obliquely to a depth of 0.5-1 cun. The Shousanli (LI10) Point is located on the forearm, 2 cun below the transverse crease of the elbow. Insert a 0.30 mm×40 mm filiform needle vertically to a depth of 1-1.5 cun. The Quchi (LI11) Point is located at the elbow, at the midpoint of the line connecting the cubital fossa and the external epicondyle of the humerus. Insert a 0.30 mm×40 mm filiform needle vertically to a depth of 1-1.5 cun. The Binao (LI14) Point is located 7 cun above the elbow, on the anterior edge of the deltoid muscle. Insert a 0.30 mm×40 mm filiform needle vertically to a depth of 1-1.5 cun. The Futu (ST32) Point is located in the anterior thigh area, 6 cun above the bottom of the patella, on the line connecting the anterior superior iliac spine and the lateral edge of the patella. Insert a 0.3 mm×50 mm filiform needle vertically to a depth of 1–2 cun. The Liangqiu (ST34) Point is located in the anterior thigh area, 2 cun above the bottom of the patella, between the vastus lateralis muscle and the rectus femoris tendon. Insert a 0.30 mm×40 mm filiform needle vertically to a depth of 1-1.5 cun. The Zusanli (ST36) Point is located on the outer side of the lower leg, 3 cun below the outer knee point, Insert a 0.3 mm×50 mm filiform needle vertically to a depth of 1–2 cun. The Jiexi (ST41) Point is located in the ankle area, in the central depression in front of the ankle joint, between the long extensor tendon of the big toe and the long extensor tendon of the toes. Insert a 0.30 mm×25 mm filiform needle vertically to a depth of 0.5-1 cun. Immediately after needling, perform vigorous lifting, thrusting, and twisting techniques. Followed by electroacupuncture stimulation, with one set of electroacupuncture connected to the same side's Quchi (LI11) Point and Hegu (LI4) Point, and another set connected to the same side's Futu (ST32) Point and Zusanli (ST36) Point. A total of 4 sets of electroacupuncture, with a continuous frequency of 2 Hz and each electroacupuncture stimulation lasting for 30 min. After enrollment, treatment is conducted 3 times per week for 8 weeks.

Sham electroacupuncture(sEA) group

1) Main Acupoint: Same acupoint as the EA Group.

2) Procedure: The Park sham placebo acupuncture device (PSD) is used for the procedure. The PSD is a dull-tipped retractable needle. The acupuncturist inserts the needle into the cannula, and once the blunt tip contacts the skin, the needle retracts into the handle, without penetrating the skin. After the needle insertion is completed, the device is connected to a placebo electroacupuncture device that only has a flashing current indicator light but no actual current output, following the same connection method as the EA group.

Observation Period: A total of 21 weeks, including a 1-week baseline period, an 8-week treatment period, and a 12-week follow-up period.

The selected acupoints and their locations are shown in Fig. 2.

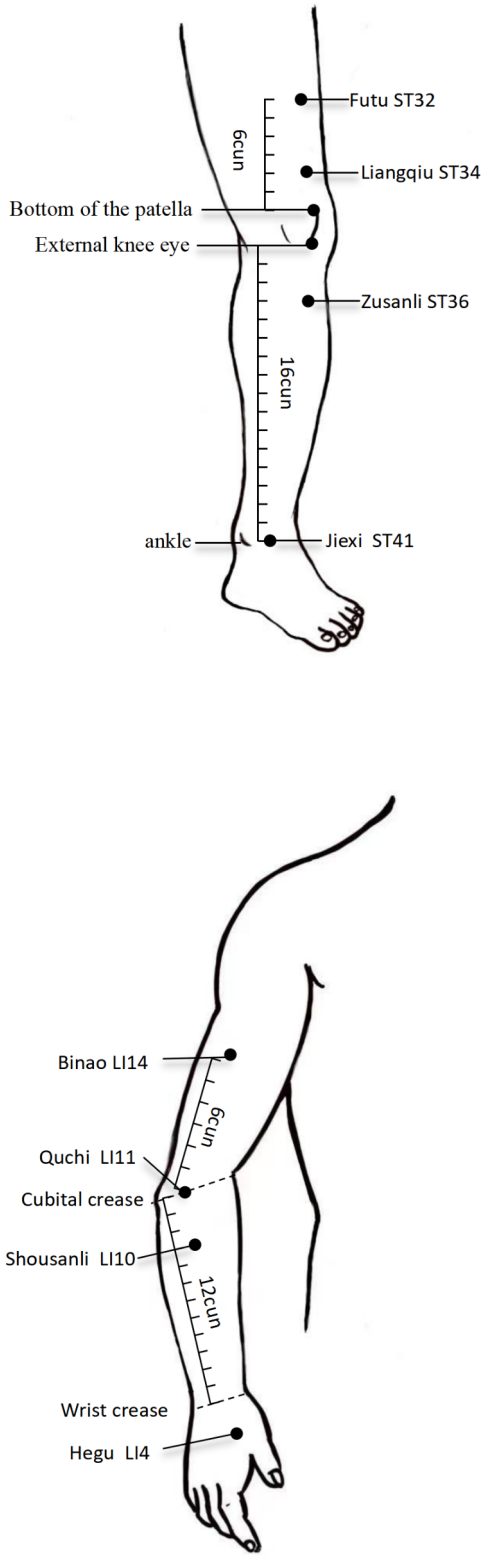

Fig. 2 Localisation of acupoints

Outcome measures

Primary outcome

Patient's grip strength (GS) change after 8 weeks of treatment: Grip strength of the dominant hand was measured using a dynamometer at both baseline and the end of the 8-week treatment period. Three measurements were taken with a 5-minute rest interval between each measurement. The average of the three measurements was calculated. The grip strength change rate was then calculated using the following formula: Grip Strength Change Rate = (Post-treatment Grip Strength-Pre-treatment Grip Strength)/Pre-treatment Grip Strength × 100%.

Secondary outcomes

1) Patient's grip strength change rate at week 4 and week 20: Grip strength of the dominant hand was measured using a dynamometer at week 4 and week 20. Three measurements were taken with a 5-minute rest interval between each measurement. The average of the three measurements was calculated. The grip strength change rate was then calculated by comparing it to the baseline grip strength.

2) Appendicular Skeletal Muscle Index (ASMI) change rate: Patient's body composition analysis was conducted using the Inbody bioelectrical impedance analysis device (BioSpace, Seoul, Korea). The commonly used SMI was used for evaluation. The SMI change rate was calculated using the following formula: SMI Change Rate = (Post-treatment SMI - Pre-treatment SMI) / Pre-treatment SMI × 100%.

3) Muscle Function Evaluation: The Short Physical Performance Battery (SPPB) was used to evaluate the muscle function of the patients.

4) Daily Function Assessment: The International Physical Activity Questionnaire (IPAQ) will be used for the assessment of It mainly evaluates the frequency and duration of common activities in the past week. Based on the metabolic equivalent tasks (METs) of each activity, weekly energy expenditure is calculated to assess the patient's daily activity level.

5) Subjective Assessment of Treatment Efficacy by Patients: ① Using a Visual Analog Scale (VAS), please rate your subjective perception of the effectiveness of electroacupuncture. A score of 0 indicates no improvement, while a score of 10 indicates complete improvement. ② Ask patients to evaluate whether electroacupuncture is helpful in treating muscle atrophy using a 7-point scale.

6)Serum inflammatory factor levels: Blood samples were collected from patients to measure CRP, IL-6, and TNF-α levels.

7) Expectation Evaluation of Electroacupuncture and Its Correlation with Primary Outcome Measures: ① Do you believe that electroacupuncture treatment will be effective for your condition? Yes, no, unsure. ② Do you think electroacupuncture will be helpful in improving symptoms such as muscle weakness? Yes, no, unsure. ③ Using a Visual Analog Scale (VAS), please rate your expectation of the effectiveness of electroacupuncture. A score of 0 indicates no improvement, while a score of 10 indicates complete improvement.

8) Evaluation of Electroacupuncture Blinding: Inform the patients about two treatment methods, one being electroacupuncture and the other being placebo electroacupuncture. Then ask the patients to choose: Do you think you received electroacupuncture treatment? Don't know, yes, no. Simultaneously evaluate the effectiveness of electroacupuncture blinding and its correlation with the patients' experience with electroacupuncture.

The outcome measurement time points are provided in detail in Table 1.

Safety evaluation

EA-related safety evaluation during treatment includes the documentation of broken needles, fainting due to needles, intolerable pinprick pain, local hematoma, infection, abscess, and other incidences of discomfort after pinprick. Adverse events will be recorded by the acupuncture physician on a standardized form.

Sample size

Based on the results of previous similar studies (Soares Mendes Damasceno G, et al. Acupuncture Treatment in Elderly People with Sarcopenia: Effects on the Strength and Inflammatory Mediators. J Aging Res. 2019 Jan 27;2019:8483576), we used a two-sided test of difference and calculated the sample size using PASS 15 software. The average grip strength for the acupuncture group was 24.4 with a standard deviation of 8.59, while the control group had an average grip strength of 21.5 with a standard deviation of 4.51. With $\alpha=0.05$, $\beta=0.2$, and Power = 0.8, each group required 70 participants. Considering a 20% dropout rate causing sample size loss, each group needed 84 participants, totaling 168 participants required for the study.

Statistical analysis

The data will be analyzed by R software (R Foundation), version 4.2.1. An independent statistician who does not know the group assignments will run the statistical analysis. Continuous variables will be described as mean ± SD with a 95% CI in a normal distribution and median (range) in abnormal distribution, while categorical variables will be represented by numbers (percentages). All statistical tests will be two-sided, and a p value <0.05 will be considered statistically significant.

All analyses will be performed according to intention-to-treat (ITT) protocol. Participants who finish the baseline assessment of primary outcome and receive at least

Table 1 Details of the planned visit schedule

Stage	Baseline period	Treatment period		Follow-up period		
Time point (week)	-2	4	8	12	16	20
Enrolment						
Eligibility screen	X					
Informed consent	X					
Demographic characteristics	X					
Medical history	X					
Expectation of electroacupuncture	X					
Assessments						
Grip strength	X	X	X	X	X	X
ASMI	X	X	X	X	X	X
SPPB	X	X	X	X	X	X
Daily Function	X	X	X	X	X	X
Gut microbiota	X		X			X
Serum untargeted metabolomics sequencing	X		X			X
Serum inflammatory factor levels	X		X			X
Usage of emergency drug or surgery	X					
Self-evaluation of therapeutic effects	X					
Rate of adverse events	X					

one session of either EA or sEA will be included in the ITT analysis. The missing values will be imputed by multiple imputations. Per-protocol population analysis will be also performed, for participants who have finished at least 80% of the treatment protocol after randomization.

The primary analysis used a linear regression model to test whether acupuncture improved GS more than sham acupuncture. Secondary analyses were done for other outcomes. Continuous data (SMI, SPPB, IPAQ scores, serum inflammatory factor levels; and patient subjective evaluation of efficacy) were analyzed using the same linear regression model. Categorical and count datawill be compared by the $\chi 2$ test or Fisher's exact test.

Discussion

The pathogenesis of sarcopenia is complex, involving factors such as age-related anabolic hormone changes, loss of motor neurons, apoptosis of muscle satellite cells, and mitochondrial dysfunction. Among these factors, inflammation plays a crucial role in the pathophysiology of sarcopenia. Studies have shown that the inflammatory marker C-reactive protein (CRP) is negatively correlated with muscle strength and mass [17]. Elevated levels of high-sensitivity CRP (hs-CRP), tumor necrosis factor α (TNF-α), and interleukin-6 (IL-6) are significant risk factors for sarcopenia [18]. A cohort study of Chinese subjects found that high levels of inflammatory markers IL-6 and TNF-α were associated with an increased risk of sarcopenia, and logistic regression analysis showed that high levels of TNF-α (11.15 pg/ml) increased the risk of sarcopenia by 7.6 times [19]. Elevated serum IL-6 and TNF-α levels can not only predict the occurrence of sarcopenia but also predict adverse clinical outcomes such as disability and death [20]. A meta-analysis showed that high levels of CRP, IL-6, and TNF-α were negatively correlated with grip strength, knee extension strength, and muscle mass, indicating that high levels of circulating inflammatory markers are significantly associated with lower skeletal muscle strength and mass [21]. It is still unclear whether electroacupuncture can exert its clinical effects on sarcopenia treatment by modulating the levels of inflammatory mediators.

Therefore, this study focuses on elderly sarcopenia patients and adopts a randomized controlled trial design. In addition to exploring the clinical effects of electroacupuncture treatment for elderly sarcopenia, we aim to preliminarily investigate the potential underlying mechanisms involving and inflammatory responses. Our goal is to provide a new treatment option for elderly sarcopenia patients, break through therapeutic bottlenecks, and ultimately benefit numerous patients.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12906-024-04723-8.

Supplementary Material 1

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Author contributions

HL and LZ contributed equally to this article. HL, LYL and LZ conceived the idea for this study. XZ participated in the design and drafted the manuscript. QW and YH will be responsible for recruiting subjects. CX and YJ are responsible for collecting the data. LT, BMZ and NL contributed to the final version of the manuscript. LZ and LYL will be responsible for monitoring

this study. All authors contributed to manuscript revision and have read and approved the submitted version.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics and dissemination
This study protocol was reviewed and approved by the Institutional Review Board of West China Hospital of Sichuan University. The participants will provide written informed consent to participate in this study.

Conflict of interest
The authors declare that the research will be conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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