The Journal of Prevention of Alzheimer's Disease 13 (2026) 100623

Contents lists available at ScienceDirect

The Journal of Prevention of Alzheimer's Disease

journal homepage: www.elsevier.com/locate/tjpad

Original Article

Tailored implementation of multidomain intervention to prevent cognitive impairment in community-dwelling older adults (Timi-Cog): A study protocol for a hybrid type 2 trial effectiveness-implementation study

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ARTICLE INFO

Keywords:
Cognitive impairment prevention
Older adults
Multidomain non-pharmaceutical intervention
Implementation science

ABSTRACT

Background & Objectives: Despite growing recognition of multidomain non-pharmaceutical interventions (NPIs) for preventing cognitive impairment, their scalable implementation remains underdeveloped in China. This hybrid type 2 effectiveness-implementation study aims to bridge this gap by identifying implementation determinants, developing tailored strategies, and evaluating both implementation or health outcomes for multidomain NPIs and tailored strategies.

Abbreviations: Timi-Cog, Tailored Implementation of Multidomain Intervention to Prevent Cognitive Impairment in Community-Dwelling Older Adults; AD, Alzheimer's disease; MCI, Mild cognitive impairment; NPIs, Non-pharmaceutical interventions; FINGER, The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability; MAKS, Motor stimulation, Activities of daily living training, Cognitive stimulation, Social functioning; cRCT, Cluster-randomized controlled trial; ADI, Alzheimer's Disease International; WHO, World Health Organization; NCOs, Non-communicable diseases; CFIR, Consolidated Framework for Implementation Research; TDF, Theoretical Domains Framework; COM-B, Capability, Opportunity, Motivation, Behavior; ERIC, Expert Recommendations for Implementing Change; CHW, Community health workers; EBP, Evidence-based practice; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; StaRi, Standards for Reporting Implementation Studies; CONSORT, Consolidated Standards of Reporting Trials; MMSE, Mini-Mental State Examination; ADL, Activities of daily living; IADL, Instrumental activities of daily living; PASE, Physical Activity Scale for the Elderly; MNA, Mini nutritional assessment; GDS-15, Geriatric Depression Scale-15; GPs, General practitioners; CNA, Configurational analysis; AI, Artificial intelligence; LLM, Large language model; BMI, Body mass index; MDT, Multidisciplinary team; DASH, Dietary Approaches to Stop Hypertension; MIND, Mediterranean-DASH Intervention for Neurodegenerative Delay; RPE, Rating of Perceived Exertion; ICC, Intracluster correlation coefficient; MoCA-B, Montreal Cognitive Assessment-Basic; CDR, Clinical Dementia Rating; CSQ-8, Client Satisfaction Questionnaire-8; BARS, Brief Adherence Rating Scale; AVLT, Auditory Verbal Learning Test; LMT, Logical Memory Test; TMT-A, Trail Making Test-A; TMT-B, Trail Making Test-B; DSST, Digit Symbol Substitution Test; DST, Digit Span Test; BNT, Boston Naming Test; KAP, Knowledge, Attitude, and Practice; PSQI, Pittsburgh Sleep Quality Index; PDI, Plant-based Diet Index; SSRS, the Social Support Rating Scale; HRQoL, Health-Related Quality of Life; NIHR, UK's National Institute for Health and Care Research; NoMAD, Normalization MeAsure Development questionnaire; PSS, Perceived Stress Scale; SIAS-6, Social Interaction Anxiety Scale-6; MFS, Mental Fatigue Scale; CTCAE, Common Terminology Criteria for Adverse Events; DMC, Data Monitoring Committee; IRB, Institutional Review Board; CI, Confidence Interval.

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https://doi.org/10.1016/j.tjpad.2026.100623
Received 22 March 2026; Received in revised form 6 May 2026; Accepted 1 June 2026
Available online 13 June 2026

Hybrid type 2 effectiveness-implementation trial

Methods: This protocol describes the design of an ongoing study. The formative phase has been completed: guided by Consolidated Framework for Implementation Research (CFIR), we integrated the COM-B model from the Behaviour Change Wheel (BCW) and the Theoretical Domains Framework (TDF) into an interview guide. Key informant interviews and focus groups identified barriers/facilitators, and the CFIR-ERIC matching tool finalized the implementation strategies. Subsequently, a hybrid type 2 cluster RCT will be conducted (or is currently underway) across 13 districts in Changxing County, Zhejiang. A total of 1170 older adults and 273 community health workers (CHWs) - including general practitioners, social workers, and volunteers - will be randomized into three study arms: Arm 1 will receive evidence-based practices (EBP) combined with intrinsic motivation; Arm 2, EBP with implementation strategies; and Arm 3 (control), health education with implementation strategies. The EBP package includes cardio-metabolic risk management, cognitive training, physical activity, and nutritional counseling. Implementation uses three bundles: (1) Capacity Building and Professional Support, (2) Collaborative Implementation and Network Building, and (3) an AI-enabled WeChat mini-program (Timi-Cog). Outcomes will be assessed using the *Re*-AIM framework over 18 months. Statistical analysis will employ mixed-effects linear models, adjusted for baseline characteristics and clustering effects.

Conclusions & Implications: This theory-informed initiative addresses the dementia prevention implementation gap in China. By combining BCW/TDF frameworks with implementation science methods and employing a hybrid design, the study will generate robust evidence on both clinical effectiveness and practical implementation, informing the integration of multidomain NPIs into China's primary care system.

Trial Registration: Chinese Clinical Trial Registry (ChiCTR2500098587).

Contributions to Literature

- ➢ This protocol presents a theory-informed, hybrid type 2 effectiveness-implementation trial that integrates the Consolidated Framework for Implementation Research (CFIR), the Behaviour Change Wheel (BCW), and the Theoretical Domains Framework (TDF) to systematically develop and evaluate tailored implementation strategies for multidomain non-pharmaceutical interventions (NPIs) in preventing cognitive impairment among Chinese older adults.
- ➢ Findings will generate context-specific evidence on facilitators, barriers, and effective implementation strategies for dementia prevention in a rapidly aging Chinese county, contributing to the integration of multidomain NPIs into primary care systems.
- ➢ It introduces a novel, three-bundle implementation strategy that combines capacity building, multi-sector collaboration, and an artificial intelligence (AI)-enabled WeChat Mini-Program ("Timi-Cog") to support scalable delivery of evidence-based NPIs in community settings.
- ➢ The study employs a cluster-randomized design with three parallel arms, allowing for concurrent evaluation of both implementation outcomes (e.g., fidelity, adoption) and health outcomes (e.g., cognitive function) within the same trial in different population.
- ➢ The protocol demonstrates the application of the *Re*-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework for multi-dimensional evaluation, offering a replicable methodology for future implementation research in low- and middle-income country (LMIC) settings.

1. Introduction

Dementia is a syndrome characterized by acquired cognitive impairment, resulting in a substantial decline in patients' capabilities for daily living, learning, work, and social interaction [1]. Recent investigations have revealed that the pathophysiological alterations in dementia commence 15–20 years prior to the onset of clinical manifestations [2]. Preclinical stage of Alzheimer's disease (AD) and Mild cognitive impairment (MCI), intermediate phases between normal cognition and the progression to dementia, features a highly variable cognitive trajectory [3]. There is a general agreement that early intervention can substantially decelerate cognitive decline and diminish the risk of transformation to dementia. The Lancet Commission has reported that early targeted interventions for high-risk factors can reduce the risk of developing dementia by 45% [4]. Conversely, once the disease advances to the stage of dementia, treatment focuses on controlling symptoms and slowing progression rather than restoring lost cognitive function [3]. Consequently, early prevention of dementia is of utmost significance to public health efforts.

Non-pharmaceutical interventions (NPIs) are critically paramount for individuals at high risk of dementia—specifically during the preclinical "golden window" of AD and MCI. This is particularly true given the global scarcity of disease-specific medications and their role in bridging the treatment divide [5]. During the early "golden window" of the disease, NPIs can promote neuroplasticity and support preventive lifestyle alterations [6]. Multidomain interventions—integrating cognitive training, physical activity, nutritional guidance, and metabolic-vascular risk management—have been proven to slow cognitive decline, reduce dementia incidence, and elevate quality of life [7,8]. Their safety and cost-effectiveness further serve to alleviate long-term medical burdens on families and society [8]. However, unidimensional NPIs (e.g., isolated cognitive or physical training) exhibit inherent limitations due to their partial modulation of dementia's complex pathological pathways. This underscores the need for a shift toward integrated, multidomain approaches, which leverage mechanisms such as neurovascular coupling to coordinately modulate neural, vascular, and metabolic processes, thereby achieving synergistic effects beyond single-target therapies [9]. Given the inherently limited efficacy of compartmentalized, mono-target therapies, multidimensional frameworks are not merely beneficial but necessary to holistically engage the complex and multifactorial etiology of the disease.

Multidomain NPIs, exemplified by Finland's FINGER (The Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability) program (combining cognitive training, physical activities, nutrition guidance, and metabolic-vascular risk factors management) [10]and Germany's MAKS project (Motor stimulation, Activities of daily living training, Cognitive stimulation, Social functioning) [11], have established paradigmatic models globally. Nevertheless, their cross-national implementation consistently encounters theory-to-application translation bottlenecks, even with the Worldwide FINGERs network accelerating knowledge exchange [12]. As part of the Worldwide FINGERS network, the MIND-China study implemented a two-year cluster-randomized controlled trial (cRCT) in rural Shandong, China, to evaluate a multidomain NPIs and has shown preliminary positive outcomes [13]. The persistent scarcity of eastern China's county-level regions in existing literature, coupled with a general absence of population-scale intervention research, highlights the necessity for validating multidimensional NPIs within diverse sociodemographic contexts across the country.

According to the Alzheimer's Disease International (ADI) 2025 assessment report, global progress in dementia prevention and control

was significantly lagging behind established targets [14]. While the World Health Organization (WHO) set a goal for 75% of member states (146 countries) to develop national dementia plans by 2025, only 45 countries (23.2% of member states) had implemented such plans as of May 2025, achieving merely 30.8% of the target [14]. The implementation of risk interventions reveals a stark global disparity. Initiatives in high-income countries such as the United States and the United Kingdom contrast sharply with the widespread difficulties in low- and middle-income countries, where the lack of systematic strategies and supportive frameworks leads to a consistent failure in on-the-ground implementation [15]. These findings revealed substantial disparities in both policy formulation and implementation across the global dementia response landscape. Responding to this challenge, China's "National Action Plan for Coping with Dementia in Older Adults (2024–2030)" was released in 2025, which has set a target of 80% coverage rate for cognitive interventions among community-dwelling older adults receiving health services by 2030 [16]. This reflected that the expanding scope and increasing complexity of China's dementia prevention and treatment mandate demand more from municipal capacity and implementers' professional expertise. However, merely issuing a national program might not yield substantial clinical changes. The translation of theory into practice varies greatly, and NPIs implementation might face barriers. For example, inadequate professional competence can lead grassroots implementers to misuse intervention methods, like substituting professional cognitive interventions with regular recreational activities, reducing effectiveness [17]. Additionally, low adherence among older adults, inconsistent participant populations, and weak social support systems (e.g., lack of family support for solitary older adults and poor community service integration) can undermine intervention sustainability [18,19]. To address this translational gap, a structured theoretical framework is indispensable. Implementation science offers a systematic methodology to identify key determinants of implementation success, thereby informing the design of targeted strategies that increase the likelihood of policy adoption and the scalability of proven interventions.

In 2016, the WHO expounded that integrating implementation science concepts into the prevention and management of noncommunicable diseases (NCOs) could mitigate the disparity between evidence and implementation, efficiently curtail the escalation of medical expenditures, and diminish the probabilities of disease prevalence and fatality [20]. Although many studies conducted out of China have applied implementation science to the screening [21,22], clinical intervention [23], and development of prevention and care systems for dementia in older adults [24,25], research on localized facilitators and barriers remains insufficient in China. While the construction of cognitive impairment friendly communities for older adults, exemplified by Changxing County, Huzhou City [26], is at the forefront in China, their core components still exhibited two critical evidence gaps: 1) The key facilitators and barriers during NPIs implementation and corresponding coping strategies; 2) The evidence-based design of a multi-dimensional effectiveness evaluation system and dissemination pathways.

Given the absence of prior studies developing tailored implementation strategies for multidomain NPIs in preventing cognitive decline among older adults—and the lack of concurrent evaluation of both implementation strategies and NPIs within specific local contexts in China, such as Changxing County—this study addresses two core questions: 1) What barriers and facilitators influence the implementation of multidomain NPIs in China, and how can they inform tailored implementation strategies? 2) What multidimensional framework can be proposed to concurrently evaluate the effectiveness of both the implementation strategies and the multidomain NPIs in China?

To systematically address these questions, the study first employed the Consolidated Framework for Implementation Research (CFIR), integrating the COM-B (Capability, Opportunity, Motivation, Behavior) model and Theoretical Domains Framework (TDF) into an interview guide to identify contextual barriers and facilitators through key informant and focus group interviews. The derived strategies were refined using the CFIR-ERIC (expert recommendations for implementing change) matching tool and are now being evaluated together with evidence-based NPIs in a type 2 hybrid cRCT, with the *Re*-AIM framework guiding the multidimensional evaluation of both implementation and health outcomes.

2. Methods

2.1. Methods: patient and public involvement, trial design

2.1.1. Patient and public involvement

Patient and public involvement was structured across two phases. During the pilot phase, high-risk older adults from participating communities ensured the intervention design aligned with their needs. In the formal intervention phase, a newly recruited cohort of high-risk older adults will receive the implemented multidomain NPIs. The research team will provide systematic training and supervision to general practitioners, social workers, and volunteers (collectively termed community health workers, CHWs). Authorization to deliver or supervise interventions for older adults will be granted only following a successful competency assessment. Additional stakeholder involvement includes policy support from the local Health Commission and Civil Affairs Bureau in Changxing county. The relevant government directive is documented in the Additional File 1 to verify regulatory compliance and study approval.

2.1.2. Trial design

A type 2 hybrid cRCT design will be employed, with districts in Changxing County (n = 13) serving as the clusters for randomization and nearly 1:1:1 allocation to parallel groups (The three arms will receive evidence-based practice, EBP, with intrinsic motivation, EBP with implementation strategies, and health education with implementation strategies, respectively). A 4-month planning phase and a 6-month pilot phase have been completed, more details are presented in data collection and randomization part. This study has been registered with the Chinese Clinical Trial Registry (registration number: ChiCTR2500098587). Besides, our reporting in this protocol is in line with the 2025 SPIRIT checklist [27] (Additional File 2), StaRi Statement [28], and CONSORT checklist for cRCTs [29].

2.1.3. Study status and timeline

This article describes the study protocol only; no outcome data are presented. The formative work (CFIR-guided qualitative interviews, CFIR-ERIC matching, pilot testing of the EBP package) was completed between March and October, 2025. The main hybrid type 2 cRCT is currently ongoing. Recruitment of older adults and CHWs has been finished before October, 2025. The 18-month follow-up will finish by June 2027. All procedures conform to the approved protocol (IRB#2025–01–1192). Any protocol modifications will be documented in trial registries and future publications. Specific timeline description is presented in Section 2.2.3.1.

2.2. Methods: participants, interventions, and outcomes

2.2.1. Trial setting

A total of 1170 older adults and 130 CHWs were recruited from community settings in Changxing County (The formula for sample size calculation can be found in Section 2.2.6.1). The participants will be allocated at a rate of 90 older adults and 10 CHWs per district. Selected for its representative profile in the Yangtze River Delta region, Changxing County presents characteristic urban-rural integration with accelerated urbanization and notable population aging. Its sociodemographic attributes, chronic disease patterns, and primary healthcare delivery system effectively reflect prevalent health challenges across Chinese counties. Research conducted within this established

CHWs contract service framework ensures both methodological validity and regional scalability of intervention outcomes.

2.2.2. Eligibility criteria

The detailed rationale for each inclusion and exclusion criterion is provided in Additional File 3 (including relevant references). This includes justifications for: (1) the AD 8 $\geq$ 2 threshold for older adults; (2) the selection of modifiable risk factors based on the 2024 Lancet Commission report, including reasons for omitting certain factors; (3) the experience and commitment requirements for CHWs; and (4) all exclusion criteria for both older adults and CHWs, with emphasis on participant safety, intervention fidelity, and data integrity.

2.2.2.1. Inclusion criteria. **1. Inclusion criteria for older adults**

This study enrolled community-dwelling adults aged 60–85 years from Changxing County, who met the following criteria:

1) Ascertain Dementia 8 (AD8, scored $\geq$2), a rapid informant-based screener, efficiently identifying high-risk older adults in community settings [30];
2) $\geq$1 modifiable risk factor identified through brain-health assessments (physical activity: activities of daily living (ADL), instrumental activities of daily living (IADL), Physical Activity Scale for the Elderly (PASE); nutrition: mini nutritional assessment (MNA); psychological status: Geriatric Depression Scale-15 (GDS-15); low education; social isolation: Social Support Rating Scale (SSRS);
3) No planned prolonged absences;
4) Absence of severe physical disabilities;
5) Capacity to provide informed consent and commit to full protocol compliance (including 18-month follow-up and randomized allocation).

2. Inclusion criteria for CHWs

1) Licensed general practitioners (GPs) with full-time employment at participating community health centers in Changxing County;

2) Minimum 2 years of clinical experience (GPs) or community work experience (social workers or volunteers), including routine management of $\geq$50 middle-aged and older patients with chronic conditions or elderly social activities annually;

3) Institutional support and written commitment to complete the one-year training program;

4) Demonstrated communication competence for patient education.

2.2.2.2. Exclusion criteria. **1. Exclusion criteria for older adults**

Participants will be excluded based on any of the following:

1) Diagnosis of dementia or severe cognitive impairment (e.g., confirmed dementia or extremely low AD 8 scores);
2) Severe physical illness with life expectancy < study period or disability preventing assessment/intervention completion;
3) Severe mental illness or major neurological disorder (e.g., stroke, Parkinson's disease);
4) Uncorrectable severe sensory impairment affecting participation (eg., hearing and vision loss);
5) Concurrent enrollment in other intervention trials in the past 3 months;
6) Planned relocation or extended absence during the study period;
7) Severe communication barriers.

2.Exclusion criteria for CHWs

1) Planned extended leave (>1 month) or anticipated employment termination during study period;

2) Concurrent participation in conflicting interventional trials or training programs;

3) Immediate family members employed by research team or funding agency.

2.2.3. Intervention and comparator

Our implementation intervention targets a multidomain NPIs package for dementia prevention in older adults, adapted from the FINGER program. This intervention package was initially piloted in Minhang District in Shanghai [31] and subsequently refined through systematic reviews and consultations with multidisciplinary experts in neurology, geriatrics, nursing, social work, public health, and public management. These processes confirmed the feasibility of the NPIs for implementation in eastern areas in China. The final multidomain NPIs roll-up banner, brochure, guidelines, and handbook, which generated the EBP package were established in February 2025 (see Additional File 4, as exemplified by brochures). The implementation have received policy support from the Civil Affairs Departments in Changxing [32].

Our implementation strategies for EBP package were developed through a multi-stage process. The primary objective was to enable both urban and rural subdistricts to effectively translate evidence-based NPIs into their local clinical contexts, tailoring them to specific determinants of practice. The EBP package underwent a six-month pilot in Changxing County (six communities in Taihu and Zhicheng subdistricts) from March to September 2025. Throughout October 2025, the research team collated interview data and formulated implementation strategies based on the pilot findings. The implementation strategies confirmation followed a structured five-phase process [33]: initiating with a updated CFIR-guided retrospective scoping review across five core domains; conducting multi-stakeholder qualitative interviews across pilot and non-pilot cognitive impairment friendly communities based on purposive sampling strategies; performing integrative coding using CFIR-TDF-COM-B frameworks for systematic analysis; applying configurational analysis (CNA) to identify critical determinant combinations (facilitators and barriers) for implementation outcomes; and concluding with evidence-based strategy mapping through CFIR-ERIC matching tool to formulate actionable recommendations, then, the final implementation strategies will be determined through expert consensus (more details are presented in Fig. 1). Implementation strategies are demonstrated in intervention program.

The study includes two intervention arms and one comparator arm: Arm 1 receives EBP combined with intrinsic motivation; Arm 2, EBP with implementation strategies; and Arm 3 (control), health education with implementation strategies (The details of the three arms are described in detail in Section 2.3 Methods: Assignment of Interventions). The EBP package consists of the following four core components: (1) management of metabolic and cardiovascular risk factors; (2) cognitive training; and (3) a combined physical activity and (4) nutritional guidance program. Each component is described in detail below. Additionally, to ensure intervention integrity, experimental group participants must refrain from any additional structured cognitive or nutritional programs for the trial's duration, although necessary rescue interventions and stable management of pre-existing conditions are permitted, with any changes reported promptly.

2.2.3.1. Intervention program. The intervention process consists of three phases. First, the feasibility of implementing EBP in the local context has been assessed. Second, facilitators and barriers have been identified, and based on these, implementation strategies have been formulated to support the rollout of EBP. Finally, the formal intervention phase has

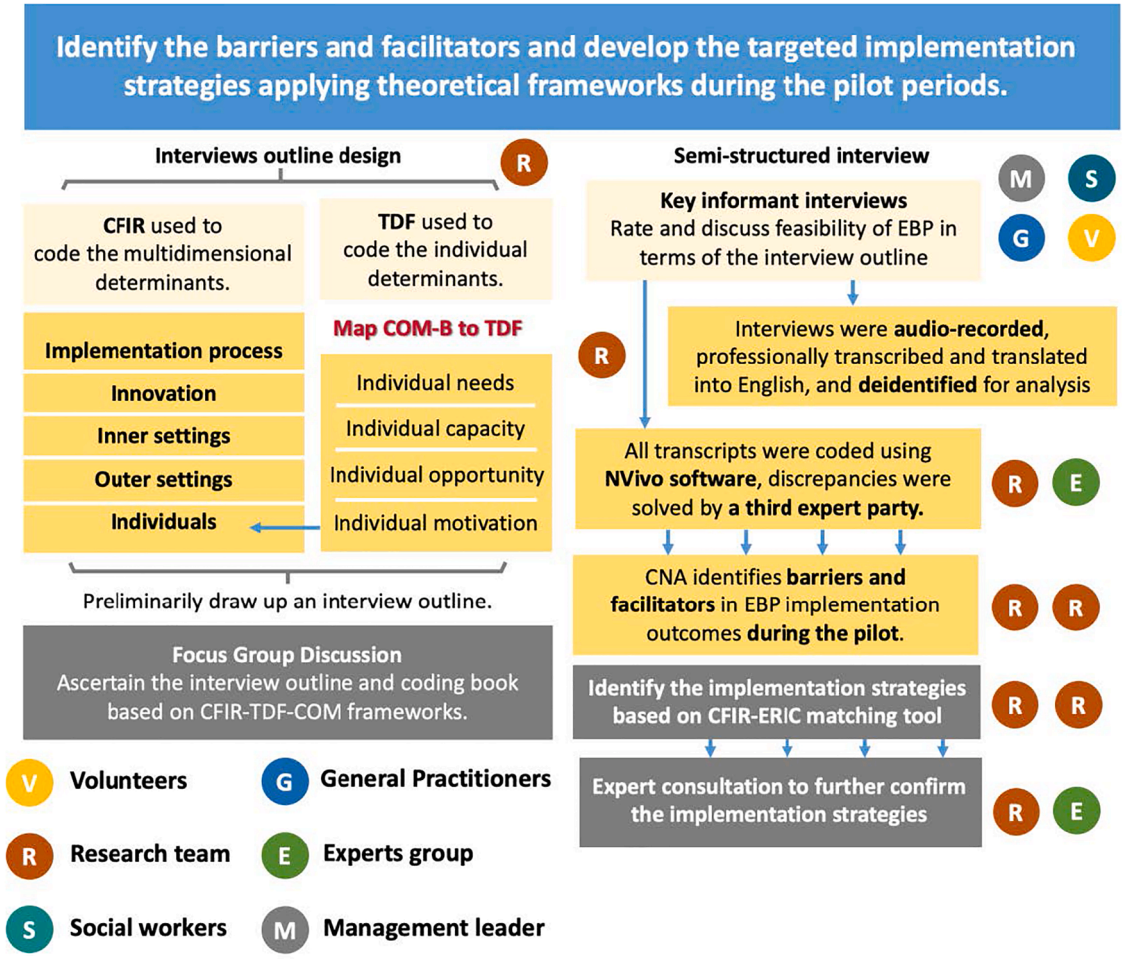

Fig. 1. the process of identifying implementation strategies.

been initiated, which includes four follow-up assessments conducted at 3, 6, 12, and 18 months post-intervention. The intervention covers four key areas: cardiometabolic risk factor management, cognitive intervention, physical activities, and nutrition intervention. Specific timelines and details of the intervention are presented in the Fig. 2 below.

Implementation strategy

The implementation approach integrates three core strategy bundles targeting human, organizational, and technological drivers to enable scalable, coordinated, and data-driven intervention delivery (Additional File 5).

Bundle 1–Capacity Building and Professional Support

Establishes a closed-loop system of selection, training, supervision, technical assistance, and resource development. It identifies general practitioners and community leaders as "Dementia Prevention Champions," adopts a train-the-trainer model with competency-based certification, and constructs a three-tier clinical supervision network (specialist physicians–trained GPs–peer learning). Complementary components include a remote technical assistance platform, a county-level multidisciplinary team anchored at the CDC, and academic partnerships (e.g., with Fudan University) that develop tiered educational materials, thereby ensuring intervention fidelity and long-term sustainability.

Bundle 2–Collaborative Implementation and Network Building

Builds a cross-sectoral, multi-level governance and coordination infrastructure. It establishes a three-tier governance structure (executive committee, expert advisory group, working groups), formalises a coalition through joint agreements between civil affairs and health departments, and weaves collaborative networks using WeChat groups, cross-site experience sharing, and facilitator-driven mechanisms. A monthly learning collaborative enables data-driven iterative improvement, while dedicated contractual funding from the Health Commission and Civil Affairs Bureau provides resource security and policy legitimacy.

Bundle 3–AI-enabled WeChat Mini-Program (Timi-Cog)

Creates a dual-sided intelligent health ecosystem. On the supply side, it equips GPs with LLM-powered modules for training and certification, predictive analytics, monitoring and feedback, personalised care plan generation, and local knowledge capture and sharing. On the demand side, older adults receive structured daily tasks (cognitive, physical, nutritional), dynamic health reports, and an incentive-based check-in system. A dedicated family portal allows caregivers to assist with check-ins and data entry while maintaining full traceability and privacy controls (the older adult can unbind at any time), thereby forming a closed-loop "physician-older adult-family" collaborative model that bridges the digital divide.

EBP package

Metabolic and Vascular Risk Factor Management

The integrated management program for metabolic and vascular risk factors focuses on the systematic prevention and control of NCOs, with particular emphasis on conditions demonstrating significant metabolic and vascular correlation features, such as diabetes, hypertension, heart failure, and coronary heart disease. Regular monitoring and health education sessions by CHWs enhance relevant disease awareness among older adults.

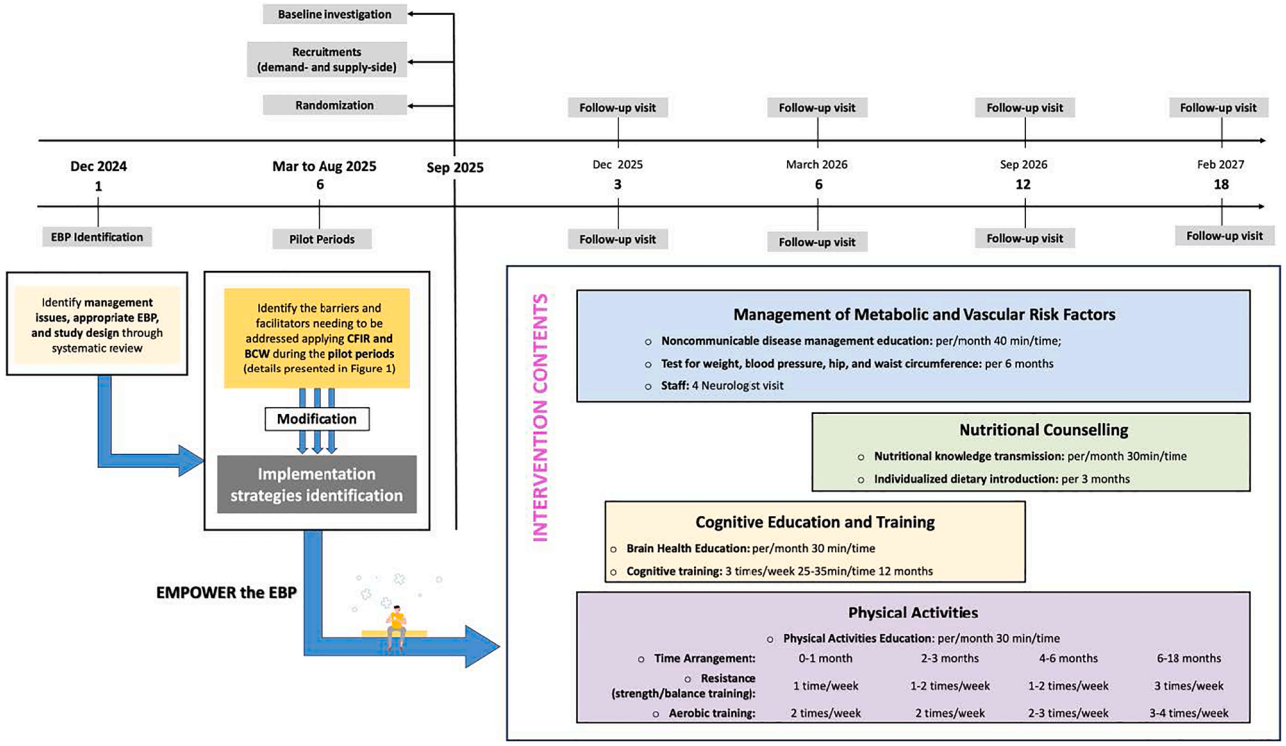

Fig. 2. Timeline of Multidomain Non-pharmaceutical Interventions and Assessments.

1) Dynamic Monitoring Mechanism: A core team of four neurologists leads implementation, providing standardized training and case supervision to CHWs at baseline and at scheduled follow-up intervals (3, 6, 12, and 18 months). Monitoring encompasses key metabolic parameters—blood pressure, blood glucose, cholesterol level, body weight, body mass index (BMI), and waist-to-hip ratio—with biometric analysis utilized for the precise assessment of abdominal fat distribution and the evolution of cardiovascular risk per six months. The development of personalized health management plans is conducted within a multidisciplinary team (MDT) collaboration framework.

2) Health Education Systems: This unified system centers on personalized, monthly 40-minute sessions delivered by CHWs. Grounded in the tracking of key metabolic parameters like blood pressure and cholesterol, these sessions translate data into actionable health strategies. Education holistically covers: chronic disease pathogenesis linked to these metrics; personalized medication plans; and brain health science—connecting vascular risks to cognitive decline, alongside mechanisms of neuronal damage from smoking and poor sleep. Each session provides tailored, WHO-aligned interventions (e.g., smoking cessation, heart-healthy diet) specifically designed to improve the monitored parameters and overall brain health [34].

After each monthly session, CHWs conduct a 5-minute structured review using three validated cardiometabolic risk screening questions from the WHO Package of Essential Noncommunicable Disease Interventions (WHO PEN) and the 2024 Chinese Hypertension Guidelines [35]: (1) "What is a healthy blood pressure target for your age?" (target: <140/90 mmHg for ages 65–79, <150/90 mmHg for ≥80); (2) "What three key health numbers should be checked regularly to prevent heart attack and stroke?" (target: blood pressure, blood glucose, total cholesterol–the WHO PEN core screening panel); (3) "Name one lifestyle change that can help control blood glucose" (e.g., post-meal walking, reducing sugary drinks, or choosing whole grains). Incorrect answers trigger immediate re-teaching. Between sessions, CHWs make brief follow-up phone calls every two weeks to remind participants to monitor their metrics, address practical barriers (e.g., device use), and encourage goal persistence.

Cognitive Education and Training

Focused on preventing cognitive decline, the Cognitive Function Promotion and Brain Health Management Plan implements systematic interventions through two main modules: cognitive science education and structured training.

1) **Cognitive Education:** Monthly 30-minute thematic science lectures focus on elucidating the biological mechanisms of brain aging, clarifying the pathological features of AD and its differentiation from physiological memory decline, while also promoting control strategies for modifiable risk factors of dementia such as smoking/alcohol cessation, physical activities, healthy diet, and social engagement.

   Immediately after each lecture, CHWs lead a 2-minute oral recap covering two core points, followed by a weekly phone call to briefly review the previous topic and ask about any difficulties. Participants who complete three consecutive knowledge checks receive a small symbolic incentive (e.g., a "brain health star" sticker or a small daily necessity such as a kitchen towel, soap, or toothpaste), which was well-received in our pilot.
2) **Evidence-Based Cognitive Training System** [10,36]: Centered on metamemory, this 12-month intervention trains individuals to strategically oversee their own cognitive processes. The standardized protocol involves three 25–35 min sessions per week, with CHWs initiating the training, community staff and volunteers ensuring its continuity. Its content is organized into three core domains:
   - ➢ **Metacognitive & Executive Control:** Cultivating metaknowledge and monitoring, reinforced through N-Back tasks and techniques to manage the "Tip-of-the-Tongue" phenomenon.
   - ➢ **Multidimensional Memory Application:** Employing techniques such as the Picture Method, Categorization, Focus-Flash-Memorize, Face-Name Association, and the Roman Room for spatial location to enhance encoding and recall.

➢ **Integrated Functional Transfer:** Utilizing computer-based simulations (e.g., locating everyday objects) to bridge cognitive skills to real-world adaptive function.

Nutritional Guidance

1) Nutritional Education:

Through tiered monthly courses, this intervention builds dietary knowledge for dementia prevention and health maintenance in older adults. It focuses primarily on the scientific principles of China's "Eight Dietary Guidelines," [37] using comparative insights from Mediterranean [38], DASH [39], and MIND diets [40] to highlight complementary neuroprotective and health-preserving mechanisms. The goal is to synthesize these evidence-based principles into a practical and sustainable eating pattern tailored for Chinese adults.

One week after each monthly course, CHWs schedule a brief follow-up call to review one practical action the participant has tried (e.g., using the plate guide, adding one vegetable serving). CHWs offer positive reinforcement and collaboratively troubleshoot difficulties (e.g., cost, taste, cooking ease). A paper-based weekly action tracker posted on the refrigerator is checked by CHWs during home visits.

2) Nutritional Counseling: To address individual needs, quarterly 30-minute nutritional counseling sessions are conducted. Based on assessments of BMI, metabolic markers, and dietary habits, a tiered dietary plan is developed. This includes optimizing plate proportions, functional nutrient supplementation, and anti-inflammatory food substitutions. Dietary prescriptions are dynamically adjusted every 3 months according to health data changes, while the supporting knowledge base is concurrently updated with seasonal and evidence-based research to foster a cycle of improved understanding and behavior.

Physical Activities

1) Physical activities Instruction:

Strictly aligned with WHO global physical activity recommendations [34], the program promotes brain health in older adults through a structured monthly 30-minute exercise session led by certified instructors. The regimen integrates four key exercise types: resistance training (using dumbbells, resistance bands, or bodyweight exercises) to build muscle strength; aerobic exercise (such as brisk walking, stationary cycling, or swimming) to enhance cardiorespiratory fitness; balance practice (including single-leg stands and weight shifting); and mind-body exercises (notably Tai Chi, Ba Duan Jin, or yoga) to improve coordination and mental focus.

2) Exercise Supervision:

Participants will undertake a supervised physical exercise program encompassing strength training, balance training, and aerobic exercise. The strength training progression schedule follows the FINGER trial phases [8]: 0–1 month, 2–3 months, 4–6 months, and 6–18 months. Strength and balance training frequency increases per phase, conducted 1–3 times per week, while aerobic and min-body training frequency increases from 2–4 times per week. The strength training regimen is based on the baseline One-Repetition Maximum (1-RM) weight, re-measured at the 6, 12, and 18-month visits. If 1-RM cannot be assessed, the Rating of Perceived Exertion (RPE) scale [41] (0 = extremely easy to 10 = extremely hard) will be used remotely to gauge exercise difficulty. Each participant's training load will target an RPE of 5–6 for maximum repetitions, with 8–10 repetitions per set. Participants will be encouraged to exercise regularly at home and maintain exercise diaries collected by community staff.

2.2.3.2. Control program. The control group receives general health education aligned with implementation stratigies. This involves distributing printed materials (multidomain NPIs roll-up banner and brochures) on broad wellness topics and delivering quarterly group lectures—without personalized plans, structured follow-up, or tailored feedback. The approach maintains general health awareness without implementing systematic interventions.

To verify the theoretically inert nature of the control condition with respect to health and implementation outcomes, we have implemented a three-pronged validation strategy. First, content design: The educational materials deliberately exclude any systematic cognitive training (e.g., memory strategies, cognitive games) or personalized behavioral prescriptions targeting cognitive function. Second, independent expert review: The intervention manual and health education materials were independently reviewed by three external experts in geriatric medicine and public health who are not involved in the trial. All three confirmed that the content lacks theoretical mechanisms known to activate cognitive protective pathways (e.g., neuroplasticity-inducing tasks, metacognitive skill building). Third, ongoing process monitoring: Throughout the trial, 10% of control group sessions will be randomly selected for audio recording and content analysis. A trained research assistant, blinded to study hypotheses, will code session transcripts to verify the absence of active ingredients such as cognitive training exercises, personalized feedback, or iterative goal setting. Any deviation will trigger retraining of the control session deliverer and be reported as a protocol violation.

All participants receive standard clinical care for any newly detected cardiometabolic condition, regardless of group assignment. If a value reaches a clinically actionable threshold during follow-up (e.g., hypertension, hyperglycaemia, dyslipidaemia), the research team informs the participant and their GPs and advises standard management. This procedure is identical across arms. Thus, the control group does not receive active EBP components (personalised exercise, cognitive training, or one-on-one nutrition counselling) but is fully supported for routine medical needs. Any new medication use will be documented and considered in sensitivity analyses (Section 2.4.2.2).

2.2.4. Follow-up and outcome measurements

This study is evaluated using the *Re*-AIM framework, with each dimension assessed from three perspectives: the supply-side (GPs, social workers, and volunteers), the demand-side (older adults), and the administrative perspective. Specifically, Reach is evaluated from the demand-side, Adoption from the supply-side, and Effectiveness and Implementation are examined from both the supply- and demand-side perspectives. Maintenance is assessed from all the demand- and supply-side and the administrative perspective. Detailed procedures and measures are outlined in Table 1.

2.2.4.1. Primary outcomes (Effectiveness/Implementation). Cognitive function was assessed using a battery of three standardized instruments. The Montreal Cognitive Assessment-Basic (MoCA-B) was utilized to evaluate multiple domains, including executive function, language fluency, orientation, calculation, attention, and etc., with a total score range of 0 to 30 where higher scores indicate better performance [42]. The MMSE was applied as a general cognitive screening tool, also scored on a 0 to 30 scale [43]. Supplementing these, the Clinical Dementia Rating (CDR) provided a structured assessment of cognitive and functional performance in domains like memory and orientation, generating a global score on a 3-point scale to quantify the degree of impairment [43]. These three instruments are used to construct a single primary cognitive outcome: the global cognitive composite Z-score. For each follow-up visit, the raw score of each test is standardized using the baseline mean and standard deviation of that test in the study population. The composite score is then calculated as the arithmetic mean of the three individual Z-scores. This approach follows the methodology established in the FINGER trial and other major multidomain intervention studies [6,8].

As for primary implementation outcome, fidelity was chosen. Structural fidelity was assessed biannually by tracking GPs, social workers, and volunteers engagement (worktime proportion) and through standardized skills assessments [20]. Process fidelity was measured via older adults' satisfaction (Client Satisfaction

Table 1
Details of follow-up and outcome measurements.

Assessment items	Perspectives	Detailed description	Time				
			Baseline	Month-3	Month-6	Month-12	Month-18
Effectiveness-primary outcomes: cognitive function	Demand-side	MMSE, MoCA-B, CDR.	√	√	√	√	√
Implementation-primary outcomets: fidelity	Supply-side	Fidelity (structural and dynamic).	√		√	√	√
Effectiveness -secondary outcome	Demand-side	**Specific cognitive domains:** memory (AVLT, LMT), execution (TMT-B, DSST), attention (DST), processing speed (TMT-A).	√	√	√	√	√
	Demand-side	**Cardiometabolic risk factors and chronic disease status: 1) Clinical Assessment:** Height, weight, waist circumference, hip circumference, blood pressure, blood glucose, lipid profile (total cholesterol, LDL-C, HDL-C, triglycerides). **Chronic disease status:** History of chronic diseases, family history, and year of diagnosis.	√				√
	Demand-side	**Physical function:** BADL, IADL	√	√	√	√	√
	Demand-side	**Lifestyles:** sleep quality (PSQI), physical activities (PASE), nutrition and diets (MNA, PDI), drinking, smoking.	√	√	√	√	√
	Demand-side	**Quality of life and social function:** HRQOL, SSRS.	√	√	√	√	√
	Demand-and supply-side	**KAP levels** (including assessment of understanding of educational course content)	√	√	√	√	√
Reach-secondary outcome	Demand-side	**Quantitative Research:** Enrollment: Eligible consenters (count/%), Adherence: Session attendance + Assessment completion (%), Dropouts: Pre-completion count/rate.	√		√	√	
	Demand-side	**Qualitative Research:** 1–2 rounds of focus group interviews stratified by participant type (participants, decliners, dropouts).			√		√
Adoption -secondary outcome	Supply-side	**Quantitative Research:** revised LiHcQ scale.	√		√	√	√
	Supply-side	**Qualitative Research:** 1–2 rounds of focus group interviews (CHWs).			√		√
Implementation-secondary outcome	Supply-side	Acceptability (AIM), appropriateness (IAM), feasibility (FIM), cost (Labor, materials, equipment, administration).	√		√	√	√
Maintenance -secondary outcome	Supply-side and Administrative perspective	**Quantitative Research:** revised NoMAD scale.	√		√	√	√
	Demand-side, supply-side, and Administrative perspective	**Qualitative Research:** focus groups with stakeholders (Government sector (2–3), Community managers (2–3), Enterprise partners (2–3), Implementation team (5–10), Elderly participants(5–10).			√		√

Questionnaire-8, CSQ-8 [44]) and adherence (Brief Adherence Rating Scale, BARS [45]). To construct a single primary implementation outcome, a fidelity composite Z-score will be calculated. Each fidelity indicator (worktime proportion, skills assessment score, CSQ-8, BARS) is standardized using its baseline mean and SD, and the composite score is the arithmetic mean of the individual Z-scores.

2.2.4.2. Secondary outcomes (Effectiveness). A battery of standardized neuropsychological tests was administered to evaluate performance in four key cognitive domains: memory (assessed by the Auditory Verbal Learning Test, AVLT, and Logical Memory Test, LMT [46]), executive function (evaluated with the Trail Making Test-B, TMT-B, and Digit Symbol Substitution Test, DSST [47]), attention (measured by the Digit Span Test, DST [48]), and processing speed (using the Trail Making Test-A, TMT-A [49]).

Other health-related outcome measures encompassed multiple domains. Knowledge, Attitude, and Practice (KAP) levels were assessed separately in older adults [50] and CHWs [51]. Cardiometabolic risk was evaluated through clinical measures for older adults (height, weight, waist/hip circumference, blood pressure), blood assays (glucose, lipid profile including TC, LDL-C, HDL-C, and TG in mmol/L), and medical/family history. Physical and mental function were gauged using the ADL [52] and Lawton IADL scale [53], and GDS-15 [54], respectively. Health behaviors were profiled using the Pittsburgh Sleep Quality Index (PSQI) [55], the PASE [56], and MNA [57]; Plant-based Diet Index, PDI [58]). Finally, social support and quality of life were measured with the SSRS [59] and a Health-Related Quality of Life (HRQoL) scale [60].

2.2.4.3. Secondary outcomes (Reach). Quantitative tracking included enrollment rates (proportion of eligible consenters), similarity analysis of participants versus eligible decliners versus the overall eligible population (demographics/lifestyle), and pre-completion dropout counts/rates. Qualitative assessment involved stratified focus groups with participants, decliners, and dropouts at 6 and 18 months to explore participation motives, and, refusal/dropout triggers [61].

2.2.4.4. Secondary outcomes (Adoption). The quantitative assessment of adoption was based on top-tier scales from the UK's National Institute for Health and Care Research (NIHR) platform [62]. Firstly, CHWs' adoption intention was quantitatively gauged using the revised LiHcQ scale [63]. This was complemented by qualitative data from CHWs focus groups at 3, 6, and 18 months, which provided in-depth insights into the real-world determinants of adoption.

2.2.4.5. Secondary outcomes (Implementation). Implementation was evaluated across multiple dimensions. Perceptions of the intervention—including its acceptability, feasibility, and appropriateness—were gauged using Weiner's implementation scale recommended by the NIHR [64], while all associated costs (labor, materials, equipment, administration) were systematically monitored.

2.2.4.6. Secondary outcomes (Maintenance). The sustainability of the intervention was evaluated using a mixed-methods approach.

Quantitatively, the institutionalization of the intervention was measured with the revised NoMAD scale, as recommended by the NIHR [65]. Qualitatively, two rounds of 1-hour focus groups were conducted at 6 and 18 months post-intervention. These involved convenience-sampled stakeholders—including government representatives, community managers, enterprise partners, and the implementation team—and focused on outcome satisfaction, long-term health/social impacts, and the resource/policy requirements for long-term maintenance.

2.2.5. Harms

A comprehensive harms monitoring plan, integrating both systematic (active) and non-systematic (passive) surveillance strategies, is essential for the safety evaluation of this 18-month, multidomain NIPs targeting community-dwelling older adults with high-risk factors.

2.2.5.1. Systematic harm surveillance. Systematic Harm Surveillance (Active/Targeted) will proactively assess pre-specified, foreseeable risks associated with the intervention components. Key areas of focus include:

Psychological and Emotional Burden: The sustained nature of the 18-month intervention may lead to intervention-related fatigue, stress, or anxiety, particularly as participants manage multiple health-related tasks. This will be measured using validated instruments—the Perceived Stress Scale (PSS) at the scheduled assessment points [66].

Physical Discomfort and Safety Risks: Interventions involving physical activity components carry a potential for musculoskeletal discomfort (e.g., joint or back pain) or an increased risk of falls.

Social and Cognitive Overload: For interventions incorporating social engagement or cognitive training, social pressure or cognitive overwhelm are potential unintended consequences that will be monitored. Social and cognitive overload will be systematically monitored at all scheduled time points (3, 6, 12, and 18 months) using the SIAS-6 [67] and Mental Fatigue Scale (MFS) [68] administered by CHWs.

2.2.5.2. Non-Systematic Harm Surveillance. To capture any unexpected adverse events, participants will be encouraged to report new health concerns to their general practitioners spontaneously throughout the 18-month study. All reported events will be documented in detail and assessed for severity and causality by the research team. To ensure objectivity, this assessment will be conducted by staff blinded to group allocation using standardized criteria, including the Common Terminology Criteria for Adverse Events (CTCAE) [31].

2.2.6. Sample size and recruitment

2.2.6.1. Sample size. Informed by the methodological framework of the FINGER study, a mean differential of –0.21 points (standardized difference, SD: 0.5) in the global cognitive composite z-score was postulated between the control and intervention arms over the 24-month trial period [69]. Given that Timi-cog, consistent with FINGER, enrolled participants at increased dementia risk rather than confirmed mild AD cases, the anticipated cognitive decrement in the control group was calibrated to half of the AD cohort's observed decline, thus establishing the –0.21-point margin as the reference effect for power calculations. For CHWs, fidelity of implementation was selected as the primary outcome, with an assumed standardized effect size (Cohen's d) of 0.5 [70,71].

To justify the assumed intracluster correlation coefficient (ICC) of 0.02 and 0.05 for the primary health outcome [69,72] and implementation outcome [22], respectively, the study has adopted standardised implementation protocols across subdistricts within the same trial arm, including uniform recruitment criteria, training, arm-specific intervention materials, and assessment tools, combined with stratified randomisation. These measures help reduce between-site variability for both older adult outcomes and CHWs-related implementation outcomes. Nevertheless, residual differences (e.g., CHWs communication styles, participant engagement) may persist; therefore, we do not assert that the actual ICCs will exactly equal the assumed values (0.02 or 0.1).

Based on this ICC of 0.02 for older adults and 0.1 for CHW, a two-sided alpha level of 0.05 (Z_1-$\alpha/2 = 1.96$), and statistical power of 80% (Z_1-$\beta = 0.84$). With a fixed cluster size of 90 elderly individuals and 10 CHW per cluster [61,69], and allowing for 25% and 10% attrition respectively, the minimum sample required per study arm was computed as 330 elderly participants and 102 CHWs. Accordingly, for a three-arm cluster-randomized design, the total sample size necessary to ensure adequate power was determined to be 990 elderly subjects and 306 CHWs.

In practice, we have recruited 1170 older adults from the 13 subdistricts of Changxing County (90 per subdistrict), which exceeds the minimum requirement. The 90 participants in each subdistrict are supported by 21 CHWs, yielding a total of 273 CHWs. . Detailed calculation procedures are provided in Additional File 6.

2.2.6.2. Recruitment. While the final inclusion criteria (high-risk status and willingness to participate) were identical across sites, the initial recruitment pathways were strategically adapted to local contexts.

The recruitment strategy in Changxing was integrated into the routine resident health check-up system, leveraging this pre-existing, government-supported public health infrastructure to enable cost-effective and efficient screening of a broad elderly population, thereby minimizing selection bias associated with more limited clinical or volunteer-based recruitment channels.

2.3. Methods: assignment of interventions

2.3.1. Intervention allocation

In Changxing, a cluster randomization approach is adopted with subdistricts as the randomization units. The experimental design comprises three arms: Arm 1 receives EBP plus intrinsic motivation; Arm 2 receives EBP plus three bundled implementation strategies—Capacity Building and Professional Support (Bundle 1), Collaborative Implementation and Network Building (Bundle 2), and the AI-enabled WeChat Mini-Program Timi-Cog (Bundle 3); Arm 3 (control) receives health education plus the same three implementation strategy bundles (Bundles 1–3). This design enables two distinct comparisons: the assessment of EBP implementation outcomes through the comparison of Arms 1 and 2, and the evaluation of health outcomes through the comparison of Arms 2 and 3 [73]. All participating sub-districts are randomly allocated to the three study groups in a 1:1:1 ratio (details presented in Fig. 3). Specific measures to prevent contamination and information leakage across arms are described in Section 2.3.2.

After the completion of all T0 (baseline) assessments, the independent project statistician will generate the final random allocation sequence using the Stata RALLOC module. This master allocation list, which links each cluster (sub-district) to one of the three study arms, will be stored securely in a password-protected file accessible only to the statistician and an independent data manager. It will not be sent to the research team.

Upon confirmation of cluster eligibility after T0 assessment, the site coordinator (located in Changxing) initiates randomization by contacting an independent data manager via a dedicated telephone line. The data manager, who has no involvement in recruitment, assessment, or intervention delivery, verifies cluster eligibility and executes allocation without disclosing the assigned study arm to the coordinator. A password-protected email is subsequently sent for formal documentation. The data manager records the date, cluster ID, and assigned arm in a secure allocation log. The site coordinator documents only that

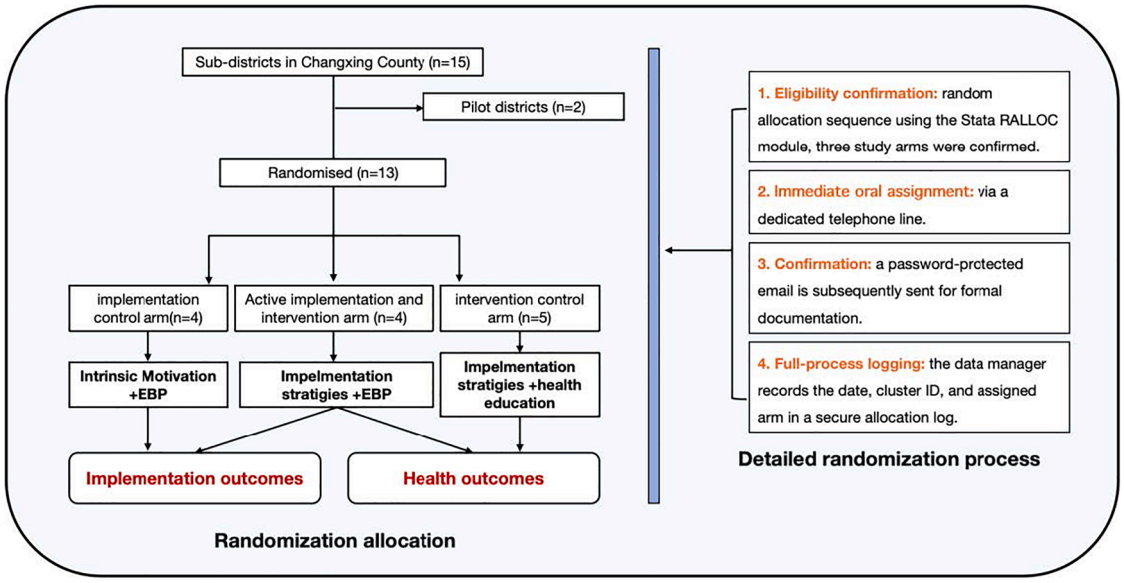

Fig. 3. Site-Specific Cluster Randomization Strategies.

allocation has been completed, without access to group assignment details.

2.3.2. *Double-Blinding*

In this behavioural trial, "double-blind" means that outcome assessors and the data analyst are fully blinded to group assignments, while older adults are not told which arm is intervention versus control. The intervention implementation team (CHWs) knows only the activities (e.g., physical activities) of their own arm and is blinded to the hypotheses and group comparisons, with no information shared across arms. The site coordinator is similarly blinded to group assignments. While participants are unavoidably aware of their own physical activity, our parallel design and blinding of critical personnel ensure that the study maintains scientifically valid double-blinding. The specific measures taken to achieve and preserve this blinding are detailed in the following sections.

First, a parallel intervention structure ensures that all three arms receive sessions matched in duration, frequency, session structure, and material appearance. The control group receives general health education that is structurally identical in format but theoretically inert, and all materials use identical packaging and formatting, making arm allocation indistinguishable to participants and CHWs (see Section 2.2.3.2 for the validation strategy). **Second,** access to the Timi-Cog WeChat Mini-Program is restricted: only Arm 2 and Arm 3 use it, and for the control arm the mini-program delivers only general health notifications and basic recording, without any active EBP modules (cognitive training, personalised nutrition, exercise supervision). This ensures the control group receives the digital strategy without producing effects comparable to the active arms. **Third,** to prevent contamination at the cluster level, randomisation is performed at subdistrict level–all individuals in the same subdistrict belong to the same arm. In Changxing, geographic buffers, independent community structures, and limited cross-subdistrict social interactions restrict information flow, supplemented by confidentiality commitments signed by all participants and CHWs. **Fourth,** separate teams deliver the active interventions and control sessions, coded labels (A/B/C) are used throughout the trial, and the implementation team remains unaware of the study's hypotheses and group comparisons.

Unblinding is allowed only in medical emergencies, requires principal investigator approval, and is performed by the independent data manager who discloses allocation exclusively to the treating physician. No routine unblinding occurs. Finally, blinding success will be evaluated at the 18-month follow-up using a brief questionnaire (group guess and confidence). The Bang Blinding Index (95% CI) [74] will be calculated, where 0 indicates successful blinding, positive values failure, and negative values reverse blinding; results will inform the interpretation of findings.

2.4. *Methods: data collection, management, and analysis*

2.4.1. *Data collection*

2.4.1.1. Quantitative data. This study implements a structured data collection protocol across five time points (baseline, 3, 6, 12, and 18 months) involving three participant groups: older adults, CHW, and program managers. The roles and procedures for assessment and data collection are as follows:

This study implements a structured data collection protocol where cognitive function assessments (e.g., MoCA-B, MMSE) for older adults are conducted by trained neuropsychology experts using paper-based questionnaires, while basic health information surveys (e.g., IADL, BADL) and harm information (e.g., PSS, MFS) are administered by the professional research team through the same paper-based format. CHW and program managers provide self-reported quantitative data through Wenjuanxing, an encrypted online survey platform accessible via digital devices. To ensure data quality, dedicated staff verify older adults' paper questionnaires for completeness and logical consistency, with telephone follow-ups conducted within 24 h to supplement missing information, while the digital platform incorporates automated consistency checks through repeated questions to verify response coherence, triggering prompts for resubmission or exclusion when inconsistencies are detected.

2.4.1.2. Qualitative data collection. During this phase, research staff will conduct data collection through semi-structured interviews with two stakeholder groups: supply-side providers (CHW) and management representatives (program managers). Data has been gathered through key informant interviews and focus group discussions using interview guides developed from the CFIR domains and the COM-B model from the BCW (combined with TDF). All interviews have been audio-recorded and transcribed verbatim, with quality assurance maintained through dual independent coding of qualitative data to ensure reliability and validity of the findings. These collected insights informed the development of an evidence-based implementation toolkit (Fig. 1).

Throughout the implementation period, research team members will systematically collect qualitative data at baseline, 6-month, and 12-month timepoints. Data will be gathered through semi-structured interviews and focus groups with the same stakeholder groups, following validated data collection protocols. All sessions will be audio-recorded, and qualitative data will undergo duplicate verification by two independent researchers to ensure accuracy and consistency. This systematic approach to data collection and analysis will support continuous refinement of implementation strategies based on RE-AIM framework metrics.

2.4.2. Statistical analysis

2.4.2.1. Qualitative data analysis. Qualitative data analysis was conducted in two sequential phases with distinct objectives but consistent analytical methods.

Phase 1 (pre-trial pilot phase, completed prior to formal intervention): To identify barriers and facilitators and develop tailored implementation strategies, we employed the CFIR. First, two researchers (ZS, GH) independently coded the pilot qualitative data based on NVivo documents. Double-checking was performed using MAXQDA software (Kappa coefficient=0.80–0.90), and discrepant cases were resolved through consensus arbitration by a third researcher (YW). Second, core themes within the CFIR domains were synthesized using thematic content analysis and then mapped to the behavior change mechanisms of the combined BCW and TDF model. Finally, targeted implementation strategies were matched using the ERIC framework. This phase informed the finalisation of the implementation strategy bundles before the main trial commenced.

Phase 2 (during the formal intervention and follow-up period): To enable dynamic adaptation and to provide explanatory evidence for quantitative outcome analyses (including factorial analyses of implementation effectiveness), we will repeat the same qualitative analytical procedures on follow-up interview data guided by the *Re*-AIM framework. Specifically, semi-structured interviews and focus groups will be conducted with stakeholders at 6 and 18 months post-baseline. The analysis will follow the identical CFIR-TDF-BCW-ERIC workflow to identify emerging barriers/facilitators and allow iterative refinement of implementation strategies. All qualitative data collection and analysis will be performed by research staff blinded to group allocation to preserve trial integrity. Additionally, to verify the theoretically inert nature of the control condition, content analysis of a 10% random sample of control session audio recordings will be performed using a predefined coding scheme based on EBP core modules; this analysis will be conducted by assessors blinded to study hypotheses and arm assignment. The findings from Phase 2 will be used to explain quantitative evaluation results and to elucidate maintenance mechanisms.

2.4.2.2. Quantitative data analysis (Participant characteristics and outcomes). First, Baseline characteristics of participants across the three study arms—EBP with implementation strategies, EBP with intrinsic motivation, and general health education plus implementation strategies—will be summarized using means (standard deviations) for continuous variables and frequencies (percentages) for categorical variables. Inter-group comparisons of baseline characteristics will be performed using Kruskal-Wallis tests for continuous variables and chi-square tests for categorical variables to assess initial equivalence.

Second, a mixed-effects linear model will be employed to examine intervention effects while accounting for the cluster-randomized design. This approach is particularly suitable for our cRCT as it can: 1) control for clustering effects at the community level; 2) incorporate random variation at both individual and time levels; 3) handle associations in longitudinal measurements across different timepoints; and 4) accommodate incomplete follow-up data using maximum likelihood estimation. Given the two co-primary outcomes targeting distinct populations—the global cognitive composite Z-score (health outcome in older adults) and the fidelity composite Z-score (implementation outcome in CHWs)—separate mixed-effects models will be fitted for each outcome, following the same general structure but applied to their respective samples. Secondary health and implementation outcomes will be analysed using the same mixed-effects model structure, with formal inference governed by the hierarchical testing strategy outlined in Section 2.2.4. The general form of the model for a continuous outcome is:

$$Y_{ijt} = \beta_0 + \beta_1 * \text{Group}_i + \beta_2 * \text{Time}_j + \beta_3 * (\text{Group} * \text{Time})_{ij} + \gamma * X_k + u_i + v_{ij} + \varepsilon_{ijk}$$

Where: Y_{ijt} is the outcome value for individual i in cluster j at time point k. β0 is the fixed intercept. β_1 primarily reflects between-group differences at baseline, while β_3 captures differences in trajectories over time across the groups. u_i and v_{ij} represent the random intercepts for individual i and cluster j, respectively, controlling for the hierarchical structure where individuals are nested within communities. The model will be adjusted for key baseline covariates, including age, gender, education level, and the baseline value of the outcome variable whenever applicable. ε_{ijk} is the residual error term. Fixed effects will include intervention group, region, time, and their interactions. Random effects will comprise random intercepts for individuals and clusters. We will employ likelihood ratio tests to evaluate the difference in model fit between models containing the key interaction term and those without it, thereby examining the statistical significance of the overall intervention effect. If the overall intervention effect is significant, we will proceed with planned post hoc pairwise comparisons, using the Tukey HSD method to adjust for multiple testing, in order to identify the optimal intervention approach. Importantly, this approach does not rely on a prespecified ICC value; instead, it estimates the variance components that quantify intra-cluster correlation directly from the data and adjusts standard errors accordingly. Thus, even if the actual ICC deviates from the assumed value of 0.02, the model still provides valid statistical inference, avoiding inflated type I error that could arise from underestimating clustering effects.

Third, for sensitivity analysis, we will evaluate the robustness of our findings from two perspectives. Above all, to address potential bias due to missing data, we will repeat the multiple imputation procedure under different missing not at random scenarios using the delta-adjustment method, systematically varying the difference in outcomes between completers and dropouts to examine the stability of our conclusions. Then, to account for potential confounding by newly initiated medications for cardiometabolic conditions during the trial, we will document the number and proportion of participants in each arm who start such treatments, and perform sensitivity analyses (e.g., excluding these participants or using inverse probability weighting) to assess the impact on primary and secondary outcomes.

Eventually, to control the overall type I error rate, a hierarchical testing procedure combined with false discovery rate (FDR) control will be used. The study has two co-primary outcomes: the global cognitive composite Z-score (health outcome, assessed in older adults) and the fidelity composite Z-score (implementation outcome, assessed in CHWs), each acting as a gatekeeper for its own secondary outcomes. **Health outcomes:** Secondary effectiveness outcomes (domai-specific cognitive scores, KAP, cardiometabolic measures, physical/mental function, health behaviours, social support, and quality of life) will be formally tested only if the cognitive composite Z-score is significant at α=0.05, using the Benjamini-Hochberg method (FDR = 0.05). Otherwise, they will be reported descriptively without inferential claims. **Implementation outcomes:** Other implementation outcomes (adoption, reach, acceptability, feasibility, appropriateness, cost, institutionalisation, and qualitative maintenance indicators) are exploratory and will be reported descriptively with unadjusted p-values; no multiplicity adjustment will be applied. Inferential claims will not be made

regardless of the fidelity composite's significance. All analysis procedures are prespecified. Both adjusted and unadjusted results will be disclosed.

The ICC will be calculated to quantify the proportion of outcome variance attributable to cluster effects. All analyses will be performed using R version 4.2.1 with the lme4 package for mixed-effects models, the emmeans package for post-hoc comparisons, and the mice package for multiple imputation. Statistical significance will be set at $\alpha=0.05$. Alongside p-values, effect estimates and their 95% confidence intervals (CI) will be presented.

2.5. Methods: monitoring

A formal Data Monitoring Committee (DMC) is not required for this cRCT evaluating low-risk, NPIs in community-dwelling older adults. The interventions, comprising general health education and psychosocial activities, pose no foreseeable physical or psychological risks beyond those of daily life. Given the study's focus on implementation effectiveness rather than drug safety or mortality, the complex interim analyses and safety monitoring typically overseen by an independent DMC are unnecessary.

Oversight for participant safety and data integrity will be ensured through alternative, robust mechanisms. The Institutional Review Board (IRB) will provide annual ethical review, while the research team will conduct continuous monitoring of trial conduct and adherence. Critically, any potential harms are actively monitored using a dedicated patient-reported outcome measure for harm questionnaires administered at each follow-up assessment. This proactive approach to harm data collection, combined with standard operating procedures for reporting adverse events to the IRB, provides a comprehensive safety monitoring framework appropriate for the risk level of this study.

Funding

This study was supported by The Noncommunicable Chronic Diseases-National Science and Technology Major Project of the National Key Research and Development Project of China (Grant No. 2017YFC1310500), the National Health Commission of China (Grant Nos. 2024ZD0524200 and 2024ZD0524203). China-World Health Organization 2024-2025 Biennial Collaborative Project Implementation Agreement (Grant GJ2-2025-WHOPO-C3).

Data availability

Not applicable

Declaration of the use of generative AI and AI-assisted technologies in scientific writing and in figures, images and artwork

During the preparation of this work, the author(s) used generative AI solely for language polishing and did not use any AI-assisted technologies for the scientific writing, data analysis, or creation of figures, images, or artwork.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the principles of the Declaration of Helsinki. The protocol was approved by the Institutional Review Board of the School of Public Health, Fudan University (IRB#2025–01–1192) and was registered with the Chinese Clinical Trial Registry (ChiCTR2500098587) (Additional File 7). Written informed consent will be obtained from all participants prior to enrollment. All data will be anonymized and kept confidential. Participants retain the right to withdraw consent at any time without penalty. As specified in the informed consent form, any data collected prior to withdrawal will remain in the study dataset for analysis.

Consent for publication

Not applicable.

CRediT authorship contribution statement

Zishuo Huang: Formal analysis, Data curation, Conceptualization. **Changmiao Shi:** Formal analysis. **Erxu Xue:** Methodology. **Gonghang Qiu:** Methodology. **Yurong Jing:** Conceptualization. **Ziyi Wang:** Conceptualization. **Xinhua Ao:** Conceptualization. **Dong (Roman) Xu:** Conceptualization. **Ying Wang:** Conceptualization.

Declaration of competing interest

All authors (Zishuo Huang, Changmiao Shi, Erxu Xue, Gonghang Qiu, Yurong Jing, Ziyi Wang, Xinhua Ao, Dong (Roman) Xu, and Ying Wang) declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We extend our sincere gratitude to the Health Bureau and the Civil Affairs Bureau in Changxing County for their invaluable administrative support, which was essential for the implementation of this study in the community setting. We also gratefully acknowledge the financial support provided by the CPIC Blue Foundation. We thank Shenzhen Dashi Qiyun Health Technology Co., Ltd. for their technical expertise and strong contribution to the development of the WeChat Mini-Program "Timi-Cog," which played a key role in the digital component of the intervention. This work was supported by the National Key Research and Development Program of China and the Key Science, and The Noncommunicable Chronic Diseases-National Science and Technology Major Project of the National Health Commission of China.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.tjpad.2026.100623.

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