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Official Title: Applied Research on a Group-based Non-pharmacological Intervention Program for Community-dwelling Older Adults With Subjective Cognitive Decline

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1.Background

Subjective Cognitive Decline (SCD) refers to a self-reported decline in cognitive function compared to one's previous normal state, in the absence of objective cognitive impairment[1]. SCD may represent the first symptom of Alzheimer's disease (AD)[1,2]. AD is a progressive neurodegenerative disease characterized by memory decline and behavioral changes. These symptoms gradually impair patients' self-care ability and eventually lead to loss of independent living[3].It is the most common type of dementia in older adults.[4,5]. The prevalence of AD among people aged 60 and above in China was 3.9%, representing approximately 9.83 million cases[6,7]. AD is considered a pathophysiological continuum divided into seven stages (stages 0 to 6), including the asymptomatic stage (stages 0–1), subjective cognitive decline (stage 2), mild cognitive impairment (MCI) (stage 3), and dementia (stages 4–6), reflecting a gradual increase in disease severity[8]. In this continuum, subjective cognitive decline appears at the preclinical stage and serves as a key transitional phase between objective cognitive impairment and intact cognition[8]. The incidence of SCD among the older population varied widely, ranging from 25% to 58.33%[9,10]. Furthermore, results from multiple studies [11–13] indicated that the progression rate from SCD to MCI or dementia ranged from 10.2% to 52%. Older adults with SCD have a higher risk of progressing to AD. Therefore, it is necessary to prioritize interventions targeting this population to prevent or delay the onset of objective cognitive impairment.

The baseline cognitive function of the population with SCD remains within the normal range, with no objective cognitive impairment yet present. This suggests that implementing non-pharmacological interventions before the disease progresses to the stage of irreversible cognitive damage may yield more favorable neuroprotective effects and greater potential for clinical benefit[14]. Non-pharmacological single-domain interventions, such as cognitive intervention and physical activity intervention, had positive effects on older adults with SCD, but their work is limited, mainly focusing on improvements in fewer dimensional indicators. In contrast, non-pharmacological multi-domain interventions, by integrating multiple components such as cognitive training, exercise, and psychosocial elements, can synergistically act

on neuroplasticity and functional compensation mechanisms, thereby achieving a comprehensive enhancement of multi-dimensional health — including cognitive function, physical activity, and mental health — in older adults with SCD[15,16]. Internationally, multi-domain intervention studies targeting older adults with SCD were still in the exploratory phase, but there was a lack of determination regarding the integration sequence of different intervention components. In China, intervention studies for older adults with SCD focused on a single domain; multi-domain interventions were relatively rare, with a lack of multi-domain intervention programs delivered face-to-face. Research has shown[17] that group-based interventions are beneficial for individuals with cognitive impairment in community settings. The group encourages interaction among participants, provides an opportunity for mutual support, helps build social networks, and allows people to share emotions and express concerns about cognitive and everyday memory problems[18], thereby delaying decline in memory and global cognitive function[19]. Intervention measures based on group can be cost-effective[20], and they can be widely applied in large-scale community populations in the future[19].

This study aims to verify the short-term and long-term effects of a non-pharmacological intervention program for community-dwelling elderly people with subjective cognitive decline through a strictly designed cluster randomized controlled trial, and to evaluate the implementation effect. This study adopts a hybrid effectiveness-implementation trial design. This approach allows us to primarily evaluate the effectiveness of the developed non-pharmacological intervention program while simultaneously exploring the implementation process[21]. To assess effectiveness, a cluster randomized controlled trial design is employed to deliver a group-based non-pharmacological intervention to older adults with SCD, and to evaluate the effects of this intervention program on global cognitive function, episodic memory, executive function, attention, language function, subjective memory function, anxiety, depression, social participation, social network, social support, gait speed, physical activity level, and healthy lifestyle in older adults with SCD. Furthermore, this study conducts a process evaluation based on the five evaluation dimensions of the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation,

Maintenance) and the CFIR framework.

2.Methods

2.1 Participants

The participants are community-dwelling older adults with subjective cognitive decline (SCD).

Inclusion criteria will be as follows:(1)aged ≥60, (2)community dwelling, (3)subjective memory decline, confirmed by Subjective Cognitive Decline Questionnaire(SCD-Q9)≥5; (3)Montreal Cognitive Assessment (MoCA) scores ≥19, 22, or 24 for participants who had primary school, middle school, or higher education, respectively;(4)overall intact activities of daily living;(5)no planned exercise or cognitive intervention activities within the past six months;(6) voluntary participants who will be informed of the study objectives by the researcher and will sign the informed consent form.

Exclusion criteria will be as follows:(1)any other neurodegenerative diseases (such as mild cognitive impairment, dementia, Parkinson's disease, stroke, etc.); (2)any severe or unstable internal medical conditions (i.e., unstable or severe asthma or heart disease, liver and kidney diseases, uncontrolled hypertension, severe metabolic diseases, etc.); (3)severe depressive, anxiety or other psychiatric disorders; (4)movement contraindications; (5)those currently participating in other research trials.

2.2 Sample Size

The sample size estimation was based on the improvement in MoCA scores observed in our research team’s preliminary pilot trial and a multi-domain study[16]. Given the limitation of the pilot trial’s self-controlled before- after design in sample size calculation, we referenced a similar study to validate the estimated sample size. That study reported a MoCA score of 19.78 ± 4.560 in the intervention group and 17.35 ± 4.764 in the control group. Using PASS 15.0 software, with a type I error rate of 5% ($\alpha = 0.05$) and power of 80% ($\beta = 0.20$), the calculated sample size was 58 participants per group. To account for the cluster randomized controlled trial design, the sample size was adjusted based on an intracluster correlation coefficient (ICC, ρ) of 0.08 (derived from pilot data). The adjustment formula used was: $1 + (n - 1) \times$

ρ [22], where n (average cluster size) = 8. Considering a 20% attrition rate, the required sample size was recalculated, leading to a final recruitment target of 218 participants (109 per group).

2.3 Study Design

This study will be a two-arm, cluster randomized, controlled, single-blind, multicenter, prospective longitudinal study conducted among community-dwelling older adults with SCD. The aim is to evaluate the effects of the intervention program on subjective and objective cognitive function, mental health status, physical activity level, and other health-related outcome measures. Communities will be randomly assigned to either the intervention group or a waitlist control group using a 1:1 allocation ratio. The study will be implemented in communities in Shenyang, Liaoning Province.

2.3.1 Community Recruitment and Eligibility Criteria

Nine districts of Shenyang (Heping, Shenhe, Huanggu, Dadong, Tiexi, Hunnan, Yuhong, Shenbei New, and Sujiatun) will be invited to participate in this study. All communities in the above districts will be contacted by telephone to introduce the study content and inquire about their willingness to participate.

Community inclusion criteria are as follows: (1) ability to recruit at least 6 older adults with SCD; (2) selected communities must have similar sociodemographic characteristics (including age distribution); (3) availability of space and personnel support; (4) voluntary agreement of the community to participate in the study.

2.3.2 Randomization and Blinding

To ensure prevent inter-group contamination, cluster randomization will be implemented. In this study, each participating community serves as a cluster[23]. Interested communities will be listed. Eligibility will be determined during site visits based on established criteria. Once identified, they will be matched into pairs based on a 1:1 ratio. Following this, one community from each pair will be randomly allocated to the intervention arm, with the other serving as the control arm. Using computer-generated random numbers, a researcher who is not involved in the intervention and data analysis will carry out the randomization process. Since the intervention group in this study will receive a non-pharmacological intervention,

blinding of participants in the intervention group and the intervention implementers cannot be unachievable. During data collection, the outcome assessors, who will be specially trained postgraduate students, will be unaware of the group allocation and the implementation of the intervention.

2.3.3 Outline of the intervention program

The intervention program is designed for community-dwelling SCD older individuals with multiple non-pharmaceutical interventions, including six components, 14 themes, and 42 intervention items. The outline of the intervention program is detailed in Table 1:

Table 1 Outline of the intervention program

Level 1 indicators （Intervention Component）	Level 2 indicators （Intervention Theme）	Level 3 indicators （Intervention Content）	Intervention form	Intervention time
1.Social intercourse	1.1Social Network	1.1.1 Friend Network	Group collaborative cognitive games	Week 1 to Week 12
		1.1.2 Home network	Interaction	Week 1and Time spent at home
	1.2 Social participation	1.2.1Breaking the ice or greeting	Group interaction	Week 1 to Week 12
		1.2.2 Structured topic discussion	Group interaction	Week 1 to Week 4
		1.2.3 Opinion Sharing	Group interaction	Week 5 to Week 8
		1.2.4 Topics initiation by older adults	Group interaction	Week 9 to Week 12
	1.3Social support	1.3.1Perceived social support	Group interaction	Week 6
		1.3.2 Active seeking of support systems	Lecture on theory+After-class practice	Week 6
2.Cognitive interventions	2.2 The Relationship between Cognitive Intervention and Brain Health	2.2.1 The benefits of cognitive intervention for brain health	Lecture on theory	Week 1

Level 1 indicators （Intervention Component）	Level 2 indicators （Intervention Theme）	Level 3 indicators （Intervention Content）	Intervention form	Intervention time
	2.3Compensatory cognitive rehabilitation	2.3.1Learning and application of mnemonic strategies	Lecture on theory+ practice	Week 1 to Week 4
		2.3.2 Learning and application of memory aid tools	Lecture on theory+ practice	Week 1 to Week 4
	2.4Cognitive training	2.4.1Memory training	Group game	Week 1 to Week 12
		2.4.2Execution training	Group game	
		2.4.3 Attention training	Group game	
		2.4.4 Linguistic training	Group game	
		2.4.5 Visuospatial training	Group game	
3.Physical activity interventions	3.1The relationship between physical activity and brain health	3.1.1The dangers of insufficient physical activity	Lecture on theory+ interaction	Week 1
		3.1.2The benefits of physical activity for brain health	Lecture on theory	Week 1
		3.1.3Physical Activity Strategies and Guidance	Lecture on theory	Week 1

Level 1 indicators （Intervention Component）	Level 2 indicators （Intervention Theme）	Level 3 indicators （Intervention Content）	Intervention form	Intervention time
	3.2Exercise interventions	3.2.1Warm-up	Group practice	Week 1 to Week 12
		3.2.2Baduanjin	Group practice	Week 1 to Week 12
		3.2.3Resistance training	Group practice	Week 1 to Week 12
		3.2.4Muscular relaxation	Group practice	Week 1 to Week 12
4.Rational diet	4.1Dietary approaches for improving cognitive function	4.1.1Mediterranean diet	Lecture on theory+ interaction	Week 1
		4.1.2Dietary Approaches to Stop Hypertension(DASH)	Lecture on theory+ interaction	Week 2
		4.1.3Mediterranean-DASH Intervention for Neurodegenerative Delay(MIND)	Lecture on theory+ interaction	Week 3
5.Understanding and risk management of diseases	5.1The Relationship between the Recognition and Cognition of Common Cardiovascular and Cerebrovascular	5.1.1Coronary heart disease and its impact on cognitive function	Lecture on theory+ video	Week 4
		5.1.2Stroke and Its Impact on Cognitive Function	Lecture on theory+ video	Week 4
		5.1.3Hypertension and Its Impact on	Lecture on theory+ video	Week 4

Level 1 indicators （Intervention Component）	Level 2 indicators （Intervention Theme）	Level 3 indicators （Intervention Content）	Intervention form	Intervention time
	Diseases and Their Risk Factors and Cognitive Function	Cognitive Function		
		5.2.1Hyperglycemia and Its Impact on Cognitive Function	Lecture on theory+ video	Week 5
		5.2.2Hyperlipidemia and Its Impact on Cognitive Function	Lecture on theory+ video	Week 5
		5.2.3Obesity and Its Impact on Cognitive Function	Lecture on theory+ video	Week 5
		5.2.4Smoking, drinking alcohol and their effects on cognitive function	Lecture on theory	Week 5
	5.2Self-management methods for preventing or controlling the risks of cardiovascular and cerebrovascular diseases	5.3.1Adjustment of lifestyle	Lecture on theory+ interaction	Week 5
		5.3.2Self-monitoring	Lecture on theory+ interaction	Week 5
6.Emotion management	6.1Identification of negative emotions	6.1.1Common negative emotions	Lecture on theory+example	Week 6
		6.1.2Identification of cognitive distortions	Lecture on theory+example	Week 6

Level 1 indicators （Intervention Component）	Level 2 indicators （Intervention Theme）	Level 3 indicators （Intervention Content）	Intervention form	Intervention time
		underlying negative emotions		
	6.2Dealing with negative emotions	6.2.1Mindfulness therapies	Lecture on theory+practice	After exercising from Week 1 to Week 12
		6.2.2Expressive activities	Lecture on theory+practice	Week6 and after-class
	6.3 Management of negative emotions when maintaining healthy behaviors is impeded	6.3.1Expression of emotional problems caused by blocked healthy behaviors	Reflection + Interaction	Week 7
		6.3.2 Analysis of reasons, peer sharing of experiences	Interaction	Week 7
		6.3.3Joint discussion of countermeasures, mastery of methods	Interaction	Week 7

2.4 Intervention Implementation

2.4.1 Intervention Group

The intervention group will receive three sessions per week for a total duration of 12 weeks, amounting to 36 intervention sessions. Six intervention components are integrated into each session and delivered in a fixed sequence, with each session lasting approximately 100 minutes. The intervention is delivered in a group format of 6 – 10 participants per group. Intervention components 1, 2, 3, and 6 will be implemented by community workers, while components 4 and 5 will be implemented by a nutritionist and a gerontology expert, respectively. All intervention personnel must receive standardized training before formally implementing the intervention program.

2.4.2 Control Group

To ensure ethical fairness, the same intervention program will subsequently be provided to the waitlist control group after positive effects are confirmed in the intervention group.

2.5 Outcome Measures and Assessment Tools

2.5.1 Effectiveness

The outcome measures listed in Table 2 will be assessed at baseline (week 0), immediately post-intervention (week 12), and at 12 weeks post-intervention (week 24) to evaluate the effectiveness of the intervention program.

Table 2 Outcomes and Instruments

Outcomes	Instruments
The feasibility outcomes	
Recruitment	(Number of recruited older adults with SCD who were assessed as meeting eligibility criteria and voluntarily consented to the intervention / Total number of recruits) × 100%
Compliance	(Number of sessions attended / Total number of sessions conducted) × 100%
Withdrawal	(Number of dropouts and losses to follow-up / Total number of participants at baseline) × 100%
Adverse events	Participants self-reported falls and/or injuries during the intervention
Reasons for withdrawal	Qualitative Report
The effectiveness outcomes	
Global cognitive function	Montreal Cognitive Assessment

Episodic memory	Auditory Verbal Learning Test
Executive function	Shape Trail Test
Attention	Digit Symbol Substitution Test
Linguistic function	Animal Fluency Test
Subjective cognitive function	Multifactorial Memory Questionnaire
Anxiety	Geriatric Anxiety Inventory-20
Depression	Geriatric Depression Scale-15
Social participation	Social participation level assessment tool
Social network	Lubben Social Network Scale-6
Social support	Perceived Social Support Scale
Gait speed	Timed “Up and Go” test
Physical activity level	International Physical Activity Questionnaire-Short
Healthy lifestyle	Dementia Risk Reduction Lifestyle Scale

2.5.2 Process Evaluation

The process evaluation of the intervention implementation will be based on the RE-AIM [24]and CFIR[25]frameworks. These frameworks allow for quantitative and qualitative assessment of the intervention's public health impact.

2.5.2.1 RE-AIM

This study will describe the dimensions of RE-AIM (Reach and Effectiveness) to assess the impact of the implementation process and ongoing support on the intervention's adaptation to real-world settings. Meanwhile, key factors influencing implementation success will be analyzed through organizational dimensions (Adoption, Implementation, Maintenance).

(1) Reach is an individual-level measure of participation, referring to the characteristics and proportion of the target population participating in the intervention [24]. In this study, participant engagement will be assessed based on three indicators: recruitment rate (percentage of SCD older adults who met eligibility criteria and voluntarily participated in the intervention study out of all recruited individuals); participation rate (percentage of sessions attended by intervention participants out of all planned sessions); retention rate (percentage of participants who completed the intervention out of those who initiated it). Additionally, changes in participants' status throughout the intervention will be evaluated, including adverse events (falls and/or injuries), hospitalizations, absenteeism, mortality, and withdrawal from the

intervention program. For this purpose, monitoring forms will be used, and implementation staff will be instructed to keep detailed records.

(2) Effectiveness is assessed at the individual level, primarily concerning the impact of the intervention on primary outcome measures[24].(see section 5.1 for details)

(3) Adoption is an organizational-level participation measure that assesses the representativeness of settings and/or agents willing to implement the intervention, considering eligible groups[24]. This study will calculate the percentage of communities that adopt this intervention program out of all eligible communities invited.

(4) Implementation (organizational level) refers to the extent to which implementation staff adhere to the various elements of the intervention protocol[24]. In this study, some components will be executed by community auxiliary staff. During the 12-week intervention period, a detailed operation manual will be developed, containing all implementation strategies and estimated completion times for each intervention session. This manual will be used to create a checklist to assess implementation fidelity and the effectiveness of strategy implementation. Trained researchers will conduct on-site observations at the intervention sites, complete the checklist, and conduct interviews with implementation staff (e.g., "What do you think might be the facilitators or barriers to large-scale community implementation of this program in the future?").

(5) Maintenance (organizational level) evaluates the extent to which the intervention has become institutionalized or integrated into routine practice and organizational policies[24]. In this study, maintenance will be assessed by whether new groups are added during implementation or whether local organizations intend to institutionalize the program. This evaluation will occur shortly after project completion through semi-structured interviews with community implementation staff.

Interview guide:

How has been your overall experience implementing this intervention program?

How willing are you to continue implementing this intervention program?

Would you recommend this intervention program to other communities?
Do you think this intervention program is suitable for large-scale community promotion? Do you have any suggestions?

2.5.2.2 CFIR

CFIR proposes 48 implementation constructs grouped into five major domains: Innovation, Outer Setting, Inner Setting, Individuals Involved, and Implementation Process.Innovation domain includes innovation source, evidence base, relative advantage, adaptability, applicability, complexity, intervention design, and cost.Outer setting domain includes 7 constructs: critical events, local attitudes, local conditions, partnerships and connections, policies and regulations, funding support, and external pressures. Inner setting domain includes 11 constructs: structural characteristics, collaboration, communication, culture, available resources, etc. Individuals involved domain includes 13 constructs: opinion leaders, implementation facilitators, implementation supervisors, implementation team members, innovation recipients, etc. Implementation process domain includes 9 constructs such as teamwork, needs assessment, etc.

Semi-structured interviews will be conducted based on the CFIR framework, using the following guide:

(1) Innovation: What advantages do you see in this program? Does it fit the characteristics or habits of the participants? What aspects need adjustment or optimization?

(2) Outer setting: What factors do you think might affect the continued application of this program? What additional support or resources do you think are needed?

(3) Inner setting: How is the division of labor and collaboration in your community? Are there any collaboration or communication barriers? Have you received training before? How effective was the training? Do you think the current personnel and capabilities in your community can meet the requirements for smooth implementation of this program? If not, what kind of talent is lacking?

(4) Individuals involved: What part are you responsible for during implementation? How difficult is the implementation of this program? Does it impose any workload or pressure on you? How confident are you in implementing this program? What impact

does the implementation of this program have on your income, benefits, or career development?

(5) Process: How do you assess the current status of the program's application? Does your community regularly reflect on and evaluate the implementation of this program?

(6) What specific problems have you encountered during implementation? Do you have any suggestions for improvement? Please provide examples.

3. Data Collection

Data from the study subjects' various scales will be collected by uniformly trained investigators. Data collection time points: pre-intervention (T0), post-intervention (T1, 12 weeks), and follow-up (T2, 24 weeks). At T0, after obtaining informed consent at the community elderly service station, investigators will collect baseline data and contact information. Collecting all questionnaire data will take approximately one hour. Considering the physical capacity of the elderly, data collection will be divided into two sessions to alleviate participant fatigue. Prior to formally starting the intervention study, participants will be contacted by phone to obtain informed consent for this intervention study, after which the intervention study will be organized.

After the intervention, researchers will collect data on implementation and maintenance of the intervention program through qualitative interviews. Before the interview, participants will be informed of the main purpose and content, and informed consent will be obtained. All interviews will take place in unoccupied rooms at the community elderly service stations, with no other persons present during personal interviews to ensure quiet. During the interviews, the interviewer will follow a pre-designed guide, flexibly adjust the order of questions according to the actual situation, and appropriately employ interviewing techniques. After each interview, the researcher will promptly transcribe the audio recording and perform a word-for-word check of the text.

4. Data Analysis

Statistical analysis will be performed using R Studio 4.4.2 statistical software, employing R packages such as haven, tidyselect, stats, lme4, ggpubr, and ggplot2. Two-sided tests will be used, with the significance level set at $\alpha = 0.05$; $P < 0.05$

will be considered statistically significant. The distribution of all continuous variables will be tested for normality using the Shapiro-Wilk test; non-parametric tests will be used for data not conforming to a normal distribution.Descriptive statistical analysis: Normally distributed continuous data will be presented as mean ± standard deviation; non-normally distributed continuous data as median and interquartile range; categorical data as frequencies and percentages.Independent sample t-tests, Mann-Whitney U tests, or chi-square tests will be used for between-group comparisons. To enhance robustness, both intention-to-treat (ITT) and per-protocol (PP) analyses will be performed. Effect estimates, 95% confidence intervals, and p-values for all outcome measures will be calculated using mixed-effects models.Qualitative interview data analysis: Data collection and analysis will be conducted concurrently. Transcription will be completed promptly; each interview will be transcribed verbatim from audio to text within 24 hours. NVivo 11.0 software will be used for importing and managing textual information, and content analysis will be employed for data analysis.

6. Risks and Corresponding Remedial Measures

The safety of older adults will be the foundation of study design and implementation. Intervention intensity and dosage will be reasonably controlled based on participants' age, physical activity capacity, etc. To ensure participant safety, researchers will provide detailed explanations and guidance on the intervention protocol to avoid unnecessary injury. Researchers will also elaborate on possible adverse symptoms during the intervention, informing participants that if hypoglycemia, shortness of breath, palpitations, or falls occur during the intervention, they should immediately notify the project leader, who will assist in contacting medical units for treatment. Should any injury-related event occur as a result of the study, the research team will assume corresponding responsibility, provide necessary treatment free of charge, and offer appropriate financial compensation according to relevant regulations. All adverse events will be documented during the intervention period, and regular research team meetings will be held to analyze the causes of adverse events. Adverse events are defined as harmful outcomes occurring during the

intervention, such as falls during exercise, etc.

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INFORMED CONSENT FORM

(Qualitative Interview)

Dear Community Workers:

Hello! We invite you to participate in a research study titled "Applied research on a group-based non-pharmacological intervention program for community-dwelling older adults with subjective cognitive decline" approved by China Medical University. This study has been reviewed by the Medical Ethics Committee of China Medical University.

Your participation is voluntary. Before you decide, please read the following information carefully to help you understand this study. If you have any questions, please feel free to ask the researchers, who will answer them. If you wish, you may also discuss it with your relatives or friends to help you make a decision. Below is an introduction to this study:

1. Background

Subjective Cognitive Decline (SCD) refers to an individual's self-reported decline in cognitive level compared to previous status , while neuropsychological tests are still within the normal range. It is considered the first symptom of Alzheimer's disease (AD) and lies in the preclinical phase of the AD pathophysiological continuum. SCD is relatively common among older adults, with an incidence rate as high as 25%–58.33%. The average progress rates from SCD to objective cognitive impairment was 7.1%. With the global aging trend, the incidence of Alzheimer's disease continue to rise, making older adults focus on cognitive function. Data showed that the prevalence of Alzheimer's disease among Chinese people aged 60 and above is 3.9%, making it a major public health issue in China. As a key transitional stage between objective cognitive impairment and intact cognition, SCD represents a critical window of opportunity to prevent or delay the onset of mild cognitive impairment or dementia. Therefore, this study will investigate the current status and influencing factors of older adults with SCD and conduct intervention studies for

older adults with SCD, aiming to prevent or slow the progression from SCD to mild cognitive impairment and Alzheimer's disease.

2. Research Purpose

Conduct semi-structured interviews with community implementers to qualitatively evaluate the implementation effect of the intervention program based on the RE-AIM and CFIR frameworks.

3. Research Content and Procedures

3.1 Research Content

This study will conduct semi-structured interviews with community implementers to obtain their process evaluation of the intervention program, analyze factors influencing successful implementation, and further optimize the program and implementation process to promote large-scale application of the program in communities.

3.2 Participants

(1) Inclusion criteria: ① Staff who have been trained and have implemented this intervention program in the community; ② Willing to participate in the interview.

(2) Exclusion criteria: ① Those who have not been trained; ② Those who discontinued implementation.

(3) Sample size: This part of the study is a descriptive qualitative study. The sample size is determined by whether the interview information reaches saturation. It is generally considered that saturation is reached when no new codes or themes emerge.

4. Your Cooperation Needed in the Study

The researcher will conduct a face-to-face interview with you. Before the interview, the researcher will communicate with you in advance to arrange a convenient time and place. Before the interview, the researcher will explain the purpose and significance of this study to you. With your consent, the entire interview will be audio-recorded using a recorder. During the interview, you need to answer the researcher's questions truthfully. After the interview, the researcher will review the main points you mentioned with you for confirmation. The entire interview will take approximately 30–40 minutes.

5. Possible Risks, Discomforts, and Management Measures

Based on the current study design and known information, this study does not involve any procedures with high risks or significant discomfort.

6. Potential Benefits and Compensation

(1) Benefits to the participant: You may not receive direct benefits from participating in this study.

(2) Benefits to society: This study provides key intervention targets for early blockade of the Alzheimer's disease pathological process, prevents or delays cognitive decline in older adults with SCD, and provides a practical pathway for healthy aging.

(3) Compensation: After the interview, the researchers will provide you with a red envelope worth 20 RMB as a token of appreciation for your participation.

7. Voluntary Participation/Withdrawal

You may choose to participate or withdraw at any time.

8. Confidentiality of Personal Information

All information collected during the study will be kept confidential and stored by the researcher. Researchers, ethics committee members, and relevant regulatory authorities have the right to review your information records within the limits permitted by law. Your personal information will not be disclosed in any research reports or publications arising from this study.

9. Contact Information

You may ask questions about this study at any time. You can contact the researcher: Zhi Cai , Tel:+86-18940226278. If you have any concerns about your participation, please contact the Ethics Committee (Tel: 02431939080). We sincerely appreciate your support for this study!

CONSENT STATEMENT

1. I have carefully read the above introduction to this study and have had the opportunity to discuss it with the researcher and ask questions.

2. I understand that participation is voluntary. I confirm that I have had sufficient time to consider this and understand that:

(1) I may ask the researcher for more information at any time;

(2) I may withdraw from the study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

Finally, I agree to participate in this study voluntarily and am willing to cooperate and complete this study according to the study protocol.

Participant's signature: _____ Date: _____ Tel: _____

Authorized representative's signature: _____ Date: _____ Tel: _____

I have fully explained and clarified the purpose, procedures, and potential risks and benefits of this study to the participant, and have satisfactorily answered all of the participant's questions.

Researcher's signature: _____ Date: _____ Tel: _____

INFORMED CONSENT FORM

(Intervention Study)

Dear Sir/Madam:

Hello! We invite you to participate in a research study titled "Application Research of a Group Non-Pharmacological Intervention Program for Community-Dwelling Older Adults with Subjective Cognitive Decline," approved by China Medical University. This study has been reviewed by the Medical Ethics Committee of China Medical University.

Your participation is voluntary. Before you decide, please read the following information carefully to help you understand this study. If you have any questions, please feel free to ask the researcher, who will answer them. If you wish, you may also discuss it with your relatives or friends to help you make a decision. Below is an introduction to this study:

1. Background

Subjective Cognitive Decline (SCD) refers to an individual's self-reported decline in cognitive level compared to previous status , while neuropsychological tests are still within the normal range. It is considered the first symptom of Alzheimer's disease (AD) and lies in the preclinical phase of the AD pathophysiological continuum. SCD is relatively common among older adults, with an incidence rate as high as 25%–58.33%. The average progress rates from SCD to objective cognitive impairment was 7.1%. With the global aging trend, the incidence of Alzheimer's disease continue to rise, making older adults focus on cognitive function. Data showed that the prevalence of Alzheimer's disease among Chinese people aged 60 and above is 3.9%, making it a major public health issue in China. As a key transitional stage between objective cognitive impairment and intact cognition, SCD represents a critical window of opportunity to prevent or delay the onset of mild cognitive impairment or dementia. Therefore, this study will investigate the current status and influencing factors of older adults with SCD and conduct intervention studies for

older adults with SCD, aiming to prevent or slow the progression from SCD to mild cognitive impairment and Alzheimer's disease.

2. Research Purpose

Conduct semi-structured interviews with community implementers to qualitatively evaluate the implementation effect of the intervention program based on the RE-AIM and CFIR frameworks.

3. Research Content and Procedures

3.1 Research Content

This study will conduct semi-structured interviews with community implementers to obtain their process evaluation of the intervention program, analyze factors influencing successful implementation, and further optimize the program and implementation process to promote large-scale application of the program in communities.

3.2 Participants

The research subjects are community-dwelling older adults with SCD. Inclusion and exclusion criteria are as follows:

Inclusion criteria: (1) Age ≥60 years; (2) Community-dwelling; (3) Subjective Cognitive Decline, confirmed by a score of ≥5 on the Subjective Cognitive Decline Questionnaire (SCD-Q9); (4) Montreal Cognitive Assessment (MoCA) score ≥19 for participants with primary education, ≥22 for secondary education, or ≥24 for higher education; (5) Unimpaired activities of daily living; (6) No planned exercise or cognitive intervention activities in the past 6 months; (7) Voluntary participation and signed informed consent.

Exclusion criteria: (1) Any other neurodegenerative disease (e.g., mild cognitive impairment, dementia, Parkinson's disease, stroke, etc.); (2) Any severe or unstable medical condition (e.g., unstable or severe asthma, heart disease, liver or kidney disease, uncontrolled hypertension, severe metabolic disease, etc.); (3) Severe depression, anxiety, or other mental disorders; (4) Contraindications to exercise; (5) Current participation in other research trials.

4. Your Cooperation Needed in the Study

4.1 Before you are enrolled in the study, the researchers will ask about and record your medical history and conduct cognitive function screening. If you are eligible, you may voluntarily participate in the study and sign the informed consent form. If you do not wish to participate, your care will proceed according to your wishes.

4.2 If you voluntarily agree to participate, the following procedures will take place:

Eligible older adults with SCD will receive the 12-week community-based group non-pharmacological intervention program for SCD, three times per week. You will be assessed three times: one week before the intervention, immediately after the intervention (week 12), and at week 24. Each assessment includes 13 questionnaires (Subjective Cognitive Decline Questionnaire, Montreal Cognitive Assessment, Auditory Verbal Learning Test (Huashan version), Shape Trails Test, Digit Symbol Substitution Test, Animal Fluency Test, Activities of Daily Living Scale, Physical Activity Scale for the Elderly, Geriatric Depression Scale, Lubben Social Network Scale-6, Social Participation Scale, Perceived Social Support Scale, and Lifestyle Scale for Reducing Dementia Risk). Each assessment will take approximately 60 minutes.

5. Possible Risks, Discomforts, and Management Measures

The study design and implementation are based on ensuring the safety of older adults. Intervention intensity and dosage are reasonably controlled according to the participants' age and physical activity ability. To ensure participant safety, researchers will explain and guide the intervention program in detail to avoid unnecessary injury. Researchers will also describe possible adverse symptoms that may occur during the intervention. Participants will be instructed to immediately inform the project leader if they experience hypoglycemia, shortness of breath, palpitations, or falls during the intervention. The project leader will assist in contacting medical units for treatment. In the event of a study-related injury, the research team will bear appropriate responsibility, provide necessary treatment free of charge, and provide corresponding financial compensation according to relevant regulations. All adverse events during the intervention will be recorded, and regular research team meetings will be held to analyze the causes of adverse events. Adverse events are defined as harmful outcomes occurring during the intervention, such as falls during exercise.

6. Potential Benefits and Compensation

(1) Benefits to the participant: Participating in this study will help you gain more knowledge and skills about SCD and may improve your cognitive function, daily living ability, and quality of life.

(2) Benefits to society: This study will construct and apply non-pharmacological intervention program for community-dwelling older adults with SCD in China, thereby preventing or delaying cognitive decline in this population, improving activities of daily living, promoting social interaction among older adults, reducing the disease burden on families and society, and providing scientific support and practical pathways for healthy aging.

(3) Compensation: After the study, you will receive a gift worth 200 RMB as a token of appreciation for your participation.

7. Voluntary Participation/Withdrawal

You may choose to participate or withdraw at any time.

8. Confidentiality of Personal Information

All information collected during the study will be kept confidential and stored by the researcher. Researchers, ethics committee members, and relevant regulatory authorities have the right to review your information records within the limits permitted by law. In accordance with research ethics standards, participants in this study have the right to be informed and to access their data after the trial period. You may obtain a copy of your personal data related to this study by submitting a written request.

9. Contact Information

You may ask questions about this study at any time. You can contact the researcher: Cai Zhi, Tel: +86-18940226278. If you have any concerns about your participation, please contact the Ethics Committee (Tel: 02431939080).

CONSENT STATEMENT

1. I have carefully read the above introduction to this study and have had the opportunity to discuss it with the researcher and ask questions.

2. I understand that participation is voluntary. I confirm that I have had sufficient time to consider this and understand that:

(1) I may ask the researcher for more information at any time;

(2) I may withdraw from the study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

Finally, I agree to participate in this study voluntarily and am willing to cooperate and complete this study according to the study protocol.

Participant's signature: _____ Date: _____ Tel: _____

Authorized representative's signature: _____ Date: _____ Tel: _____

I have fully explained and clarified the purpose, procedures, and potential risks and benefits of this study to the participant, and have satisfactorily answered all of the participant's questions.

Researcher's signature: _____ Date: _____ Tel: _____

Medical Ethics Committee of China Medical University

Ethical review approval document

No.: Lun Shen [2026] No. 161

Project Name	Applied research on a group-based non-pharmacological intervention program for community-dwelling older adults with subjective cognitive decline				
Project Source	☐Vertical projects □Horizontal projects ☑University-funded projects or others				
Principal Investigator	Yu Liu	Title	professor	phone	+86-18940226278
The affiliated college	School of Nursing		Department	community care	
Responsible research Institution	China Medical University				
Collaborating Research Institution	——				
Research start and end dates	June 1, 2026 – December 1, 2029				

Type of ethical review	☐ Committee review ☑Expedited review
Review decision	This committee has reviewed the research process, objectives, source materials, and the informed consent plan for participants of the project submitted in this application. After preliminary review, the ethical issues related to biomedical research involving human subjects in this project comply with the requirements of the Declaration of Helsinki and the 'Measures for Ethical Review of Life Sciences and Medical Research Involving Human Subjects'. Accordingly, the committee approves the implementation of the project according to the proposed research plan Chairperson: Medical Ethics Committee of China Medical University Year Month Day
Note: 1.During the research process, any amendments to the study protocol, informed consent form, and other relevant documents, as well as changes of the principal investigator, require submission of an 'Amendment Review' application. Such amendments may only be implemented after approval by the Ethics Committee. 2. In the event of serious adverse events or suspected unexpected serious adverse reactions, these must be reported promptly to the Ethics Committee. The Ethics Committee has the authority to make new decisions based on its assessment of such events.	
List of review materials: Ethical review application form, research protocol, informed consent form, applicant's letter of commitment, and special circumstances explanation.	