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Effectiveness of HAPA-based multidomain fall risk management for older adults with declining intrinsic capacity in nursing homes: protocol of a randomised controlled trial

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ABSTRACT

Introduction Accidental falls are a common geriatric syndrome that hinders healthy ageing in older adults. Older adults who live in nursing homes (NHs) are at a greater risk of accidental falls than those who reside in communities. Intrinsic capacity (IC) decline has been shown to be an independent influencing factor for fall risk. Moreover, healthy behaviour is a prerequisite for IC. Therefore, this study considers IC as a starting point, with an aim of developing, implementing and evaluating a low-administration-cost multidomain fall risk management intervention programme based on the Health Action Process Approach.

Methods and analysis The target population includes older adults with declining IC in Chinese NHs. A random lottery method will be adopted to divide the 100 participants into the control group and intervention group. The project will be conducted in three parts over 24 weeks. In the first part, a fall risk management intervention pathway and programme will be developed with the theoretical and IC framework, which will be refined via the Delphi method. In the second part, a randomised controlled trial will be implemented. The control group will receive usual care and health education, and the intervention group will complete a three-stage process to complete fall risk management behaviour intention and behaviour maintenance. In the third part, follow-up will be conducted to clarify the maintenance effectiveness of the programme in fall risk management. Behaviour change techniques and an interactive handbook will be used to increase the feasibility of the programme. The primary outcomes will include the IC composite score (cognition, locomotion, vitality, sensation and psychology) and fall risk. The secondary outcomes will include gait and balance, strength, fall efficacy, fall prevention self-management, fall management behaviour stages and healthy ageing. The outcomes will be assessed at baseline, and then after 4 weeks, 16 weeks and 24 weeks in both groups. The effectiveness of the intervention will be analysed via linear mixed models on a range of outcomes.

Ethics and dissemination The trial was approved by the Huzhou University Committee (No.2023-06-06). The results will be submitted for publication in a peer-reviewed journal and presented at conferences.

Trial registration number NCT05891782.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study aims to design a visualisation intervention pathway of 'Health Behaviour→IC→Healthy Ageing'.
⇒ The Health Action Process Approach will be applied for the first time in programmes and handbooks on multidomain fall risk management for older adults with declining intrinsic capacity.
⇒ The blinding of participants, healthcare teams and study members is not possible given the non-pharmacological nature of the trial.
⇒ The single-centre trial site may cause contamination bias, and findings may not be generalisable to individuals in other contexts and settings.

INTRODUCTION

In response to the phenomenon of population ageing, the United Nations (UN) designated the time period from 2021 to 2030 as the 'Decade of Healthy Ageing'. This initiative is being spearheaded by the WHO to facilitate worldwide implementation.[1] Healthy ageing has shifted the focus from the absence of disease to the promotion of functional ability, which enables older adults to fulfil their values.[2] Geriatric syndrome, which manifests itself as the simultaneous occurrence of several complex health problems (often involving multiple potential factors and multiple organ systems), has become one of the core tasks of the response to population ageing.[2] Among them, accidental falls are a prevalent geriatric syndrome that hinders healthy ageing.

Statistics show that 30% of adults over 65 years of age fall each year and that the likelihood of falling increases with age.[3] Concurrently, approximately 50% of the falls experienced by elderly individuals lead to physical injury.[4] In addition to experiencing fractures or organ damage, individuals often experience significant psychological and socioeconomic consequences.[5] A history of falls is an independent risk factor for the occurrence of a fear of falling, and almost half of the older adults who fall will subsequently suffer from a fear of falling.[6 7] Additionally, the Centers for Disease Control and Prevention (CDC) reported that falls among the elderly population contribute to US$50 billion in annual healthcare expenditures.[8]

Crucially, serious injuries caused by falls contribute considerably to the deaths of older persons, with the WHO indicating that falls are the second greatest cause of unintentional injury deaths throughout the world. Moreover, fatal falls constitute the highest proportion of deaths within the population aged 60 years and above.[9] In China, the overall mortality rate associated with falls among people aged 60 years or older has exhibited a consistently increasing trend since 2013.[10] Accidental falls are more prevalent in nursing homes (NHs) than in community-dwelling older adults; throughout the world, more than 50% of older adults experience falls each year in NHs, which is three times greater than that reported in communities.[2] Nevertheless, the available evidence has demonstrated that the implementation of relevant interventions reduces the risk of falls by 20–40%.[11] Therefore, there is an urgent need for interventions for mitigating fall risks in older adults in NHs.

In 2015, the WHO proposed a framework for healthy ageing, which included an internal structure of intrinsic capacity (IC), functional ability and the environment. One novel concept involves IC, which is defined as 'the composite of all the physical and mental capacities of an individual'.[2] As a quantifiable indicator of healthy ageing, the IC consists of the following five dimensions: cognition, locomotion, vitality, sensation (vision and hearing) and psychology.[12] Studies have shown that 43–85% of older adults had decreased IC (at least one dimension exhibiting a decline), and 19–33% were classified as having low IC (at least three dimensions exhibiting a decline).[13–16] Notably, decreased IC has been shown to be an independent predictor of fall risk, with a 2.4-fold increase in the risk of fall occurrence being observed for each dimension of decline.[13 17] In addition, an Indian study revealed that older adults with low IC values exhibited significantly greater probabilities of experiencing falls, multiple falls and fall-related injuries than did those with high IC values.[18] According to Charles *et al*,[19] higher scores in balance (locomotion) and nutrition (vitality) are associated with a decrease in fall risk among older persons residing in NHs. Consequently, comprehensive assessments and the integration of interventions for IC are effective ways to reduce the fall risks of older adults with declining IC in NHs.

Moreover, for fall risk intervention strategies for older adults, the WHO has summarised four categories of evidence, including medication withdrawal or review, environment (home safety and aids for personal mobility), exercise intervention and multifactorial intervention.[20] There is a strong recommendation from a global initiative to use multidomain interventions for the prevention of falls; however, the overall quality of supporting evidence is low.[20 21] The CDC has developed the Stopping Elderly Accidents, Deaths and Injuries (STEADI) tool kit (https://www.cdc.gov/steadi/index.html) to provide fall risk assessments and prevention guidance in inpatient care, outpatient care and primary care settings.[22] However, the overall situation of older adults in NHs is unique; specifically, from a national perspective, NHs (which are China's guaranteed resources for elderly individuals) are characterised by people who are older, have weaker functionality and have multimorbidity, which makes operations riskier for them. From the institutional perspective, there is a relative lack of resources allocated for NHs. According to the Specifications of Post Settings and Staffing for Senior Care Organisation (MZ/T 187–2021),[23] the ratios of care workers to elderly individuals are 1:20 (self-care elderly) and 1:12 (partially self-care elderly). In 2024, a member of the Chinese People's Political Consultative Conference reported that there is a shortage of approximately 10 million caregivers and a serious imbalance in the ratio of caregivers to elderly individuals in NHs.[24] From the individual perspective, there is a correlation between depression and the visitation activities of family members, and older adults lack constant support from family and friends in NHs.[25] It has been shown that health education interventions have a significant positive impact on falls, whereas a more intensive frequency of education provides more benefits than does a low-intensity intervention.[26] Given the abovementioned background, there is an urgent need to mobilise the autonomy of fall risk management among older adults and improve empowerment in NHs. Therefore, the development of self-management programmes to improve fall-related intrinsic factors is a feasible intervention pathway.

Health behaviours are widely recognised as being prerequisites and determinants of IC.[27] Moreover, theory-based health education has gradually become a research hotspot for the promotion and self-management of health behaviour. The Health Action Process Approach (HAPA) was developed by Schwarzer *et al*,[28] who suggested that health behaviour can change and that maintenance is the result of a combination of cognition, emotion and behaviour. Additionally, the HAPA emphasised the translation of intentions into actual actions, thereby dividing them into the three stages of preintenders, intenders and actors.[27] Preintenders referred to individuals who had not yet formed a clear intention to adopt a specific health behaviour; intenders represented individuals who had formed a behavioural intention but had not yet initiated sustained action; actors represented individuals

who had initiated and maintained the target behaviour.[27] Currently, HAPA is widely used for chronic disease self-management, physical activity promotion and active lifestyle improvement.[28–31] However, the application of HAPA in fall risk management strategies for older individuals remains unexplored.

Aim

In this context, this study focuses on IC as an entry point and health behaviour as a transitional factor when considering fall risks, with an aim of evaluating the feasibility and effectiveness of the HAPA-based multidomain fall risk management (HAPA-MFRM) programme for reducing fall risks in a sample of older adults in NHs who are experiencing a decline in IC. Second, we will investigate the impact of the intervention on enhancing fall prevention management, IC, functional ability and healthy ageing.

METHODS

Study design and setting

This study is a single-centre, parallel-arm randomised controlled trial. We completed a visualisation pathway of the HAPA-MFRM programme with the HAPA and IC frameworks to guide the implementation of the intervention (see figure 1). (1) Participants will receive three stages of MFRM as the intervention group. (2) Participants will receive usual care and health education as the control group. This study will be performed at the Huzhou Social Welfare Center in China, which provides a combination of medical care and health, in alignment with the established requirements outlined in the Basic Specification of Service Quality for Senior Care Organisation (GB/T 35 796–2017).[32] The trial began in December 2023 and will end in December 2024 (patient recruitment will start in April 2024). Prior to the trial, we combined

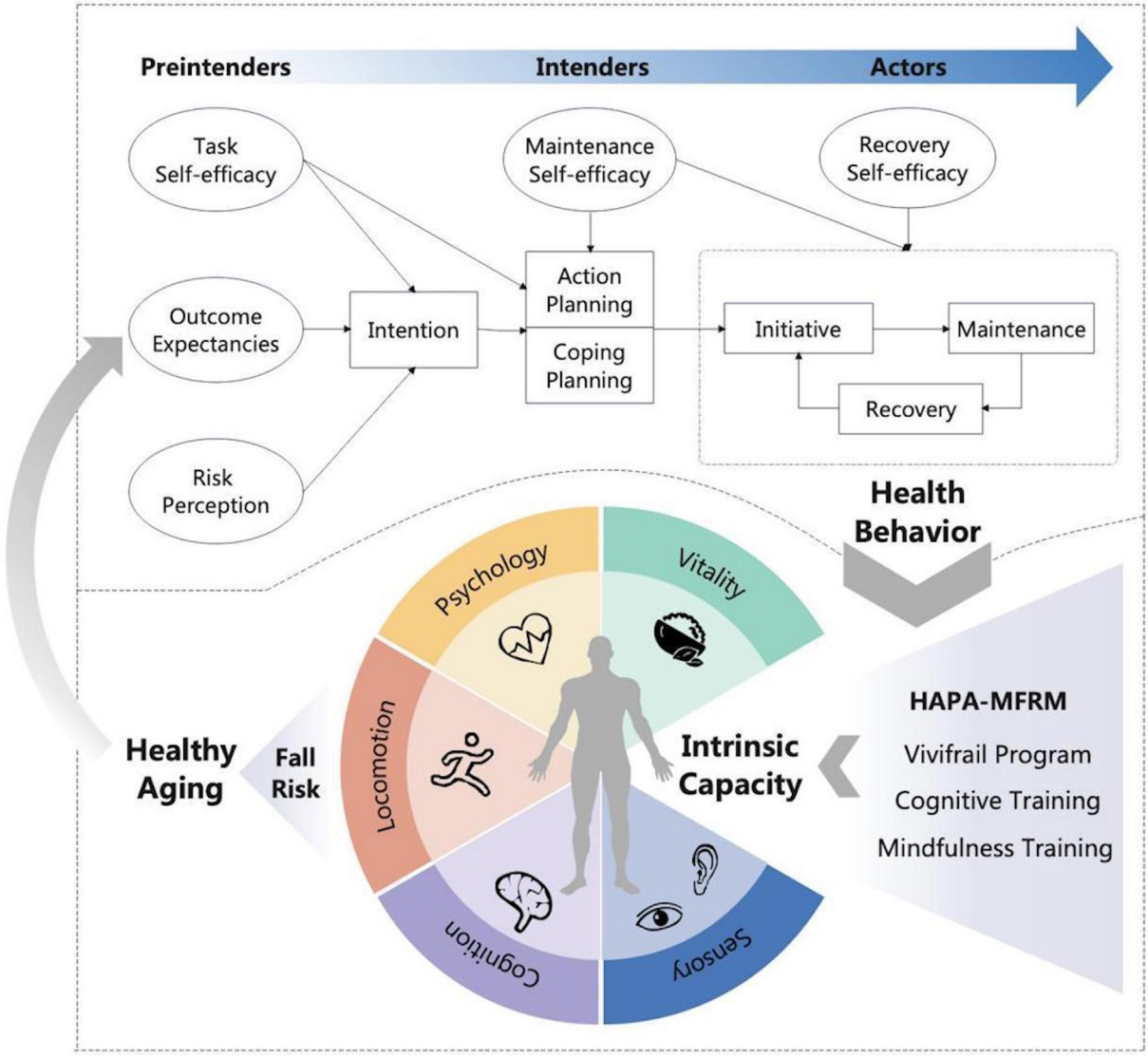

Figure 1 A visualisation pathway of the HAPA-MFRM programme. The multidomain fall risk management intervention programme based on the Health Action Process Approach (HAPA-MFRM) creates a virtuous cycle that transforms individuals from preintenders to actors, with health behaviours working on intrinsic capacity to reduce fall risk and ultimately achieve the outcome expectation of healthy ageing.

interviews with older adults with the Delphi method to assess the acceptability and feasibility of the intervention.

The participants will be recruited from the Social Welfare Centre. Four trained researchers will screen the participants according to the criteria using the demographic characteristics questionnaire and WHO Integrated Care for Older People (ICOPE) screening tool (including cognitive, locomotor, vitality, sensory and psychological dimensions).[12] The trial will be reported according to the CONsolidated Standards of Reporting Trials (CONSORT) statement for randomised trials of non-pharmacological treatments,[33] and the protocol items will be addressed according to the Standard Protocol Items: Recommendations for Interventional Trials statement to improve research transparency (see online supplemental file 1).[34]

Study participants

Experienced nurses, physicians and researchers will be responsible for participant recruitment. First, after authorisation from the director of the Huzhou Social Welfare Center is obtained, the healthcare work platform, which is an internal electronic platform that records and updates the health status and trial participation experiences of all older adults (with in-house staff being used to protect data privacy), will be used for review and screening. A list of potential participants will then be formed, and staff will identify and observe them during the workday. Once identified, potential participants will be referred to the research team. Potential participants who respond to recruitment will be contacted by research team members and will be identified as participants during face-to-face interviews. The interviews will ask participants about their medical history and trial history. Moreover, older adults with a decline in IC will be identified via the WHO ICOPE screening tool.[12] Participants who meet the eligibility criteria will be fully informed about the study purpose, process, risks and benefits. Participants will be able to participate in the study by signing a written informed consent form (see online supplemental file 2). In addition, the intervention for the locomotion dimension will be the Vivifrail programme, which provides different exercise models based on the outcomes of the Short Physical Performance Battery (SPPB), including models for healthy, prefrail, frail and disability.[35] Individuals with a disability (0–3 points) will require one-on-one assistance from a caregiver. Therefore, this study will not involve the recruitment of people with a disability when considering the issues of staff allocation and participant safety.

Inclusion criteria

1. Age ≥60 years.
2. Living in the nursing home for ≥3 months.
3. The WHO screening tool identifying at least one dimension of decline in IC.
4. Ability to move independently (non-disabled) with a score of ≥4 on the SPPB.
5. Voluntary involvement in the trial and informed consent provided by the participant.

Exclusion criteria

1. Severe visual or hearing deprivation.
2. Severe mental impairments or severe cognitive deficits (ie, severe depression or schizophrenia).
3. Patients who have severe and terminal heart, liver, brain or kidney disease (ie, tumours or brain trauma).
4. Participation in other trials that were conducted within 6 months prior to the study.

Randomisation and blinding

The nursing home has a total of 12 nursing units. After IC screening, equal-level randomisation will be implemented for nursing units of similar size. A random lottery method will be adopted to divide the participants into groups; specifically, four nursing units will constitute the intervention group, whereas the other four will constitute the control group. The included participants will be generated from an electronic randomisation list (http://www.randomizer.org/) and allocated to the combined intervention group (HAPA-MFRM) or the control group (usual care). Due to the characteristics of the non-pharmacological intervention, trial coordinators (QZ, SC, LQ, JY and MC) will not be blinded, and the central telephone will be used to implement the allocation sequence. Prior to the trial, the coordinators will undergo a uniform training and assessment and will be allowed to provide interventions only through internal evaluation. The outcome evaluators (SS, TL, YY and DL) will remain blinded to the intervention allocation. The trial will maintain separation of the outcome evaluators from the trial coordinators.

Data collection

The subjects will be assessed by blinded evaluators for primary and secondary outcomes at study baseline (T0), at 4 weeks for the intention intervention (T1), at 12 weeks for the action intervention (T2) and at 8 weeks for the follow-up (T3). Data collection for the trial is expected to be completed by late 2024 (see figure 2).

Sample size

A priori statistical power analysis was used to calculate the sample size via G*Power V.3.1. Based on the factor (ie, two groups), repeated measures (ie, 4 phases: baseline, 4-week, 16-week and 24-week measurements) analysis of variance (ANOVA) indicated that a sample size of 41 in each group was required. We set a medium effect size (Cohen's d=0.25), with power (1–β) set at 0.80 and a significance level (α) set at 0.05. Based on a conservative estimate of 20% attrition rates, we aim to recruit 50 participants per group.

Statistical analysis

For data entry, EpiData V.3.1 will be used, and for the statistical analysis, SPSS V.26.0 will be used. Demographic characteristics will be compared via descriptive analyses,

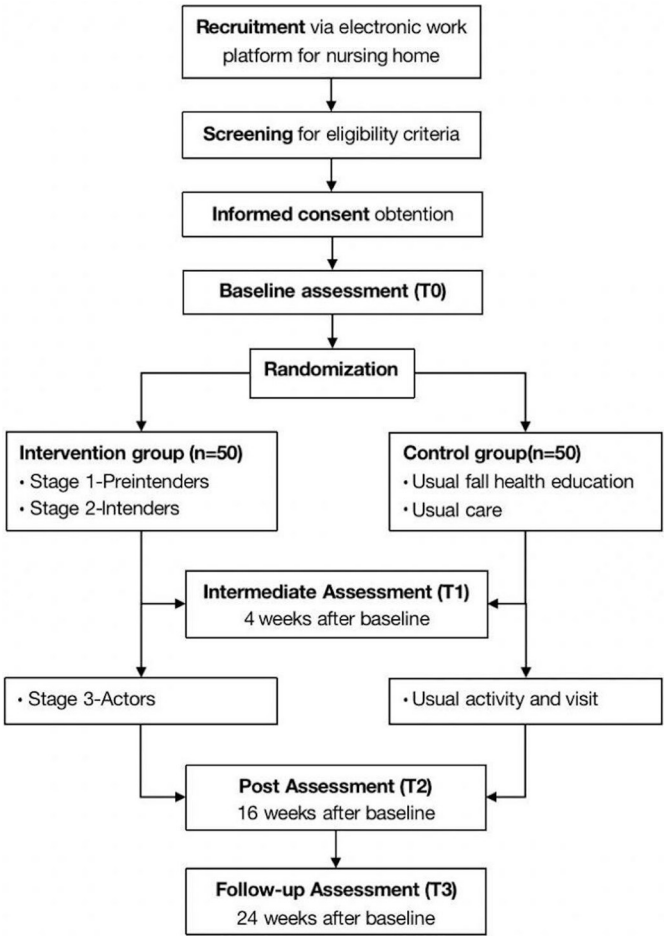

Figure 2 Overview of the study procedure. The study will conduct recruitment, screening, informed consent, assessment and intervention.

independent sample t-tests, Fisher's exact tests or Mann-Whitney U tests. According to an intention-to-treat analysis approach, missing values will be handled via multiple interpolations.[36] Repeated measures data will be used to determine how well the intervention works. Quantitative data with a normal distribution will be analysed via repeated measures ANOVAs that take advantage of two effects: the type of intervention (HAPA-MFRM and usual care) and the outcome assessment (T0, T1, T2 and T3). Group×time interactions will be performed to analyse the discrepancies caused by the outcomes related to the two groups of participants. One-way ANOVA and paired t-tests will subsequently be applied to assess simple effects on the outcome variables. When the quantitative data are not normally distributed, generalised estimating equations (GEEs) will be applied to the analysis; when there is an interaction effect, the source of the difference will be clarified via simple effects analysis (Mann-Whitney U test, Friedman test and Wilcoxon signed-rank test). Furthermore, qualitative data will be analysed via GEE, and the source of the interaction effect will be clarified via simple effects analysis (χ^2 test, Bowker test and McNemar test). The superiority of all of the outcomes (bilateral) will be analysed, and 5% of the outcomes that are statistically significant will be considered.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this study.

INTERVENTION

Control group (usual care)

The control group will receive the same overall duration and frequency of interventions as the intervention group. Weeks 1–4 will be provided with fall-related regular health education lectures, such as the rational choice of assistive tools, medications and clothing. Weeks 5–16 will involve regular activities, such as Tai χ, movie screenings and choral activities, according to the daily arrangement of the NH. Moreover, telephone, WeChat (Chinese social media) or face-to-face interviews will be conducted on a fortnightly basis to understand the needs of the participants. In addition, health education seminar materials will be distributed, and fall-related knowledge will be provided on the bulletin board every month. During the process, staff will provide usual care, such as vital sign monitoring, disease treatment, medication prescription and health record maintenance.

Intervention group (HAPA-MFRM)

In addition to usual care, the intervention group will receive the HAPA-MFRM programme, which will be divided into preintenders (task self-efficacy, outcome expectancy and risk perception), intenders (action planning and coping planning) and actors (restoration of self-efficacy, action control and social support), according to the stage and internal structure. Due to the complexity of health behaviour interventions, relevant technology is essential to provide effective guidance. Moreover, the CONSORT requires accurate reporting of behaviour change interventions.[33] Behaviour change techniques (BCT) were developed by Michie *et al*[37] in 2013 and use the Delphi method, cluster analysis and other steps to form 16 clusters of techniques, such as expected outcomes, rewards and challenges, feedback and monitoring and goals and plans. The technique has been applied in HAPA-related intervention programmes and fall prevention programmes, thus confirming its scientific validity and feasibility.[38 39] Therefore, BCT will be applied as a reference (see table 1).

Stage 1: preintenders

The main formats will involve group lectures and scenario simulations, with each intervention lasting for 30–45 min. Intervention content will use BCT (5.1, 5.3, 5.5, 5.6, 9.3 and 15.1) to enhance participants' fall prevention outcome expectations, management task self-efficacy, fall risk perceptions and progression to intenders via the enhancement of IC.

Table 1 Description of the intervention group (Health Action Process Approach-multidomain fall risk management)

	Topic	Content/point	BCT	Time/form
Stage 1 Preintenders	Outcome expectancies	► Informing about the adverse physical, psychological and socioeconomic effects of accidental falls and the benefits of self-management – Overview of falls (epidemiology, outcomes) ► Introducing the concept of IC, and informing the benefits of enhancing IC for health and fall prevention	Comparative imagining of future outcomes (9.3) Anticipated regret (5.5)	Week 1 Group lectures
	Task self-efficacy	► Explaining first aid treatment after accidental falls to reduce the fear of falling – Steps for self-aid and aid to others – Use of assistive tools ► Providing cases to enhance IC and improve compliance	Verbal persuasion to boost self-efficacy (15.1)	Week 1 Scenario simulation
	Risk perception	► Informing of fall-related risk factors, including sensory, locomotion, nutrition, cognition, psychology, diseases, medication and external environment – Fall risk (intrinsic, extrinsic factors) ► Explaining measures to protect vision and hearing, and listing solutions to improve the living environment ► Explaining the basic nutrients and introducing the health diet – Improvement of sarcopenia ► Introducing cognitive improvement and mood regulation measures – Exercise training – Cognition training – Mindfulness training ► Introducing self-management strategies for chronic diseases and medication	Health consequences (5.1) Emotional consequences (5.6) Social and environmental consequences (5.3)	Week 2–3 Group lectures/ Scenario simulation
Stage 2 Intenders	Maintenance self-efficacy and action planning	► Understanding intentions of falls risk management and improving compliance ► Developing personalised falls risk management goals and concrete plans (8, 16, 24-week goals) ► Explaining the use of the Tumbler: Fall Risk Management handbook – Fall prevention, time log, health diary	Goal setting (behaviour) (1.1) Goal setting (outcome) (1.3) Action planning (1.4) Instruction on how to perform a behaviour (4.1)	Week 4 Group lectures/ One-to-one interviews
	Coping planning	► Predicting possible problems for actors and developing barrier-centred self-regulation strategies ► Developing an emergency response plan to inform the support pathways of healthcare staff	Problem solving/coping planning (1.2)	Week 4 Group lectures/ One-to-one interviews

Continued

Table 1 Continued

	Topic	Content/point	BCT	Time/form
Stage 3 Actors	Recovery self-efficacy	▶ Understanding the difficulties and blind spots in falls risk management and providing targeted guidance to enhance self-efficacy and compliance ▶ Timely identification of negative emotions, encouragement and support from healthcare staff and family members to increase commitment to the plan	Discrepancy between current behaviour and goal standard (1.6) Regulate negative emotions (11.2) Social support (emotional) (3.3)	Week 7, 10, 13 Group discussions
	Maintenance	▶ Weekly monitoring of the plan, feedback on the recording of time log and health diary and giving available resources ▶ Dynamic adjustment of the programme according to the acceptance and satisfaction of the intervention by the older adults	Self-monitoring of behaviour (2.3) Feedback on behaviour (2.2)	Week 5–16 One-to-one interviews
	Consolidation and outlook	▶ Inviting participants with a high level of compliance to share their insights and gains ▶ Providing long-term strategies to prevent the risk of falls and clarifying intentions for healthy behaviour habit	Incentive (10.1) Habit formation (8.3)	Week 16 Group discussions

BCT, behaviour change techniques; IC, intrinsic capacity.

Stage 2: intenders

This stage will use mostly group lectures or one-to-one interviews to provide an action and coping plan to participants for fall risk management. This will apply BCT (1.1–1.4, 4.1) at week 4. First, three individualised targets (weeks 8, 16 and 24) will be established, including the IC (five dimensions), the environment and diseases. Second, healthcare professionals and participants will collaborate to develop an implementation plan, understand the training required for the next stage and provide self-regulation strategies for coping with barriers.

Stage 3: actors

BCT (1.6, 2.2, 2.3, 3.3, 8.3, 10.1 and 11.2) will be applied to recover self-efficacy and behavioural control. Depending on the decline in each dimension of intrinsic ability, participants will choose between three types of training (the Vivifrail programme, cognition training and mindfulness training). In addition, participants with decreased vitality or sensation will review the lecture content of the preintenders stage. The vitality dimension will be based on research by Agostini *et al*,[40] which will clarify the importance of supplementing the diet with nutrients such as antioxidants, unsaturated fatty acids, vitamins and proteins to alleviate muscle loss. The sensory dimension refers to the ICOPE guidelines for visual improvement through environmental factors (eg, lighting or wearing glasses) and individual factors (eg, eye hygiene or hand hygiene) and for hearing improvement through the use of assistive devices such as hearing aids, cochlear implants and amplifiers.[12] Recovery of self-efficacy will be implemented as group discussions, with each intervention lasting 15–30 min. This portion will identify gaps between behaviours and goals while focusing on challenges with fall prevention; thus, professional support can be promptly given. Maintenance will be implemented in one-to-one interviews, with each intervention lasting 15–30 min. This portion will dynamically monitor changes in health behaviour and the effectiveness of the programme. Finally, the consolidation and outlook will provide the foundation for the habit formation of healthy behaviours.

The Vivifrail programme is a multicomponent exercise strategy aimed at maintaining functional ability and preventing falls in older adults. This multicomponent exercise consists of resistance, cardiovascular, balance and flexibility training. After the screening assessment, the training models will be individually selected for health (10–12 points in the SPPB score), prefrailty (7–9 points) and frailty (4–6 points)[35] (see table 2). Disability (0–3 points) will not be included in this study because of the exclusion criteria. Moreover, mobile applications and guidelines have been produced to enhance adherence (www.vivifrail.com). When considering the existence of a digital divide among elderly individuals in NHs, paper guidelines (see online supplemental file 2) will be applied alternately with wheel exercises (resistance/power, balance and flexibility exercises) and walking

Table 2 The multicomponent exercise types of the Vivifrail programme

	Cardiovascular	Resistance	Balance	Flexibility
Health	Walk	Twist a towel	Get up from a chair	Stretch arms
		Lift a bottle	Up and down stairs	Stretch legs
			Walk while touching the balloon	
			Walk in a figure of 8	
Prefrailty	Walk	Twist a towel	Get up from a chair	Stretch arms
		Lift a bottle	Obstacles	Stretch legs
			Walk in a figure of 8	
Frailty	Walk	Lift a bottle	Pretend to sit	Stretch arms
		Squeeze a ball	Walk on tiptoes and heels	Stretch legs

(cardiovascular endurance exercises). Exercise training will be practiced at least three times a week for 30–45 min.

Cognition training will enhance cognitive capacity via attention, numeracy and memory exercises. Concentration practice will be performed according to the Schulte grid (5×5) format, which is a method that develops attention control, expands peripheral vision and hand-eye coordination.[41] This study designed Schulte grid puzzle material (see online supplemental file 2) to help in practicing this method. First, participants should cut 25 puzzle pieces according to the instructions, randomly form 5×5 squares and determine and read 1–25 numbers in turn under a specific time period. The numeracy practice will use the puzzle materials and arithmetic symbols to choose random mathematical calculations. Memory practice will again adopt puzzle materials, with the random selection of five puzzle pieces being performed. The pieces are placed into rows in order to memorise the colours and numbers, as their ability can gradually result in an increased number of puzzle pieces. Cognitive training will be practiced at least three times a week for 30–45 min.

Mindfulness training is recommended for enhancing psychological capacity. In this study, breathing awareness and body scanning, which are the most common and elementary practices, will be used to help relieve anxiety and stress.[42] The participants should be in a quiet and safe environment, remain in a comfortable position, select the recommended guided audio (see online supplemental file 2) and follow the exercises. The training will be performed at least three times a week for 30–45 min.

Simultaneously, the 28-page A4 (297 mm × 210 mm) 'Tumbler: Fall Risk Management Handbook' will be distributed. This handbook is divided into three sections: fall prevention, time log and health diary (see online supplemental file 2). All of the sections contain interactive elements such as texts, audios and illustrated examples. To safeguard the control group, they will also be given the handbook at the end of the study.

- Fall prevention: this section mainly refers to the World Guidelines[21] and the STEADI older adult fall prevention resources (https://www.cdc.gov/steadi/)[22] and compiles textual content related to fall prevention. The IC assessment outcomes and action planning will be completed.
- Time log: according to the ICOPE guidelines,[12] three trainings will be selected to improve IC. This section will record and track the training by filling in the circles in the time log.
- Health diary: this section will record the nutritional intake, sensation development and environmental improvement via a diary to assist in monitoring and providing feedback on health behaviours throughout the entire process.

OUTCOME MEASURES

IC composite outcomes

With reference to the ICOPE guidelines, standardised measures of each dimension will be administered to the participants after screening. Following the methodological approach that has been previously reported by other scholars,[43–45] the individual dimension outcome measures will be used in conjunction with each other to calculate an IC composite score.

- Cognition capacity: the Mini-Mental State Examination (MMSE) is a widely used assessment instrument with a score range of 0–30, and the Cronbach's alpha coefficient is 0.833 for internal consistency. Subject to age and culture, the normal thresholds are classified according to education level and the classification criteria include illiterate (>17), primary (>20) and high school and above (>24) as being cognitively normal.[46]
- Locomotion capacity: the SPPB, as a recommended physical performance test, combines the balance test, the gait speed test and the chair rise test. The total scores range from 0 (worst performance) to 12 (best performance), and the Cronbach's alpha coefficient is 0.76 for internal consistency.[47]
- Vitality: the Mini Nutritional Assessment (MNA), which covers anthropometric indicators and dietary and subjective assessments, is suitable for assessing the vitality of older individuals. The total score of the scale is 30; 24–30 is considered to indicate good nutritional status, 17–23.5 indicates a risk of malnutrition and

Table 3 Intrinsic capacity composite score assigned

Capacity	Measurement	Evaluative criteria	Score
Cognition	MMSE	Score ≤17 (illiteracy)/score ≤20 (primary school)/score ≤24 (middle school and above)	1
Locomotion	SPPB	Score ≤9	1
Vitality	MNA	Score <24	1
Sensory (vision)	Self-report/ Tumbling E chart	Yes/ Decimal record <0.8	1
Sensory (hearing)	Self-report/ Whisper voice test	Yes/ Repeat two or fewer words correctly	
Psychology	PHQ-9	Score ≥5	1

MMSE, Mini-Mental State Examination; MNE, Mini Nutritional Assessment; PHQ-9, Patient Health Questionnaire-9; SPPB, Short Physical Performance Battery.

<17 is considered malnutrition. The Cronbach's alpha coefficient is 0.71 for internal consistency.[48]

- Sensory capacity: visual capacity will use the self-report (one item of the WHO ICOPE screening tool) format. If the participant denies visual impairment, a tumbling E chart will be used to standardise visual testing. In accordance with the Standard for Logarithmic Visual Acuity Charts (GB11533-2011), the decimal record will be used.[49] Hearing capacity will be assessed via self-reports (two items of the WHO ICOPE screening tool). If the participant denies hearing impairment, a whisper voice test will be used. The examiner will stand behind the participant at an arm's length (0.6 m). The examiner will then whisper four common and unrelated words, and the participant will be required to repeat the words.[50]
- Psychological capacity: the Patient Health Questionnaire-9 (PHQ-9) will assess the frequency of nine depressive symptoms over the previous 2 weeks. The scale has a total score range of 0–27, with scores of 5 and above considering observation or counselling. The Cronbach's alpha coefficient is 0.82 for internal consistency.[51]
- IC composite score: each dimension of capability will be assigned a score of 1; therefore, the composite score ranges from 0 to 5, with higher scores representing a decline in IC (see table 3).

Fall-related outcomes

The selection of outcome measures will adhere to the guidelines established by the American Geriatrics Society/British Geriatrics Society[52] and CDC.[53] When considering the completeness of the research, the fall risk, gait, balance and strength will be reported. Additionally, to assess the effectiveness of the HAPA in the intervention, fall-related self-efficacy, risk perception, intention and action will be reported.

- Fall risk: the Self-rated Fall Risk Questionnaire (SFRQ) was developed by the CDC and contains 12 items totalling 14 points, with a score of ≥4 suggesting a risk of falling; moreover, the Cronbach's alpha coefficient is 0.724 for internal consistency.[54]
- Gait and balance: the Timed-Up-and-Go test (TUG) assesses gait and balance in older adults. The participant will sit on the chair, and when the command 'start' is heard, they will walk forwards as fast as possible to a distance of 3 m, after which they will turn around and walk back to the chair.[55]
- Strength: the Hand Grip Strength (HGS) will be tested via a hand dynamometer (Camry). The participants will be required to rest for at least 1 min before their grip strength is measured. Measurements will be taken in a seated position with the dominant hand, with the elbow angle at 90° and the forearm in a neutral position. A maximal squeeze will be performed during the measurement, the body posture will be maintained and the values will be averaged three times.[56]
- Self-efficacy: the Modified Falls Efficacy Scale (MFES) was revised in 1996 by Hill *et al*.[57] The scale is suitable for measuring fear of falling (FOF) and activity balance confidence.[58] It consists of 14 items (9 indoor activities and 5 outdoor activities), each of which can be selected on a scale of 0–10 and the Cronbach's alpha coefficient is 0.974 for internal consistency.
- Self-management: the self-management ability for fall prevention in elderly individuals questionnaire was developed by Hu *et al* in 2017. The questionnaire contains 7 dimensions with 42 items; moreover, the total score ranges from 42 to 210, and the Cronbach's alpha coefficient of the questionnaire is 0.775.[59]
- Intention: the fall management behaviour change stage assessment was developed based on the results of Lippke *et al*.[60] This scale consists of only one query: do you follow the principles of 'appropriate exercise, proper diet, emotional adjustment, cognitive improvement, visual and auditory improvement, management of illness and medication, and environmental screening' for fall risk management? The participants can select 'No, I have no intention to start falls risk

management at this time' for the preintention stage; 'No, but I have decided to start falls risk management' for the intention stage; and 'Yes' for the action stage. The scale has a retest reliability of 0.851.

Healthy ageing outcome

In the healthy ageing framework, functional capacity is composed of an individual's IC and relevant environmental characteristics.[2] Research has shown that the SPPB is effective in predicting and assessing physical performance and functional capacity.[61 62] Therefore, the assessment of functional capacity will not be repeated in this study.

- Healthy ageing: the Healthy Ageing Instrument (HAI) was developed by Thiamwong and Soonthorndhada.[63] The HAI covers 9 aspects of 35 items, with higher scores indicating a better level of healthy ageing; moreover, the Cronbach's alpha coefficient is 0.93 for internal consistency.

The questionnaires will be completed in both paper and electronic formats, and outcomes will be determined by interviewing the participants. All of the instruments were translated and validated in Chinese. The IC composite score (MMSE, SPPB, MNA, sensory capacity and PHQ-9) and SFRQ score will be the primary outcomes; TUG, HGS, MFES, self-management ability for fall prevention in the elderly questionnaire, fall management behaviour change stage and HAI will be the secondary outcomes. The IC composite outcomes, fall-related outcomes and healthy ageing outcomes will be measured at the baseline assessment (T0), intermediate assessment (T1), postassessment (T2) and follow-up assessment (T3), as shown in table 4.

ETHICS AND DISSEMINATION

All of the procedures will adhere to ethical principles of the Declaration of Helsinki. The trial ethics and data monitoring have been approved by the Huzhou University Committee (Ref No. 2023-06-06) and registered in the US Clinical Trials Registry (NCT05891782), which was last updated on 31 October 2024. All data will be confirmed, reconciled and stored in an electronic database, participants' identifying information (eg, real name) will not appear in the relevant reports of the trial to protect their

Table 4 Assessment instruments used for the study

	–T1 Recruitment	T0 Basal	T1 Stage 1–2 4 weeks	T2 Stage 3 16 weeks	T3 Follow-up 24 weeks
Eligibility screen	X				
Informed consent	X				
Intervention		◆	———	———	◆
Assessment					
(IC composite outcomes)					
MMSE		X	X	X	X
SPPB		X	X	X	X
MNA		X	X	X	X
PHQ-9		X	X	X	X
Sensory (visual and hearing)		X	X	X	X
IC composite score		X	X	X	X
(Fall-related outcomes)					
SFRQ		X	X	X	X
TUG		X		X	X
HGS		X		X	X
MFES		X	X	X	X
Self-management abilities for fall prevention in elderly questionnaire		X	X	X	X
Fall management behaviour change stage assessment		X	X	X	X
(Healthy ageing outcome)		X		X	X

HGS, Hand Grip Strength; IC, intrinsic capacity; MFES, Modified Falls Efficacy Scale; MMSE, Mini-Mental State Examination; MNE, Mini Nutritional Assessment; PHQ-9, Patient Health Questionnaire-9; SFRQ, Self-rated Fall Risk Questionnaire; SPPB, Short Physical Performance Battery; TUG, Timed-Up-and-Go.

privacy. Dissemination plans include conference presentations at a variety of scientific institutions and publication of results in peer-reviewed journals.

DISCUSSION

According to the UN, it has been projected that by the year 2050, the global population of those individuals aged 65 years and over will constitute approximately 16.5% of the population. Furthermore, it is anticipated that China's senior population will surpass the threshold of 30% during the same time period.[64] Healthy ageing is considered to be the least costly and most effective means of coping with population ageing, with an emphasis that 'healthy ageing is not the absence of disease, but the maintenance of functional ability is of paramount importance'.[12] However, during the process of healthy ageing, the issue of accidental falls in the elderly population cannot be ignored, particularly within populations exhibiting a decline in IC. This geriatric syndrome is characterised by a high prevalence, numerous complications and a high incidence of disability and mortality.

An average of 1.6 falls per bed per year has been reported, especially in NHs.[65] A meta-analysis revealed that the prevalence of falls among older adults in NHs ranged from 22% to 62%, whereas 25% to 87% of NH transfers to hospitals were due to falls, with up to 67% of these transfers considered to be avoidable.[66–69] Therefore, the accurate identification and prevention of fall-related influences is critical for reducing the incidence of accidents. It has been demonstrated that NH older adults walk slower than their non-institutionalised peers do, and they take more time to complete the TUG test; moreover, they exhibit lower MFES.[70 71] The maintenance of postural stability in NH older adults requires the interplay of strong muscles and the skeletal and sensory systems[66]; cognitive impairments lead to walking speed-related falls, and depression and impaired locomotion are important and preventable risk factors for falls.[66 70] According to the conceptual model constructed by Chhetri *et al*,[27] the abovementioned preventable factors correspond to the five dimensions of IC, which are influenced by health behaviours, psychosocial factors and disease. Falls can be considered as health stressors, and when the body is stimulated by stressors (falls), different outcomes, such as health recovery, frailty, disease or death, are produced. Therefore, this study will construct a 'health behaviour→IC→healthy ageing' visualisation pathway and mobilise health behaviours and IC to cope with stressors (falls), in order to achieve a healthy ageing outcome.

Multidimensional interventions are among the main fall prevention and IC enhancement strategies. Studies have shown that multidimensional interventions have significant effects on the endpoints of falls, recurrent falls and hip fractures due to falls, with low-to-moderate confidence in the evidence; furthermore, strong recommendations are justified. [26] Currently, relatively few intervention studies have focused on enhancing IC in older adults. Scholars in various countries have proposed corresponding programmes based on the ICOPE programme, such as France (INSPIRE ICOPE-CARE), South Korea (ICOOP_Frail) and Spain (AMICOPE).[72–74] However, all of these programmes are still in the research period, and the effects of the interventions have not yet been clarified. Only secondary analysis can be used to assess the IC enhancement of elderly people in NHs.[45] In addition, the WHO ICOPE screening tool will hopefully simplify the original cumbersome assessment process in NHs, which will reduce staff workload and promote dynamic assessment.

Moreover, health education interventions applying health behaviour-related theories, such as health belief theory and behaviour change wheel, are the main tools for fall prevention self-management.[75 76] However, a meta-analysis revealed that only one study investigating a group education programme in a long-term care setting reported a significant reduction in the incidence of falls and a significant reduction in FOF.[77] Although confidence in the evidence was low due to the paucity of studies conducted in NHs, the significant impact of the intervention was still considered to be strongly recommended.[26] In the future, BCT and group form could be added to existing fall prevention strategies, with the aim of changing FOF and preventing falls.

In addition, fall efficacy, as a sense of self-efficacy, is defined as 'the perceived ability to manage the potential threat of falling'; in conjunction with fall perception, fall efficacy explains the confidence of self-management in falls.[78 79] This finding aligns with the HAPA, and self-efficacy has been confirmed to be important in predicting health behaviours in the motivation, intention and action stages,[80] thus corroborating the applicability of the theory in fall risk management. To summarise, multidimensional interventions based on fall-related health behaviours are lacking and necessary for older adults with declining IC in NHs.

The aim of this study is to evaluate the effectiveness of an innovative HAPA-MFRM programme for reducing IC in older adults. The construction of a fall risk management strategy that meets the functional ability level and subjective initiative of older adults will contribute to enhancing IC and preventing falls. Therefore, healthcare resources should be used, existing fall prevention tools should be expanded and the sustainable development of HAPA in the field of geriatric syndromes should be promoted both efficiently and rationally.

Limitations

This study also has several limitations. First, the site that was selected for this study will be a large NH to ensure that the same level of usual care will be implemented in the two groups, but contamination bias will arise. Second, in a non-pharmacological trial, participants and intervention implementers will be difficult to blind; thus, bias will inevitably arise. Third, this study was designed as a multidisciplinary intervention, which may not be able to determine the fall risk effects of each measure; thus, subgroup analyses will be conducted with additional groups in the future. Fourth, a major challenge is that participants with

a decline in IC (particularly low IC) may be exposed to unplanned death or acute illness, thus resulting in sample attrition. Fifth, individuals with a disability are common in nursing facilities. Due to considerations of programme safety and staff allocation, this study will exclude older adults with a disability, which will undoubtedly affect the prevalence of the programme and they will be considered in the future.

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