



Research Article

# A Randomized Control Trial for a Comprehensive Fall Prevention Model for Self-Supporting Older Adults (PM-ACTIVAS): A Study Protocol

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## Abstract

Falls among older adults are a major global public health issue. This study protocol for a two-arm randomized controlled trial was designed to evaluate a comprehensive model based on house calls oriented towards fall prevention. A sample of 220 high-functioning older adults assigned to the intervention group (n = 110) will receive house calls and educational interventions, and the control group (n = 110) will receive standard care. Fall risk factors, fall risk perception, and fall frequency will be measured. Participants will receive a 'Falling Prevention Kit' and 'Fall and Events Calendar'. If the distribution of results is normal, differences between groups will be verified by Mann-Whitney U and Chi-square tests. The differences between measurements will be estimated using the Wilcoxon signed-rank test. A significance value of  $p < 0.05$  will be accepted. If tests for normal distribution are negative, statistical tests for non-normally distributed variables will be performed. This study will produce an original, comprehensive intervention addressing contextual and environmental factors to prevent falls among older adults. Based on new evidence, the program evaluation and feasibility study will help advance the practice of nurses, physicians, and other health care professionals. Registered in ClinicalTrials.gov (ID: NCT04313062) in November 2020.

**Keywords:** Accident prevention; Aged; Clinical trial; House calls; Nursing; Protocol.

## Introduction

Falls among older adults are a major public health problem worldwide. Globally, the highest mortality rates due to falls occur among those aged over 60 years. Those having to cope with

disabilities due to falls, particularly older adults, are more likely to require long-term care and admission to an institution, along with having to deal with the associated emotional, family, social, and economic costs [1].

Developing countries, such as Chile, are currently in the last stages of the demographic transition process towards aging, which is associated with factors such as greater socioeconomic, political,

and technological-scientific developments of the country. This has resulted in some repercussions, such as a higher proportion of adults aged over 65 years, representing approximately 16.2% of the population [2], and a life expectancy at birth of approximately 80 years [3]. With this aging population, the challenge for all sectors of society is to ensure that the longevity achieved is supported with the best possible state of health and by assuring quality of life, autonomy, and independence [4]. Additionally, avoiding or controlling the functional limitations of older adults has a positive impact on important predictors of mortality, morbidity, disability, and falls, which lead to functional limitations [5].

A prior study reported that 25.9% of the population over 75 years of age living at home experience falls in a given year [6]. In Chile, the prevalence of falls with fractures in people aged 65 years and above is 27.8% (30.5% in women, 24.1% in men), with an average of 1.3 falls in the previous year (1.6 in women, 0.8 in men) [7]; according to this study, 26.8% of hospital discharges due to trauma in older adults evolved from a femur fracture, with an average stay of 8 days. Further, the mortality rate due to accidental falls in people over 65 years of age is 40 per 10,000; of the total deaths due to accidental falls in 2011 (952), 74.4% occurred among those aged 65 years and above [8]. Sufficient evidence supports the relevance of the issue and describes the consequences of falls among older adults. It is a prevalent health problem that has an impact on high morbimortality and the possibility of transitioning from self-care to dependence, even conditioning the need for the institutionalization of older adults under self-care before suffering from a fall [9,10]. Research on the care of older adults has mainly focused on the consequences of established geriatric syndromes or frailty, with only a few studies concentrating on community-based strategies and a primary prevention approach [11].

Falls in older adults cannot be ascribed to a single cause- they result from inter-actions between factors and constitute a geriatric syndrome considered in the scientific community as a 'giant of geriatrics' [12,13]. The health conditions of older adults most frequently associated with falls include neurological, cardiac, and other disabling conditions; the collateral effects of medications; physical inactivity; loss of balance; as well as cognitive, visual, and mobility problems [14]. Several studies have reported that one in four older people had at least one fall during the previous year [9,15,16], which is associated with high costs for persons who fell, their families, and the institutions providing assistance to cope with the consequences of falls [17]. Experts estimate that the direct cost of hospital care for treating a hip fracture in Latin America ranges between 94-411 million USD, depending on the fracture type, with an average hospital stay of 5-7 days [18].

