

# Baduanjin exercise for alleviating bone pain and improving balance function in patients with primary osteoporosis: a randomized controlled trial

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## Plain English summary of protocol

### Background and study aims

Osteoporosis is a systemic bone disease caused by the decrease of bone density and bone quality due to various reasons. With the aging of the world's population, traditional Chinese exercises such as Baduanjin have attracted attention for the treatment of osteoporosis in recent years. Studies have shown that it improves bone mineral density and reduces clinical symptoms, and its safety is relatively good. To sum up, Baduanjin exercise is suitable for clinical promotion due to its easy-to-learn movements, no site constraints, safety, and effectiveness. This study aims to evaluate the effectiveness of Baduanjin exercise for primary osteoporosis.

### Who can participate?

Patients (female aged between 45 and 70 years combined with female menopause time from greater than 2 years; male aged between 50 and 70 years) with primary osteoporosis

### What does the study involve?

Participants will be randomly divided into two groups (the treatment group and the control group). Patients in the control group will be treated with Calcium Carbonate D3 Chewable tablets and patients in the treatment group will be given Baduanjin exercise combined with Calcium Carbonate D3 Chewable tablets. Lower back pain, balance ability and compliance with health education will be evaluated. All patients will be treated for 6 months and followed up for 6 months after the end of treatment.

### What are the possible benefits and risks of participating?

The possible benefits of this study include relief of lower back pain and improvement in balance ability. The possible risks include accidental fractures and sprains during exercise.

### Where is the study run from?

Wangjing Hospital of China Academy of Chinese Medical Sciences (China)

When is the study starting and how long is it expected to run for?

July 2021 to July 2025

Who is funding the study?

Science and Technology Innovation Project, China Academy of Chinese Medical Sciences (China)

Who is the main contact?

Prof. Xu Wei

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## Contact information

### Type(s)

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

Efficacy of Baduanjin exercise on primary osteoporosis

**Study objectives**

Baduanjin exercise can relieve bone pain and improve balance function in patients with primary osteoporosis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Approved 03/05/2022, Medical Ethics Committee of Wangjing Hospital, China Academy of Chinese Medical Sciences (No. 151, Guangwen Street, Kuiwen District, Weifang City, Shandong Province, 261041, China, Beijing, 100102, China; +86 (0)10-84739223; wjec@163.com), ref: WJEC-YJS-2022-020-P001

2. Approved 03/05/2022, Ethics Committee of Wangjing Hospital of China Academy of Chinese Medical Sciences (Huajiadi Street, Chaoyang District, Beijing; +86 (010) 84739047; email not available), ref: WJEC-WJS-2022-020-P001

## **Study design**

Multicenter randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Primary osteoporosis

## **Interventions**

Patients who meet the inclusion and exclusion criteria will be randomly divided into the control group and the treatment group, with 80 patients in each group. The researchers will entrust a professional data management department to generate random numbers and control data quality. They will use SAS 9.1.2 to generate a random number grouping table according to the number of cases. This form is kept in a safe place by the data management unit. The investigators will be engaged in applying for a random number throughout the trial. According to the group designated by the random number, the clinician accurately records the patient's random number, group, and treatment measures.

Before treatment, general physical examination, laboratory tests (blood), and bone mineral density detection will be conducted while the degree of pain and the ability to balance will be scored.

During the treatment period, patients in the control group will be given Calcium Carbonate D3 Chewable tablets, its dosage will be 0.6 g/time, two times/day, and orally half an hour after meals. Patients in the treatment group will be given Baduanjin exercise combined with Carbonate D3 Chewable tablets. The intervention lasts 6 months. The requirements for the Baduanjin exercise will be:

A) Preparatory stage (the first 2 weeks, familiar with and mastering movement stage):

The patients need to concentrate on practising Baduanjin exercise three times a week. The researchers will hire professional coaches to guide and correct the movements. During the rest of the time, the researchers will distribute free videos to practice by themselves at home.

B) Implementation stage (the last 22 weeks, regular exercise):

The patients need to exercise three times a week, 30 to 60 minutes each time, and the amount of exercise should be as long as the patients do not experience fatigue. The trained members of the research group will lead the exercise once a month, and the rest time will be practised by themselves. The researchers will give monthly follow-up calls or home visits to record the

completion, and adjust the exercise frequency according to the actual conditions. During the trial period, the researchers will instruct the patients to avoid other physical activities as much as possible, such as swimming.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. Lower back pain is measured using the visual analogue scale (VAS, 0-10 points) at baseline, after the 6th month of enrollment, and the 6th month of follow-up after the end of treatment.
2. Balance ability is measured using the Berg balance scale (BBS, 0-56 points) at baseline, after the 6th month of enrollment, and the 6th month of follow-up after the end of treatment.

## **Key secondary outcome(s)**

1. Bone mineral density (BMD) is measured using dual-energy X-ray absorptiometry (DXA) at baseline, after the 6th month of enrollment, and the 6th month of follow-up after the end of treatment
2. Laboratory tests (blood) using Luminex Assay at baseline, after the 6th month of enrollment, and the 6th month of follow-up after the end of treatment. The serological indicators include Type I Procollagen N-terminal Propeptide (P1NP),  $\beta$ -collagen Degradation Product ( $\beta$ -CTX), Myostatin (MSTN), Fibroblast Growth Factor-23 (FGF-23), Neuropeptide Y (NPY).
3. Fall risk is measured using the timed "up and go" test (TUGT) and morse fall scale (MFS, 0-125 points) at baseline, after the 6th month of enrollment, and 6th month of follow-up after the end of treatment
4. Lower extremity muscle strength is measured using five-times sit-to-stand test (FTSST) at baseline, after the 6th month of enrollment, and the 6th month of follow-up after the end of treatment

## **Completion date**

31/07/2025

## **Eligibility**

### **Key inclusion criteria**

1. Primary osteoporosis: T-value of bone density measurement is less than or equal to -2.5
2. Female aged from 45 to 70 years old and female menopause time is greater than 2 years, which are met at the same time. Male aged from 50 to 70 years old
3. Visual analogue scale (VAS) is greater than or equal to 3 points
4. Willing to participate in the study

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Lower age limit**

45 years

**Upper age limit**

70 years

**Sex**

All

**Key exclusion criteria**

1. Lumbar fusion or severe degeneration hinders normal bone mineral density measurement and there are less than two continuous intact lumbar vertebrae that can be evaluated by dual-energy X-ray absorptiometry (DXA)
2. Patients with serious primary diseases such as cerebrovascular, digestive tract, and lung diseases, because these diseases' clinical manifestations may interfere with the results of this study
3. Secondary osteoporosis, including rheumatoid arthritis, multiple myeloma, gout, malabsorption syndrome, systemic lupus erythematosus and metabolic diseases, such as diabetes, thyroid disease, Cushing's syndrome and other diseases
4. The patients take drugs that affect bone metabolism within 3 months before enrollment, such as bisphosphonates, glucocorticoids, calcitonin, anticonvulsant drugs, heparin and other drugs
5. Those with a history of severe mental illness or poor compliance
6. Allergic constitution
7. Those who have participated in other clinical trials within 3 months

**Date of first enrolment**

01/08/2022

**Date of final enrolment**

01/08/2023

**Locations**

**Countries of recruitment**

China

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## Sponsor information

**Organisation**  
China Academy of Chinese Medical Sciences

**ROR**  
<https://ror.org/042pgcv68>

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
China Academy of Chinese Medical Sciences

**Alternative Name(s)**  
CACMS

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
China

## Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		16/09/2023	18/09/2023	Yes	No