ISRCTN17889491 https://doi.org/10.1186/ISRCTN17889491

Survey and intervention study on the health status of older adults

Submission date
27/04/2025

Recruitment status
No longer recruiting

Registration date
21/05/2025

Overall study status
Ongoing

Last Edited
28/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Subthreshold depression (StD) affects approximately 18.6% of older adults worldwide. There is a paucity of evidence to guide the management of StD in older adults. Baduanjin, a traditional Chinese mind-body exercise, shows promise in addressing this gap in this population. However, the research on its efficacy and underlying mechanisms remains unclear. This study aims to evaluate the effects of Baduanjin exercise on depressive symptoms and StD related symptoms, and to explore the antidepressant mechanisms through a multidimensional assessment of older individuals with StD.

Who can participate?
Older adults aged 60 to 80 years old with StD from six communities

What does the study involve?
This study will randomly assign participants to either a Baduanjin intervention group or a control group for 12 weeks. Primary outcomes (depressive symptoms) and secondary outcomes (anxiety, sleep quality, frailty, biochemical parameters, autonomic nervous function, and brain function) will be assessed at baseline, post-intervention and one-month follow-up. Intention-to-treat analyses will be conducted for all collected data using linear mixed-effects models.

What are the possible benefits and risks of participating?
The present study intends to provide valuable insights into the efficacy of Baduanjin exercise in ameliorating depressive symptoms and StD-related symptoms in older adults with StD. Moreover, this study also seeks to investigate the antidepressant mechanisms of Baduanjin exercise through multimodal neurophysiological assessments. The findings of this study will advance understanding of Baduanjin exercise as a potential non-pharmacological intervention for the management of StD and prevent its progression to major depressive disorder in aging populations.

This is a low-risk interventional study involving no sensitive data or harmful interventions. Therefore, no significant risks are anticipated.

Where is the study run from?
Shandong University, China

When is the study starting and how long is it expected to run for?
August 2022 to July 2026

Who is funding the study?
The National Social Science Fund of China, China

Who is the main contact?
Mingqi Wang, e-mail: wangmingqi 0606@163.com

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Mr Mingqi Wang

Contact details
17922 Jingshi Road
Jinan, Shandong
China
250061
+8617658591347
wangmingqi0606@163.com

Type(s)
Public

Contact name
Mr Benke Xu

Contact details
17922 Jingshi Road
Jinan, Shandong
China
250061
+8617724023477
2665136377@qq.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
National Social Science Fund of China Grant No. 23FTYB003

Study information

Scientific Title
Survey and intervention study on the health status of older adults

Study objectives
We hypothesize that Baduanjin exercise intervention may significantly reduce depressive symptoms among older adults with subthreshold depression.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/08/2022, Ethics Committee of Public Health in Shandong University (44 West Wenhua Road, Ji'nan, Shandong, 250012, China; +86 531 8838 2091; sunshuai@sdu.edu.cn), ref: LL20220801

Study design
Single-blind cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Older adults with subthreshold depression

Interventions
This cluster-randomized controlled trial will enroll a total of 92 older adults with subthreshold depression from six communities, who will be randomly assigned to (1:1 ratio) either a Baduanjin intervention group (three supervised 60-minute sessions/week) or a control group (will not receive any training) for 12 weeks.

Randomization: After completing baseline evaluations, the six communities will be randomly assigned to either the Baduanjin exercise group or the control group in a 1:1 allocation ratio. The allocation sequence, generated via the Sealed Envelope website (www.sealedenvelope.com), will be concealed using sequentially numbered and opaque envelopes by an independent researcher with no involvement in participant recruitment, intervention, and outcome assessment. The envelopes will be opened sequentially only after each community has completed participant recruitment and passed baseline data verification.

Baduanjin intervention: Participants assigned to the Baduanjin group will engage in a 12-week, supervised group-based Baduanjin exercise program. The standardized protocol comprises three 60-minute in-person sessions per week in a community-based setting. This protocol will be in accordance with the Fitness Qigong: Baduanjin guidelines (General Administration of Sport of

China, 2003). Each session will comprise 15 minutes of preparatory exercises (warm-up), 40 minutes of Baduanjin practice, and 5 minutes of post-exercise muscle relaxation.

Intervention Type
Behavioural

Primary outcome(s)
Depressive symptoms measured using the 10-item Center for Epidemiologic Studies Depression Scale at baseline, post-intervention and one-month follow-up

Key secondary outcome(s))
The following secondary outcome measures will be assessed at baseline, post-intervention and one-month follow-up:
1. Cognitive performance will be measured using the Stroop test
2. Anxiety symptoms will be measured using the 7-item Generalized Anxiety Disorder scale
3. Physical frailty will be measured using the Fried frailty phenotype
4. Sleep quality will be measured using the Pittsburgh Sleep Quality Index
5. Heart rate variability will be measured using a physiological monitoring system (DHD-6000, DonghuaYuan Medical Co., Ltd., China)
6. Biochemical parameters will be measured using commercial ELISA kits
7. Gut microbiome will be measured using 16S rRNA gene amplification
8. Magnetic resonance imaging will be collected using a 3.0-T GE MR750 scanner

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Age >=60 years
2. Clinically relevant depressive symptoms (Geriatric Depression Scale-15 [GDS-15] score >=5)
3. No regular physical exercise within the past year (regular exercise defined as 3–4 sessions /week, 30 minutes/session, sustained for >=3 months)
4. Provided informed consent

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. History of depression, bipolar disorder or other psychiatric disorders
2. Contraindications to exercise (e.g., cardiovascular or cerebrovascular diseases, musculoskeletal disorders, neurological disorders)
3. Severe cognitive impairment, MMSE score <=24
4. Current receiving structured psychotherapeutic interventions
5. Contraindications to MRI (e.g., claustrophobia, implanted metal devices such as cardiac pacemakers, cochlear implants, artificial heart valves; if MRI was used)

Date of first enrolment
31/05/2025

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
China

Study participating centre
Shandong University
17922 Jingshi Road
Jinan, Shandong
China
250061

Sponsor information

Organisation
Shandong University

ROR
https://ror.org/0207yh398

Funder(s)

Funder type
Government

Funder Name
National Social Science Fund of China

Alternative Name(s)
Chinese National Funding of Social Sciences, , National Social Science Foundation of China, National Social Science Foundation, NSSFC

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mingqi Wang, wangmingqi 0606@163.com on publication of the paper.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes