Study Protocol

AI-assisted, Village Doctors and Express Services-Involved, Community-Based Multicenter Cluster Randomized Controlled Trial for Fall Prevention Among Rural Older Adults

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Content

Introduction

Falls are the leading cause of injury-related deaths among older adults aged 65 and above in China, and the primary cause of injury-related disability and doctor's visits in this population [1–3]. According to the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD 2019), the incidence of falls, fall-related deaths, and disability-adjusted life years (DALY) due to falls has consistently increased from 1990 to 2019 in China [4]. Alarmingly, rural areas have experienced a faster rise in the burden of fall-related diseases, with the incidence of falls in rural settings far exceeding that in urban areas[5]. This disparity underscores the need for targeted, effective fall prevention strategies tailored to the unique characteristics and challenges of rural settings [6].

Despite the robust evidence supporting the effectiveness of fall prevention interventions—ranging from multifactorial risk assessments to exercise and home safety modifications[7–10]—most research has focused on urban populations, with little attention paid to rural areas, particularly in developing countries including China. A systematic review of fall prevention strategies highlighted that while interventions have been successful in urban settings, their applicability and feasibility in rural communities remain underexplored [6]. The limited healthcare infrastructure, shortage of trained healthcare professionals, and geographical barriers in rural China contribute to the slow adoption of fall prevention strategies [11]. Furthermore, older adults in rural areas often face barriers to participation, including lack of awareness, fear, stigma, and inadequate social support. The Chinese government has recognized the growing need for fall prevention, with the National Health Commission issuing the "Technical Guidelines for Fall Prevention and Control in Community-Dwelling Older Adults"[12]. These guidelines provide evidence-based recommendations but face significant challenges in implementation, particularly in resource-limited rural regions[6,13]. The gap between evidence-based guidelines and their real-world implementation in rural areas is widening, highlighting the pressing need for locally tailored, scalable implementation strategies.

Implementation science provides a valuable framework for addressing these challenges by focusing on the factors that influence the uptake and sustained integration of evidence-based practices in real-world settings[14]. Previous studies have shown that while fall prevention programs can be effective in controlled settings, their real-world implementation is often hindered by a range of barriers[15], including a lack of healthcare professional training, insufficient community awareness, and limited integration of fall prevention into routine care[11]. In particular, health professionals in rural areas may face barriers such as time constraints, inadequate support, and insufficient knowledge about fall prevention guidelines[16]. Furthermore, older adults may not recognize their own fall risk or may be reluctant to participate in fall prevention programs due to fear, stigma, or lack of social support[17]. As such, the need for feasible, rural-specific interventions is more critical than ever. This highlights the gap between evidence-based fall prevention guidelines and their effective implementation in rural areas, where resources are constrained.

To bridge the gap between evidence-based guidelines and real-world implementation in rural China, we initiated the EXpress Prevent Rural oldEr adults' fallS, fractureS and dependency (EXPRESS) project. This initiative aims to evaluate the effectiveness of a multifactorial, AI-assisted, community-based fall prevention intervention that integrates the efforts of village doctors and express service providers. By embedding the intervention within existing rural health structures and community resources, EXPRESS seeks to improve accessibility, feasibility, and scalability in resource-limited settings. A central innovation of the EXPRESS intervention lies in its population-wide fall risk screening and tailored response strategy. Rather than adopting a one-size-fits-all model, EXPRESS combines subjective risk assessments conducted by trained village doctors with objective motion analysis captured via smartphones and analyzed using AI algorithms. These assessments are synthesized into an AI-powered decision support system that generates personalized fall prevention packages for each older adult. These packages address a range of modifiable risk domains—including physical inactivity, environmental hazards, social isolation, and low health literacy—and are delivered directly to participants by trained couriers, enhancing both precision and community trust. Emerging evidence supports multifactorial risk reduction strategies, particularly those grounded in systematic assessments and tailored to individual profiles, as effective in reducing fall incidence among high-risk populations [18].

Notably, this approach—universal screening coupled with individualized intervention—resonates with the logic of the Prevention Paradox, a foundational concept in public health. First introduced by Geoffrey Rose, the Prevention Paradox describes a key challenge in preventive strategies, that is, population-wide interventions can achieve substantial public health gains, even though the benefits to any single individual may appear minimal[19]. In contrast, targeting only high-risk individuals may yield large individual benefits but has limited impact on the overall burden of disease [19]. EXPRESS addresses this paradox through a pragmatic, dual-strategy design. By conducting universal risk factor screening among all older adults, the intervention ensures broad population coverage and inclusivity. At the same time, the results of these assessments enable the delivery of risk-informed, tailored interventions to those with specific vulnerabilities. This continuum of care allows lower-risk individuals to benefit from general education and prevention resources, while those with higher risk receive intensified support, including AI-guided exercise prescriptions and behavioral recommendations. By embedding this model into the routine public health workflow of village doctors and leveraging trusted local actors for delivery, EXPRESS ensures that individual relevance and population reach are not mutually exclusive. It exemplifies a hybrid strategy that operationalizes the key insight of the Prevention Paradox, that is, in order to achieve meaningful improvements in population health, interventions must combine universal engagement with risk-sensitive personalization.

To ensure the effective delivery and sustainability of personalized fall prevention services in rural settings, the EXPRESS project adopts a task-sharing model that mobilizes local resources beyond the traditional health workforce. In particular, village-based express mail service (EMS) providers—who routinely reach nearly all households—are engaged as key delivery agents for the intervention. These couriers are not only geographically accessible but are also well integrated into local social networks, making them ideal partners for community-level health promotion efforts. In rural China, local community leaders, village doctors, and EMS providers are essential to the provision of health services and the delivery of medical supplies [20]. These stakeholders are trusted by older adults and are crucial to ensuring the success and sustainability of the intervention[21]. By leveraging these local resources, the EXPRESS aims to integrate fall prevention into existing healthcare structures, utilizing a community-based delivery model that is both culturally and contextually relevant.

AI-assisted tools are combined with the practical experience and social familiarity of these local agents to provide a personalized, scalable intervention that enhances feasibility and fosters community trust.

Theoretical framework and approach

The EXPRESS project is underpinned by a hybrid theoretical foundation that integrates population-level and risk targeted strategies through a dual-track approach. Central to this design is the Prevention Paradox, which suggests that while interventions targeting high-risk individuals may have a significant impact on individual outcomes, population-level health gains often depend on universal interventions that reach a broader audience [19]. EXPRESS reconciles this paradox by combining universal fall risk screening with personalized, AI-assisted interventions, ensuring that all older adults benefit from fall prevention resources while those with multiple risk factors for falls receive tailored support. To operationalize this strategy in rural, resource-constrained contexts, the project draws upon the COATS framework (Concepts and Opportunities to Advance Task Shifting and Task Sharing) [22]. COATS guides the redistribution of fall prevention tasks across a broader, community-embedded workforce. Village doctors are responsible for professional assessments and clinical oversight, while local express mail service (EMS) couriers—already embedded in the daily lives of residents—are trained to deliver educational content, assist with intervention logistics, and provide ongoing participant engagement. This task-sharing model enhances coverage, reduces costs, and increases feasibility by tapping into the existing trust and reach of non-specialist workers.

The integration of artificial intelligence (AI) further strengthens this model. AI-assisted tools support village doctors in conducting efficient and standardized risk assessments, while simultaneously generating individualized intervention plans based on a combination of subjective and objective data inputs. The resulting workflow allows health professionals to focus on tasks requiring specialized expertise, while enabling trained couriers to manage community-facing responsibilities. To guide implementation, EXPRESS employs the EPIS framework (Exploration, Preparation, Implementation, and Sustainment) from implementation science [23]. During the Exploration phase, community needs and local capacities are assessed. The Preparation phase includes team formation, training on AI tools and fall prevention practices, and planning of delivery workflows. The Implementation phase focuses on deploying the intervention and promoting its uptake across villages. Finally, the Sustainment phase ensures ongoing delivery through periodic refresher training, feedback loops, and integration into routine public health services. This phased framework supports long-term integration by aligning intervention components with community capacity, cultural relevance, and existing healthcare infrastructure. Figure 1 shows the theoretical framework of this study.

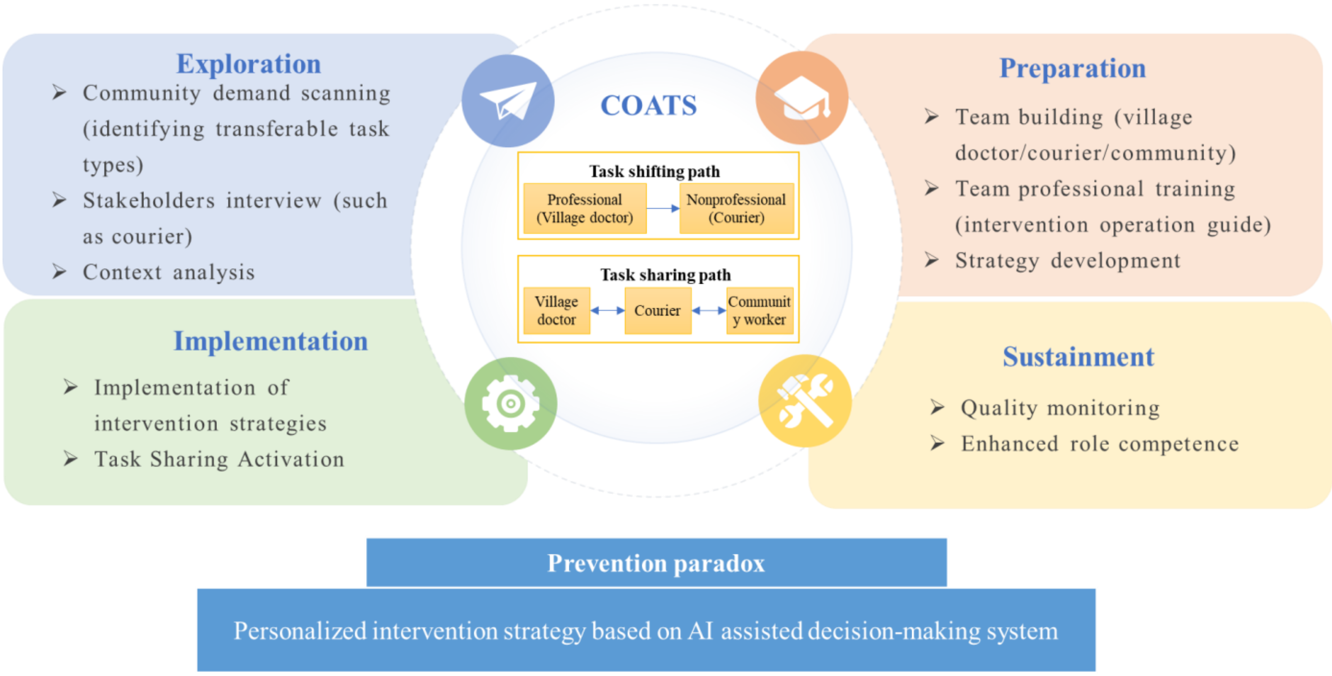

Figure 1. The theoretical framework of this study.

Study objectives

The primary objective of the EXPRESS trial is to evaluate the effectiveness of an AI-assisted, personalized, village doctors and express services-involved, community-based fall prevention intervention in reducing fall rates among rural older adults. Secondary objectives include assessing the impact of the intervention on quality of life, healthcare utilization, and cost-effectiveness compared to standard fall prevention strategies. Our research questions are as follows:

1. **Effectiveness and Precision of AI-assisted Fall Prevention**: What is the impact of an AI-assisted, personalized, village doctors and express services-involved, community-based fall prevention intervention on reducing fall-related injuries and improving health outcomes among older adults in rural China, compared to standard care? How does the use of AI in risk assessment enhance the precision and scalability of fall prevention efforts?

2. **Feasibility, Stakeholder Engagement, and Contextual Adaptation**: How feasible is the implementation of the AI-assisted fall prevention strategy in rural settings, and what are the key barriers and facilitators for its successful integration into routine care? What role do local healthcare providers, community leaders, and stakeholders play in adapting and sustaining the intervention?

3. **Cost-Effectiveness and Scalability for Public Health**: What is the cost-effectiveness of the AI-assisted fall prevention intervention in a rural healthcare context, and how do its economic impacts compare to potential reductions in healthcare utilization and disability? How scalable is this model for broader adoption in other low-resource settings, both within China and globally?

Methods

Trial design

The EXPRESS study is a cluster-randomized controlled trial with randomization at the village level and a 1:1 allocation to parallel intervention and control groups. The EXPRESS trial is conducted in 16 rural villages across four provinces in China: Beijing, Hubei, Shanxi, and Anhui. Villages were selected using a stratified cluster sampling method to ensure geographical diversity and contextual representativeness. Within each province, villages were first stratified by key characteristics such as location, population size, and healthcare infrastructure. From each stratum, villages were randomly selected, with four villages per province ultimately enrolled—two allocated to the intervention group and two to the control group. Recruitment of villages started in June 2024 and was completed in July 2024. Baseline survey prior to randomization started on August 6 2024 and was completed on August 27 2024. The intervention was delivered since September 1 2024, after the completion of the baseline survey. The intervention will last for 12 months and the effectiveness evaluation will be conducted in August 2025.

Regulatory approvals and ethical considerations

The Biomedical Ethics Review Committee of Peking University approved the EXPRESS protocol on August 2, 2024 (IRB00001052-24070). The study employs a tiered monitoring system, with the independent Data Safety and Monitoring Board conducting annual reviews and implementing triggered additional reviews when pre-specified safety thresholds (participants experience serious adverse events such as injury falls, fractures, or deaths) are reached. The External Advisory Board maintains annual oversight of overall trial conduct. All study process will adhere to ethical guidelines of the Declaration of Helsinki[24], and informed consent will be obtained from all participants before their inclusion in the study. Participants will be fully informed about the nature of the study, the data being collected, and their right to withdraw at any time. Data will be managed according to strict privacy standards, and confidentiality will be maintained throughout the study period. To ensure participants' privacy, all personal and health-related data will be anonymized, and secure storage protocols will be followed.

Study setting and participants

The study will be conducted across 16 rural villages in four provinces of China—Beijing, Hubei, Shanxi, and Anhui. Four villages from each province will be randomly assigned to either the intervention group or the control group. The sample size calculation for this study is based on the following formula[25]:

$$n = \frac{\left(Z_\alpha + Z_\beta\right)^2 [P_1(1 - P_1) + P_2(1 - P_2)]}{(P_1 - P_2)^2}$$

Here, n represents the required sample size per group, P_1 denotes the pre-intervention fall incidence, P_2 refers to the post-intervention fall incidence, Z_α is the standard normal value corresponding to the significance level of α, and Z_β is the standard normal value corresponding to the power level (1-β). Based on a prior meta-analyses, the fall incidence among older adults in rural China is estimated to be 23.1% [26], which is adopted as the likely fall incidence without intervention P_1. Assuming the intervention could reduce the fall incidence in the intervention group by 10% (P_2 = 13.1%)), and setting α= 0.05 and β= 0.20 (80% power), the calculated minimum sample size per group is 233 participants. For cluster randomized controlled trials, the sample size calculation should account for the cluster design effect (CDE), i.e., the reduction in statistical power caused by clustering[27]. The CDE is calculated as follows:

$$CDE = 1 + (m - 1) \times \rho$$

Here, m is the average cluster size, and ρ is the intra-cluster correlation coefficient (ICC). Assuming ρ = 0.01 and that the average number of older adults per village is 120, the calculated CDE is 2.19. After adjusting for the CDE, the minimum required sample size per group is 510 participants, leading to a total sample size of 1,020 participants.

Villages eligible for inclusion in this study are as follows: Each village should have a health clinic with at least one full-time village doctor, ensuring access to primary healthcare services that are essential for the implementation of the intervention. Additionally, both village officials and village doctors agree to participate in the study and agreed to establish a cooperative relationship between the two to ensure community engagement and successful delivery of fall prevention intervention. Villages must be situated more than 2 kilometers from other villages to reduce potential contamination between them. Exclusion criteria include villages that serve as administrative centers for township governments, as these may experience confounding due to the centralized use of medical resources, which could bias the study results. Villages that have previously participated in fall-related health promotion or intervention trials are also excluded.

As for participants, the inclusion criteria are aged 65 or older and have lived in the village for at least 12 months before enrollment. Exclusion criteria included: (1) individuals with severe diseases, such as cancer, stroke; (2) Individuals with disabilities, cognitive impairments, or significant hearing or language impairments.

Randomization and blinding

A cluster randomization approach will be employed to allocate the 16 villages across four provinces (Beijing, Hubei, Shanxi, and Anhui) into either the intervention group or the control group. Randomization will be conducted after the baseline (T0) to ensure that any pre-existing differences between villages do not bias the allocation process. The randomization will be carried out by a third-party statistician using a computer-generated randomization schedule to ensure impartiality. In each province, two villages will be randomly assigned to the intervention group, which will conduct the AI-assisted, village doctors and express services-involved, community-based intervention strategy, and two villages will be assigned to the control group, where standard health management practices will be followed. This randomization will help control for potential confounding factors at the village level, such as regional healthcare availability or socioeconomic status, ensuring that the effects observed can be attributed to the intervention rather than other extraneous variables[28]. Allocation concealment will be ensured through the use of centralized randomization managed by an independent data management team. The allocation sequence will be stored securely, and intervention assignments will only be revealed after baseline assessments. This study is a single blind design, where the researchers know the grouping after randomization, but the village doctors and older people after grouping do not know the grouping situation.

Intervention strategy

The intervention strategy for the EXPRESS project is grounded in high-level evidence recommended by the guidelines, including the Technical Guidelines for Fall Prevention and Control in Community-Dwelling Older Adults published by China's National Health Commission [12]. All components of the intervention have been carefully adapted to address the unique characteristics and constraints of rural areas, where healthcare resources are often limited, and older adults face significant barriers to accessing preventive services. By incorporating local knowledge, cultural practices, and existing infrastructure, the intervention was designed to be contextually relevant, operationally feasible, and sustainable in rural settings.

The intervention design of the EXPRESS project draws upon core principles of implementation science, aiming to bridge the gap between evidence-based fall prevention guidelines and real-world application in under-resourced rural settings. Grounded in the EPIS framework (Exploration, Preparation, Implementation, and Sustainment), the strategy emphasizes local feasibility, adaptability, sustainability, and stakeholder engagement. It also integrates the COATS framework (Concepts and Opportunities to Advance Task Shifting and Sharing), redistributing fall prevention tasks among village doctors, community workers, and couriers to address the critical shortage of healthcare professionals in rural China. The EXPRESS intervention is structured around five key components—SAFER (Table 1), each designed to address rural health resource limitations, enhance accessibility, and provide personalized fall prevention services through technology and community integration.

S – Screening: Fall risk screening and assessment tailored to rural older adults. All participants undergo comprehensive fall risk assessments through a dual approach. First, village doctors administer a 10-item rural-adapted fall risk scale, developed by the research team for ease of use and specificity to the rural aging population. The scale captures key indicators such as mobility, balance, and prior fall history, offering a structured yet practical tool for frontline healthcare workers in resource-limited settings. Second, participants are instructed to complete sit-to-stand and 6-meter walking task (3 meters out and back) at their natural pace on a marked 3-meter mat. The smartphone is mounted on a specialized tripod on the opposite side, 2 meters from the endpoint of the mat, with a 30° downward angle to optimize the motion capture field of view. These recordings are analyzed using deep learning model and AI-powered motion analysis to extract five objective dimensions associated with fall risk: (1) balance (via sway and bilateral symmetry), (2) gait speed, (3) stride length, (4) trunk rotation (via turning motion), and (5) lower limb strength (via sit-to-stand movement). This combined subjective-objective assessment ensures accurate risk assessment and supports tailored interventions. Importantly, this risk screening and tailored health counseling process has been designed to be embedded within China's National Essential Public Health Service (EPHS) framework, particularly under the older adult health management program, which requires village doctors to conduct an annual physical examination for all residents aged 65 and above. As part of this initiative, the EXPRESS project incorporates the fall risk assessment and individualized consultation into the existing annual check-up workflow, allowing the service to be delivered efficiently during the routine health visit. To further support integration and incentivize adoption, the EXPRESS project offers a performance-based subsidy of RMB 6 per older adult to village doctors who complete both the fall risk screening and individualized counseling during the EPHS check-up. This approach not only promotes the institutionalization of fall prevention services, but also enhances sustainability and alignment with national health priorities in rural China.

A – AI-assisted recommendations: Personalized, AI-assisted falls prevention suggestions and health education. Collected assessment data are integrated into a decision-support system powered by artificial intelligence, which synthesizes evidence-based guidelines, expert consensus, and real-world data. The AI system generates personalized fall prevention plans tailored to each participant's risk profile and rural lifestyle. These plans assist village doctors in making informed, evidence-based decisions and provide actionable recommendations suitable for local implementation. Through the "1+1" transmission mechanism, village doctors conduct one-on-one risk assessments and explain the plan's key content, improving older people's health literacy and awareness of fall prevention. Meanwhile, a risk assessment and health recommendation report combining text and images will be issued to participants, using large fonts and including risk warning icons to ensure they are age and cultural appropriate.

F – Fitness: Tailored balance and strength training via Health Intervention Cartoon Brochure and Action Demonstration Video. Based on the risk assessment results, each older person will receive an individualized training recommendation customized by rehabilitation experts, which includes targeted training movements (such as balance training, lower limb strength training, etc.), supporting graphic and textual list (large font, easy to understand), and operation demonstration videos. Additionally, exercise rehabilitation experts develop a manual with 10 low-barrier exercises suitable for rural life scenarios, such as "bench balance training" and "big arm swings." Instructional videos are distributed to village doctors and participants. Village doctors are encouraged to lead group exercise sessions at village clinics, creating a community-driven atmosphere for physical activity.

E – Events-based engagement: Seasonal prevention activities and prevention materials integrated with traditional festivals and solar terms of the traditional Chinese calendar. To improve community engagement and intervention sustainability, the EXPRESS trial designed three round of intervention leveraging seasonal intervention packages (Figure 2) that align with key traditional cultural events: the Chongyang Festival (October), the Spring Festival (January/February), and the Qingming Festival (April). These packages include culturally relevant and visually engaging materials, such as fall prevention calendars, fans printed with safety messages, and weather-specific tips. In addition, each package includes seasonal fall prevention tips, such as staying indoors during snowy weather, wearing non-slip shoes in winter, and being cautious during spring farming activities, thereby strengthening fall prevention awareness among older adults. The distribution of these packages aims to strengthen and consolidate the knowledge, beliefs, and behaviors of fall prevention among participants at different time points, leveraging local traditions to promote adherence, enhancing their sense of participation and sustainability in the intervention.

R – Reach-home delivery: The final and most important intervention strategy is home delivery of fall prevention services by express service. To alleviate the burden on village doctors and address the shortage of healthcare personnel in rural areas, the EXPRESS trial inspired by the Task Shifting/Sharing Theory and incorporates local couriers as community health support agents. Fall prevention intervention materials are remotely prepared by the technical team and distributed through a task-sharing platform. These couriers did their routine job and delivered intervention materials—including personalized health reports, educational calendars, and seasonal care packages—directly to participants' homes. This delivery model ensures the timeliness and coverage of fall prevention services to the doorsteps of older adults in rural and other regions with limited health care personnel. Figure 3 shows the framework of intervention strategies.

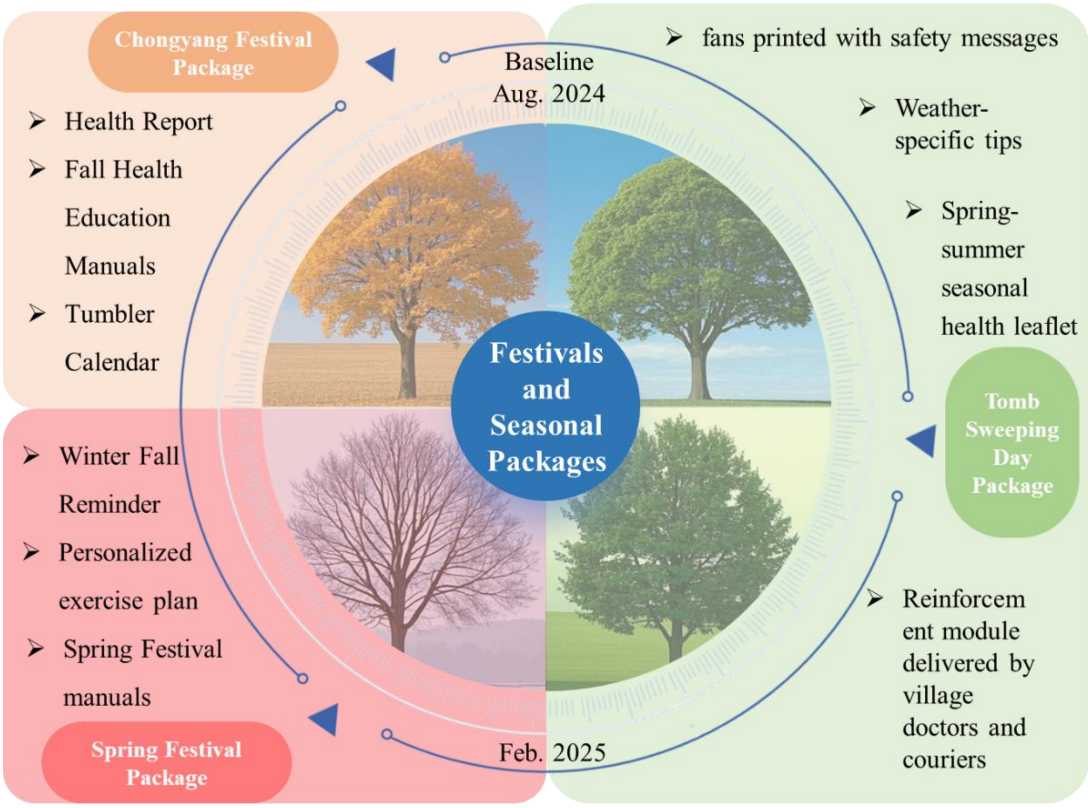

Figure 2. The contents of three festival packages.

Figure 3 Framework of intervention strategies

Table 1 EXPRESS five core intervention matrix

Intervention project	Implementation form	Technical support	Execution subject
S – Screening: Fall risk screening and assessment	10 subjective risk factors Five objective dimensions	10-item assessment scale and smartphone	Village doctors
A – AI-assisted falls prevention recommendations	Risk assessment reports/manuals	AI decision-making system	Research team
F – Fitness: Tailored balance and strength training.	Customized Exercise Plan	Exercise Prescription	Rehabilitation experts
E – Events-based engagement: Seasonal prevention activities and materials	Three festival packages	AI decision-making system	Research team
R – Reach-home delivery: Home delivery of fall prevention services	Express delivery system	Task sharing platform	Courier

The implementation framework of intervention strategy

Figure 4 outlines the research activities and timeline across each phase of the EPIS (Exploration, Preparation, Implementation, and Sustainment) framework, which guides the structured deployment of the EXPRESS intervention.

During the Exploration phase, a comprehensive needs assessment was conducted in each participating village to identify local barriers and facilitators to fall prevention. This included evaluating community-specific risk factors, healthcare infrastructure, and stakeholder engagement. Input was gathered from older adults, village doctors, local officials, and couriers to ensure contextual relevance and to inform subsequent program design. In the Preparation phase, village-level local change teams were formed, comprising village doctors, village officials, and trained couriers. These teams received standardized training sessions focused on fall risk assessment using both subjective and objective tools, operation of the AI-assisted decision support system, and strategies for effective fall prevention education. This phase emphasized building local capacity and fostering cross-sector collaboration.

The Implementation phase involved the staged rollout of the five-component intervention strategy. Activities included the delivery of personalized fall prevention materials to older adults' homes, risk-based exercise recommendations, culturally adapted seasonal packages, and coordinated outreach efforts led by the local change teams. Intervention delivery was aligned with major cultural festivals to maximize community participation and behavioral reinforcement. Finally, the Sustainment phase focuses on maintaining the intervention's long-term effectiveness and integration into routine village health services. This includes ongoing technical support, refresher trainings for local team members, and periodic community engagement activities.

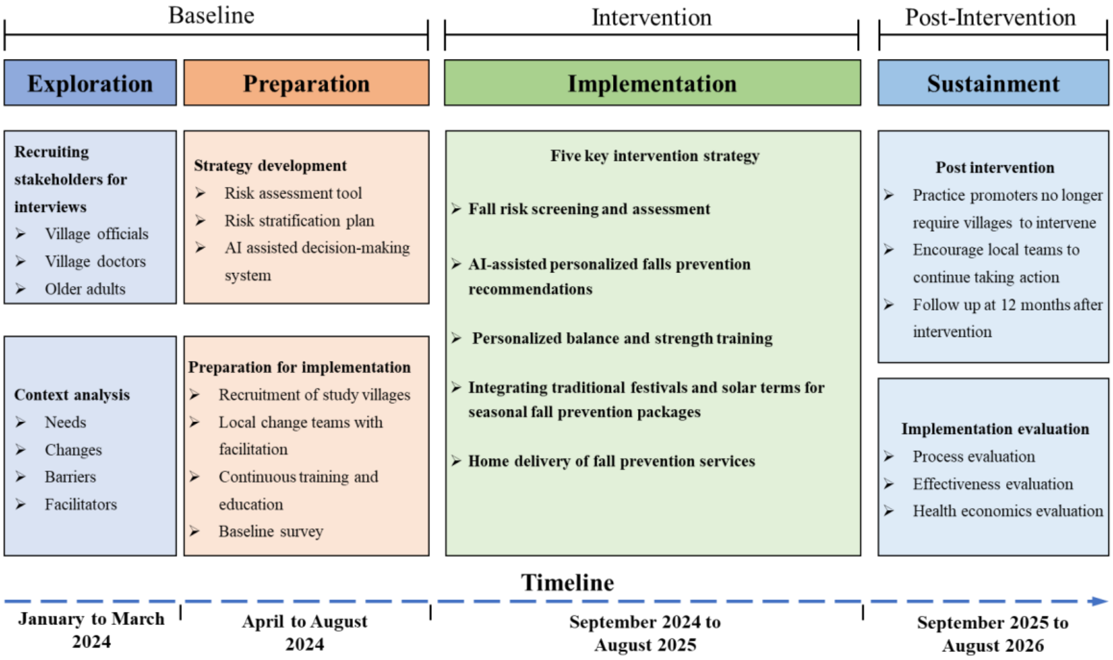

Figure 4. The research activities and timeline for each EPIS phase

Control Group

The control group will receive standard health management through Primary Public Health Services and will be provided with a basic calendar to record fall events.

Primary Outcome Measures

The primary measure will be the fall incidence (rate of falls per person-year), the proportion of participants with ≥1 fall and that of fall-related injuries (including fractures) over the 12-month intervention period.

Fall incidents will be recorded using multiple methods to reduce recall bias: self-reporting by older adults and their families on the fall calendar, quarterly follow-ups by couriers, and a final interview-based endpoint assessment.

Fall-related injuries, such as fractures, head injuries, hospitalizations, other events requiring medical attention, will also be collected via self-reporting, quarterly check-ups, and endpoint assessments. To ensure consistency and reliability in the reporting of falls, we will ask participants to refer to the three fall types as defined by the ICD-11 classification system[29]. Participants will be asked about their fall incidents based on the ICD-11 classification for falls. This will include three fall type: (1) PA60 (Unintentional fall on the same level or from less than 1 meter): this category encompasses falls from slipping, tripping, or stumbling, as well as falls involving stairs, steps, ramps, and escalators. PA60 also covers falls from furniture, such as from chairs, beds, and playground equipment. (2) PA61 (Unintentional fall from a height of 1 meter or more): this category includes falls from greater heights, such as ladders, scaffolding, trees, or buildings. (3) PA6Z (Unintentional fall from unspecified height): the category includes falls where the height is unknown, such as falls from standing positions or accidental falls at home. The use of ICD-11 will enhance the accuracy of the fall data and valid comparisons across the two groups.

Secondary Outcome Measures

Secondary outcomes include fall health literacy, activities of daily living (ADL), quality of life, depressive symptoms, cognitive function, dementia, physical function and performance, incidence of chronic non-communicable diseases, frailty, and sleep quality.

Fall health literacy will be measured using a scale developed by the researchers, which will assess changes in participants' knowledge of fall prevention strategies. ADL will be assessed using the Barthel Index[30] to determine if the intervention has an effect on the participants' independence and daily functioning. Quality of life will be measured using the EQ-5D-5L questionnaire [31]. Depressive symptoms will be assessed using the short version of Geriatric Depression Scale [32]. Cognitive function will be evaluated using the mini-mental state examination [33], and dementia will be assessed using the Clinical Dementia Rating [34] and evaluated by a professional physician.

Physical function and performance will be assessed using an AI-assisted analysis of standardized physical tasks, including a sit-to-stand test and a 6-meter walk test on a 3-meter mat. A smartphone records participants' movements, which are analyzed by a deep learning model to extract indicators such as gait speed, stride length, center of pressure sway area (reflect the balance situation), trunk rotation, and lower limb strength. The chronic non-communicable diseases include hypertension, diabetes, arthritis, sarcopenia, cervical spondylosis, heart problem, osteoporosis, kidney disease, hyperlipidemia, liver disease, lung disease, stomach disease, intestinal diseases. The incidence of chronic non-communicable diseases will be determined based on physician-diagnosed medical records, collected during routine health check-ups and follow-up visits by trained medical staff. Frailty will be assessed using the FRAIL scale, a validated five-item questionnaire evaluating fatigue, resistance, ambulation, illness, and weight loss[35]. Sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI), a standardized self-reported questionnaire that evaluates sleep duration, latency, disturbances, and overall quality over the past month[36].

Data collection and management

Data will be collected at three time points: baseline (T0: August 2024), immediately after the intervention period (T1: August 2025), and 12 months post-intervention (T2: August 2026). At baseline, demographic information, health status, and fall risk data will be collected from participants. We will also collect data from participating villages, including healthcare infrastructure and community engagement metrics, at baseline to ensure consistency and comparability between intervention and control villages. At T1, falls, falls injuries, and health status in the past year data will be collected. At T2, fall-related information and health status will be gathered again to evaluate the sustainability of the intervention's effects over times.

Data collection will be conducted using bespoke electronic questionnaires via smartphone. Investigators will be trained to access the questionnaire on smartphones and conduct one-on-one interviews with study participants. These investigators will be blinded to the study's grouping (intervention vs. control) to prevent any bias in the data collection process. The training will include standardized procedures for administering questionnaires, conducting interviews, and recording fall-related incidents. The electronic questionnaires will include sections on demographics, health status, mobility, prior fall history, and outcome measures such as fall rates, quality of life, and health service utilization. Once the survey is completed, investigators will click "submit" to transfer the responses to a secure database. Upon submission, data will be immediately stored on a centralized server and cannot be modified, ensuring data integrity. Each submission will receive a timestamp, confirming the exact time of data entry. The process is designed to minimize data entry errors by eliminating manual data handling. To promote data accuracy and minimize error rates, investigators will undergo standardized training on questionnaire administration, including guidelines for ensuring participant comprehension and handling any issues during the interview. In addition, random audits will be conducted where 10% of the completed questionnaires will be cross-checked for accuracy by a second investigator. These audits will help ensure that the data collection process is being carried out consistently and with high quality.

Health Economic Evaluation

Health economic evaluations will be integrated into the design of the EXPRESS trial and be conducted primarily from a societal perspective over 12 months. The primary economic evaluation will take the form of cost-effectiveness analysis, based on the reduction in fall and fall-related injuries. Incremental cost-effectiveness ratios (ICER) [37], expressed as the incremental cost per additional reduction in fall and fall-related injuries, will be calculated. A cost-utility analysis will also be performed. Responses to the EQ-5D-5L questionnaire will be converted to health utility scores using a value set for the Chinese population [38]. Based on these utility scores, Quality-Adjusted Life Year (QALYs) [38] – a widely accepted measure that combines both the quantity and quality of life years gained through the intervention[39,40] – will be estimated. Cost-effectiveness will be assessed in terms of the incremental cost per QALY gained, calculated by dividing the difference in mean costs between the two treatment groups by the differences in their mean QALYs [32].

Cost-effectiveness analysis requires a comprehensive assessment of the costs associated with the intervention and its comparator. These will include the cost of the intervention, healthcare resource use and the wider societal costs (e.g. out-of-pocket costs and productivity loss). Cost data will be collected via a bespoke resource use questionnaire. Unit costs will be mainly derived from local and national sources.

To fully consider the uncertainty in important components of economic evaluation, several sensitivity analyses will be conducted[41]. These include a sensitivity analysis from a narrower healthcare perspective and another under alternative missing data assumptions [42]. A subgroup analysis will also be conducted to assess the cost-effectiveness of the intervention among specific demographic or health status groups, such as older adults with mobility impairments or those at higher risk of falls, informed by the data collected from the main trial. Cost-effectiveness planes and cost-effectiveness acceptability curves [43] will be reported.

Process Evaluation

A qualitative process evaluation of the EXPRESS will be conducted to assess key aspects of the intervention's feasibility, implementation, and impact [44,45]. This evaluation will provide a deeper understanding of how the intervention is received by participants, healthcare providers, and the broader community, as well as the factors that influence its success or challenges during the implementation phase. The evaluation will be structured around three core modules: feasibility, impact, and implementation.

Statistical Analysis

The statistical analysis for this study will follow an intention-to-treat principle[46], ensuring that all participants, regardless of their adherence to the intervention, are included in the analysis. Descriptive statistics will summarize baseline characteristics, with continuous variables reported as means ± standard deviations (SD) and categorical variables as frequencies and proportions. We will assess the baseline characteristics between the intervention and control groups to ensure comparability, and account for potential confounders that could affect the outcomes, including age, gender, socioeconomic status, and baseline fall risk.

For primary analyses, mixed-effects regression models will be used to compare fall incidence and fall-related injury rates between intervention and control groups, incorporating fixed effects for treatment allocation, baseline covariates (age, gender, socioeconomic status), and random intercepts to account for clustering at the village level. Secondary outcomes (health literacy, quality of life, activities of daily living [ADLs]) will be analyzed via generalized linear mixed models (GLMMs) with appropriate link functions (e.g., logit for binary outcomes, identity for continuous). Prior to the main analysis, a preliminary data cleaning process will be carried out to assess the completeness and integrity of the dataset. If necessary, appropriate estimation techniques such as multiple imputation will be applied to impute missing data in the main analysis. Sensitivity analyses will also be conducted to evaluate the robustness of findings to alternative missing data assumptions and model specifications (e.g., inclusion/exclusion of covariates).

In addition, subgroup analyses will be also used to examine how the intervention affects outcomes like fall risk and mobility among different groups based on baseline characteristics (e.g., age, sex). Interaction terms will be included in the regression models to assess the differential effects of the intervention by subgroup, allowing for a deeper understanding of the potential heterogeneity of treatment effects across different demographic groups. To account for the clustering of participants within villages, we will adjust for intra-cluster correlation by clustering the standard errors at the village level. All analyses will be conducted in STATA 17.0 (Stata Corp, College Station, TX, USA), with statistical significance defined as a two-tailed $p < 0.05$.

Funding

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