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The benefits of Baduanjin on the risk of falls and balance in the elderly

Submission date
01/07/2024

Recruitment status
No longer recruiting

Registration date
17/07/2024

Overall study status
Completed

Last Edited
10/07/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Physical function declines in older adults as they age, and failure to detect incorrect body postures or restore balance increases the likelihood of falls. Therefore, improving the balance function of the elderly has become an important goal in geriatric rehabilitation. Baduanjin is one of the traditional Chinese qigong treatment methods. Compared with other forms of exercise, it focuses more on the integration of body and mind and improves the physical function of the elderly and various clinical populations. However, previous studies on Baduanjin have only used subjective scales that indirectly assess fall risk. The effects of Baduanjin on gait biomechanics and balance in older adults are unknown. Therefore, this study evaluated the impact of 12 weeks of Baduanjin on the risk of falls from all aspects, including balance, isometric knee joint strength, and gait parameters.

Who can participate?
People aged 60-75 years who have normal cognitive ability and cognitive impairment

What does the study involve?
Before the intervention, participants were screened for their health status and randomly divided into the Baduanjin group or the control group. Participants are instructed not to reveal their group allocation to the assessor. Before the first week of intervention, the research team spent a week demonstrating and teaching the correct movements, warm-up and stretching skills of these exercises to the participants. The mid-intervention assessment is performed after the sixth week of intervention. While the post-intervention assessment was performed at the completion of the intervention (week 13th). Similar assessments are performed during pre-, mid- and post-intervention.

What are the possible benefits and risks of participating?
Participants can increase balance and reduce the risk of falls by participating in this study and getting their own exercise prescription. The risk mainly includes delayed muscle soreness after exercise. Researchers will protect the safety of the whole sports meeting.

Where is the study run from?
Shanxi Normal University (Malaysia)

When is the study starting and how long is it expected to run for?
February 2023 to February 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Shihao Xie, usmxieshihao1995@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
USM/JEPeM/22080521

Study information

Scientific Title
Effects of 12-Week Baduanjin intervention on the balance, lower limb strength and risks of falls among elderly people

Study objectives
1. HO: After 12 weeks of intervention, the Baduanjin group had no significant effect on the balance among elderly people.

Ha: After 12 weeks of intervention, the Baduanjin group had a significant effect on balance among elderly people.
2. HO: After 12 weeks of intervention, the Baduanjin group had no significant effect on leg strength among elderly people.
Ha: After 12 weeks of intervention, the Baduanjin group had a significant effect on leg strength among elderly people.
3. HO: After 12 weeks of intervention, the Baduanjin group had no significant effect on gait biomechanics among elderly people.
Ha: After 12 weeks of intervention, the Baduanjin group had a significant effect on the gait biomechanics among elderly people.
4. HO: After 12 weeks of intervention, the Baduanjin group had no significant effect on gait stability among elderly people.
Ha: After 12 weeks of intervention, the Baduanjin group had a significant effect on gait stability among elderly people.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/02/2023, Universiti Sains Malaysia Human Research Ethics Committee (Universiti Sains Malaysia Kampus Kesihatan, Kubang Kerian, Kelantan, Kota Bharu, 16150, Malaysia; +60 (0) 9 767 2351; jepem@usm.my), ref: USM/JEPeM/22080521

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Care home, Community, University/medical school/dental school

Study type(s)
Quality of life, Treatment, Safety

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Balance, lower limb strength and risks of falls among elderly people

Interventions
The participants are divided into groups by drawing lots through the blind box with two kinds of paper strips: B and C. The number of two kinds of paper strips is equal, and male participants first drew lots. After the allocation is completed, female participants then drew lots to ensure that the gender ratios of the two groups are consistent. They were randomly divided into two groups. The Baduanjin group received a 12-week Baduanjin exercise intervention, exercising three times a week. The control group underwent walking exercises of equal intensity.

Intervention Type
Behavioural

Primary outcome measure
Risk of falls assessed using the Morse Fall Scale at baseline, week 6, and week 13

Secondary outcome measures
1. Balance function assessed using a single leg standing test at baseline, week 6 and week 13
2. Gait symmetry assessed using gait testing at baseline, week 6 and week 13
3. Knee extensor strength assessed using isometric muscle strength tester at baseline, week 6 and week 13

Overall study start date
02/02/2023

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 60-75 years
3. Have normal cognitive ability and cognitive impairment as indicated by Mini-mental State Examination (MMSE) of <21
4. Not participating in other exercise intervention

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
60 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
46

Total final enrolment
46

Key exclusion criteria

1. Have any diseases associated with the nervous system
2. Have diabetes, cardiovascular diseases, peripheral vascular diseases, implanted electrical devices, non-ambulatory status and presence of systemic inflammatory arthritis
3. Have vestibular dysfunction

Date of first enrolment
01/03/2023

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
China

Study participating centre
Shanxi Normal University
No. 339 Taiyu Road
Xiaodian District
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Sponsor information

Organisation
Universiti Sains Malaysia

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Universiti Sains Malaysia Kampus Kesihatan
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Sponsor type
University/education

Website
https://www.usm.my/index.php/en/

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
25/05/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication