ISRCTN15775827 https://doi.org/10.1186/ISRCTN15775827

Preventive intervention of mild cognitive impairment in Anhui, China

Submission date	Recruitment status	[ ] Prospectively registered
29/08/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2022	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aim
Alzheimer's disease (AD) is the most common cause of dementia, a general term for memory loss and other cognitive abilities serious enough to interfere with daily life. AD has become a significant global public health challenge. Early preventive intervention to delay AD onset has become a key measure for many countries worldwide to address the challenge. Mild cognitive impairment (MCI) is the intermediate transition stage from normal cognitive people to AD. Thus MCI is of significant public health significance for preventing AD. Early prevention of MCI for those at risk of MCI is the key to slowing the spread of AD. In this study, the idea of a hierarchical preventive intervention for MCI was applied as a primary prevention strategy, aiming to reduce the MCI risk among older community dwellers effectively and at a low cost.

Who can participate?
People aged 55-75 years with normal cognitive function

What does the study involve?
The MCI risk assessment tool was developed and applied to assess the risk of MCI for older community dwellers. The participants are categorized into three risk groups (high, medium, and low) based on the risk score of MCI. Different lifestyle intervention plans are given to the participants according to their risk group and the sources of the risk. Changes in MCI total risk, somatic function, cognitive function, activities of daily living, and psychological status are evaluated at 8, 16, and 24 weeks after the intervention.

What are the possible benefits and risks of participating?
There are not thought to be any risks involved with participating in the study. A possible benefit could be that participants will develop a healthy lifestyle that has a wide range of benefits and prevents many chronic diseases including AD.

Where is the study run from?
Sample communities in Hefei, Anhui province (China).

When is the study starting and how long is it expected to run for?
March 2020 to December 2023

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
Miss Yan Zhang
zhangymail@ahmu.edu.cn

Contact information

Type(s)
Principal investigator

Contact name
Prof Yan Zhang

Contact details
Anhui Medical University
81 Meishan Road
Hefei
China
230032
+86 (0)551 65116395
zhangymail@ahmu.edu.cn

Additional identifiers

Study information

Scientific Title
Risk stratification and hierarchical intervention strategy for mild cognitive impairment among older community dwellers

Study objectives
After the intervention, the subjects will demonstrate lower scores on the total risk score, better levels of somatic function, cognitive function, activity of daily living, and psychological status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2020, Anhui Medical University ethics committee (81 Meishan Road, Hefei, Anhui Province, China; +86 (0)551 65161053; email: not applicable), ref: 20200323

Primary study design
Interventional

Study design
Community trial with a cross-over design

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mild cognitive impairment (MCI)

Interventions
The intervention was divided into two stages. In the first stage, the 24-weeks of intervention were given to the intervention group (community A), and for the control group (community B) only natural development was observed. In the second stage, the intervention was stopped for community A, but only follow-up observation continued; however, the same 24-weeks preventive intervention started for community B.

Interventions focused on nine risk factors: social isolation, cognitive reserve, drinking, smoking, hypertension, hyperlipidemia, diabetes, exercise, and depression. The specific intervention list is as follows:

Social isolation:
High-risk group:
1. Health education (professionals, once a month, 4 times in total)
2. Social engagement (once a month, 4 times in total)
3. Health education (once a month, 4 times in total)

Medium risk group:
1. Health education (two lectures by professionals)
2. Social engagement (once every 2 months, two times in total)
3. Health education (twice a month, 8 times in total)

Low-risk group:
1. Health education (two lectures by professionals)
2. Health education (twice a month, eight times in total)

Cognitive reserve
High-risk group:
1. Memory training (twice a month, eight times in total) (two rounds)
2. Educational activities (twice a month, eight times in total) (two rounds)
3. Educational activities for the elderly

Medium risk group:
1. Memory training (once a month, four times in total)
2. Educational activities (once a month, four times in total)
3. Educational activities for the elderly

Low-risk group:
1. Memory training (once every two months, two times in total)
2. Educational activities (once every two months, two times in total)
3. Educational activities for the elderly

Drinking:
High-risk group:
1. WeChat official account push (based on the 5R model, dedicated person responsible, once every 2 weeks, eight times in total)

2. Signing an abstinence pledge (heavy drinkers)
3. Abstinence Self-monitoring Questionnaire (once a month, four times in total)
4. Abstinence Family Member Monitoring Questionnaire (once a month, four times in total)

Medium risk group:
1. WeChat official account push (based on the 5R model, dedicated person responsible, once every 2 weeks, eight times in total)
2. Signing an abstinence pledge (heavy drinkers)
3. Abstinence Self-monitoring Questionnaire (once a month, four times in total)
4. Abstinence Family Member Monitoring Questionnaire (once a month, four times in total)

Low-risk group:
1. Popular science information push (from Popular Science China, dedicated person responsible, two times in total)
2. Signing an abstinence pledge (heavy drinkers)
3. Abstinence Self-monitoring Questionnaire (once a month, four times in total)
4. Abstinence Family Member Monitoring Questionnaire (once a month, four times in total)

Smoking:
High-risk group:
1. WeChat official account push (based on the 5R model, dedicated person responsible, once every 2 weeks, eight times in total)
2. Signing a pledge to stop smoking (heavy smokers)
3. Smoking Cessation Self-monitoring Questionnaire (once a month, four times in total)
4. Smoking Cessation Monitoring Questionnaire for family members (once a month, four times in total)

Medium risk group:
1. WeChat official account push (based on the 5R model, dedicated person responsible, once every 2 weeks, eight times in total)
2. Signing a pledge to stop smoking (heavy smokers)
3. Smoking Cessation Self-monitoring Questionnaire (once a month, four times in total)
4. Smoking Cessation Monitoring Questionnaire for family members (once a month, four times in total)

Low-risk group:
1. WeChat official account push (from Popular Science China, dedicated person responsible, three times in total)
2. Signing a pledge to stop smoking (heavy smokers)
3. Smoking Cessation Self-monitoring Questionnaire (once a month, fourtimes in total)
4. Smoking Cessation Monitoring Questionnaire for family members (once a month, four times in total)

Hypertension:
High-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions, three times in total)
2. Individual medication and dietary guidance (professional doctor is responsible, once a month, four times in total)
3. Personalized exercise prescription (professional sports coach is responsible for it, once a month, four times in total)
4. Health education

5. Dietary records for 3 days (mobile phone photography, once a month)
6. Exercise sharing on WeChat (once a week)
7. Blood pressure self-monitoring (once a day)

Medium risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions, two times in total)
2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach, one time in total)
4. Health education
5. Dietary records for 3 days (mobile phone photography, once a month)
6. Exercise sharing on WeChat (once a week)
7. Blood pressure self-monitoring (three times a week)

Low-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions, one time in total)
2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach is responsible for it, one time in total)
4. Health education
5. Dietary records for 3 days (mobile phone photography, once a month)
6. Exercise sharing on WeChat (twice a week)
7. Blood pressure self-monitoring (once a week)

Hyperlipidemia:
High-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions, three times in total)
2. Individual medication and dietary guidance (professional doctor is responsible, once a month, four times in total)
3. Personalized exercise prescription (professional sports coach is responsible for it, once a month, four times in total)
4. Blood lipid test (two times in total, with an interval of more than 3 months)
5. Health education
6. Dietary records for 3 days (mobile phone photography, once a month)
7. Exercise sharing on WeChat (once a week)

Medium risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions,two times in total)
2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach is responsible for it, one time in total)
4. Blood lipid test (two times in total, with an interval of more than 3 months)
5. Health education
6. Dietary records for 3 days (mobile phone photography, once a month)
7. Exercise sharing on WeChat (once a week)

Low-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia and diabetes) (professionals give lectures and answer questions, one time in total)

2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach is responsible for it, one time in total)
4. Blood lipid test (two times in total, with an interval of more than 3 months)
5. Health education
6. Dietary records for 3 days (mobile phone photography, once a month)
7. Exercise sharing on WeChat (once a week)

