Pilot Project Programme for Prevention of Falls among Community-dwelling Elderly in Guangzhou

Guangzhou Centre for Disease Control and Prevention

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I. Background of the study

According to China's seventh population census, the population aged 60 and above reached 264 million in 2020, accounting for 18.7 per cent of the total population, and by 2025, the total number of elderly people will exceed 300 million. Falls are the leading cause of injury and death among the elderly, and 20-30 per cent of elderly people who recover from fall-related injuries will suffer a decline in self-care ability or even premature death. Currently, China has a large elderly population in urban communities, and falls among the elderly have become a public health issue of public concern.In 2019, the State Council issued the Opinions on the Implementation of Healthy China Actions, which emphasises "accelerating the promotion of the shift from treating illnesses as the centre of health care to people's health as the centre of health care", and will " Implementing health promotion actions for the elderly" as an important part of maintaining health throughout the life cycle. Falls in the elderly are not an accident, but the result of the interaction of multiple risk factors. Most of these risk factors can be changed and prevented. At this stage, the majority of older people in our city live in the community, and about 61.7 per cent of falls occur at home or in other community settings. The community is the main venue for the implementation of the strategy of "prevention first, moving the gate forward, and lowering the centre of gravity" for the prevention and control of chronic diseases. However, there are no evidence-based scientific and systematic intervention techniques, models and tools that can be directly scaled up in our city.In 2022, there will be only 16.84 public health doctors and 112 public health nurses per 100,000 people in our city, and public health services are severely under-resourced

due to the surge in the number of patients suffering from chronic diseases such as diabetes and high blood pressure. The healthcare system is also facing an increasing economic burden and unprecedented challenges. Therefore, it is important to explore a fall prevention intervention service model that meets the city's economic, cultural, and environmental conditions under limited community healthcare resources, so that more older adults can benefit from fall prevention intervention services to improve the quality of life of older adults and to reduce the burden of healthcare.

Risk factors for falls in older people include gait and balance disorders, visual impairment, syncope and arrhythmia, irrational use of medication, foot disorders and environmental hazards. Intervention studies on falls in the elderly began in developed regions and countries in the 1980s, and the studies were mainly divided into two categories: single-factor interventions targeting a single risk factor and multifactorial interventions targeting multiple risk factors. Since the 1990s, there has been a gradual increase in the number of multifactorial intervention studies on falls in older adults in developed countries, and the number of high-quality randomised controlled studies has also gradually increased. Existing evidence suggests that targeted interventions targeting the various risk factors for falls in older adults are the most effective strategy for preventing falls in older adults. Population-based community-based integrated interventions that address single risk factors, such as improving balance function and home environment, can also be effective in preventing falls in older adults and reducing the severity of injuries caused by falls. Based on this, the research group organised two rounds of the project "Research on the Effectiveness of Community-Based Intervention of Health Education Group Activities for Fall Prevention in the Elderly" in 2020 and 2022 in some communities in Guangzhou. The project is a multifactorial intervention based on the community population, through the implementation of seven health education programmes, including fall risk assessment and management, health self-management skills, exercise guidance, rational use of medication, and one

door-to-door modification of the fall-related hazardous environment. Twelve months after the first round of the project, the incidence of falls in the intervention group was 4.35%, compared with 24% in the control group, $p < 0.05$. Both rounds of the project were effective in raising the awareness of fall prevention and the level of fall prevention knowledge and skills among the elderly, and reducing the number of falls, which resulted in a better intervention effect.

However, the intervention programme of seven health education classes and one home assessment in the pre-programme, if it needs to be widely promoted in our city, may put more pressure on the existing working mode of primary healthcare institutions, and the curriculum needs to be streamlined for easy promotion. In addition, the effectiveness of individual intervention components was not studied in the pre-intervention, and the mechanism of action of individual elements of the intervention with respect to outcome effects could not be confirmed. When the performance of individual intervention components is unknown, it is not clear which factor has the least effect on outcomes. The components selected for removal may be the main cause of any effects observed in the RCT, and therefore may result in a streamlined intervention that is less effective or even ineffective.

Therefore, this study intends to build on the results of the previous research, selecting community elderly in Baiyun District as the intervention target, assessing the fall risk factors of the intervention target through qualitative analysis of fall risk, and targeting the formation of health education activity groups; the intervention target of each group randomly receives different combinations of interventions under the guidance of professional and technical personnel; and evaluating the effects of different interventions through a randomised controlled trial with analytic factor design to screen the The effectiveness of different interventions will be evaluated through a randomised controlled trial with a causal analysis design, in order to screen the comprehensive intervention elements, optimise the mode of intervention combinations, and save the research

resources and costs; furthermore, the study will provide scientific references and practical tools for the city to carry out the fall intervention services for the elderly applicable to the primary healthcare institutions, and ultimately reduce the incidence of falls among the elderly, and improve the quality of their lives.

II. Objectives of the Study

(1) General objectives of the study

Using a multi-stage optimisation strategy, the group will optimise the project intervention programme in the improvement phase, conduct a randomised controlled trial using a factorial design, quantitatively compare the effects of different falls programmes on falls prevention, carry out an economic evaluation of the different intervention groups, and ultimately determine the optimal combination of intervention strategies for the project. To explore and establish a community-based falls prevention intervention model for the elderly, and to provide a scientific basis and a practical tool for the establishment of a community-based falls prevention service model for the elderly that is suitable for implementation by primary healthcare organisations in the city. Ultimately, through city-wide dissemination and implementation, we will achieve the goal of reducing the incidence of falls among older adults and improving their quality of life.

(2) Specific objectives

1. To be achieved through a 2-month intervention for the target population within 12 months after the start of the implementation of the intervention:

1.1 Apply a multi-stage optimisation strategy, centred on an analytic design randomised controlled trial, to screen for elements of a community falls prevention intervention for older people and optimise a comprehensive intervention management strategy for community falls prevention in older people;

1.2 Evaluate the inputs and outputs of the multifactorial intervention strategy for the prevention of falls in older people, to provide a basis for the dissemination of the intervention strategy and government decision-making.

III. Study subjects

The researcher used the Screening Form for Research Subjects (Annex 2) to select eligible elderly people as research subjects among the elderly population by means of questionnaires and scale assessments.

(1) Study subjects

All 24 streets within Baiyun District of Guangzhou City were included in the study area. Sampling should take into account the state of socio-economic development, the age of the population, the gender ratio of the neighbourhood committees (villages) as consistent as possible, and the balanced distribution of the sample; taking into account the principle of cost-effectiveness and the feasibility of the sampling scheme. Through centralised open recruitment, household recruitment and other forms of recruitment, followed by face-to-face survey, telephone survey, on-site assessment, etc., eligible elderly people are selected as intervention research subjects and randomly assigned to each intervention group.

1.1 Inclusion Criteria for Research Subjects

1.1.1 Inclusion criteria:

- ✓ Age 60-80 years old, including 60 and 80 years old
- ✓ Living in the community
- ✓ Expected to live in their current place of residence for the next 12 months
- ✓ can walk 50 metres without the assistance of an assistive device

1.1.2 Exclusion criteria:

- ✖ Exclusion of study subjects with acute illnesses or acute stages of chronic diseases

1.1.3 Requirements for the proportion of recruited subjects

In order to increase the homogeneity of study subjects, study subjects can be recruited with reference to the following gender and age requirements:

① 20% male, 80% female; ② 30%-35% aged 60-65 years, ③ 30%-35% aged 66-70 years, ④ 30%-35% aged 71-75 years, ⑤ less than 10% aged 76-80 years.

(2) Sample size estimation

After scientific calculations, combined with the actual work, a total of 888 people are needed for this project, then each group needs a sample size of n=111, and a total of 37 people are recruited in each street (town). The sample size calculation process is as follows:

This study uses the dichotomous variable "whether a fall occurs" as the outcome indicator. According to the results of the occurrence of falls among the elderly in the community in Guangzhou City in 2023, the incidence of falls among the elderly in Baiyun District was 17%. After discussion with experts, it was concluded that a 35% reduction in the incidence of falls after the intervention was considered to be of public health significance. In this study, the test level was set at $\alpha=0.05$ and the test efficacy at 0.8 (i.e., $\beta=0.2$). The proposed factorial design for this study is based on the sample size formula (below) for factorial designs in which the outcome variable is a dichotomous variable, and the sample size required for each test condition can be obtained as:

$$n=\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2}{2^k\,[arcsin(\sqrt{\frac{\rho+\rho\delta}{2}})-arcsin(\sqrt{\frac{\rho-\rho\delta}{2}})]^2}\approx83$$

$$\rho=0.17,\ \delta=0.35,\ Z_{1-\alpha/2}=1.96,\ Z_{1-\beta}=0.84,\ k=3.$$

The total sample size required for the 8 test conditions was:

$$N_{conditions}=83\times8=664$$

According to S. Bhasin, T.M et al, the design effect of whole cluster randomisation can be obtained by estimating ICC = 0.0076 and mean number of individuals in the cluster m = 28:

$$DE=1+（m\text{-}1）\times ICC=1+（28\text{-}1）\times 0.0076=1.2052$$

The sample size was set to be the same for the eight test conditions, and the total sample size required for the study was:

$$N=N_{conditions}\times DE\div(1-10\%)\approx888$$

The required sample size for each test condition was then 111 cases;

Each of the 24 streets recruited 37 study participants.

(3) Intervention groups

The study subjects were grouped in a completely randomised manner, with a statistician independent of the research team using a computer to generate random numbers, and equal proportions of the study subjects recruited from the 24 streets (towns) were allocated to the 8 experimental condition groups, so that each experimental condition contained all the study subjects from 3 streets (towns). After grouping was completed, a database of basic information about the study participants was created, as shown in Table 1.This study was blinded only to the data collectors and data analysers.

Table 1 Subgroups of the Community Falls Prevention for Older People Pilot Project

groups	Fall Prevention Education Course	Development of personal exercise skills	Environmental assessment
Group 1	Yes	Yes	Yes
Group 2	Yes	Yes	No
Group 3	Yes	No	Yes
Group 4	Yes	No	No
Group 5	No	No	No
Group 6	No	Yes	Yes
Group 7	No	Yes	No
Group 8	No	No	Yes

IV. Intervention Strategies

(1) Strategy 1: Falls prevention education programme

To organise the research subjects in the intervention group to set up a fall prevention health education activity group, in which the project team will disseminate knowledge and concepts of fall prevention through lectures, discussions, questions and answers, and sharing, so as to enhance the knowledge base required by the research subjects to prevent falls and to cultivate the relevant concepts.

(2) Strategy 2: Developing personal exercise skills

Through lectures, demonstrations, on-site exercises and practices, the project team taught the intervention group participants to improve their balance function, lower limb muscle strength, endurance exercise and other fall prevention exercise skills, and to use fall prevention aids through group activities.

(3) Strategy 3: Environmental Assessment

Through the staff's home assessment and guidance, the project team instructed the study participants to assess the risk factors of fall-related home environment and made suggestions for modification.

V. Main intervention activities

(1) Strategy 1: Fall prevention education programme:

1.1 Frequency of intervention

4 times

1.2 Duration and intensity of intervention

60 minutes/time, once in each of the 1st, 3rd, 5th and 8th weeks of the intervention period.

1.3 Intervention format

group intervention, 12 people in a group (in principle, no more than 15 people).

1.4 Intervention content

The content of health education includes (1) fall risk and preventability in the elderly (2) improving the home environment to prevent falls (3) identifying environmental risk factors in the community and public places (4) changing fall-prone behaviours.

See Table 2 for specific content.

1.5 Intervention tool

accompanying teaching materials (PPT)

1.6 Intervention providers

the intervention was completed by trained staff of the community health service centres in the project area, with at least two staff members required in each community, one staff member acting as the health education activity group leader, who was mainly responsible for organising and implementing each health education group activity (lecturing, organising discussions, teaching exercise movements, answering questions from the study participants, and generally arranging the group's activities); the other staff member As an assistant, the other staff member worked with the group leader to implement the group activities, and visited and protected the study participants during the exercise period.

(2) Strategy 2: Development of individual exercise skills:

2.1 Frequency of intervention

4 times

2.2 Duration and intensity of intervention

30 minutes/time, once in each of the 1st, 3rd, 5th and 8th weeks of the intervention period.

2.3 Intervention format

group intervention, 12 people in a group (in principle, no more than 15 people).

2.4 Intervention content

The content of health education included (1) basic knowledge of exercise safety, 4 methods of balance function exercise (2) review of 4 methods of balance function exercise (3) methods of exercising muscle strength (4) 2 methods of endurance exercise. See Table 3 for specific content.

2.5 Intervention tool

accompanying teaching text (PPT)

2.6 Intervention providers:

same as before.

Table 2 Time, frequency and main content of the implementation of the 4 fall prevention education courses

Number of group activities	intervention time	Key knowledge skills
First time	Week 1	Fall risk and preventability in the elderly
Second time	Week 3	Improving the home environment to prevent falls
Third time	Week 5	Identify environmental risk factors in communities and public places
Fourth time	Week 8	Change behaviours that predispose to falls. Reviewing skills and exercises that have already been learnt

Table 3 Time, frequency, and main content of 4 development of individual exercise skills

Number of group activities	intervention time	Key knowledge skills

First time	Week 1	Basic knowledge of exercise safety 4 methods of exercising balance function
Second time	Week 3	Reviewing learned exercise methods 4 methods of exercising balance function
Third time	Week 5	Reviewing learned exercise methods 3 ways to build muscle strength
Fourth time	Week 8	2 endurance exercise methods Reviewing learned exercise methods

(3) Strategy 3: Environmental assessment

3.1 Duration and intensity of intervention:

The integrated intervention group and the environmental intervention group community implemented 1 home falls environmental risk factor assessment and modification guidance for the intervention group study participants in the 6th week after the start of the health education group activities.

3.2 Intervention method, intervention content and intervention tools:

3.2.1 Intervention content

①Assessment of environmental risk factors for falls in the indoor environment of the homes, hallways, or courtyards where the elderly people live on a daily basis;

②Provide in-person guidance on the environmental risk factors found and fill out two written environmental assessment and modification recommendations, one to be filled out by the investigator and then filed and entered; the other record to be left for the use of the respondents;

③ Provide at least the services of a night light, bathroom non-slip mats, fall prevention warning signs, and double-sided adhesive fixed carpet floor mats. Conditional areas are encouraged to provide more retrofitting services.

3.2.2 Intervention Methods

After making an appointment, the project staff will enter the households at the agreed time to conduct fall risk assessment of the study subject families in the intervention group.

3.2.3 Intervention Tools

When carrying out the guidance on assessing the risk factors for falls in the home environment, project staff mainly used the "Risk Factors for Falls in the Home Environment of the Elderly and Suggestions for Retrofitting" (Appendix 4) to carry out the assessment on an article-by-article basis and to provide suggestions for retrofitting. Other intervention tools included night lights, non-slip mats, fall prevention warning signs, double-sided tape, and other tools.

3.3 Intervention providers

Trained project community social workers or CHC staff.

3.4 Implementation Records

When carrying out the home environment risk assessment, with the consent of the study participants, record the time of the assessment, the participants, the assessment process, the assessment results, and the guidance suggestions using pictures, videos, and words, and fill in the "Record of Home Environment Assessment and Improvement Form" (Appendix 8); special attention is paid to the collection of comparisons before and after the environmental modification.

VI. Project evaluation

Project evaluation includes baseline survey evaluation, effectiveness evaluation and

economics evaluation.

(1) Baseline survey assessment

1.1 Pre-intervention status of research subjects (baseline survey)

1.1.1 Implementation time

May 2024-June 2024.

1.1.2 Subjects of the survey

All older adults in the 8 study groups.

1.2 Baseline survey assessment content

1.2.1 Basic demographic information

Name, gender, age, address, contact information, ethnicity, cohabitation, occupational status, and education level.

1.2.2 Physical activity

Daily physical activity.

1.2.3 Illness and medication status

Type and number of illnesses, type and number of medications.

1.2.4 Falls-related information

Specific information on the occurrence of falls in the past year, fall effectiveness level.

1.2.5 Assessment methods and tools

① Assessment methods

Questionnaire survey, on-site observation and other methods are selected according

to different assessment contents.

② Assessment tools

Self-administered questionnaire: basic demographic information, physical activity, illness and medication use, and occurrence of falls (occurrence of falls in the last year);

Established scale measurements: Falls Effectiveness Scale for the Elderly, Quality of Life Scale.

See Annex 5 for specific assessment methods and tools.

Table 4 List of project baseline survey and assessment contents, methods and tools

Content		Method	Tool
classification	item		
Basic demographic information	Name, sex, age, address, contact details, ethnicity, level of education, living with the family, occupational status	Survey	Annex 5: Survey Assessment Form (Part I)
Illness, Medication and Medical conditions	Type and number of illnesses, type and number of medicines used	Survey	Annex 5: Survey Assessment Form (Part II)
Information about falls	Incidents of falls, history of falls	Survey	Annex 5: Survey Assessment Form (Part III)
	Falls Related Knowledge, Attitude and Action	Survey	Annex 5: Survey Assessment Form (Part IV)
	Falls efficacy	Scale	Annex 5: Survey Assessment Form (Part V)
Quality of Life Scale	Capacity for daily living	Scale	Annex 5: Survey Assessment Form (Part VI)
Gait	"Stand-up-and-walk" timing test	on-site test	Annex 5: Survey Assessment Form (Part VII)

1.2.6 Main Evaluation Indicators

① Indicators reflecting the occurrence of falls: rate of people falling (number), rate of people falling (number), rate of people falling (number), rate of people falling

(number), rate of people falling (number), and rate of people falling (number).

The rate of people falling (number), the rate of people falling (number), the rate of people falling (number), the rate of people falling (number).

② Reflecting the effectiveness of falls: the score of the Falls Effectiveness Assessment Scale.

③Reflecting the ability to perform daily living tasks: score on the Quality of Life Scale.

(2) Process evaluation (intervention phase)

2.1 Evaluation time

May 2024-November 2024 (the whole process of project implementation)

2.2 Assessment Objects

Research subjects, project team staff.

2.3 Assessment contents and methods

2.3.1 Completion of group activities of research subjects

Evaluation of group activity attainment. The intervention team calculates the group activity attendance rate of the research subjects based on their attendance in the group activity record (number of research subjects who actually participated and completed the current group activity/number of research subjects who should have participated in the current group activity × 100%). The record form is shown in Appendix 3, "Record Form of Research Subjects' Participation in the Project Process".

2.3.2 Quality of the organisation and implementation of intervention activities

On-site assessment team of CDC institutions at municipal and district levels, selecting at least 30% of group activities for on-site quality assessment (on-site listening), required to cover all 4 activities and at least 50% of intervention communities, focusing on understanding the quality of the implementation of group activities and the learning effect of the elderly. The on-site assessment should cover all intervention groups. For details of the recording tool, please refer to Annex 6 "On-site quality assessment form for group activities

2.3.3 Satisfaction of study participants with group activities

① Groups 1, 2, 3, 4, 6 and 7 Intervention Communities Each community, after completing the health education group activities, organises a satisfaction survey and group interviews with the study participants to find out the satisfaction, feelings and suggestions of the study participants in participating in the group activities. For details of the recording tools, see Annex 7, "Intervention Participants' Satisfaction Survey Form (Elderly)".

② After the completion of household environmental assessment, guidance and improvement in the intervention community, ask for their satisfaction and record it in Annex 8, "Record Sheet for Household Environmental Assessment and Improvement Guidance".

2.3.4 Household guidance and assistance in environmental improvement

Evaluate the implementation of guidance and assistance in completing the environmental modification of household risk factors for study participants who have been admitted to households. Based on the record of household visits, calculate the completion rate of household guidance and assistance in environmental modification

(number of households actually visited and completed guidance and assistance in environmental modification / number of households that should be visited for guidance and assistance in environmental modification x 100%). For the record sheet, please refer to Annex 8 "Record Sheet for Household Environmental Assessment and Improvement Guidance Work".

2.4 Assessment Tools

Different assessment tools such as observation record sheets, questionnaires, interview outlines, etc. were selected and used according to the different contents and methods of the process assessment, as detailed in Table 5.

Table 5 List of project process evaluation contents, methods and tools

Content	Subject	Method	Tool
1. Completion rate of group activities by study participants	Study subjects in the intervention group	on-site observation	Record of Participation of Research Subjects in the Project Process (Annex 3)
2. Quality of the organisation and implementation of the intervention	Implementation team activities staff	on-site observation	Panel activity site quality assessment form (annex 6)
3. Satisfaction of study participants with group activities	Study subjects in the intervention group	Survey	Project Activity Satisfaction Questionnaire (Elderly) (Annex 7)
4. Household guidance and assistance in environmental rehabilitation	Staff implementing guidance on environmental improvements to households	Summary of work records	Household Environmental Assessment and Improvement Guidance Record Sheet (Annex 8)

(3) Assessment of effects

It is proposed to study the effect of the intervention at 6 and 12 months after the start of the intervention. The assessment of the occurrence of falls will be collected by filling in the monthly fall calendar; the changes in fall efficacy, knowledge, beliefs and

behaviours will be collected through on-site survey and testing.

3.1 Data collection on the occurrence of falls in the study population

3.1.1Assessment subjects

All study subjects in the 8 study groups.

3.1.2 Assessment period

From May 2024 to May 2025, information on the occurrence of falls was collected on a monthly basis during the period from the start of the intervention to the completion of 12 months of the intervention.

3.1.3Assessment content

Basic information on the occurrence of falls, with the same content as the baseline survey and assessment.

3.1.4 Assessment methods and tools

①Study participants use the Monthly Record of Falls Occurrence Calendar (Appendix 9) to record whether a fall has occurred or not.

Staff collected the Monthly Falls Record Calendar on a monthly basis, and used the Baseline Survey Questionnaire on the Occurrence of Falls among the Elderly (Annex 5, Part III) to conduct a detailed investigation on the time of falls that occurred.

3.2 First Effectiveness Assessment (after the start of the first intervention, at the completion of 6 months)

3.2.1 Subjects of assessment

All study subjects in the 8 study groups.

3.2.2 Assessment time

The assessment time for the study subjects should be from the first implementation of the intervention activities, when 6 months are completed (the control assessment time is within ± 7 days) to implement the first effect assessment.

3.2.3 Assessment content

The content of the assessment includes: fall-related knowledge, attitude and behaviour, daily life ability and fall efficacy.

3.2.4 Assessment methods and tools

The same assessment methods and tools as the baseline survey (Annex 5, Part IV, Part V and Part VI).

3.3 Second Effectiveness Assessment (at 12 months after the commencement of the first intervention)

3.3.1 Subjects to be assessed

All study subjects in the 8 study groups.

3.3.2 Assessment time

The assessment time for the study subjects should be from the first implementation of the intervention activities, when 12 months are completed (the control assessment time is within ± 7 days) to implement the second effect assessment.

3.3.3 Assessment content

The content of the assessment includes: the same as the baseline survey ("Annex 5, Part III, Falls" does not need to be surveyed).

3.3.4 Assessment methods and tools

The same assessment methods and tools as the baseline survey.

(4) Economics Evaluation

Targeted cost-effect and cost-utility analyses from a social perspective will help evaluate the real effects of the interventions in preventing falls in old age, and provide a data basis for the governmental decision-making authorities to formulate reasonable intervention policies.

4.1 Municipal Project Office

4.1.1 Collection time

After 6 months of intervention (after the end of the 6-month evaluation) and 12 months (after the end of the 12-month evaluation).

4.1.2 Collection content

The municipal project office intervention cost collection mainly includes the direct

costs and time invested to carry out the falls intervention programme. Direct costs mainly include travel costs for training, venue costs, expert costs, programme and manual production costs, and survey tool costs. The time invested in carrying out the falls intervention project includes the time invested by the municipal project office in designing and preparing the project, initiating and managing the project, carrying out the first level of training, attending the second level of training, and supervising the work.

4.1.3 Collection method

The main person in charge of the project in the municipal project office will fill in the "Questionnaire on Workload and Cost Expenditure of Falls Intervention Project for the Elderly in the Municipal Project Office" (Appendix 10) on his/her own, taking into account the details of the financial expenditures.

4.2 District-level project offices

4.2.1 Collection time

Intervention full 6 months (6 months after the end of the assessment) and 12 months (12 months after the end of the assessment).

4.2.2 Collection of content

The district-level project office intervention cost collection mainly includes the direct cost of expenditure and time invested to carry out the falls intervention programme. Direct costs include questionnaires, measurement tools, home environment improvement supplies, and labour costs. The time invested in carrying out the falls intervention programme includes the time invested in attending the primary training, carrying out the secondary training, recruiting/screening older people in the community, conducting the baseline survey, implementing the intervention, evaluating the process, and evaluating the effects.

4.2.3 Method of collection

The main person in charge of the project in the district-level project office will fill in the "Questionnaire on Workload and Cost Expenditure of Elderly Falls Intervention Project in District-level Project Office" (Annex 11) by himself/herself in conjunction with the breakdown of financial expenditure.

4.3 Primary health care institutions

4.3.1 Collection time

Intervention full 6 months (6 months after the end of the assessment) and 12 months (12 months after the end of the assessment).

4.3.2 Collection content

The primary project office intervention cost collection mainly includes the direct cost of expenditure and time invested in carrying out the falls intervention programme. Direct costs mainly include printing questionnaires, purchasing measurement tools and supplies for home environment improvement, and labour costs. The time invested in the falls intervention programme included the time invested in attending Level 1 and Level 2 trainings, recruiting/screening older people in the community, conducting baseline surveys, implementing interventions, and evaluating outcomes.

4.3.3 Method of collection

The main person in charge of the project in the grassroots project office, together with the breakdown of financial expenditure, filled in the "Questionnaire on Workload and Cost Expenditure of Falls Intervention Programme for the Elderly in the Grassroots Project Office" on his/her own (Annex 12).

4.4 Collection of Costs Related to Research Subjects

4.4.1 Collection time

From the beginning of the intervention to the end of the endline assessment, collected on a monthly basis (accompanied by a monthly calendar of falls).

4.4.2 Collection content

Costs related to falls of the study participants mainly include outpatient/emergency room visits, hospitalisation costs, drug costs, nutritional costs, home care and carer/nanny costs due to falls during the project period.

4.4.3 Collection method

The staff of the grassroots project office used the "Questionnaire on Falls-Related Expenses during the Intervention Period of the Study Subjects" (Appendix 13), which was obtained through face-to-face surveys, combined with the data from the elderly's medical expenditure records and financial documents.

As different types of expenses may be incurred by a particular fall of the study participant, when completing the "Questionnaire on Falls-related Expenses during the Intervention Period of the Study Participants" (Annex 13), staff members filled in the corresponding questionnaire in Annex 13 according to the different treatments actually incurred by the study participant. Possible treatment situations include self-treatment (Part I of Annex 13), outpatient emergency visit (Part II of Annex 13), inpatient treatment (Part III of Annex 13), out-of-hospital rehabilitation treatment (Part IV of Annex 13), and review (Part V of Annex 13). In case of inpatient treatment for study subjects, the final cost was entered at the time of discharge. The information collected is not duplicated with that collected in the previous month. If the study participant had rehabilitation treatment, rehabilitation in outpatient emergency clinic was counted in the outpatient

emergency clinic fee schedule (Annex 13 Part II), rehabilitation during inpatient hospitalisation was counted in the total inpatient hospitalisation fee (Annex 13 Part III), and out-of-hospital rehabilitation was counted in the out-of-hospital rehabilitation fee (Annex 13 Part IV).

VII. Methods of Statistical Analysis

(1) Data collection

The collection and management of all research data will be done relying on the REDCap platform. After the formation of the preliminary database, the database will be checked and cleaned again for logical errors and missing values, and the database will be finally formed after further verification and correction by telephone follow-up with the respondents.

(2) Data collation and analysis

SPSS20.0 was used for statistical processing. Variables such as general demographic characteristics, disease characteristics, previous falls, and level of social support at baseline were compared to see if there were any differences between the different intervention groups, and variables with differences would be corrected in the subsequent analyses. Intent-to-treat (ITT) analysis is proposed to evaluate the intervention in this study. Descriptive analysis: statistical descriptions of primary outcome variables, secondary outcome variables, intervention implementation and other synergistic factors, etc., and independent samples t-tests (continuous variables such as Older Adult Falls Efficacy Scale scores, Quality of Life Scale scores, Older Adults' Falls Knowledge and Belief Behaviour Scale scores, etc.) and chi-square tests (categorical variables such as attitudes towards the intervention strategy, incidence of falls, etc.) to compare the between-groups differences were used.

The study proposes to assess the economic benefits using Incremental Cost-Effectiveness Ratio (ICER), which is the increased cost per unit of effect.

VIII. Safety Guarantee

(1) When carrying out the various screening, assessment, training, exercise and other activities of the project, the safety and physical health of the research subjects should be ensured as the first principle.

(2) During the various screening and assessment processes, research subjects should be clearly informed of the testing methods and possible risks. The project may conduct demonstrations and allow research subjects to practise before taking formal measurements. The staff should remind the participants that they should not pursue "good results" in the test.

(3) In the process of training and exercise, the basic principles are gradual and according to one's ability, and research subjects should not be forced to perform movements that are beyond their ability. All exercises are subject to the subjective feeling of the research subjects themselves, while attention should be paid to correcting the research subjects' sense of "not obeying the old" and stopping dangerous actions in time.

(4) When carrying out the assessment activities, the staff should clean up the risk factors in the environment beforehand, removing slippery ground, unevenness, obstacles and other environmental risk factors that may cause injuries to the research subjects. Seats or similar facilities for research subjects to rest should also be provided.

(5) Staff should prepare first-aid medication and related equipment at all project sites, and staff who can administer primary first aid should be present at each site.

IX. Quality control

(1) Quality control of the process of formulating and developing the project programme and related intervention tools

At different stages, through the organisation of experts in different fields, work programmes such as the overall project programme, the survey and assessment programme, and the intervention implementation programme; the design and use of questionnaires, checklists and record forms for various types of surveys and assessments; and the content and form of interventions are validated.

(2) Quality control of data collection

2.1 Unify tools and methods

Unify survey, measurement and assessment methods and tools.

2.2 Training

Conduct unified training and assessment for researchers participating in data collection regarding the use of work programmes, techniques and tools related to assessment information collection. They will be allowed to work only after passing the assessment.

2.3 On-site verification of data collection

All surveys, measurements and assessment work must be carried out at the site for corresponding verification and quality control. Mainly includes on-site verification of questionnaires and measurement items. Some of the research subjects are taken to repeat

the measurements. For details of the specific methods, please refer to the Requirements for On-site Quality Control Work of Survey and Evaluation (Annex 15).

2.4 Data entry and cleaning

According to the questionnaire or form, create and use REDCap to establish a unified entry file and set up preliminary logical calibration. Randomly select more than 20% of the entered questionnaires for secondary calibration to ensure the quality of data entry. Establish uniform data cleaning regulations and document the data cleaning process.

(3) Quality control of the implementation of intervention group activities

3.1 Unify the content, methods and tools of group activities.

Develop a unified programme of group activities and use unified training manuals and tools.

3.2 Training and evaluation of group activity implementers

Organise certified training of trainers (team leaders and assistants) to implement intervention group activities. They will pass the unified standardised training, practice and assessment, and will only be allowed to work after passing the assessment.

3.3 On-site evaluation of the quality of intervention group activities

On-site evaluation teams from CDC agencies at the city and district levels conduct on-site quality assessment of group activities. See the process evaluation section for details.

(4) Management of lost visitors

4.1 Definition of lost visitors:

Lost visitors were defined in this study as 1) study participants who explicitly refused to continue with the intervention via text message, WeChat applet, or phone call; and 2) withdrawal from the study due to the occurrence of an adverse health outcome, including hospitalisation for somatic or psychological illnesses, etc. Hospitalisation of study subjects due to unintentional injuries was not used as a criterion for study subject withdrawal from the study, but was recorded as a health outcome.

4.2 Controlling for loss of study subjects

4.2.1 Incentive

During the implementation of the project, each community health service centre will make use of local resources and advantages to provide certain free medical and health services (not related to fall prevention) or a certain degree of material incentives, to continuously maintain contact and communication with the study subjects, and to encourage the study subjects to participate in the project-related interventions, assessments, and monitoring activities.

4.2.2 Follow-up Confirmation

At least once a month, project staff will conduct a follow-up visit and communicate with the research subjects by phone, in-home or face-to-face to confirm that the research subjects are not missing, encourage the research subjects to continue to participate in the activities, and record the follow-up information in the "Record of Follow-up Visits to Research Subjects" (Annex 16).

4.2.3 Using project activities to understand absenteeism

During the group activities of each group, when reporting the monthly report card on falls, and during the regular evaluation of the effectiveness of the project, when there are cases of non-participants who should have participated in the activities, we should go to the households or make phone calls to find out the reasons for the absences, and whether they are able to continue to participate in the project, so as to encourage the research subjects to persist in participating in the follow-up activities of the project.

4.3 Management of lost visitors

In the event of a missed visit, the reasons for the participant's withdrawal from the study will be recorded in detail in the "Record of Participation of Research Subjects in the Project Process" (Attachment 3), and an evaluation of the effectiveness of the project will be carried out as far as possible according to the actual situation.

4.4. Monthly Reporting System of Research Subjects' Information

Report the participation of research subjects in intervention activities and loss of visits in the four research groups on a monthly basis.

(5) Control of pollution

5.1 Avoid the influence of other projects

During the intervention period the project community tries not to participate in other similar studies and projects that may affect the intervention effect. And record the implementation of all relevant projects in the project community during the intervention period.

5.2 Handling of contamination between research groups

Obedience to the project programme, the research subjects between the groups will not participate in the activities of other groups for any reason during the intervention period. Once appeared should be stopped immediately and recorded truthfully.

(6) Concealment of research subjects' groups

Study subjects were not grouped during the recruitment stage to avoid possible bias.

(7) Blinding

7.1 Establishing an independent assessment work team

An independent evaluation work team is set up to implement the baseline survey and effect evaluation (including the monthly report survey on the occurrence of falls). The composition of the assessment team should exclude the staff implementing the intervention. The evaluation site should not reveal information about the group of study participants and ensure that the evaluators do not know the group of study participants. At a minimum, the independent assessment team should assess fall occurrence, gait and fall effectiveness.

7.2 Hidden group information in the database

Groups are coded in the database using group codes that are not recognisable to analysts, ensuring that data analysts do not know which intervention group the study participant is in by using the group information in the database.
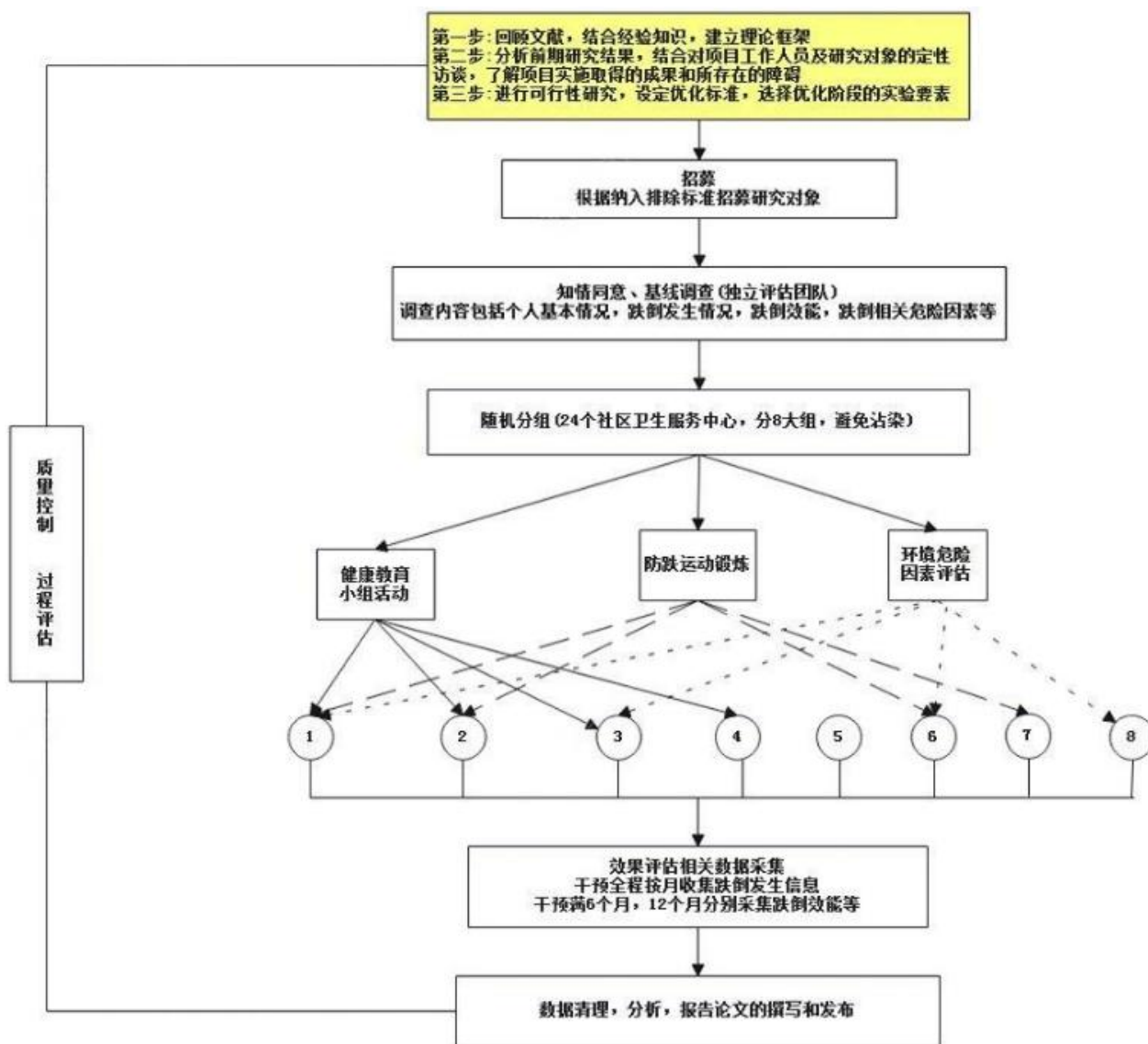
X. Research flow chart

Figure 1 Project Flowchart
Note: Work completed in yellow

XI. Organisational management and division of responsibilities

(1) Guangzhou Centre for Disease Control and Prevention

Overall responsible for the project work, formulate the work plan, organise expert demonstration, pre-test, organise the implementation of intervention, evaluation and summary. It is responsible for conducting first-level training, overall implementation of quality control work, and work supervision. According to the project programme, select the project site area and clarify the division of responsibilities among the cooperation units. Responsible for coordinating the cooperation units in the district, carrying out training, implementing interventions, implementing quality control work requirements, guiding the implementation of evaluation and other work, and organising work supervision.

(2) CDC of the project site area

According to the project programme, it is responsible for implementing and coordinating the project communities/sections to carry out intervention activities, implementing training, assessment, quality control, and daily management of the project.

(3) Community Health Service Centre of the project site

Organise and implement the project work in the district and implement the quality control requirements.

广州市疾病预防控制中心医学研究伦理审批件

研究名称	社区老年人预防跌倒方案构建研究：基于多阶段优化策略的随机对照试验
研究分类	预防医学
负责人	黄婷苑
审批编号	GZCDC-ECHR-2024P0116

（项目简介　1、研究时间；2、研究内容；3、研究人群范围；　4、采用方法5、知情同意及保障措施）

项目研究时间：从 2024 年 6 月至 2027 年 6 月

研究内容：基于前期研究成果，健康教育课程+发展个人运动技能+环境评估干预方案，并通过检验不同干预组别跌倒效果，评估不同组别的的投入-产出，筛选出最经济最优化的干预方案，解决原干预方案耗时长，较难全面推广的问题，为我市开展适用于基层医疗卫生机构实施的老年人跌倒干预服务提供科学参考和实用工具。

研究人群范围：招募888 名年龄为60～80 岁（含 60 岁和 80 岁）的社区常住老年人。

采用方法：在改善阶段对前期项目有效的干预方案进行改良，利用部分析因设计进行随机对照试验，定量定性比较不同跌倒方案对于预防跌倒的效果，开展不同干预方案的经济学评估。

知情同意及保障措施：项目开展前每个研究对象均需签署知情同意书，为保证整个项目安全进行，每次集中授课均需考虑天气等因素，并派

医务人员给予医疗保障。

经广州市疾病预防控制中心伦理委员会讨论，认为该研究所涉及的内容符合《涉及人的生物医学研究伦理审查办法》（中华人民共和国国家卫生和计划生育委员会令第 11 号）的要求，同意开展研究。

广州市疾病预防控制中心伦理委员会

2024 年 6 月 3 日

Pilot Project on Prevention of Falls among Community-dwelling Elderly in Guangzhou
Informed Consent Form (Group 1)

Dear Elderly Friend, Hello!

Before you decide to participate in this study, we would like to explain to you the purpose of the study, the possible risks and benefits. Your decision to participate or to withdraw from the study is completely voluntary.

Falls are a major health threat to older people, seriously affecting their health and quality of life. Domestic and international evidence shows that falls in the elderly can be effectively prevented through the use of scientific preventive measures. This study was conducted to determine the effectiveness of the intervention of a pilot project to prevent falls in older adults in Guangzhou. This study was conducted by the Guangzhou Municipal Centre for Disease Control and Prevention (GZCDC), the Baiyun District CDC, and the _____ Community Health Service Centre, and the person in charge of this study is Dr Liang Boheng, Chief Physician of the GZCDC.

If you agree to participate in this project, you will be assigned to one of the following study groups and will participate in related project activities.

You will participate in the following: ① Fall prevention education programme. The main content is to organise regular fall prevention health education courses to learn about fall prevention. ② Exercise programme, the main content is to help the study participants to learn fall prevention exercise skills and use fall prevention related aids. ③ Environmental assessment, the main content of the door-to-door assessment of environmental risk factors for falls.

In addition, you need to receive regular survey assessments. The main content is to understand your basic information, illness and medication, daily physical activity, fall-related information and balance function through questionnaires and test assessments. A survey and assessment takes about 20-30 minutes to complete. The project as a whole requires a total of two surveys and assessments at 6 months and 12 months after the start of the project.

To organise health education group activities, we will provide the venue and conditions for learning, provide learning materials, fall recording tools, provide professionals to teach the knowledge and conduct guidance on exercise and environmental inspection. Exercises included in the group programme are safe, fitness-oriented and do not cause any health damage, and the risk is no greater than that of daily activities. Medicines and first-aid equipment and medical staff were provided during the assessment and exercise sessions so that emergencies could be dealt with in a timely manner.

During the survey, assessment and intervention, trained staff will complete the survey,

testing and guidance. They will explain every question to you in order to eliminate your doubts. The costs incurred in the survey and evaluation activities related to this project will be borne by the project. In addition, the project will keep all information that may involve the privacy of you and your family members in strict confidentiality; data entry will be recorded using coded identifiers to record information, and your name and identity will not be displayed; when the results are released, only the results of the group survey will be reported, and there will not be any results related to individuals, so that the risk of information leakage will be minimised as much as possible through these measures. During the course of the study, if you agree to take part in the study, the results of medical examinations related to your health will be fed back to you directly and further health counselling will be provided to you. In the event of an injury such as a fall due to other unforeseen reasons, we can provide you with counselling services. Of course, you also have the right to refuse to participate or withdraw from the study at any point in time, and your rights will not be affected in any way.

This project is a public welfare project, and there is no remuneration or compensation for your participation in this project. However, your participation will enable us to better understand the effectiveness of the interventions of the pilot project on prevention of falls among the elderly in Guangzhou City, so that we can provide support for the prevention of falls among the elderly in Guangzhou City. Therefore, we sincerely hope that this study will receive your strong support and co-operation!

If you have any health related questions and suggestions, please ask and we will try our best to help, you can also contact our survey office directly.

Contact: Huang Ting Yuan

Tel: 36052333-1610

Informed Consent Statement:

I have read this informed consent form and know the purpose of the study, the steps of implementation, and the risks and benefits, and all questions have been addressed.

My choice is: I voluntarily ☐ agree, ☐ do not agree to participate in this survey.

Subject's name (signature):   Date:

I have explained the purpose of the study to all subjects and have answered all of the

subjects' questions. It is my understanding that the subject is aware of the purpose, process, risks and benefits of the study.

Name of staff member who obtained informed consent (signature):   Date: