Research Protocol

Home-based Baduanjin for Depressive Symptoms and Exploratory Prefrontal Haemodynamic Responses in Older Adults: A Pilot Randomized Controlled Study

1. Background and Objectives

1.1 Background

Depression in older adults is a major mental health issue in ageing societies. It is frequently accompanied by vascular burden, impaired neurovascular regulation, and abnormalities in cerebral microcirculatory perfusion. These physiological changes may contribute to the occurrence, persistence, or progression of depressive symptoms in later life. Therefore, interventions that can simultaneously improve emotional symptoms and modulate physiological function may have potential value as adjunctive non-pharmacological strategies for older adults with depression.

Non-pharmacological interventions, particularly mind-body exercises such as Baduanjin, have received increasing attention because of their low physical demand, favourable safety profile, and integrated regulation of movement, breathing, and attention. Baduanjin is a traditional Chinese exercise composed of slow, coordinated movements and breathing regulation. It may be suitable for older adults and may help improve mood, anxiety, physical wellbeing, and self-management ability.

Diffuse Correlation Spectroscopy (DCS) is a non-invasive optical technique that can continuously assess cerebral microvascular blood flow and haemodynamic responses. DCS-derived indicators provide objective physiological measurements that may help explore the potential mechanisms by which Baduanjin affects depressive symptoms, particularly through changes in prefrontal microcirculatory perfusion.

1.2 Study Objectives

The objectives of this study are:

1. To evaluate the effect of a 12-week home-based Baduanjin exercise programme on depressive symptoms, measured using the 17-item Hamilton Depression Rating Scale (HAMD-17), in older adults with mild-to-moderate major depressive disorder.
2. To explore the effects of Baduanjin on anxiety symptoms, cognitive function, and DCS-derived prefrontal haemodynamic indicators, including relative cerebral blood flow change (ΔrCBF) and recovery slope.
3. To preliminarily investigate whether Baduanjin may exert its antidepressant effect by improving prefrontal microcirculatory perfusion.

2. Study Design and Methods

This is a prospective, single-centre, assessor-blinded, parallel-group, randomized controlled pilot study. Eligible participants will be randomly allocated in a 1:1 ratio to either the Baduanjin group (BDJ group) or the health education group (HEW group). Both groups will complete the assigned intervention in a home-based setting over a

12-week intervention period.
Outcome assessments will be conducted at three time points: baseline (T0), immediately after the 12-week intervention (T1), and 1 month after completion of the intervention (T2).

2.1 Study Design

This study adopts a single-centre, assessor-blinded, parallel-group, randomized controlled design.
Randomisation will be performed using a computer-generated random sequence. Participants will be allocated in a 1:1 ratio to the BDJ group or the HEW group. Outcome assessors will be blinded to group allocation. Due to the nature of the behavioural intervention, participants and intervention providers cannot be blinded.
The assessment time points are as follows: T0: Baseline assessment before randomisation and intervention; T1: Assessment after completion of the 12-week intervention; T2: Follow-up assessment 1 month after completion of the intervention

3. Participants

3.1 Inclusion Criteria

Participants will be eligible for inclusion if they meet all of the following criteria:
1. Aged 50 years or older.
2. Meet the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnostic criteria for major depressive disorder.
3. Have mild-to-moderate depressive symptoms, defined as a HAMD-17 score of 15 or above.
4. Have no dementia, defined as a Mini-Mental State Examination (MMSE) score of 25 or above.
5. Have not previously practised Baduanjin or other mind-body exercises before enrolment.
6. If receiving antidepressant medication, the medication regimen must have been stable for at least 4 months before enrolment.
7. Are willing and able to provide written informed consent.

3.2 Exclusion Criteria

Participants will be excluded if they meet any of the following criteria:
1. History of psychiatric disorders other than major depressive disorder, such as bipolar disorder or schizophrenia.
2. Severe or unstable physical disease, such as uncontrolled hypertension, heart failure, or malignant tumours.
3. Moderate-to-severe cognitive impairment, defined as an MMSE score of less than 18.
4. Participation in other mind-body exercises during the study period, such as Tai Chi, yoga, or Qigong.
5. Current participation in another clinical trial.

4. Sample Size

A total of 40 participants will be recruited, with 20 participants in each group. As this is a pilot randomized controlled study, the sample size is intended to provide preliminary evidence on the feasibility, safety, and potential efficacy of the home-based Baduanjin intervention, and to inform the design and sample size estimation of future larger-scale studies.

5. Interventions

5.1 Baduanjin Group

Participants in the BDJ group will receive a 12-week home-based Baduanjin exercise programme.

The intervention will consist of standard Baduanjin, including all eight movements, combined with breathing regulation and focused attention. Participants will practise four times per week, 50 minutes per session. Each session will include: 10 minutes of warm-up; 35 minutes of core Baduanjin movements; 5 minutes of cool-down.