The factors that most frequently result in falls among older people include extrinsic factors, such as hazards in the physical environment, and intrinsic factors related to in-creased individual

susceptibility and risk behaviours, most of which are potentially modifiable or manageable with preventive measures [19]. The most relevant extrinsic factors are limited mobilization space due to the overcrowding of objects and the lack of security in the home and environment [14,20]. These conditions are often aggravated by a lack of resources, as determined by families' socioeconomic conditions [21,22]. Approximately 40% of the households in which older adults live belong to the first two quintiles of income [23].

The houses in which older adults reside lack the required security, habitability, and accessibility facilities, thereby generating situations of fall risks that need special care and adaptations for greater security and a suitable living environment [20,24]. Effective fall prevention among older adults requires a comprehensive approach [12,13,19,25]. The most effective fall reduction programs include systematic fall risk assessment and selected interventions, such as exercise programs and inspections of the physical environment with risk reduction programs [26,27]. A prior related study re-reported that some interventions introduced in older people's homes comprised modifications to their houses and environment to reduce risks, training in the use of technical aids, and guidelines on mobility improvement; interestingly, falls had decreased by 31% in the intervention group compared to the control group (incidence rate ratio 0.69, 95% CI 0.51 to 0.97). Moreover, the interventions [28] were more effective in a subgroup of participants who reported having had two or more falls during the year before enrolment in the study [13].

Another factor involved in reducing the frequency of falls is risk perception-the subjective assessment of the likelihood of such a fall occurring and the evaluation of its consequences [28]. Risk perception is a multidimensional process influenced by experiences, individual and social values, knowledge about the risk origin, and the possibilities to control the situation where the risk is present; it is relevant to consider risk perception in older adults as a key factor in fall prevention [26,29,30].

The above contention supports the position that preventing falls among older adults is a public health problem that needs to be addressed in all care situations, including family, community, hospital, and institutional settings. Such prevention efforts would help professionals identify risk factors and reduce the incidence of falls and injuries from falls [31]. However, scientific literature on the subject comprises more information regarding institutionalized older adults or those who have already suffered the consequences of falls, as opposed to prevention [32].

Knowledge on specific strategies for fall prevention in self-supporting older adults living in the community is lacking. Fall prevention is incorporated in the organizational culture of closed care, for example, in hospitals and geriatric institutions, as an indicator of safety standards in care. Similarly, this situation has

been described and studied mainly in institutionalized older adults, although the largest population at risk constitutes healthy and self-care older people living at home. However, this population does not receive specific attention that would allow them to identify the personal practices that place them at greater risk of falls or to perceive, in their immediate environment, the factors that make it potentially unsafe. With this gap in research and intervention, the probability of falling increases for these older adults, with the consequences compromising their well-being and that of their families [33]. Considering the high prevalence of falls in this group (27.8 %), it is necessary to address older adults' fall prevention in all health care contexts [7]. In this effort, it is essential to develop, for example, a network of primary care establishments with day-care centres, which would provide an opportunity to contact older adults and review the settings in which to apply prevention strategies.

To better understand the phenomenon at a local level, part of this project's research team conducted a controlled clinical trial during 2011-2012, aiming to evaluate the effect of a multidimensional intervention on the perception and management of intrinsic and extrinsic fall risk factors and the frequency of falls in older people living in the community. The results indicated that the intervention group presented a greater perception of the risk of falling associated with surfaces ( $r = 0.25$ ), shoes ( $r = 0.24$ ), walking ( $r = 0.21$ ), and the presence of furniture or objects ( $r = 0.36$ ). Further, in the intervention group, 7.9% of the participants suffered at least one fall in a 5-month period in comparison with 27.7% of the participants in the control group ( $p = .004$ ). It was concluded that the multi dimensional intervention effectively reduced the frequency of falls and helped manage extrinsic risk factors [28].

Evaluating interventions to prevent falls with a comprehensive and transdisciplinary approach at the community level is urgently needed due to the following reasons: 1) older adults present an objective risk of falling, which impacts their self-valence, well-being, and quality of life at the personal and family levels; 2) falls in older adults do not have a single cause but result from interactions between multiple intrinsic and extrinsic factors, and it is relevant to identify the significance of each; 3)

a significant proportion of those factors could be controlled with a tailored plan achievable by older adults and within their family environments; and 4) the literature review as well as the progress and previous results of projects related to fall prevention by the proposed team are significant. The suggested evaluation implies working with healthy older adults in their immediate environments and including their families in the process.

Considering the promising results of a previous controlled trial [28] and recent studies [1,14,19,20], an intervention was designed to address the lack of interventions for fall prevention in self-care older adults living at home. We hypothesized that older adults who participate in the PM ACTIVAS Model will present a lower frequency of falls, will improve the management of risk factors, and will achieve a greater perception of risk factors for falls. This paper describes a study protocol for an ongoing two-arm randomized controlled trial, the specific objectives of which are: (a) To develop the components of a comprehensive model based on home visits for fall prevention; (b) To implement the PM ACTIVAS model among self-sufficient older adults living in their homes; and (c) To evaluate the effect of the PM ACTIVAS comprehensive model for fall prevention in self-sufficient older adults living in their homes, in terms of fall frequency, risk factor management, and risk perception of falls, compared with the usual care that older adults receive.

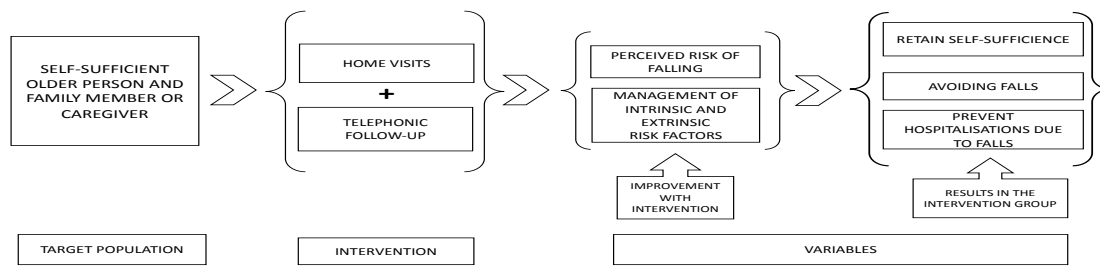
## **Materials and Methods**

### **Study Design**

The study design of this protocol corresponds to a controlled clinical trial with two parallel arms - an intervention group (IG) and a control group (CG), following the recommendations of the CONSORT 2010 Statement for Reporting Randomized Controlled Trials [34]. It will be reported using the Guidelines for Reporting Outcomes in Trial Protocols (SPIRIT) [35] and using the Template for Intervention Descriptions and Replication checklist (TIDieR) [36].

### **PM ACTIVAS Transdisciplinary Model**

The PM ACTIVAS intervention proposes a comprehensive and transdisciplinary model, with two components (Figure 1):



**Figure 1:** PM ACTIVAS model components.

**1. Multidimensional assessment of the risk factors for falls:**

This will be performed by using specific instruments developed for the application of the model, including a battery of images for risk perception in the physical environment and a guideline for checking the intrinsic and extrinsic risks of falls. Further details on these instruments are presented in Section 2.7. Using the instruments, we aim to collect information on the perception of the current risk of falls in older adults and compare it with the actual intrinsic and extrinsic risk factors.

**2. Management plan for the fall risks detected:** Once the instruments have been administered, we aim to establish, in agreement with the older adults and their family members, which of the detected factors will be considered in interventions and on what terms (i.e. short, medium, or long term). This includes the detection of the human and material resources involved in the plan, a feasibility analysis of its realization, and the detection of possible barriers. Likewise, at this stage, the ‘Fall Prevention’ kit will be delivered, which includes a simple support bar, non-slip covers for carpets, rolls of non-slip tape for uneven surfaces, and non-slip tape for bathrooms and showers.

*The strategies for implementing the PM ACTIVAS model components are as follows:*

**a. Home visits:** These refer to consultations to be conducted at older adults’ homes by trained professionals. They are characterized by a family and community approach and aim to prevent the occurrence of falls in self-supporting older adults. This strategy allows the assessment of older adults and their families in real-life conditions and observations of the presence of risk factors in situ. It also facilitates meetings with family members and soliciting their involvement in the design and implementation of an agreed-upon plan for fall prevention.

**b. Telephonic follow-ups:** These follow-ups provide support to older adults and their families in implementing their plan, monitoring progress, achieving goals, and reviewing barriers or

difficulties encountered as well as exploring possible ways to face them [37]. Contact could also be established with a family member of the older adult if they are involved and aware of the project activities and live in the same house as the older adult.

**Training and skills development:** To successfully implement the model, applying its elements through home-visit strategies and telephone follow-ups, the personnel in charge of its execution (nurses) will participate in an initial training process and a quality verification process to deliver the intervention. In this effort, the model considers the development of support materials for each activity, including training instances: a course, an instruction manual, a home-visit protocol, a telephone-monitoring protocol, and registration forms.

**Participants**

The study participants will be self-sufficient older adults aged between 65 and 80 years belonging to the family health care centres of the Renca Municipality in Santiago de Chile. The Renca Municipality corresponds to a low-income area within the city of Santiago. The study settings include these family health care centres and the participants will be initially contact by the health care centre professionals. Once they accept to participate, they will be contacted by a member of the research team.

**Inclusion Criteria**

The inclusion criteria are as follows: 1) self-sufficient older adults, and 2) having passed a functionality evaluation conducted during the 12 months before the beginning of the study. This assessment will be considered valid for study participation.

**Exclusion Criteria**

The exclusion criteria are as follows: 1) older adults whose addresses are out of the geographical reach of the family health care centres, 2) those with any visual or auditory alteration that would render effective communication impossible, and 3) those with de-pression or moderate to severe mood disorders.

## Intervention Description

The PM ACTIVAS model will be applied in the IG, which will be implemented at home and executed by a trained team of monitors. Telephonic follow-ups and additional home visits will also be conducted prior to the final measurement. The basic safety kit for fall prevention at home will be delivered during the first home visit. Additionally, the IG will receive the usual care for older adults. During the same period, the CG participants will receive the usual care from the respective health care centres. The usual care for people over 65 years of age involves conducting the preventive medicine examination of older adults, performed once a year, which includes evaluations related to the following: anthropometric measurements, blood pressure control, health history, functionality, support networks, fall risks, abuse suspicion, addiction, and blood tests. Intervention description details are presented in Table 1, according to the TIDierR checklist [36].

	TIDierR Items	Intervention Group	Control Group
1.	<b>Brief name</b>	PM ACTIVAS Model (acronym explained in the section 1). A model for fall prevention in self-care older adults living at home.	Usual care provided to older adults at their respective health care centres
2.	<b>Why</b>	Effective fall prevention among older adults requires a comprehensive approach. The most effective fall reduction programs include systematic fall risk assessments; fall risk perception assessments; and selected interventions such as exercise programs and inspections of the physical environment with risk reduction programs, modifications to their houses and environment to reduce risks, training in the use of technical aids, and guidelines for mobility improvement. Preventing falls among older adults is a public health concern that needs to be addressed in all care situations, including in family and community settings, and not only in hospital and institutional settings. In Section 2.2., a detailed description of the components of the PM ACTIVAS transdisciplinary model is presented.	-----
3. 4.	<b>What</b> (materials; procedures)	<b>Personnel performing the intervention:</b> To successfully implement the model, applying its elements through home-visit strategies and telephone follow-ups, the personnel in charge of its execution will participate in an initial training process and a quality verification process to deliver the intervention. In this effort, the model considers the development of support materials for each activity, including training instances: a course, an instruction manual, a home-visit protocol, a telephone-monitoring protocol, and registration forms.	-----
		<b>Older adults and their families:</b>  1. Multidimensional assessment of the risk factors for falls: This will be performed by using specific instruments developed for the application of the model, including a battery of images for risk perception in the physical environment and a guideline for checking the intrinsic and extrinsic risks of falls. Detailed descriptions of these instruments are presented in Section 2.7. Through the instruments, information on the perception of the current risk of falls in older adults will be collected, and compared with the actual intrinsic and extrinsic risk factors.  2. Management plan for the fall risks detected: Once the instruments have been administered, in agreement with the older adults and their family members, which of the detected factors will be considered for interventions and on what terms (i.e. short, medium, or long term) will be established. This includes the detection of the human and material resources involved in the plan, a feasibility analysis of its realization, and the detection of possible barriers. Likewise, at this stage, the 'Fall Prevention' kit will be delivered, which includes a simple support bar, non-slip covers for carpets, rolls of non-slip tape for uneven surfaces, and non-slip tape for bathrooms and showers.	-----

5.	<b>Who</b> (intervention providers)	<p><b>Personnel performing the intervention:</b> The training course will be delivered by seven research team members (six community nurses and a physician) with experience working with older adults and their families in self-care interventions.</p> <p><b>Older adults and their families:</b> The intervention for older adults and their families will be delivered at their homes, by the previously trained personnel, who are all registered nurses.</p>	-----
	<b>How</b>	<p><b>Personnel performing the intervention:</b> The training course ‘Tools for the implementation of the PM ACTIVAS Model for the prevention of falls in self-sufficient older adults living in their homes’ will be conducted in person. The course will cover three units of content: background of falls in community-dwelling older adults, theoretical framework, and components of the PM ACTIVAS model. These concepts will be developed through participatory classes and a workshop. In addition, each course participant will receive the support materials mentioned above.</p>	-----
6.		<p><b>Older adults and their families:</b> The model will be implemented through two interventions that will be carried out with the older adults and their families.</p> <p>a. Home visits: Consultations to be conducted at older adults’ homes by trained professionals. They will adopt a family and community approach and aim to prevent the occurrence of falls in self-supporting older adults. This strategy will allow the assessment of older adults and their families in real-life conditions and observations of the presence of risk factors in situ. It will also allow meetings with family members and their engagement in the design and implementation of an agreed-upon plan for fall prevention.</p> <p>b. Telephonic follow-ups: These follow-ups will provide support to older adults and their families in implementing their plan, monitoring progress, achieving goals, and reviewing barriers or difficulties encountered as well as exploring possible ways to face them. Contact could also be established with a family member of the older adult if they are involved and aware of the project activities and live in the same house as the older adult.</p>	-----
7.	<b>Where</b>	<p><b>Personnel performing the intervention:</b> The course will take place at the School of Nursing facilities where the researchers who will teach the course are employed.</p>	-----
		<p><b>Older adults and their families:</b> The home visits will take place at each older adult’s home. The telephonic follow-ups will be carried out at the School of Nursing where the researchers from the team are employed.</p>	-----
8.	<b>When and how much</b>	<p><b>Personnel performing the intervention:</b> Before the intervention takes place in five sessions of 4-hours each.</p>	-----
		<p><b>Older adults and their families:</b> The intervention will start at the older adult’s home with an initial home visit. Participants will be followed up by telephone by the same staff who were part of the initial home visit until the final home visit, which will take place 12 months after recruitment. During the final home visit, the trained professional will evaluate the plan with the older adult and family, request the ‘Calendar of Falls and Events’ handed over at recruitment (wherein the older person and/or his/her family recorded each trip or fall during the 12-month period), and conduct the final survey.</p>	-----
9.	<b>Tailoring</b>	All participants will receive the same intervention.	-----
10.	<b>Modifications</b>	Since this is a report of the protocol of the study, this item cannot be described until the study has been completed.	-----

11.	<b>How Well-Planned</b>	The research team will maintain a field diary to record the development of each of the intervention’s components, to maintain and guarantee fidelity.	-----
12.	<b>Actual</b>	Since this is a report of the protocol of the study, this item cannot be described until the study has been completed.	-----

**Table 1:** Intervention description [36].

**Outcome Measures**

We now present descriptions of the following outcome measures: 1) The fall frequency during the study period, 2) management of intrinsic and extrinsic risk factors for falls, and 3) perception of risk factors for falls.

**Fall Frequency**

Since this is an intervention to prevent falls, the domain chosen for the primary outcome selection is ‘falls’. The participants are living at home; hence, a self-report of falls is the approach chosen.

The number of falls will be recorded in the ‘Falls and Events Calendar’ by both the IG and CG. This is a typical calendar wherein the participant and/or family must record the days that the participant fell or tripped. The participants will be provided with the calendar at recruitment and both groups will be taught how to record falls, trips, and related events. The research team will collect data during the final home visits.

**Management of External and Internal Fall Risk Factors**

The research team will measure this outcome with a previously validated checklist comprising 41 questions, to which the patient must reply yes or no. The questions are related to internal and external fall risk factors [28]. This survey will be conducted with both the IG and CG at recruitment and during the final home visit.

**Perception of Risk Factors for Falls**

The researchers will measure each participant’s perception

of fall risk factors in the home setting with a set of drawings where the participant must identify what they consider as fall risk factors. The research team will perform this assessment at recruitment and during the final home visit for both the IG and CG.

**Sociodemographic Characteristics**

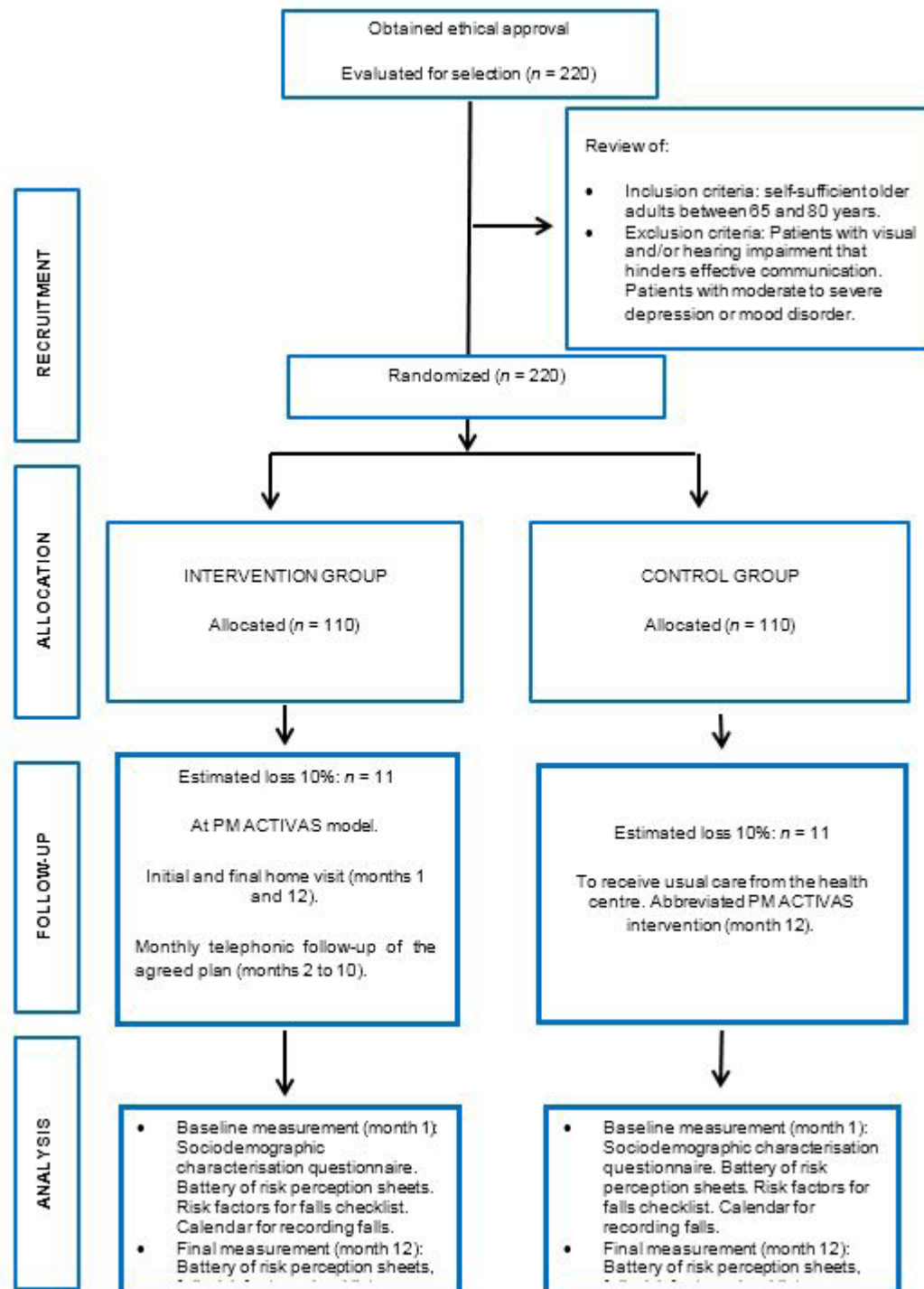
A questionnaire designed for this study will be used to collect participants’ socio-demographic details.

**Sample Size Calculation**

A sample size of 210 people is estimated: 110 each for the IG and CG. A 0.05 error will be calculated considering a power of 0.80, a small- to medium-effect size considering the behaviour of the fall frequency variable using mean difference for unrelated samples and considering the previous experience of the work team and a 10% sample size loss during the study.

For randomization, simple random sampling will be applied in the sampling frame of the health care centres selected from the Renca municipality for study execution. The nurses who will perform the home visits will enrol participants after checking the inclusion and exclusion criteria; they will then call the field work coordinator, who will assign participants to the IG or CG according to the allocation sequence. Outcome assessors and data analysts will be blinded. Each participant will be assigned an ID number to conceal their identity. Unblinding will not be permissible under any circumstances.

The recruitment and follow-up processes of participants have been designed following the recommendations of the CONSORT 2010 statement for randomized trials [34] (Figure 2).orkflow.



**Figure 2:** Workflow.



## Analysis Plan

For statistical analysis, a plan is proposed based on the usual distribution of the variables of interest as reported by current evidence [28], and randomization in the process of assigning participants to the IG and CG. This will be carried out by testing for normal distribution. In case of a positive result, first, possible differences between the CG and the IG in the baseline measurement will be verified using the Mann Whitney U test for continuous variables and Chi-square test for dichotomous variables. To estimate the differences in the outcomes of interest between the initial and final measurements, a Wilcoxon signed-rank test for related samples will be performed. In all cases, a significance value of  $p < 0.05$  will be accepted. If the tests for normal distribution are negative, the corresponding statistical tests for non-normally distributed variables will be carried out. Additionally, the analysis by intention to treat, information on the ability to contact participants over the telephone, and the degree of compliance with the agreement plan will be reported.

Methodological and statistical experts form part of the research team who are re-sponsible for proposing modifications to the original plan of analysis according to the results obtained, which will not imply changes in the objectives or alteration of the hypotheses guiding the study.

## Reliability and Validity

Each component of the PM ACTIVAS model was designed and validated by content experts, based on a literature review. The components of the model were previously evaluated in a preliminary controlled clinical trial [28]. Validated data collection instruments will be used in this study. This protocol was reviewed by the grant entity and ethics committee. The CONSORT 2010 statement was used to design the study protocol [34].

## Data Management and Monitoring

The funding agency (ANID-Fondef) tracks the technical execution of a particular project, including data management, in three ways. First, it assigns an executive in charge of project supervision. At the beginning of the project and based on the research objectives, the team proposes milestones and results to be met at different times, which are validated by the executive, who, as the dates are met, will ask the research team for the evidence supporting the achievement of the milestone and the respective results. In addition, ANID-Fondef forms a committee (area committee) composed of relevant actors recognized by the agency in the project's field of action. The project team will present its progress to the area committee annually and will be available to the committee if new presentations are requested. Finally, the agency requires the formation of a board of directors. It comprises representatives of the institutions associated with the project and the funding agency. The research team is required to report

on the progress of the project to the board once a year. In terms of internal control, the project will define a training program for research assistants involved in data collection. This program will be validated by the academic unit's quality management system and will include evaluation and learning support materials.

Data entry will be performed by each nurse during or after the visit (the same day) using Kobo Toolbox. The data will be stored digitally in an encrypted database and will be checked each week to detect any anomalies. The primary outcome will be assessed multiple times, not only at the final visit but also during the monthly phone calls in the IG. Cases with complete information will be used for data analysis.

## Ethics

Ethical principles that protect the participants' dignity will be maintained throughout the study through the informed consent process, ensuring compliance with the ethical requirements for clinical studies [38]. The research team members will present the objectives, possible benefits, and risks to the participants, and invite them to participate in the study. It will be clearly and continually stated that participation is voluntary and that participants may withdraw at any time without this affecting their healthcare conditions. All personal information will be handled confidentially, anonymized, and used only for research purposes. Completed consent forms will be obtained after the information has been provided to participants by one of the research team members, in verbal and written forms, before data collection starts. The Scientific Ethical Committee of the corresponding university approved the study in December 2019 (Protocol ID: 190318014). This committee has procedures and communication channels in place to make amendments if necessary or to communicate relevant situations. Reports on any important protocol modifications will be submitted to the area committee and the board of directors who will decide whether to approve the changes; these will then be informed to the trial participants, if applicable.

## Discussion

This paper describes a study protocol for an ongoing two-arm randomised controlled trial that will be conducted to evaluate the effect of the PM ACTIVAS model on the fall frequency, risk factor management, and risk perception of falls compared with the standard care that older adults receive. The model will contribute to improving risk factor management for falls, both intrinsic and extrinsic, and is expected to reduce the probability of falls occurring and bring subsequent benefits (preservation of self-sufficiency, contribution to well-being, and improved quality of life). Furthermore, the model promotes adaptation to and safe use of the physical environment, promoting mobility and safe travel [14,20,28,39], components considered in the recently published world guidelines for falls prevention and management

for older adults [1]. This study contributes to the training of health professionals who will deliver the interventions in identifying fall risks, assessing fall risk perception by older adults and their families, and elaborating a consensus plan oriented to fall prevention at home. This is a novel aspect of this proposal since most interventions do not consider the training of professionals. This coincides with a suggestion in the recently published global guidelines for falls prevention [1]. Limited national studies have reported interventions of this type in older adults living in their homes [28]. National publications on falls in older people are generally only descriptive in nature [40,41]. Against this background, in the current study, we expect to demonstrate the effects of the model among older adults according to the following variables: fall frequency, fall perception, and risk factor management. We also aim to present information on participants' self-sufficiency and user satisfaction.

## Conclusions

This protocol will allow the development of the components of a comprehensive model based on home visits to prevent falls in self-sufficient older adults who live in the community. Its implementation will allow us to evaluate the effect of the PM ACTIVAS comprehensive model, considering the frequency of falls, the management of risk factors and the perception of the risk of falls, in comparison with the usual care that older adults receive. Such targeted interventions for older adults and their families can contribute, at the individual level, to enhance quality of life, and at the public health level, to a more efficient use of resources. Specifically, in the Renca Municipality, this intervention could contribute to reduce inequities in access to specialised care at home for the prevention of falls in self-sufficient older adults living in their homes, especially those living in areas with limited resources, thus seeking to generate positive outcomes that reduce equity gaps and address health determinants such as the physical environment, in order to reduce their negative impact on health. The results of this protocol will be important, given the large number of older people in developing countries who experience difficulties in receiving support from health systems with limited financial resources.

## Author Contributions

Conceptualization, and Methodology, Claudia Alcayaga-Rojas, Claudia Bustamante-Troncoso; Ignacio Ibarra-Torres; Camila Lucchini-Raies, and Francisca Marquez-Doren; Funding acquisition, Claudia Alcayaga-Rojas, Claudia Bustamante-Troncoso; Camila Lucchini-Raies, and Francisca Marquez-Doren; Project administration, Claudia Bustamante-Troncoso; Resources, Ignacio Ibarra-Torres; Camila Lucchini-Raies, and Francisca Marquez-Doren; Supervision, writing—original draft preparation, and writing—review and editing, Camila Lucchini-Raies, and Francisca Marquez-Doren. All authors have read and

agreed to the published version of the manuscript.

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## Clinical Trial Registration Number and Name of Trial Register

The study protocol was prospectively registered at ClinicalTrials.gov in November 2020; Trial ID: NCT04313062.

## Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of Pontificia Universidad Católica de Chile (protocol code: 19031801. Date of approval: 20th December 2019).

## Informed Consent Statement

Informed consent will be obtained from all participants involved in the study.

## Data Availability Statement

Not applicable.

## Acknowledgements

The authors would like to thank the health professionals of the health care centres in which the project was conducted.

## Conflicts of Interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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