ISRCTN76945140 https://doi.org/10.1186/ISRCTN76945140

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

Submission date
01/06/2022

Registration date
07/06/2022

Last Edited
04/08/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
weixu.007@163.com

Contact information

Type(s)
Principal investigator

Contact name
Prof Xu Wei

ORCID ID
https://orcid.org/0000-0001-6723-9604

Contact details
Wangjing Hospital
China Academy of Chinese Medical Sciences
No. 6 Zhonghuan South Road
Huajiadi Street
Chaoyang District
Beijing
China
100102
+86 (0)13488716557
weixu.007@163.com

Type(s)
Scientific

Contact name
Prof Xu Wei

ORCID ID
https://orcid.org/0000-0001-6723-9604

Contact details
Wangjing Hospital
China Academy of Chinese Medical Sciences
No. 6 Zhonghuan South Road
Huajiadi Street
Chaoyang District
Beijing
China

100102
+86 (0)13488716557
weixu.007@163.com

Type(s)
Public

Contact name
Prof Xu Wei

ORCID ID
https://orcid.org/0000-0001-6723-9604

Contact details
Wangjing Hospital
China Academy of Chinese Medical Sciences
No. 6 Zhonghuan South Road
Huajiadi Street
Chaoyang District
Beijing
China
100102
+86 (0)13488716557
weixu.007@163.com

Additional identifiers

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

Primary study design
Interventional

Study design
Multicenter randomized controlled trial

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), β-collagen Degradation Product (β-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

Study participating centre
Wangjing Hospital of China Academy of Chinese Medical Sciences
No. 6 Zhonghuan South Road
Chaoyang District
Beijing
China
100102

Study participating centre
The Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine
No. 28, Shahe Street
Hebei District
Tianjin
China
300150

Study participating centre
Shaanxi University of Chinese Medicine
No. 1, Weiyang West Road
Xianyang
China
712046

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?
Protocol article		16/09/2023	18/09/2023	Yes	No