During the first 2 weeks, participants will receive face-to-face instruction from a professional coach once per week in a group session. For the remaining sessions, participants will practise at home with support from instructional videos and written manuals.

Participants will also be asked to practise at home for at least 20 minutes per day and to record their practice in an exercise diary. The total intervention period will be 12 weeks.

5.2 Health Education Group

Participants in the HEW group will receive a 12-week structured health education programme matched to the BDJ group in frequency and duration.

The health education programme will include topics such as nutrition, sleep hygiene, chronic disease management, mental health, and healthy lifestyle behaviours. Participants will attend group-based educational sessions and complete home-based review activities.

The frequency and duration will be consistent with the BDJ group: four sessions per week, 50 minutes per session. Participants will also complete at least 20 minutes of home-based reading or online learning each day. The total intervention period will be 12 weeks.

6. Outcomes

6.1 Primary Outcome

The primary outcome is the change in depressive symptoms, measured using the 17-item Hamilton Depression Rating Scale (HAMD-17).

HAMD-17 will be assessed at baseline (T0), after completion of the 12-week intervention (T1), and at 1-month follow-up after completion of the intervention (T2). The main comparison will focus on changes in HAMD-17 scores from baseline to T1 and T2.

6.2 Secondary Outcomes

The secondary outcomes include:

1. Anxiety symptoms: Anxiety symptoms will be assessed using the Hamilton Anxiety Rating Scale (HAMA) at T0, T1, and T2.

2. Cognitive function: Cognitive function will be assessed using the Mini-Mental State Examination (MMSE) at T0, T1, and T2.

3. DCS-derived prefrontal cerebral blood flow indicators: DCS-derived indicators will include relative cerebral blood flow change (ΔrCBF) during active tasks, including the verbal fluency task (VFT) and higher cognitive task (HCT).

4. Recovery slope after passive challenges: The recovery slope of prefrontal haemodynamic responses will be calculated within 30 seconds after passive challenges, including voluntary breath holding (VBH) and postural challenge task (PCT).

5. Exercise adherence: Exercise adherence will be assessed using participant practice diaries.

6. Adverse events: Adverse events will be recorded throughout the intervention period and follow-up period.

7. Assessment Schedule

Assessment item	T0: Baseline	T1: 12 weeks after intervention	T2: 1-month follow-up
HAMD-17	Yes	Yes	Yes
HAMA	Yes	Yes	Yes
MMSE	Yes	Yes	Yes
DCS measurements: VFT, HCT, VBH, PCT	Yes	Yes	Yes
Exercise adherence diary	No	Yes	Yes
Adverse event record	No	Yes	Yes

8. DCS Measurement Procedure

DCS measurements will be performed using a self-developed diffuse correlation spectroscopy system with a 785 nm laser and source-detector separations of 2.0 cm and 3.0 cm. Continuous monitoring will be conducted over the prefrontal region.

The task sequence will be as follows:

1. Resting baseline for 2 minutes
2. Verbal fluency task for 1 minute
3. Rest for 1 minute
4. Higher cognitive task for 1 minute
5. Rest for 1 minute
6. Voluntary breath holding for up to 1 minute
7. Rest for 1 minute
8. Postural challenge task
9. Recovery monitoring for 2 minutes

The blood flow index (BFI) will be extracted from the electric field autocorrelation function. Relative cerebral blood flow change will be calculated using the following formula: ΔrCBF = (BFI_task - BFI_baseline) / BFI_baseline × 100%

The recovery slope will be calculated using linear regression within the first 30 seconds after the task or challenge.

9. Statistical Analysis

Statistical analyses will be performed using SPSS version 25.0 and GraphPad Prism version 8.0.1. Continuous variables will be presented as mean ± standard deviation.

Within-group changes across different time points will be analysed using repeated-measures analysis of variance, followed by Bonferroni-corrected post hoc comparisons when appropriate. Between-group comparisons will be performed using independent-samples t-tests.

A two-sided P value of less than 0.05 will be considered statistically significant. The primary outcome will be the change in HAMD-17 score. DCS-derived indicators will be interpreted as exploratory outcomes.

10. Ethical Considerations

This study will be conducted in accordance with the principles of the Declaration of Helsinki. The study has received ethics approval from the Ethics Committee of North University of China, with the ethics approval reference number NUC-BME-202411-037.

All participants will provide written informed consent before enrolment. Before signing the consent form, participants will be fully informed about the study purpose, procedures, possible benefits, potential risks, and their rights as research participants.

Participants will have the right to withdraw from the study at any time without giving a reason. Withdrawal from the study will not affect their subsequent medical care, treatment rights, or other legitimate interests.

All personal information and study data will be kept strictly confidential and used only for the purposes of this study. Participant identities will be protected during data collection, analysis, reporting, and publication.

Adverse events will be monitored and recorded throughout the intervention and follow-up period. Any unexpected or clinically significant adverse event will be evaluated and managed according to the study protocol and relevant ethical requirements.