Effects of sitting-style Baduanjin on older adults with heart failure: Study Protocol for a Randomized Controlled Trial

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Study protocol

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**Additional Declarations:** No competing interests reported.
Abstract

Importance:
Heart failure (HF) is a complex disease, mainly caused by structural or functional changes such as ventricular filling or cardiac ejection, leading to clinical symptoms and signs and seriously affecting patients' quality of life. Guideline-directed medical therapy can significantly alleviate patients' symptoms and reduce mortality and hospitalization rate. Exercise can improve cardiopulmonary function, and all major guidelines unanimously recommend exercise-centered cardiac rehabilitation. However, unscientific exercise increases myocardial oxygen consumption and aggravates symptoms in patients with HF. Therefore, choosing appropriate exercise to improve patients' exercise tolerance and quality of life has become a research hotspot. Sitting Baduanjin, a traditional Chinese exercise method that combines movement with rest, is easy to understand, highly recognized by society, and can be widely promoted. Moreover, some studies have indicated that sitting Baduanjin can ameliorate cardiopulmonary function and improve patients' quality of life. Therefore, studying the influence of sitting Baduanjin on senile HF is significant.

Methods and analysis:
This single-blind randomized controlled trial is designed to demonstrate that regular sedentary exercise and guided medication can significantly improve the quality of life of patients with HF. In this trial, 136 eligible patients will be randomly assigned to the Baduanjin and control groups in a ratio of 1:1. The Baduanjin group will practice sitting Baduanjin at home (45 min each time, three times a week) along with routine treatment, while the control group will only receive basic routine treatment. The primary outcome is the Minnesota HF questionnaire. Secondary outcomes include N-terminal proB-type natriuretic peptide (NT-proBNP), left ventricular end-diastolic diameter (LVEDD), left ventricular ejection fraction (LVEF), and left ventricular end-systolic diameter (LVESD). Researchers blinded to treatment allocation will analyze the data.

Conclusion
This study will provide strong evidence to establish regular sitting-style Baduanjin exercise effectiveness in significantly improving the quality of life of patients with HF.

Clinical registration:
We have registered with the China Clinical Trials Registration Center on November 18, 2022, the registration number is ChiCTR2200065921.
1. Introduction

According to China's cardiovascular health and disease report in 2021, there are approximately 8.9 million heart failure (HF) cases in China. The morbidity and mortality of HF remain high, which seriously threatens people's lives and property safety. HF is a complex syndrome with symptoms and signs such as fatigue, dyspnea, and fluid retention (pulmonary congestion and systemic circulation congestion) caused by abnormal cardiac structure or function resulting in ventricular contraction or filling disorder, influencing the patient's quality of life. The treatment recommended in the guidelines can significantly alleviate patients' symptoms and reduce the mortality and hospitalization rate. However, to improve exercise tolerance and patients' quality of life, the American College of Cardiology (ACC) / the American Heart Association (AHA) and the European College of Cardiology recommend exercise rehabilitation for improved cardiac function in patients with HF. Many studies have shown that exercise-centered cardiac rehabilitation can significantly improve exercise endurance, quality of life, and mood, significantly reduce the risk of re-hospitalization and improve the clinical prognosis of patients with chronic HF. It also improves left ventricular remodeling and diastolic function. Therefore, exercise rehabilitation significantly improves exercise tolerance and patients' quality of life in HF.

Choosing a suitable exercise rehabilitation method for patients with HF has become an important research direction for cardiologists and cardiac rehabilitation physicians. Sitting Baduanjin was first seen in the Living the Heart Method about 600 years ago. Sitting eight-segment brocade absorbs the essence of Chinese traditional culture, organically combines medical treatment, sports, and health care, and takes improving the quality of life and the state of life as its basic goal. The sitting Baduanjin consists of 12 movements that combine movement and stillness. The static exercise includes meditation, etc. The dynamic exercise includes sitting exercises and self-massage. The whole set of movements is simple and clear. Breathing, guiding, and thinking cooperate during the exercise. It is easy to learn and practice. The movements are soft, natural, and smooth. It is suitable for people of different ages. To sum up, the sitting Baduanjin has a long history, high social recognition, a combination of movement and stillness, is easy to learn, and the range of exercise is gentle and slow. It is suitable for HF patients with decreased sports endurance and can be widely promoted.

The Minnesota HF Quality of Life Questionnaire is widely used to assess the quality of life of patients with HF from multiple dimensions of physical and social restrictions, emotions, and symptoms and has been widely recognized by clinicians.

Based on the above background, we designed a trial, the effect of sitting Baduanjin on older patients with HF, to compare the 8-week sitting Baduanjin combination guidance treatment and the guidance treatment.

2. Materials and methods

2.1 Design and implementation
This study adopts a prospective, randomized, controlled clinical design to be implemented mainly by Baoding No. 1 Hospital of Traditional Chinese Medicine and Guang’anmen Hospital of the Chinese Academy of Traditional Chinese Medicine. After obtaining informed consent, 136 eligible participants will be included and randomized into the sitting Baduanjin and control groups in a ratio of 1:1. The Baduanjin group will receive 8 weeks of sitting Baduanjin training combined with Guideline-directed medical therapy (GDMT). The control group will receive GDMT. Figure 1 shows the specific process of this study. This experiment follows the SPIRIT guidelines[14] and meets the criteria for reporting trials[15].

2.2 Recruitment

Patients will be recruited by putting up posters, etc., and they will be recruited to the first traditional Chinese Medicine Hospital in Baoding and Guanganmen Hospital. The researchers will communicate with potential participants, who will be informed about the study, including objectives, processes, interventions, observation indicators, testing procedures, testing methods, benefits, and possible adverse reactions. The researchers will screen patients, and patients who volunteer for the study will sign an informed consent form.

2.3 Study population

2.3.1 Inclusion criteria

This clinical trial will include those who meet the following conditions:

1) Age $\geq$ 60 years.

2) Conform to the diagnostic criteria for chronic HF (refer to the management guidelines for HF issued by the ACC / AHA / American HF Association in 2022).

3) The NYHA classification of cardiac function is II, III, and IV (refer to the NYHA classification issued by New York Heart Association).

4) Sign the informed consent form.

2.3.2 Exclusion criteria

Anyone with any of the following shall be excluded:

1) Severe congestive heart failure (CHF) or restricted activities for other reasons.

2) Acute attack period of CHF.

3) Hypertension (systolic blood pressure $\geq$ 160mmHg and/or diastolic blood pressure $\geq$ 100mmHg).

4) The resting heart rate exceeds 100 bpm, or it is accompanied by malignant arrhythmia (paroxysmal ventricular tachycardia).
5) Complicated with severe hepatic and renal insufficiency.

6) Serious respiratory diseases, such as cor pulmonale, respiratory failure, etc.

7) Psychosis and moderate neurosis.

8) Complicated with severe primary diseases such as hematopoietic system and tumor.

9) Practicing traditional Chinese medicine skills (such as Taijiquan, Wuqinxi, etc.) not later than 3 months.

2.3.3 Criteria for rejection, shedding, and termination

2.3.3.1 Rejection: Participants who should not be included but have been included in the group, including those who were wrongly accepted, misdiagnosed, did not receive any Baduanjin intervention, or did not have any test records. No statistical analysis of the curative effect will be made for these cases.

2.3.3.2 Shedding: Cases that have been enrolled but have not completed clinical observation, including patient resource stop, loss to follow-up, compliance check (Baduanjin intervention has not been completed by 30%), or the researcher considers it necessary to stop the test according to the patient's physical movement evaluation. The reason for the shedding case shall be explained. If there is baseline exercise evaluation data, the last major efficacy index result shall be transferred to the final result for statistical analysis, and the case report form (CRF) shall be kept for future reference.

2.3.3.3 Termination: In the course of this study, if participants have cardiovascular events, including cardiac death, myocardial infarction, readmission due to acute attack of CHF/acute coronary syndrome/malignant arrhythmia, or other cardiovascular and cerebrovascular diseases that restrict activities, the trial should be stopped, the study should be terminated in advance, and the CRF should be recorded in detail.

2.3.4 Randomization and Blinding

The participants will be randomly divided into the Baduanjin and control groups in a ratio of 1:1. The grouping information will be sealed in an opaque envelope, and participants will be recruited without knowledge of the grouping. After opening the envelope, the investigator will get the serial number of the participant and the grouping information.

The details of the participants and coaches will be concealed during the trial because the intervention items are completely different. Similarly, the operators, inspectors, result analysts, and statisticians of ultrasonic electrocardiograms will be unknown.

2.3.4.1 Baduanjin Exercise Group
1) The Baduanjin group will practice sitting Baduanjin along with drug treatment. The sitting style Baduan Brocade adopts the exercise intensity and movement arrangement standard of the traditional Chinese medicine sitting style Baduan Brocade (hereinafter referred to as the national sports version of sitting style Baduan Brocade) promoted by the Fitness Qigong Management Center of the General Administration of Sport of China including massaging the head and neck, tapping the teeth and gargling, scraping the eyebrows and rubbing the eyes, tinnitus and drumming, moving the arms and strengthening the waist, rubbing the abdomen and dredging the intestines, and observing the interest and regulating the heart (Figure 2).

2) Week -2-0: The participants in the Baduanjin group will learn the sitting Baduanjin under the guidance of the doctors and nurses who have mastered the procedure, and the guiding doctors and nurses will determine the action standard. The patient's condition is evaluated by cardiovascular experts, which can meet the exercise intensity of $\geq 45$ min.

3) Week 1-8: Sitting Baduan Brocade Exercise Period: The participants will exercise at home against the pictures of the sitting Baduan Brocade in the national sports version three times weekly, 45 min each time.

4) Assess the patient at week 9.

2.3.4.2 Control group

The control group was only given conventional drug treatment.

2.3.4.3 Concomitant Treatment

All participants shall receive GDMT, such as angiotensin receptor enkephalinase inhibitors (Sacubitril-valsartan tablets), angiotensin II receptor antagonists (such as irbesartan and telmisartan), angiotensin-converting enzyme inhibitors (such as enalapril and benazepril), $\beta$ receptor blockers (such as atenolol and bisoprolol), mineralocorticoid receptor antagonists (spironolactone, eprodisone), sodium-glucose transporter inhibitors (dapagliflozin, empagliflozin), diuretics (furosemide, torsemide), etc. During the clinical observation, according to the complications such as hypertension, arrhythmia, diabetes, and other diseases, corresponding treatment can be given, but it should not affect the efficacy of this study. In the CRF, the investigator shall detail the reason for drug use, drug name, dosage, etc.

2.4 Outcomes

2.4.1 Primary and Secondary Outcomes

Table 1 shows the outcome indicators to be tested and the time for data collection.

The primary outcome index of this experiment is Minnesota living with HF questionnaire (MLHFQ), and the researchers will collect data before and after the intervention. The contents include physical,
emotional, and other fields with eight, five, and eight corresponding items. The score of each project is 0-5, with a total of 105 points. The score is inversely proportional to the quality of life.

The secondary outcomes are NT-proBNP, LVEF, LVEDD and LVESD.

Table 1: Measurement time of outcome index.

<table>
<thead>
<tr>
<th>Study phase</th>
<th>Screen/e enrollment</th>
<th>Allocation</th>
<th>Intervention period</th>
<th>Intervention end</th>
<th>Follow-up period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time points</td>
<td>Screen/e enrollment</td>
<td>Allocation</td>
<td>Intervention period</td>
<td>Intervention end</td>
<td>Follow-up period</td>
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<tr>
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<td>Random allocation</td>
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<tr>
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<tr>
<td>Control group</td>
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<tr>
<td>Outcome</td>
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<tr>
<td></td>
<td>NT-proBNP</td>
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<td>LVEF</td>
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<td>LVESD</td>
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2.5 Safety index

The researchers will measure safety indicators, including routine blood tests, liver and kidney function tests, and electrocardiograms at weeks 0 and 8. They will also monitor the patient's vital signs during the trial and at the 8-week follow-up.

2.6 Quality Control

Before the experiment, all the researchers will be given unified training to understand this experiment's research scheme fully. Special researchers will be responsible for urging patients to complete their daily exercise. The investigators will record the data before and after the intervention and keep the data in the CRF. The CRF will be kept in the doctor's office and only accessible to the researchers. The clinical questionnaire will be improved and revised after case review, literature research, and expert argumentation. Investigators can participate in the clinical investigation only after they have received
unified training and passed the consistency assessment. After the clinical investigation, the completed questionnaire shall be reviewed and evaluated by a physician in the research team with the title of deputy director or above.

2.7 Data collection and management

During the experiment implementation, we will communicate by telephone to ensure the integrity of the experimental data for patients who deviate from the intervention. After the intervention, we will fill in the CRF with the collected data (including patients’ basic information and the data to be collected before and after the intervention). Patients' cases and test sheets will be kept intact in the hospital. Only authorized researchers, ethical review committees, and relevant management departments can access patient information. Important information, such as the patients’ names and ID card numbers, will not be disclosed in possible future papers. The core staff of the experiment will do everything possible to protect patients’ privacy as permitted by law.

2.8 Sample Size

This experiment is a randomized controlled trial implemented using SAS 9.0 statistical software. The western medicine standard treatment scheme specified in the guidelines, combined with health education, is selected as the control group. The sitting Baduanjin treatment and standard western medicine treatment are selected as the test group. The number of cases in the test and control groups in this clinical trial is assigned in a ratio of 1:1. According to the literature report, the MLHFQ score of patients with chronic HF after sitting Baduanjin treatment was 9.96 ± 2.18, and the MLHFQ score of patients with chronic HF in the control group was 11.16 ± 2.26. According to bilateral inspection (α= 0.05, β= 0.2, efficacy=80%), the estimated number of cases in the treatment group should be 54, and 54 in the control group[16]. The formula is as follows:

\[ n = \left( \frac{z_{α/2} + z_β}{δ / σ} \right)^2 \left( Q_1^{-1} + Q_2^{-1} \right) \]

Q1 and Q2 are sample proportions, i.e., Q1=n1/n, Q2=n2/n, n=n1+n2. If n1=n2, Q1=Q2=0.5. z is the difference between the two groups, σ combines the standard deviation for the two groups.

Considering the factor of abscission, the case is increased by 20% abscission rate. The number of cases in this clinical trial is determined as follows: a total of 136 participants, including 68 in the experimental group and 68 in the control group.

2.9 Statistical methods

The results of the experiment will be statistically analyzed by using SPSS25 for unwitting researchers. When patients are enrolled in the group, we will analyze their basic population data to ensure the comparability of this trial. We will test the normality of the collected receipts, and the measurement data
that conform to the normal distribution will be described in the form of mean ± standard deviation; the median is used to describe measurement data that do not conform to normal distribution. Independent sample t-test or single-factor variance is used to analyze counting data in accordance with normal distribution, while nonparametric test or chi-square test is used to analyze counting data that do not conform to normal distribution. p<0.05 means statistically significant.

2.10 Safety Assessment

The safety of this study will be evaluated using the safety index. The researchers will evaluate adverse events (disability, death, etc.) that occur during treatment and report them to the Ethics Committee. Damages related to the study shall be dealt with accordingly after being identified by the Medical Malpractice Identification Committee of Baoding City and followed up until the recovery, or the condition is stable; the hospital will bear the cost.

3. Discussion

The purpose of this experiment is to evaluate the efficacy and safety of sitting Baduanjin in the treatment of patients with HF, and whether it can be promoted as a rehabilitation exercise for patients with heart failure.

HF refers to abnormal changes in the structure and function of the heart.\[17\]. The data show that the incidence of HF is mostly flat or declining in the past 10 years, and although great efforts are being made to treat and manage heart failure, mortality and hospitalization burden are still on the rise.\[18\]. A prospective study shows that cardiopulmonary function is negatively correlated with mortality from cardiovascular disease.\[19\]. In recent years, exercise has been regarded as a tool for the diagnosis and prognosis of chronic HF as well as a therapeutic intervention, but for patients with HF, how to exercise has always been a hot topic. Previous experiments have proved that Baduanjin has a significant effect on improving the motor ability, physical function and quality of life of patients with HF.\[11, 13, 20, 21\]. And a new systematic review shows that there are no serious adverse events reported among the participants in Baduanjin exercise, and the sport is relatively safe.\[22\]. Based on this, we designed this experiment.

This randomized, single-blind trial aims to verify the capacity of sitting Baduanjin to improve the quality of life of patients with HF. As everyone knows, HF reduces activity tolerance and seriously affects patients' quality of life. With the in-depth study of HF, the use of drugs inhibiting ventricular remodeling, slowing myocardial oxygen consumption, and inducing diuresis can reduce the symptoms and mortality of patients with HF. However, how to improve the activity tolerance of patients is still a great challenge. Therefore, exercise-centered cardiac rehabilitation can significantly improve exercise endurance and is strongly recommended by various guidelines. Sitting Baduanjin is a traditional Chinese exercise method which combines movement with rest. It is suitable for patients with HF who have decreased exercise endurance. Therefore, it is meaningful to study whether regular sitting Baduanjin exercise can improve the activity tolerance of patients with HF.
This experiment mainly has the following limitations. This study is a two-center clinical trial with a relatively small sample size. The participants in the experiment are mainly Chinese, and it is unclear whether it will produce similar results in people of other races. The follow-up period of this experiment is only 8 weeks. To observe the effect of sitting Baduanjin on improving HF patients, we can appropriately prolong the follow-up time and observe its long-term effect.

**Declarations**

**Ethics approval and consent to participate**

The study was conducted in accordance with the principles outlined in the Helsinki Declaration. The study has been approved by the ethics committee of Baodiing NO.1 Hospital of Traditional Chinese Medicine bdsdyzzyy-IRB-20220929-001. This study has been registered in the Chinese Clinical Trials Registry (ChiCTR2200065921).

**Consent for publication**

Not applicable

**Availability of data and materials**

Not applicable

**Competing interests**

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

**Funding**

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**Authors’ contributions**

WM, JX, JMH, LR, LMW, and SHL developed and conceived the study. WM and LMW designed the study protocol and developed the intervention. WM and JX wrote the first draft of the manuscript and participated in the coordination and implementation of the study. WM revised and finalized the study protocol. †These authors contributed equally to this work and share first authorship.
References


Figures
Figure 1

Experimental flow chart.
Figure 2

Eight postures of Baduanjin exercise.