Diabetes:
High-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia, and diabetes) (professionals give lectures and answer questions, three times in total)
2. Individual medication and dietary guidance (professional doctor is responsible, once a month, four times in total)
3. Personalized exercise prescription (professional sports coach is responsible for it, once a month, four times in total)
4. Glycosylated hemoglobin test (two times in total, with an interval of more than 3 months)
5. Health education

Medium risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia, and diabetes) (professionals give lectures and answer questions, two times in total)
2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach is responsible for it, one time in total)
4. Glycosylated hemoglobin test (2 times in total, with an interval of more than 3 months)
5. Health education
6. Weight monitoring (once a month, four times in total)
7. Dietary records for 3 days (mobile phone photography, once a month)
8. Exercise sharing on WeChat (once a week)

Low-risk group:
1. Carry out health lectures on chronic diseases (hypertension, hyperlipidemia, and diabetes) (professionals give lectures and answer questions, one time in total)
2. Individual medication and dietary guidance (the professional doctor is responsible one time)
3. Personalized exercise prescription (professional sports coach is responsible for it, one time in total)
4. Glycosylated hemoglobin test (two times in total, with an interval of more than 3 months)
5. Health education
6. Weight monitoring (once a month, four times in total)
7. Dietary records for 3 days (mobile phone photography, once a month)
8. Exercise sharing on WeChat (once a week)

Exercise:
High-risk group:
1. Health education (professionals give lectures and answer questions, one time in total)
2. Personalized exercise prescription (professional sports coach, once a month, four times in total)
3. Health education
4. Exercise sharing on WeChat (once a month, four times in total)

Medium risk group:
1. Health education (professionals give lectures and answer questions, one time in total)
2. Personalized exercise prescription (professional sports coach, two times in total)
3. Health education
4. Exercise sharing on WeChat (once a month, four times in total)

Low-risk group:
1. Health education (professionals give lectures and answer questions, one time in total)
2. Personalized exercise prescription (professional sports coach, one time in total)
3. Health education
4. Exercise sharing on WeChat (once a week)

Depression:
High-risk group:
1. Mental health guidance by professional doctors (two times in total)
2. Popular science videos pushed to the WeChat official account (from the National Center for Mental Health, eight times in total)
3. Health education

Medium risk group:
1. Mental health guidance by professional doctors (two times in total)
2. Popular science videos pushed to the WeChat official account (from National Center for Mental Health, four times in total)
3. Health education

Low-risk group:
1. Popular science videos pushed to the WeChat official account (from National Center for Mental Health, four times in total)
2. Health education

An individualized intervention plan will be made based on an individual's personal risk factors (the utmost three risk factors contributing most significantly to the risk scores)

Intervention Type
Behavioural

Primary outcome(s)
The change in the total risk score of each individual was used as the main observation index at baseline and at 8, 16, and 24 weeks

Key secondary outcome(s)
1. Somatic function measured using the results evaluated by neurology professionals at baseline and at 8, 16, and 24 weeks
2. Cognitive function measured using the Mini-Mental State Examination (MMSE) at baseline and at 8, 16, and 24 weeks
3. Activities of daily living measured using the activities of daily living (ADL) at baseline and at 8, 16, and 24 weeks
4. Psychological status measured using the 9-item Patient Health Questionnaire (PHQ-9) at baseline and at 8, 16, and 24 weeks
5. Quality of life measured using the EQ-5D at baseline and at 8, 16, and 24 weeks

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Aged 55-75 years, male or female
2. Owning a smartphone, have Instant Messenger (e.g., WeChat), and can use it proficiently
3. Is a permanent resident of the community and has no plan to leave the community for a long-term residence elsewhere within 1 year
4. Normal cognitive function (MMSE score of 24 or higher)
5. Be aware of the purpose of this study and willing to participate (sign informed consent)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
200

Key exclusion criteria
Older adults with MCI or AD at baseline

Date of first enrolment
01/01/2022

Date of final enrolment
30/03/2022

Locations

Countries of recruitment
China

Study participating centre
Anhui Medical University
81 Meishan Road
Hefei
China
230032

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date